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

FORM 10-K

(Mark One)

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

For the fiscal year ended **December 31, 2022**

or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number **000-13789**

ADHERA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**11-2658569**
State or Other Jurisdiction of Incorporation or Organization	(I.R.S. Employer Identification No.)

8000 Innovation Parkway, Baton Rouge, LA 70820
(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: **(919) 518-3748**

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

Title of each class	Trading Symbol	Name of each exchange on which registered
None	NA	NA

Securities registered pursuant to Section 12(g) of the Act:
Common stock, par value $0.006 per share

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark 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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

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

Indicate by check mark whether the registrant 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 U.S.C. 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 ☒

The aggregate market value of the common stock held by non-affiliates of the registrant as of June 30, 2022, was approximately $3.1 million as computed by reference to the closing price of such common stock on the OTC Markets on such date.

The registrant had 3,178,738 shares of common stock, par value $0.006 per share, outstanding as of March 31, 2023.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement to be filed by the registrant for its 2023 Annual Meeting of Stockholders are incorporated by reference in Items 10, 11, 12, 13, and 14 of Part III of this Annual Report on Form 10-K.

ADHERA THERAPEUTICS, INC.
2022 FORM 10-K ANNUAL REPORT
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PART I

ITEM 1. BUSINESS

Overview

We are an emerging specialty biotech company with a focus on drug development and commercialization of "small molecule" drugs to treat Parkinson's disease (PD) and Type 1 diabetes. Companies operating in the drug development and biotech sectors typically in-license early-stage inventions or pre-clinical (stage) compounds from universities and other companies and apply their own drug discovery and development expertise and resources to further these drug candidates towards regulatory approval by the Food and Drug Administration (FDA), and potentially other regulatory bodies overseas. The ultimate objectives are to secure regulatory authorizations in the USA and territories internationally, and to generate revenues from marketing activities. Drug candidates may also be licensed (out) to pharmaceutical companies prior to obtaining final regulatory approvals and marketing authorizations for valuable consideration, including upfront payments, milestone payments and royalties.

We utilize a "virtual" drug development model, also prevalent in this industry sector. In this model, Contract Research Organizations (CROs) are typically employed to undertake certain drug discovery and development services on the Company's behalf and under the Company's direct supervision.

A unique feature of Adhera's accelerated drug development strategy is to identify candidates that have previously been developed for other indications (uses), but where development was discontinued due to lack of efficacy (vs. safety) in these initial indications. The Company secures regulatory approval to commence Phase 2 clinical trials without the need to embark on costly drug discovery or Phase 1 clinical studies. The Company's most advanced development programs are MLR-1019, a small molecule drug candidate being developed for Parkinson's disease and MLR-1023 being developed to treat Type 1 diabetes. Both drugs are "clinical-stage," i.e., are ready to proceed to Phase 2 clinical trials and to Phase 3 clinical trials within 24 months. Both drugs have been shown to be safe and well tolerated in previous clinical trials (in other indications) or following long-term exposure in large numbers of patients.

MLR-1019 in Parkinson's Disease and L-DOPA-Induced Dyskinesia

PD is a chronic neurodegenerative multi-system disorder. Its defining clinical manifestations are motor disturbances, specifically tremor, rigidity, bradykinesia, and postural instability, which are caused by the loss of dopaminergic neurons in the brain. The most effective current treatment for PD is dopamine replacement with the dopamine precursor levodopa (L-DOPA). However, long-term L-DOPA therapy is commonly associated with motor complications that include response fluctuations and involuntary movements called L-DOPA-induced dyskinesias (LID).

L-DOPA remains the most common, effective treatment to improve motor symptoms in PD. L-DOPA is initially well-tolerated for many patients and provides substantial improvement in motor function for Parkinson's patients. However, the long-term use of L-DOPA in patients with PD is often associated with abnormal involuntary movements such as dystonia, chorea and athetosis (collectively referred to as dyskinesias). These L-DOPA-induced dyskinesias, referred to as PD-LID, can be as debilitating as the parkinsonian symptoms (lack of movement or akinesia) experienced by patients suffering from PD. Indeed, PD-LID can often limit the dose of L-DOPA that can be safely administered to patients. To the extent that any improvement of the occurrence of PD-LID is observed, it is largely due to an evolving practice of limiting L-DOPA administration and the drug-induced side-effects while potentially compromising direct therapeutic activity.

The pathogenesis of PD-LID remains enigmatic, but it has been shown that sudden changes in dopaminergic stimulation produced by pulsatile L-DOPA treatment plays a role. Because L-DOPA has a relatively short half-life (50 minutes), multiple doses must be administered during a day. Peak dose dyskinesias are the most common dyskinesia, occurring during peaks of L-DOPA-induced dopamine levels in the brain, a time during which the patient experiences the otherwise beneficial effect of L-DOPA in terms of treating the parkinsonian symptoms. Altering the dose and/or timing of L- DOPA can initially alleviate these dyskinesias, but once PD-LID is present, it becomes more difficult to control the clinical response to L-DOPA.

The intermittent dosing schedule undertaken with L-DOPA leads to pulsatile stimulation of post- synaptic receptors. It has been suggested that this stimulation leads to downstream changes in proteins and genes, ultimately producing dyskinesias by permanently altering striatal dopaminergic homeostasis. As support for this theory, changes in levels of the neurotransmitters serotonin and norepinephrine occur, which may be an attempt to counteract the dysregulation in dopamine levels.

Any current option for addressing PD-LID is associated with compromises in patient benefit. Current strategies include preventing the onset of PD-LID by delaying the start of treatment with L-DOPA, or by initially treating with dopamine agonists instead of L-DOPA. Ropinirole and pramipexole are two dopamine agonist drugs that have been shown to help reduce the occurrence of PD-LID but, to date this strategy has been largely unsuccessful. Although the dyskinesias may be reduced, this is achieved at the expense of inadequately treating the parkinsonian symptoms.

There are few current strategies available for treating PD-LID once they have occurred. Amantadine, an N-methyl-D-aspartate (NMDA) receptor antagonist, was originally introduced as an antiviral compound to treat influenza and was found to ameliorate parkinsonian symptoms in a patient with PD. Since that original finding, many clinical trials have been conducted investigating the efficacy of amantadine alone and in combination with L-DOPA for treating the symptoms of PD. These clinical trials have shown amantadine to have anti-dyskinetic effects and reduce the severity of PD-LID when given in combination with L-DOPA. However, side effects of amantadine are numerous and significantly limit its use as a practical therapy. These side effects include anxiety, increased impulse control disorders, insomnia, nightmares, blotchy skin, and anti-cholinergic effects. Catechol-O-methyl transferase (COMT) inhibitors can be used to increase the half-life of L-DOPA by slowing the metabolism of L-DOPA, thereby reducing PD-LID between doses. There are currently two COMT inhibitors on the market, entacapone (Comtan®) and tolcapone (Tasmar®). A third medication, Stalevo®, is a combination of carbidopa, levodopa and entacapone and has proved beneficial for patients with advanced PD and PD-LID symptoms. Tolcapone has been associated with hepatic abnormalities and the FDA is evaluating clinical trial data suggesting that patients taking Stalevo® for PD may be at an increased risk of prostate cancer. The anti-psychotic medication clozapine has been assessed for the treatment of drug-induced psychosis often seen in patients with PD. Some studies have investigated the effectiveness of clozapine in decreasing the dyskinesia's seen in patients with PD-LID. Although clozapine may show some beneficial effects on dyskinesia and psychosis in PD, patient compliance is poor due to the requirement for a weekly blood draw to monitor for the potential of drug-induced agranulocytosis.

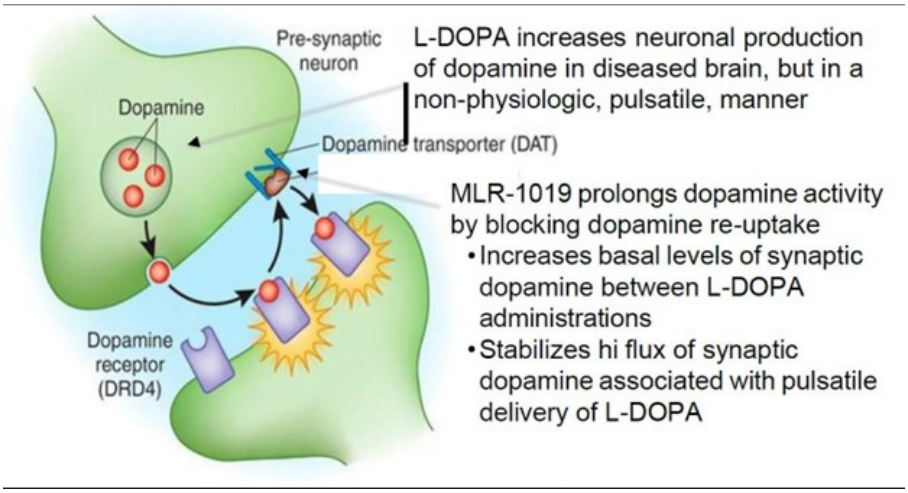
At least two invasive procedures have been assessed for treating PD-LID, intra-duodenal infusion of L-DOPA in a specially formulated suspension (Duodopa®) and deep brain stimulation (DBS). However, the surgical procedures and post-surgical monitoring required for these interventions limit their acceptance. Duodopa® provides L-DOPA delivery directly to the duodenum. The continuous infusion of L-DOPA may prevent the pulsatile stimulation and therefore reduce PD-LID. DBS of the globus pallidus interna (GPi) or the subthalamic nucleus (STN) with implanted electrodes can reduce the severity and duration of PD-LID. Patients receiving this treatment experience significant improvement in PD-LID symptoms, possibly from the reduction in the need for L-DOPA treatments.

As successful as this surgery is for treating PD-LID symptoms, not all PD-LID patients can benefit from this procedure. Patients suffering from dementia or other impairments may not qualify to receive treatment in this manner. The fact that procedures that are as invasive as DBS and the administration of Duodopa® are considered a core part of the armamentarium towards PD-LID is a testimony to the debilitating nature of PD-LID and the significant unmet medical need that exists for well-tolerated oral therapeutics to treat this condition.

Rationale for the use of MLR-1019 as a treatment for PD-LID

The Company is developing MLR-1019, a highly selective dopamine re-uptake inhibitor, for treating PD-LID. As mentioned previously, dopamine-promoting agents may be effective in treating the dyskinesias associated with chronic L-DOPA treatment in PD patients. MLR-1019 prolongs dopamine activity by blocking dopamine re-uptake through the dopamine transporter (DAT) and in this way MLR-1019 maintains dopamine levels between L-DOPA doses and also stabilizes high flux synaptic dopamine associated with the pulsatile delivery of L-DOPA. Thus, MLR-1019 maintains dopamine "tone" by stabilizing dopamine levels and activity, and thereby dopamine receptor levels and activity, effectively maintaining dopamine homeostasis and reducing dyskinesias (see Figure 1). The remarkable attribute of MLR-1019 is that, it is the only DAT inhibitor that has no pharmacologically relevant activity for the inhibition of other catecholamine transporters (norepinephrine transporter [NET] or serotonin transporter [SERT]), which may be a critical feature for the purpose of PD-LID therapy.

Figure 1: Mechanism of action for MLR-1019



The Importance of selective DAT inhibition

MLR-1019 is the most highly selective dopamine reuptake transporter (DAT) inhibitor that has been described in the scientific literature. It exhibits high selectivity for DAT versus the norepinephrine reuptake transporter (NET) (176-fold; 10-fold higher selectivity that the next most selective DAT inhibitor described) and 1,200- fold selectivity for DAT versus the serotonin reuptake transporter (SERT) (20-fold greater than the next most selective DAT inhibitor. In fact, the ki values for NET and SERT binding by MLR-1019 are high enough that there should effectively be no amount of NET or SERT inhibition by MLR-1019 at the doses typically administered *in vivo*. In this respect MLR-1019 is the only DAT inhibitor that does not possess physiologically relevant levels of NET or SERT inhibition.

A growing body of literature indicates that inhibition of other catecholamine transporters, especially NET, exacerbate or even induce dyskinesias. In this way, all DAT inhibitors, *other than MLR-1019*, presumably have opposing effects towards therapeutic effect on PD-LID; on the one hand providing benefit vis-à-vis DAT inhibition and mitigating dopamine flux as discussed above, but on the other hand exacerbating dyskinesias vis-à-vis NET and possibly SERT inhibition. This recently developed understanding for the role of NET and SERT towards dyskinesia can explain the disappointing results that have been observed with a number of DAT inhibitors evaluated in PD clinical trials. These results also strongly predict that MLR-1019 will be differentiated from all other DAT inhibitors in the context of PD therapy.

Patent protection

MLR-1019 is protected by a total of 21 issued patents, 2 allowed patent applications, and 4 pending patent applications in the following territories: United States, Australia, Brazil, Canada, China, Eurasia, Europe, France, Germany, Great Britain, Ireland, Luxemburg, Monaco, Switzerland, Hong Kong, Israel, Japan, Mexico, New Zealand, Singapore, South Africa, and South Korea. Patent expiry is 2034.

Accelerated development pathway for MLR-1019

MLR-1019 is the active moiety of mesocarb, a product that was marketed in Russian and Eastern Europe for indications unrelated to PD for 37 years. The drug has strong safety and tolerability profiles following use in >1 million patients across a wide dosing range. In pre-clinical studies, MLR-1019 demonstrates robust attenuation of L-DOPA induced dyskinesia (PD-LID) and potentiates the anti-Parkinsonian activity of L-DOPA. In addition, MLR-1019 stabilizes the disrupted sleep/wake cycles commonly associated with PD.

Manufacturing of MLR-1019 is underway in preparation for a Phase 2 multi-center clinical trial in 60 PD patients with L-DOPA induced dyskinesias, with the potential to initiate a Phase 3 clinical trial within 24 months.

MLR-1023 in diabetes

MLR-1023 was originally developed by Pfizer and previously in clinical development for the treatment of gastric ulcers in the 1970s. Pfizer discontinued development of the drug, due to lack of efficacy (vs safety issues) for the primary indication (healing of gastric ulcers) in a phase 2 clinical trial.

The Company is developing MLR-1023 (tolimidone) for the treatment of Type 1 diabetes with additional potential indications for nonalcoholic steatohepatitis (NASH), and the prevention of pulmonary edema.

Type 1 and type 2 diabetes both occur when the body cannot properly store and use glucose, which is essential for energy. This glucose then collects in the blood and does not reach the cells that need it, leading to serious complications. Type 1 and Type 2 diabetes are similar insofar as both share (similar) symptoms, including excessive thirst, increased urination, increased infections, fatigue, weight loss, and blurred vision. However, there are often differences in how rapidly symptoms first appear. Type 1 diabetes (T1D) usually appears first in children and adolescents, but it can also occur in adults. In T1D, the immune system attacks pancreatic beta cells so that they can no longer produce insulin. Around 5-10% of people with diabetes have Type 1. T1D seems to have a genetic component and can be diagnosed early in life but also in adulthood. Its causes are not fully known, and there is currently no cure. People with T1D are dependent on injected or pumped insulin to survive.

Type 2 diabetes is more likely to appear as people age, but children may still develop it. In this type, the pancreas produces insulin, but the body cannot use it effectively. Lifestyle factors appear to play a role in its development. The majority of people with diabetes have Type 2, although some 1.7 million people are living with Type 1.

Initially evaluated for the treatment of Type 2 diabetes, MLR-1023 is pharmacologically and structurally different from metformin and sulfonylureas, drugs routinely used in clinical practice for the management of Type 2 diabetes and lowers blood glucose through a unique mechanism of action as a potent and selective inhibitor of lyn kinase (Lyn). Lyn is a member of the Src family of protein tyrosine kinases, which is mainly expressed in hematopoietic cells, in neural tissues liver, and adipose tissue. MLR-1023 also demonstrates glycemic control via insulin sensitization in animal models of Type 2 diabetes. MLR-1023 does not affect PPARα, β, or γ-mediated transactivation, GLP-1-mediated insulin release, or DDP-IV activity. In studies conducted in *in vivo* models of Type 2 diabetes, MLR-1023 decreased blood glucose levels in mouse and rat oral glucose tolerance tests, in db/db mice and Zucker rats. Blood glucose lowering was produced with both acute and chronic dosing regimens. In addition, MLR-1023 produced efficacy with acute oral administration. In combination studies, MLR-1023 was additive with metformin in lowering blood glucose and blocked rosiglitazone-mediated weight gain in chronic dosing studies.

MLR-1023 and T1D

Most recently MLR-1023's potential utility in T1D has been demonstrated by several studies including those conducted independently (of Adhera) at the University of Alberta, where Professor Jean Buteau confirmed lyn kinase (see also above) as a key factor for beta cell survival and proliferation. Importantly, MLR-1023 was able to induce proliferation in beta cells isolated from human cadavers and subsequent studies (at the University of Alberta) have demonstrated that the administration of MLR-1023 was able to induce a "cure" for T1D in animal models. From a mechanism of action perspective, MLR-1023 has been shown to both preserve beta cell degradation and to stimulate beta cell proliferation.

Accelerated development pathway for MLR-1023 in T1D

Commensurate with Adhera's accelerated drug development strategy, The FDA has granted an Investigational New Drug Application (IND) for a Phase 2 study designed to evaluate the efficacy of MLR-1023 in adult T1D patients. It is anticipated that this clinical trial can be completed in 6 months paving the way to the initiation of a pivotal phase 3 clinical trial in less than 24 months.

Rationale for MLR-1023 in the treatment of nonalcoholic steatohepatitis (NASH), and the prevention of pulmonary edema

Extensive preclinical data is highly supportive of the development of MLR-1023 for NASH and also the prevention of pulmonary edema. MLR-1023 reduced fibrosis in a CCl_4 liver fibrosis model and reduced several symptoms of NASH in a modified high fat diet mouse model of NASH as well as in a NASH model involving modified high fat diet model with chronic low dose CCl_4. When administered prophylactically, once per day (q.d.) for 7 days, MLR-1023 significantly mitigated the development of pulmonary edema in mice challenged with an inflammatory insult that modeled sepsis.

Patent Protection

MLR-1023 is protected by a total of 50 issued patents, 3 allowed patent applications, and 20 pending patent applications in the following territories: United States, Australia, Brazil, Canada, China, Europe, France, Germany, Great Britain, Ireland, Luxemburg, Monaco, Switzerland, Hong Kong, Israel, Japan, Mexico, New Zealand, Russia, Singapore, South Africa, and South Korea. Patent expiries range between 2026 and 2038 (with patent term adjustments).

As described below, the Company was previously a commercially focused entity that leveraged innovative distribution models and technologies to improve the quality of care for patients in the United States suffering from chronic and acute diseases with a focus on licensed fixed dose combination therapies for hypertension. On January 4, 2021, the licensor terminated the licensing agreement for the product candidate. As a result, we were left with several license agreements, none of which we are exploiting.

On July 28, 2021, we as licensee and MP2 entered into an exclusive license agreement for the development and commercialization of MLR-1019. MLR-1019 is being developed as a new class of therapeutic for PD and is, to the best of our knowledge, the only drug candidate today to address both movement and non-movement aspects of PD. Under the Agreement, we were granted an exclusive license to use MP's patents and know-how related to MLR-1019 to develop products in consideration for cash payments upon meeting certain performance milestones as well as a royalty of 5% of gross sales.

On August 20, 2021, we as licensee entered into an exclusive license agreement regarding the development and commercialization of Melior's MLR-1023 (the "MLR-1023 Agreement") with Melior Pharmaceuticals I, Inc. ("MP1"). In this Annual Report, we refer to MP2 and MP1 as "MP" or "Melior". This second license is for the development and commercialization of MLR-1023, which is being developed as a novel therapeutic for Type 1 diabetes.

On October 20, 2021, we as licensee expanded the exclusive MLR-1023 Agreement with MP1 to include two additional clinical indications, one for Non-Alcoholic Steatohepatitis (NASH) and the other for pulmonary inflammation.

On November 17, 2021, Melior extended the Company's timeline under the MLR-1023 Agreement from 120 days to 180 days from the effective of the MLR-1023 Agreement for the Company to raise $4 million unless, by 180 days Adhera is in the process of completing transactions to complete the fundraising, then an additional 30 days would be provided to allow for the completion of required fundraising. On February 16, 2022, an addendum to the MLR-1023 Agreement dated August 4, 2021 (the "First Addendum"), was executed by the Company and Melior, which extended the requirement by the Company to raise $4 million (the "Raise Requirement") to June 16, 2022.

On July 18, 2022, the Company and Melior entered into the Second Addendum to the License Agreement (the "Second Addendum"). In accordance with the Second Addendum and subject to the terms and conditions therein, the Raise Requirement was extended to February 1, 2023. Pursuant to the Second Addendum, Melior has a right to terminate the MLR-1023 Agreement as a result of the Company's inability to achieve certain milestones, including the requirement to:

(i) raise $500,000 in working capital;
(ii) resume engagement with Davos Pharmaceutical Manufacturing and Maladi Drugs & Pharmaceuticals such that the initial steps of MLR-1019 API manufacture were initiated;
(iii) pay Melior Pharma l, $136,921 as a license payment;
(iv) maintain the full-time employment of the Chief Scientific Officer who was hired pursuant to the First Addendum;
(v) continue to engage with Aegis Capital on activities aimed at providing an up-listing event;
(vi) for the duration of the MLR-1023 Agreement, Adhera will not in-license any additional assets other than those which it has already in-licensed (MLR-1023 and MLR-1019), except for the Taxeme compound (PGT) previously mentioned in the Second Addendum, however, no funds will be expended on discovery or development of the Taxeme compound during this period; and
(vii) fulfill the Raise Requirement defined in the MLR-1023 Agreement which was extended to February 1, 2023.

As of February 1, 2023, the Company had not raised the additional $500,000 of capital, commenced API manufacturing, nor completed the Raise Requirement as defined in the MLR-1023 Agreement. In March 2023, the Company obtained a verbal agreement with Melior to extend the terms of the MLR-1023 Agreement until such time that the milestones have been met, including payment of the maintenance costs of the MLR-1023 patent. However, Melior may terminate the license of MLR-1023 at any time due to non-performance of continuing license obligations with a 60-day required notice to cure non-performance. Any termination or loss of use of MLR-1023 would have a material adverse effect on our business, which would likely result in the Company discontinuing all operations and seeking bankruptcy protection.

To the extent that resources have been available, we have continued to work with our advisors in an effort to restructure our Company and to identify potential strategic transactions, including the Melior transactions described above, to enhance the value of the Company. However, because of our substantial unpaid debt, if we do not raise additional capital in the immediate future, we might not have sufficient funds available to meet our obligations and it is likely that this would also result in the Company discontinuing all operations and seek bankruptcy protection.

The milestones, payment obligations and other material terms under the foregoing license agreements with Melior are qualified in its entirety by the complete text of the agreements, each of which are provided as an exhibit to this Annual Report on Form 10-K.

Corporate History

Adhera was incorporated under Delaware law under the name Nastech Pharmaceutical Company on September 23, 1983.

On November 15, 2016, Adhera entered into an Agreement and Plan of Merger with IThenaPharma, Inc., a Delaware corporation ("Ithena"), IThena Acquisition Corporation, a Delaware corporation and a wholly-owned subsidiary of IThena ("Merger Sub"), and a representative of the stockholders of IThena (the "Merger Agreement"), pursuant to which, among other things, Merger Sub merged with and into IThena, with IThena surviving as a wholly-owned subsidiary of Adhera (such transaction, the "Merger"). As a result of the Merger, the former holders of IThena common stock immediately prior to the completion of the Merger owned approximately 65% of the issued and outstanding shares of Adhera common stock immediately following the completion of the Merger.

IThena was incorporated under Delaware law on September 3, 2014. IThena is deemed to be the accounting acquirer in the Merger, and thus the historical financial statements of IThena will be treated as the historical financial statements of our company and will be reflected in our quarterly and annual reports for periods ending after the effective time of the Merger. Accordingly, beginning with our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, we started to report the results of IThena and Adhera and their respective subsidiaries on a consolidated basis.

Subsequent to the Merger, we acquired the rights to commercialize Prestalia, an anti-hypertensive drug approved by the FDA from Symplmed Pharmaceuticals LLC in June 2017 pursuant to a license agreement. We marketed Prestalia in the U.S. from June 2018 until December 2019. The license agreement together with all rights to future commercialization activities with respect to the product was terminated in January 2021.

Partnering and Licensing Agreements

Melior

As described above, the Company has acquired licenses to develop and commercialize certain products owned by Melior. The below table summarizes the milestones and payment obligations under each such license agreement.

MLR-1019:

Under the MLR-1019 license, we agreed to make the following milestone payments if the applicable milestone is reached:

Milestone	Milestone Payment
Last patient enrolled into the Phase 2a study	$ 250,000
Positive outcome of the Phase 2a study	$ 1,500,000
Initiation of a Phase 3 study	$ 10,000,000
New Drug Application approval	$ 10,000,000
Total Milestone Payments	$ 21,750,000

Under the license, the Company also agreed to royalty payments of 5% of gross sales if the product is commercialized. The MLR-1019 license terminates upon the last expiration of the patents licensed by the Company, which is presently 2034 subject extensions and renewals of any of such patents. If the Company fails to have its common stock listed on Nasdaq or the NYSE within 12 months after the Company receives a Clinical Trial Authorization from the European Medicines Agency, then the Company's commercial license and rights to MLR-1019 under the license agreement will terminate.

MLR-1023:

Under the MLR-1023 license, we agreed to make the following milestone payments if the applicable milestone is reached:

Milestone	Milestone Payment
Last patient enrolled into the Phase 2a study	$ 250,000
Positive outcome of the Phase 2a study	$ 1,500,000
Initiation of a Phase 3 study	$ 10,000,000
New Drug Application approval	$ 10,000,000
Total Milestone Payments	$ 21,750,000

The agreement also included royalty payments upon commercialization of the product as follows: (i) 8% of future gross product sales, applicable to the first $400,000,000 of gross product sales; (ii) 10% of future gross product sales, applicable to sales after $400,000,000 and up to $800,000,000; and (iii) 12% of future gross product sales applicable to sales after $800,000,000.

Proprietary Rights and Intellectual Property

We have relied primarily on patents and contractual rights and obligations with third parties to protect our proprietary rights and further our operational objectives. We have sought, and, to the extent that we continue our business operations, intend to continue to seek, appropriate patent protection for important and strategic components of our proprietary technologies by filing patent applications in the U.S. and certain foreign countries. To date, the U.S. and non-U.S. patent applications that we have filed, and the patents that have been granted to us, relate to our legacy intranasal and RNA interference programs. As noted elsewhere in this Prospectus, we are in the process of evaluating the path forward for such programs, including seeking options to continue certain programs or to divest assets. There can be no assurance that any of our patents will be guaranteed protection or market exclusivity for our products and product candidates, and to the extent that we do not properly maintain (including paying any required fees) such patents, it is possible that any protection provided to us will be impaired or lost altogether.

We also use license agreements both to access external intellectual property rights and technologies and to convey certain intellectual property rights to others. To the extent that we continue our business operations, our financial success will be dependent in part on our ability to obtain (and maintain) commercially valuable patent claims and to protect our intellectual property rights and to operate without infringing upon the proprietary rights of others.

Further, we have purchase rights for the Licensed Products including the patents and related intellectual property from Melior with respect to the following product candidates:

- MRL 1019 (Patent No. 10,188,651) for the treatment of PD; and
- MRL 1023 (Patent No. 11,033,548) for the treatment of Type 1 diabetes, NASH and pulmonary inflation.

Research and Development

On July 28, 2021, we as licensee and MP2 as licensor, entered into an exclusive license agreement for the development, commercialization, and exclusive license of MLR-1019. MLR-1019 is being developed as a new class of therapeutics for PD and is, to the best of our knowledge, the only drug candidate today with the potential to address both movement and non-movement aspects of PD.

On August 20, 2021, we as licensee entered into the MLR-1023 Agreement for the exclusive license regarding the development and commercialization of Melior's MLR-1023. This second license is for the development and commercialization of MLR-1023, which is being developed as a novel therapeutic for Type 1 diabetes.

On October 20, 2021, we as licensee expanded the MLR-1023 Agreement with MP1 to include two additional clinical indications for Non-Alcoholic Steatohepatitis (NASH) and pulmonary inflammation.

On July 20, 2022, the Company and Melior entered into the Second Addendum. In accordance with the Second Addendum and subject to the terms and conditions therein, the Raise Requirement was extended to February 1, 2023, in exchange for a $136,921 licensing payment that was made by the Company on July 28, 2022. In addition, the Company was required to hire and retain a Chief Scientific Officer, and raise an additional $500,000 in capital in addition to other requirements set forth in the Second Addendum and MLR-1023 Agreement.

As of February 1, 2023, the Company had not raised the additional $500,000 of capital, commenced API manufacturing, nor completed the Raise Requirement as defined in the MLR-1023 Agreement. In March 2023, the Company obtained a verbal agreement with Melior to extend the terms of the MLR-1023 Agreement until such time that the milestones have been met and the Company pays outstanding patent maintenance costs. However, Melior may terminate the license of MLR-1023 at any time due to non-performance of continuing license obligations with a 60-day required notice to cure non-performance.

During the latter part of 2021 and the year 2022, we have been actively engaged in early development activities relating to MLR-1019 and MLR-1023 alongside our licensing partner, CRO's, and patent counsel. In this regard, we have continued to conduct scientific experiments to expand potential clinical indications and file, prosecute, and maintain patents potentially enforceable in the USA and multiple overseas territories.

The drug development process requires ongoing dialogue with the FDA, including the submission of any new drug data. During 2022, the company has maintained an active Investigational New Drug (IND) application required to conduct a Phase 2 clinical trial of MLR-1023 in Type 1 diabetes. We have also developed a protocol for this clinical trial in conjunction with our licensing partner and the Global Contract Clinical Research Organization, PPD. The multi-center Phase 2 clinical trial seeks to evaluate the efficacy of MLR-1023 in 45 adult patients with established Type 1 diabetes. Most recently, in 2022 and in collaboration with the Alberta Diabetes Institute, we have developed a protocol for the initiation of a single center study of MLR-1023 in Type 1 diabetes patients.

The conduct of clinical trials (or the planned conduct of clinical trials) requires that clinical trial supplies are tested on an ongoing basis for stability. These studies have been conducted by Frontage Laboratories (PA) on behalf of the company.

In regard to MLR-1019, our drug candidate for PD, we have similarly developed a clinical protocol for the evaluation of MLR-1019 in up to 60 patients with Parkinson's disease and managed issues arising from clinical supply manufacture, and regulatory considerations arising from these ongoing studies.

We have been also collaborating with two major pharmaceutical companies with a view to out-licensing certain rights to MLR-1019 in Europe, China, and potentially in the USA.

The direction and supervision of these activities necessitated the hire of a Chief Scientific Officer (Dr. Zahed Subhan) with both familiarity with the both MLR-1019 and MLR-1023, and expertise in drug discovery, development, and commercialization.

Facilities

We do not own or lease any real property or facilities. If we advance our business operations, we may seek to lease facilities of our own in order to support our operational and administrative needs. There can be no assurance that such facilities will be available, or that they will be available on suitable terms. Our inability to obtain such facilities could have a material adverse effect on our future plans and operations.

Corporate History

Adhera was incorporated under Delaware law under the name Nastech Pharmaceutical Company on September 23, 1983.

On November 15, 2016, Adhera entered into an Agreement and Plan of Merger with IThenaPharma, Inc., a Delaware corporation ("IThena"), IThena Acquisition Corporation, a Delaware corporation and a wholly-owned subsidiary of IThena ("Merger Sub"), and a representative of the stockholders of IThena (the "Merger Agreement"), pursuant to which, among other things, Merger Sub merged with and into IThena, with IThena surviving as a wholly-owned subsidiary of Adhera (such transaction, the "Merger"). As a result of the Merger, the former holders of IThena common stock immediately prior to the completion of the Merger owned approximately 65% of the issued and outstanding shares of Adhera common stock immediately following the completion of the Merger.

IThena was incorporated under Delaware law on September 3, 2014. IThena was deemed to be the accounting acquirer in the Merger, and thus the historical financial statements of IThena will be treated as the historical financial statements of our company and will be reflected in our quarterly and annual reports for periods ending after the effective time of the Merger. Accordingly, beginning with our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, we started to report the results of IThena and Adhera and their respective subsidiaries on a consolidated basis.

Subsequent to the Merger, we acquired the rights to commercialize Prestalia, an anti-hypertensive drug approved by the U.S. Food and Drug Administration (the "FDA") from Symplmed Pharmaceuticals LLC in June 2017 pursuant to a license agreement with Les Laboratories, Servier, a French pharmaceutical conglomerate . We marketed Prestalia in the U.S. from June 2018 until December 2019. The license agreement with Les Laboratories, Servier together with all rights to future commercialization activities with respect to the product was terminated in January 2021.

Need for Future Financing

We will require substantial additional funds on an immediate basis to continue our business operations. We have in the past raised additional capital to supplement our commercialization, clinical and pre-clinical development and operational expenses through the issuance of common stock, indebtedness including promissory notes and convertible notes, and other derivative securities which have a dilutive effect on existing stockholders. We will need to raise additional funds through equity financing, debt financing, strategic alliances, or other sources, which may result in significant further dilution in the equity ownership of our shares or result in further encumbrances being placed on our assets. There can be no assurance that additional financing will be available when needed or, if available, that it can be obtained on commercially reasonable terms, or that it will be sufficient for us to successfully engage in any of our planned business operations, including re-starting the drug development and discovery programs relating to our legacy RNA interference assets and furthering the research and development efforts with respect to product candidates under our license from Melior. If we are not able to obtain additional financing on a timely basis as required or generate significant capital from the out-licensing and/or divestiture of existing assets, we will not be able to meet our other obligations as they become due and will be forced to scale down or even cease our operations altogether.

As of December 31, 2022, we have $1.7 million of convertible notes including approximately $424,000 in accrued interest outstanding. All of the convertible notes including accrued interest are currently in default. In addition, we have $8.0 million of non-convertible notes and approximately $3.0 of accrued interest outstanding with approximately $5.7 million of principal and $2.9 million of interest in default.

On November 16, 2022, holders of approximately $5.7 million of principal on outstanding promissory notes that were in default agreed to amend the Notes to make them automatically convertible into units consisting of a new series of convertible preferred stock and warrants upon an up-listing financing transaction in which the Company's common stock is listed on The Nasdaq Capital Market or the NYSE American, in exchange for the Holders agreeing to forbear repayment of their Notes and accrued interest until the up-listing transaction has been completed.

The terms for the amendment of the Notes include no less than the following:

- The Notes will automatically convert upon the Uplisting Transaction into the Preferred Stock at 90% of the public offering price;
- In addition, each Holder will receive 0.3 Warrants for every $1.00 of principal on the Holder's original Note;
- The shares of Preferred Stock will be subject to a six-month lock-up period from date of issuance; and
- The Company has agreed to register the Holders' sale of the shares of common stock issuable upon conversion of the Preferred Stock and upon the exercise of the Warrants such that those shares will be freely tradeable following the Uplisting Transaction and expiration of the lock-up period.

The interest on the Notes, as accrued through the date of conversion, will convert into common stock at the offering price for the Up-listing Transaction.

We can provide no assurance that the Company will be able to complete an up-list transaction per the amended terms of the notes or be able to raise additional funding to repay the notes.

Sales and Marketing

We terminated our commercial activities related to Prestalia in December 2019, and the license agreement was subsequently terminated by the licensor in January 2021. Our activities in 2021, were primarily related to inventory storage and destruction for Prestalia.

Competition

The biopharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. The key competitive factors affecting the success of any products and product candidates that we may develop or acquire, to the extent that we may continue to engage in the biopharmaceutical industry, are their efficacy, safety, convenience, price, the level of generic competition and the availability of reimbursement from government and other third-party payors. While we believe that our technology, knowledge and experience provide us with certain competitive advantages, we face potential competition from many different sources, including major and minor pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies, and public and private research institutions. Many of these competitors have greater for capital resources and access to capital than we do, and personnel with more industry experience and scientific background than those we utilize. Our products, and any product candidates that we successfully develop and/or acquire, and later commercialize, will compete with existing therapies and new therapies that may become available in the future.

We anticipate that many of the companies against which we may compete in the future will have significantly greater financial and other resources and expertise in research and development, manufacturing, product acquisition, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the biopharmaceutical industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete, or may compete, with us in recruiting and retaining qualified scientific and management personnel, as well as in acquiring technologies and products complementary to, or that may be necessary for, our programs.

The commercial opportunity for any product candidates that we may acquire and/or develop could be reduced or eliminated if our competitors develop and commercialize drugs or therapies that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any drugs that we may acquire or develop. Our competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic drugs. See "Risk Factors" for more information on the risks we face with respect to our competition.

To date, we have not fully developed, received regulatory approval for or commercialized any of our current product candidates. Our ability to compete will depend, to a great extent, on the speed in which we and our collaborators can develop safe and effective product candidates, complete clinical testing and regulatory approval processes, and coordinate with third parties to produce and distribute the resulting products in sufficient commercial quantities to create and maintain a market for such products at favorable costs and prices. If we do complete development of and obtain regulatory approval to market any product candidate, we anticipate that the competition we would face with respect to such product would be based on a combination of a number of factors including efficacy, safety, reliability, availability, price, patent position, and other factors.

Government Regulation

Government authorities in the U.S. and other countries extensively regulate the research, development, testing, manufacture, labeling, promotion, advertising, distribution and marketing, among other things, of drugs and pharmaceutical products. To the extent that we continue to engage in the biopharmaceutical industry, of which there can be no assurance, all of the products that we anticipate seeking to develop and/or commercialize are expected to be regulated as drug products.

In the U.S., the FDA regulates drug products under the Federal Food, Drug and Cosmetic Act (the "FDCA"), and other laws within the Public Health Service Act. Failure to comply with applicable U.S. requirements, both before and after approval, may subject us to administrative and judicial sanctions, such as a delay in approving or refusal by the FDA to approve pending applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, and/or criminal prosecutions. Before any drug products that we may develop and/or acquire are marketed, they must be approved by the FDA. The steps required before a drug product is approved by the FDA include: (1) pre-clinical laboratory, animal, and formulation tests; (2) submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin; (3) adequate and well-controlled clinical trials to establish the safety and effectiveness of the product for each indication for which approval is sought; (4) submission to the FDA of a New Drug Application ("NDA"); (5) satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug product is produced to assess compliance with cGMP and FDA review; and finally (6) approval of an NDA.

Pre-clinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. The results of the pre-clinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND, which must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions, such as the conduct of the trials as outlined in the IND. In such a case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. There can be no assurance that submission of an IND will result in FDA authorization to commence clinical trials. Once an IND is in effect, each clinical trial to be conducted under the IND must be submitted to the FDA, which may or may not allow the trial to proceed.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified physician-investigators and healthcare personnel. Clinical trials are typically conducted in three defined phases, but the phases may overlap or be combined. Phase 1 usually involves the initial administration of the investigational drug or biologic product to healthy individuals to evaluate its safety, dosage tolerance and pharmacodynamics. Phase 2 usually involves trials in a limited patient population, with the disease or condition for which the test material is being developed, to evaluate dosage tolerance and appropriate dosage; identify possible adverse side effects and safety risks; and preliminarily evaluate the effectiveness of the drug or biologic for specific indications. Phase 3 trials usually further evaluate effectiveness and test further for safety by administering the drug or biologic candidate in its final form in an expanded patient population. To the extent that we engage in any clinical studies, our product development partners, the FDA, or we may suspend clinical trials, if any, at any time on various grounds, including any situation where we or our partners believe that patients are being exposed to an unacceptable health risk or are obtaining no medical benefit from the test material.

Assuming successful completion of the required clinical testing, the results of the pre-clinical trials and the clinical trials, together with other detailed information, including information on the manufacture and composition of the product, are submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. Before approving an application, the FDA will usually inspect the facilities where the product is manufactured and will not approve the product unless cGMP compliance is satisfactory. If the FDA determines the NDA is not acceptable, the FDA may outline the deficiencies in the NDA and often will request additional information. If the FDA approves the NDA, certain changes to the approved product, such as adding new indications, manufacturing changes or additional labeling claims are subject to further FDA review and approval. The testing and approval process require substantial time, effort, and financial resources, and we cannot be sure that any approval of any products that we develop and/or acquire will be granted on a timely basis, if at all.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making available in the U.S. a drug for this type of disease or condition will be recovered from sales in the U.S. for that drug. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same drug for the same indication, except in very limited circumstances, for seven years. The FDA granted orphan drug designation to CEQ508 for the treatment of FAP in December 2010. We are evaluating the best path forward to re-start development activities regarding CEQ508, and evaluating options for our other programs relating to RNA interference.

In addition, regardless of the type of approval, to the extent that we continue to engage in the biopharmaceutical industry, we and our partners will be required to comply with a number of FDA requirements both before and after approval with respect to any products that we may develop, acquire or commercialize. For example, we and our partners will be required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with certain requirements concerning advertising and promotion for products. In addition, quality control and manufacturing procedures must continue to conform to cGMP after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP. Accordingly, manufacturers must continue to expend time, money and effort in all areas of regulatory compliance, including production and quality control to comply with cGMP. In addition, discovery of problems, such as safety problems, may result in changes in labeling or restrictions on a product manufacturer or NDA holder, including removal of the product from the market.

In addition to FDA regulations for the marketing of pharmaceutical products, there are various other state and federal laws that may restrict business practices in the biopharmaceutical industry. These include the following:

- The federal Medicare and Medicaid Anti-Kickback laws, which prohibit persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual, or furnishing or arranging for a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- Other Medicare laws, regulations, rules, manual provisions and policies that prescribe the requirements for coverage and payment for services performed by our customers, including the amount of such payment;

- The federal False Claims Act which imposes civil and criminal liability on individuals and entities who submit, or cause to be submitted, false or fraudulent claims for payment to the government;

- The Foreign Corrupt Practices Act ("FCPA"), which prohibits certain payments made to foreign government officials;

- State and foreign law equivalents of the foregoing and state laws regarding pharmaceutical company marketing compliance, reporting and disclosure obligations;

- The Patient Protection and Affordable Care Act ("ACA"), which among other things changes access to healthcare products and services; creates new fees for the pharmaceutical and medical device industries; changes rebates and prices for health care products and services; and requires additional reporting and disclosure; and

- The Health Insurance Portability and Accountability Act, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), which imposes requirements on certain types of people and entities relating to the privacy, security, and transmission of individually identifiable health information, and requires notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information;

If our operations are found to be in violation of any of these laws, regulations, rules or policies or any other law or governmental regulation, or if interpretations of the foregoing change, we may be subject to civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid programs and the curtailment or restructuring of our operations.

If we bring a product candidate to clinical trial, we may undertake to commence such a trial in a foreign jurisdiction, in which case we and third parties on which we rely would be subject to such foreign government's laws and regulations pertaining to the research and development, including clinical testing on human subjects, of therapeutic product candidates. Further, to the extent that any of the products that we develop and/or acquire are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals. None of our products were ever developed or sold outside the United States.

ITEM 1A. RISK FACTORS

Summary of Risk Factors

An investment in our common stock involves a high degree of risk. You should carefully consider the risks summarized below. These risks are discussed more fully in the "Risk Factors" section immediately following this summary. These risks include, but are not limited to, the following:

Risks Related to Our Business

- Our ability to continue as a going concern is in doubt absent obtaining adequate new debt or equity financing.

- We have $12.8 million of indebtedness including accrued interest and penalties outstanding, of which $10.3 million is in default with increased interest rates, which we may be unable to pay as and when due or at all, and when combined with outstanding warrants and convertible preferred stock would have a dilutive effect on our stockholders and could reduce the price of our common stock.

- Because we expect to need additional capital to fund our growing operations, we may not be able to obtain sufficient capital and may be forced to limit the scope of our operations, discontinue operations and/or commence bankruptcy proceedings.

- If we are not successful in our fund raising and research activities, you may lose your entire investment.

- Because we have a limited operating history under our current business model to evaluate our company, the likelihood of our success must be considered in light of the problems, expenses, difficulties, complications and delay frequently encountered by a new company.

- If we are unable to successfully commercialize MLR-1019, MLR-1023 or any of our other future product candidates our result of operations would be adversely affected.

- Our business may be adversely affected by the COVID-19 pandemic or other world events, and the full extent of such impact remains uncertain.

- We do not have current research and development operations, and we may continue to incur significant operating losses for the foreseeable future and may never generate future revenue from product sales.

- Because we have yet to generate any revenue from product sales from our current business model on which to evaluate our potential for future success and to determine if we will be able to execute our business plan, it is difficult to evaluate our prospects and the likelihood of success or failure of our business.

- Because early-stage drug development requires major capital investment, as we continue to incur operating losses, we will need to raise additional capital and/or form strategic partnerships to support our research and development activities in the future.

Risks Related to the Discovery, Development, and Commercialization of Product Candidates

- If current or future strategic alliances are unsuccessful or are terminated including our Melior agreements, we may be unable to develop or commercialize certain product candidates and we may be unable to generate revenues from our development programs.

- We expect to rely on third parties to conduct some or all aspects of our compound formulation, research and preclinical testing, if those third parties do not perform satisfactorily our business and future prospects would be materially and adversely affected.

- If we are able to commercialize a product candidate, we will rely on third-party manufacturers to produce our preclinical and clinical supplies, or commercial supplies of any approved product candidates, which would subject us to a variety of risks.

- Because we expect to rely on limited sources of supply for the drug substance and drug product of product candidates, any disruption in the chain of supply may cause a delay in developing and commercializing these product candidates.

- If third party manufacturing issues arise, it could increase product and regulatory approval costs or delay commercialization.

- If we do not succeed in our efforts to identify or discover additional potential product candidates, your investment may be lost.

- Because our future commercial success depends on gaining regulatory approval for our products, we cannot generate revenue without obtaining approvals.

- If we are unable to successfully complete preclinical testing and clinical trials of our product candidates or experience significant delays in doing so, our business will be materially harmed.

- Our product candidates may cause adverse effects or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.

- We may not succeed in obtaining or maintaining necessary rights to drug compounds and processes for our development pipeline through acquisitions and in-licenses.

- Because third parties may develop or be developing competitive products without our knowledge, we may later learn that competitive products are superior to our product candidates which may force us to terminate our research efforts of one or more product candidates.

Risks Related to Our Business Operations and Industry

- We rely on a license agreement with Melior Pharmaceuticals I, Inc. for the development and commercialization of Melior's MLR-1023, and if this license is breached or otherwise terminated, we could lose the ability to continue the development and potential commercialization of MLR-1023.

- If we cannot obtain or protect intellectual property rights related to our future products and product candidates, we may not be able to compete effectively in our markets.

- If third-party intellectual property infringement claims are asserted against us, it may prevent or delay our development and commercialization efforts and have a material adverse effect on our business and future prospects.

- We depend on intellectual property licensed from third parties, and termination of any of these licenses could have a material adverse effect on our business.

- We may need to obtain additional licenses to intellectual property rights from third parties.

- We may in the future be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

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

- The commercial success of our product candidates will depend upon the acceptance of these product candidates by the medical community, including physicians, patients and healthcare payors.

- If we lose key management or scientific personnel, cannot recruit qualified employees, directors, officers, or other personnel or experience increases in our compensation costs, our business may materially suffer.

Risks Relating to Ownership of Our Common Stock

- We may not be able to satisfy listing requirements OTCQB or maintain a listing of our common stock on any national market.

- The price of our common stock is volatile, which may cause investment losses for our stockholders.

- The sale of a significant number of our shares of common stock could depress the price of our common stock.

- Future issuance of additional shares of common stock and/or preferred stock could dilute existing stockholders. We have and may issue preferred stock that could have rights that are preferential to the rights of common stock that could discourage potentially beneficial transactions to our common stockholders.

- Our articles of incorporation allow for our Board to create new series of preferred stock without further approval by our stockholders, which could adversely affect the rights of the holders of our common stock.

- We do not anticipate paying any cash dividends on our capital stock in the foreseeable future.

- If securities industry analysts do not publish research reports on us, or publish unfavorable reports on us, then the market price and market trading volume of our common stock could be negatively affected.

- If our securities become subject to the penny stock rules, it would become more difficult to trade our shares.

- Anti-takeover provisions may limit the ability of another party to acquire our company, which could cause our stock price to decline.

- We are authorized to issue "blank check" preferred stock without stockholder approval, which could adversely impact the rights of holders of our securities.

- We filed a Certificate of Amendment to effect a reverse stock split of our outstanding common stock on September 30, 2022 at a ratio of 1-for-20. We may effect additional splits of our common stock to meet NASDAQ uplisting requirements.

- Even if the reverse stock split achieves the requisite increase in the market price of our common stock, we cannot assure you that we will be approved for listing on the Nasdaq Capital Market or able to comply with other continued listing standards of the Nasdaq Capital Market.

- The reverse stock split may decrease the liquidity of the shares of our common stock.

Risk Factors

Investing in our Common Stock involves a high degree of risk. You should carefully consider the following Risk Factors before deciding whether to purchase or sell securities of Adhera. Additional risks and uncertainties not presently known to us, or that we currently deem immaterial, may also impair our business operations or our financial condition. If any of the events discussed in the Risk Factors below occur, our business, consolidated financial condition, results of operations or prospects could be materially and adversely affected. In such case, the value and marketability of the Common Stock could decline.

Risks Related to Our Business

We rely on a license agreement with Melior Pharmaceuticals I, Inc. for the development and commercialization of Melior's MLR-1023, and if this license is breached or otherwise terminated, we could lose the ability to continue the development and potential commercialization of MLR-1023.

We have entered into the Melior Agreement with Melior under which we have an exclusive license to develop and commercialize MLR-1023 worldwide. Under the Melior Agreement, we are subject to various obligations, including obligations with respect to development and commercialization activities, payment obligations upon achievement of certain milestones, capital raising activities, engagement with third parties, as well as other material obligations. Melior has a right to terminate the MLR-1023 Agreement at any time and as a result of the Company's inability to achieve certain milestones, including the requirement under the Second Addendum to: (i) raise $500,000 in working capital; (ii) resume engagement with Davos Pharmaceutical Manufacturing and Maladi Drugs & Pharmaceuticals such that the initial steps of MLR-1019 API manufacture were initiated; (iii) pay Melior Pharma l, $136,921 as a license payment; (iv) maintain the full-time employment of the Chief Scientific Officer who was hired pursuant to the First Addendum; (v) continue to engage with Aegis Capital on activities aimed at providing an up-listing event; (vi) for the duration of the MLR-1023 Agreement, Adhera will not in-license any additional assets other than those which it has already in-licensed (MLR-1023 and MLR-1019), except for the Taxeme compound (PGT) previously mentioned in the Second Addendum, however, no funds will be expended on discovery or development of the Taxeme compound during this period and (vii) fulfill the Raise Requirement defined in the MLR-1023 Agreement which was extended to February 1, 2023.

As of February 1, 2023, the Company had not raised the additional $500,000 of capital, commenced API manufacturing, nor completed the Raise Requirement as defined in the MLR-1023 Agreement. In March 2023, the Company obtained a verbal agreement with Melior to extend the terms of the MLR-1023 Agreement until such time that the milestones have been met, including payment of the maintenance costs of the MLR-1023 patent. However, Melior may terminate the license of MLR-1023 at any time due to non-performance of continuing license obligations with a 60-day required notice to cure non-performance.

The loss of or significant modifications to the MLR-1023 Agreement could prevent us from developing, commercializing, or entering into future strategic transactions relating to MLR-1023. Any termination or loss of use of MLR-1023 would have a material adverse effect on our business, which would likely result in the Company discontinuing all operations and seeking bankruptcy protection. Because of our current financial situation, if we do not raise additional capital in the immediate future, we might not have sufficient funds available to meet our obligations the Company may discontinue all operations and seek bankruptcy protection.

The risks described elsewhere pertaining to our other intellectual property rights also apply to the intellectual property rights that we license, and any failure by us or our licensors to obtain, maintain and enforce these rights could have a material adverse effect on our business. In addition, our business depends on our ability to license from third parties. If we fail to meet our obligations under our current license agreements, we may lose the ability to enter into licenses for the development of additional product candidates in the future, which would adversely affect our business.

Our ability to continue as a going concern is in doubt absent obtaining adequate new debt or equity financing.

We have limited capital and have an accumulated deficit of $55.8 million, and have a working capital deficiency of $22.2 million as of December 31, 2022. In addition, we have $12.8 million of indebtedness including principal and interest on convertible notes and promissory notes of which $10.3 million is currently in default. On November 16, 2022, a majority of the holders of approximately $8.3 million in promissory notes including accrued interest, agreed to amend the notes to make them automatically convertible into units consisting of a new series of convertible preferred stock and warrants as defined in the agreement upon an up-listing financing transaction in which the Company's common stock is listed on The Nasdaq Capital Market or the NYSE American in exchange for the holders agreeing to forbear repayment of their Notes and accrued interest until the offering has been completed. However, there is no assurance that an up-listing financing transaction will occur. If the Company does not complete any significant strategic transactions, or raise substantial additional capital, in the immediate future, it is likely that the Company will seek bankruptcy protection or discontinue all operations. Because we do not have sufficient working capital and cash flows for continued operations for at least the next 12 months, our auditors have issued an unqualified opinion with a going concern explanatory paragraph for the year ended December 31, 2022, indicating that there is substantial doubt about our ability to continue as a going concern. Our continued existence is dependent upon us or obtaining the necessary capital to meet our expenditures. We cannot assure you that we will be able to raise adequate capital to meet our future working capital needs.

We have approximately $12.8 million of indebtedness outstanding including accrued interest, with $10.3 million currently in default with increased interest rates, which we may be unable to pay as and when due or at all, and the conversion when combined with outstanding warrants and convertible preferred stock would have a dilutive effect on our stockholders and could reduce the price of our common stock.

As of December 31, 2022, we have a total of $12.8 million of outstanding indebtedness including approximately $1.8 million of outstanding convertible promissory notes including accrued interest with various conversion prices and $11.0 in non-convertible notes including accrued interest. Given our history of operating losses and continued expenditures, which we expect to increase in the short-term as we attempt to establish and grow our operations and to develop and commercialize existing and new product candidates, we may face difficulty paying these obligations as and when they come due. All of our outstanding convertible notes are in default, with default interest rates from 15% - 24% per annum. The convertible notes may contain price protection or full-ratchets upon the issuance of additional equity which may entitle the holder to receive more shares of common stock upon conversion at a lower exercise price. Conversions of our convertible debt would therefore have a dilutive effect on our stockholders. Further, if we are unable to raise sufficient capital to repay some of our lenders or restructure our outstanding indebtedness, we will likely be forced to cease operations or seek bankruptcy protection, in which case our stockholders would likely receive little to no return on their investment.

Because we expect to need additional capital to fund our growing operations, we may not be able to obtain sufficient capital and may be forced to limit the scope of our operations, discontinue operations and/or commence bankruptcy proceedings.

We currently need substantial working capital. Our accumulated deficit, outstanding indebtedness or a future slowdown in the global economy which may be caused by external forces such as the COVID-19 pandemic or geopolitical turmoil, or national banking related events may adversely affect our ability to raise capital. If adequate additional debt and/or equity financing is not available on reasonable terms or at all, we may not be able to remain in business, and we will have to cease operations. If we do not complete any significant strategic transactions, or raise substantial additional capital, to continue in the biopharmaceutical industry or to enter any other industry in the immediate future, it is likely that we will discontinue all operations and seek bankruptcy protection.

Even if we secure the necessary working capital, we may not be able to negotiate terms and conditions for receiving the additional capital that are acceptable to us. Any future equity capital investments will dilute existing stockholders. In addition, new equity or convertible debt securities issued by us to obtain financing could have rights, preferences and privileges senior to our Common Stock. We cannot give you any assurance that any additional financing will be available to us, or if available, will be on terms favorable to us.

If we are not successful, you may lose your entire investment.

Prospective investors should be aware that if we are not successful in our new business operations, which may involve the use of our legacy product candidates which we have failed to fully develop and commercialize in the past, or new product candidates which are unproven, their entire investment in the Company could become worthless. Even if the Company is successful, we can provide no assurances that investors will derive a profit from their investment. Even if we can raise sufficient capital or generate revenue, we cannot guarantee any resulting proceeds to us will be sufficient for us to grow our operations and become profitable. If we are not successful, you may lose your entire investment.

Because we have a limited operating history under our current business model to evaluate our company, the likelihood of our success must be considered in light of the problems, expenses, difficulties, complications and delay frequently encountered by a new company.

Since we have a limited operating history under our current business model, it is difficult for investors to evaluate our business and prospects. You must consider our prospects in light of the risks, expenses and difficulties we face as an early-stage company with a limited operating history. Investors should evaluate an investment in our company in light of the uncertainties encountered by start-up companies in a highly competitive industry such as ours, which contains significant barriers to market entry. There can be no assurance that our efforts will be successful or that we will be able to attain profitability.

If we are unable to successfully commercialize MLR-1019 or any of our other product candidates and are unable to make milestone payments, our result of operations would be adversely affected.

We recently entered into an exclusive license agreement with Melior to develop and commercialize MLR-1019 as a new class of therapeutics for Parkinson's Disease, or PD. Upon MLR-1019 meeting certain milestones, the Company is required to make milestone payments which total approximately $21.75 million. We currently do not have enough capital to meet any of the milestone payment requirements and cannot assure you will be successful in raising the $250,000 we need to meet the first milestone for the enrollment of a final patient in the Phase 2a study for the product. In the event we are able to negotiate an extension to the MLR 1023 license. The milestone payments are the same as those for the MLR-1019 license. If any milestone is met, there can be no assurance that we will be able to raise sufficient capital in order to fund that milestone. Further, if the drug candidate fails to meet any of the milestones and therefore is unable to be commercialized, we will receive no benefits from these licenses. In any such event, our results of operations will suffer and we may need to cease operations including pursuing bankruptcy. Additionally, MLR–1019 is currently classified as a controlled substance in the United States which may have an adverse effect on our future revenues even if we are able to commercialize it in the United States.

Our business may be adversely affected by the COVID-19 pandemic or other world events, and the full extent of such impact remains uncertain.

Although the COVID-19 pandemic appears to be winding down, we cannot be certain new variants may not arise and cause significant future impact. The United States and global impact from the COVID-19 virus has had a material adverse effect on us in a number of ways including:

- If our personnel or the third parties on which we depend (or the family members of such persons) are infected with the virus, it may hamper our ability to engage in future research activities;
- If these third parties are affected by COVID-19, they may focus on other activities which they may devote their limited time to other priorities rather than to our joint research;
- There have been numerous supply chain disruptions, including shortages, delays and price increases in laboratory equipment and supplies, which could impact our research activities;
- As a result of the continuing impact of the virus, we may fail to get access to third party laboratories which would hinder our research activities;
- We may face challenges related to restrictions and efforts to avoid further spread of the virus, in our efforts the conduct our planned clinical trials consistent with normally applicable approaches and good clinical practice standards, and although regulators including the FDA have offered guidance applicable during the COVID-19 pandemic allowing for flexibility of standards in certain areas and alternate methods of meeting trial oversight obligations (for example, via remote monitoring), the potential impact of these challenges cannot be fully predicted at this time;
- We may fail to appropriately allocate resources or adapt to the rapidly evolving market and regulatory environment caused by the pandemic; and
- We may sustain problems due to the serious short-term and possible longer term economic disruptions and market volatility as the U.S. and global economy faces unprecedented uncertainty.

We have never generated revenue from product sales under our current business model, do not have current research and development operations, and we may continue to incur significant losses for the foreseeable future and never generate revenue from product sales.

We are a pre-clinical and early stage clinical, biopharmaceutical discovery and development company. We currently rely primarily on a license for two product candidates which may never be fully developed for a number of possible reasons which are described elsewhere in these Risk Factors but include the need for sufficient funding to meet milestones, regulatory challenges and uncertainty, and a large number of better capitalized competitors.

Because the research and development of a biopharmaceutical product is an expensive and time-consuming process, we do not anticipate generating revenue from any product sales for the near future and will continue to sustain considerable losses. Should we fail to raise sufficient capital to meet our needs to develop one or more products, we would be forced to discontinue our operations and seek bankruptcy protection.

Because we have yet to generate any revenue from product sales on which to evaluate our potential for future success and to determine if we will be able to execute our business plan, it is difficult to evaluate our prospects and the likelihood of success or failure of our business.

Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with partners, to successfully complete the development of, obtain the regulatory approvals for and commercialize pharmaceutical product candidates. We have no pharmaceutical product candidates that have generated any commercial revenue, do not expect to generate revenues from the commercial sale of pharmaceutical products for foreseeable future, and might never generate revenues from the sale of pharmaceutical products. Our ability to generate revenue and achieve profitability will depend on, among other things, the following:

- identifying and validating new therapeutic strategies;
- entering into collaborations with other pharmaceutical or biotechnology companies;
- initiating and completing clinical trials for pharmaceutical product candidates;
- seeking and obtaining regulatory marketing approvals for pharmaceutical product candidates that successfully complete clinical trials;
- establishing and maintaining supply and manufacturing relationships with third parties;
- launching and commercializing pharmaceutical product candidates for which we obtain regulatory marketing approval, with a partner or, if launched independently, successfully establishing a sales force, marketing and distribution infrastructure;
- maintaining, protecting, enforcing, defending and expanding our intellectual property portfolio; and
- attracting, hiring and retaining qualified personnel.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we cannot predict the timing or amount of increased expenses and when we will be able to achieve or maintain profitability, if ever. Our expenses could increase beyond expectations if we are required by regulatory agencies to perform additional unanticipated studies and trials.

Even if one or more pharmaceutical product candidates we develop independently or with partners is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved pharmaceutical product candidate. Moreover, even if we can generate revenues from the sale of any approved pharmaceutical products, we may not become profitable and may need to obtain additional funding to continue operations.

Because early-stage drug development requires major capital investment, as we continue to incur operating losses, we will need to raise additional capital and/or form strategic partnerships to support our research and development activities in the future.

We are still in the early stages of development of our product candidates and have no products presently in clinical trials or approved for commercial sale. Following the termination of our licensing agreement with Les Laboratories, Servier, a French pharmaceutical conglomerate, for a hypertension treatment product candidate in January 2021, we have continued to strategically evaluate our focus including a return to a drug discovery and development company. To that end, we have entered into licensing agreements for product candidates related to Parkinson's Disease, Type 1 diabetes, Non-Alcoholic Steatohepatitis (NASH) and pulmonary inflammation, in addition to engaging in preliminary discussions regarding potential transactions in our legacy licenses for product candidates. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is capital-intensive. As a rule, research and development expenses increase substantially as we advance our product candidates toward clinical programs. We currently have no product candidates that are in the process of or have completed Phase 3 clinical trials. To conduct trials for our product candidates, we will need to raise additional capital to support our operations and/or form partnerships, in addition to collaborative alliances, which may give substantial rights to a partner. Such funding or partnerships may not be available to us on acceptable terms, or at all. Moreover, any future financing may be very dilutive to our existing stockholders.

As we move lead compounds through toxicology and other preclinical studies, also referred to as nonclinical studies, we will be required to file an Investigational New Drug application ("IND") or its equivalent in foreign countries, and as we conduct clinical development of product candidates, we may have adverse results that may cause us to consume additional capital. Our partners may not elect to pursue the development and commercialization of our product candidates subject to our respective agreements with them. These events may increase our development costs more than we expect. We may need to raise additional capital or otherwise obtain funding through strategic alliances if we initiate clinical trials for new product candidates other than programs currently partnered. We will require additional capital to obtain regulatory approval for, and to commercialize, product candidates.

In securing additional financing, such additional fundraising efforts may divert our management's attention from our day-to-day activities, which may adversely affect our ability to develop and commercialize product candidates. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we cannot raise additional capital when required or on acceptable terms, we may be required to:

- accept terms that restrict our ability to issue securities, incur indebtedness, or otherwise raise capital in the future, or restrict our ability to pay dividends or engage in acquisitions;
- significantly delay, scale back or discontinue the development or commercialization of any product candidates;
- seek strategic alliances for research and development programs at an earlier stage than otherwise would be desirable or on terms less favorable than might otherwise be available; or
- relinquish or license on unfavorable terms, our rights to technologies or any product candidates we otherwise would seek to develop or commercialize ourselves.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from pursuing development and commercialization efforts, which will have a material adverse effect on our business, operating results and prospects or may render the Company unable to continue operations.

Risks Related to the Discovery, Development, and Commercialization of Product Candidates

If current or future strategic alliances are unsuccessful or are terminated, we may be unable to develop or commercialize certain product candidates and we may be unable to generate revenues from our development programs.

We use, and if we can continue our operations are likely to use, third-party alliance partners for financial, scientific, manufacturing, marketing and sales resources for the clinical development and commercialization of certain product candidates. These strategic alliances will likely constrain our control over development and commercialization of our product candidates, especially once a candidate has reached the stage of clinical development. Our ability to recognize revenues from successful strategic alliances may be impaired by several factors including:

- a partner may shift its priorities and resources away from our programs due to a change in business strategies, or a merger, acquisition, sale or downsizing of its company or business unit;
- a partner may cease development in therapeutic areas which are the subject of our strategic alliances;
- a partner may change the success criteria for a program or product candidate delaying or ceasing development of such program or candidate;
- a significant delay in initiation of certain development activities by a partner could also delay payment of milestones tied to such activities, impacting our ability to fund our own activities;

- a partner could develop a product that competes, either directly or indirectly, with an alliance product;

- a partner with commercialization obligations may not commit sufficient financial or human resources to the marketing, distribution or sale of a product;

- a partner with manufacturing responsibilities may encounter regulatory, resource or quality issues and be unable to meet demand requirements;

- a partner may exercise its rights under the agreement to terminate a license or strategic alliance, including termination without cause or termination upon meeting certain conditions. For example, under our license agreement with M1 for the MLR-1023 product, as of February 1, 2023, the Company had not raised the additional $500,000 of capital, commenced API manufacturing, nor completed the Raise Requirement as defined in the MLR-1023 Agreement. In March 2023, the Company obtained a verbal agreement with Melior to extend the terms of the MLR-1023 Agreement until such time that the milestones have been met, including payment of the maintenance costs of the MLR-1023 patent. However, Melior may terminate the license of MLR-1023 at any time due to non-performance of continuing license obligations with a 60-day required notice to cure non-performance.

- a dispute may arise between us and a partner concerning the research, development or commercialization of a program or product candidate resulting in a delay in milestones, royalty payments or termination of a program and possibly resulting in costly litigation or arbitration which may divert management attention and resources; and

- a partner may use our proprietary information or intellectual property to invite litigation from a third-party or fail to maintain or prosecute intellectual property rights possibly jeopardizing our rights in such property.

Termination of a strategic alliance may require us to seek out and establish alternative strategic alliances with third-party partners. This may not be possible, including due to restrictions under the terms of our existing collaborations, or we may not be able to do so on terms acceptable to us. If we fail to establish alternative strategic alliances with third-party partners on terms acceptable to us, or at all, we may be required to limit the size or scope of one or more of our programs or decrease our expenditures and seek additional funding by other means. Such events would likely have a material adverse effect on our results of operations and financial condition.

We expect to rely on third parties to conduct some or all aspects of our compound formulation, research and preclinical testing, if those third parties do not perform satisfactorily our business and future prospects would be materially and adversely affected.

We do not expect to independently conduct most aspects of our drug discovery activities, compound formulation research or preclinical testing of product candidates. Instead, we expect to rely on third parties to conduct some aspects of our preclinical testing and on third-party Clinical Research Organizations (“CROs”) to conduct clinical trials.

If these third parties terminate their engagements, we will need to enter into alternative arrangements which would delay our product development activities. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. If in the future, we elect to develop and commercialize any product candidates on our own, we will remain responsible for ensuring that each of our IND-enabling preclinical studies and clinical trials are conducted under the respective study plans and trial protocols. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our studies under regulatory requirements or our stated study plans and protocols, we will not be able to complete, or may experience delays in completing, the necessary clinical trials and preclinical studies to enable us or our partners to select viable product candidates for IND submissions and will not be able to, or may be delayed in our efforts to, successfully develop and commercialize such product candidates.

If we are able to commercialize a product candidate, we will rely on third-party manufacturers to produce our preclinical and clinical supplies, or commercial supplies of any approved product candidates, which would subject us to a variety of risks.

We have limited manufacturing experience and expect to rely on third parties to assist with manufacturing and related functions. Our anticipated reliance on third-party manufacturers to produce products we may develop in the future entail risks to which we would not be subject if we supplied the materials needed to develop and manufacture our product candidates ourselves, including but not limited to:

- the inability to meet any product specifications and quality requirements consistently;
- a delay or inability to procure or expand sufficient manufacturing capacity;
- discontinuation or recall of reagents, test kits, instruments, and other items used by us in the development, testing, and potential commercialization of products;
- manufacturing and product quality issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- a failure to comply with current Good Manufacturing Practices ("cGMP") and similar foreign standards;
- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- the possibility of breach or termination or nonrenewal of manufacturing agreements with third parties in a manner that is costly or damaging to us;
- the reliance on a few sources, and sometimes, single sources for raw materials, such that if we cannot secure a sufficient supply of these product components, we cannot manufacture and sell product candidates in a timely fashion, in sufficient quantities or under acceptable terms;
- the lack of qualified backup suppliers for any raw materials currently purchased from a single source supplier;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier;
- carrier disruptions or increased costs beyond our control;
- misappropriation of our proprietary technology for the purpose of manufacturing a "generic" version of our product or sale of our product to organizations that distribute and sell counterfeit goods, including drugs; and
- failing to deliver products under specified storage conditions and in a timely manner.

These events could lead to clinical study delays or failure to obtain regulatory approval or impact our ability to successfully commercialize future products. Some of these events could be the basis for regulatory actions, including injunction, recall, seizure or total or partial suspension of production.

Because we expect to rely on limited sources of supply for the drug substance and drug product of product candidates, any disruption in the chain of supply may cause a delay in developing and commercializing these product candidates.

We intend to establish manufacturing relationships with a limited number of suppliers to manufacture raw materials, the drug substance, and the drug product of any product candidate for which we are responsible for preclinical or clinical development. Each supplier may require licenses to manufacture such components if such processes are not owned by the supplier or in the public domain. As part of any marketing approval, a manufacturer and its processes must be qualified by the FDA or foreign regulatory authorities prior to commercialization. If supply from the approved vendor is interrupted, there could be a significant disruption in commercial supply. An alternative vendor would need to be qualified through a New Drug Application ("NDA") or marketing authorization supplement, which could cause further delay. The FDA or other regulatory agencies outside of the United States may also require additional studies if a new supplier is relied upon for commercial production.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing our products successfully. Furthermore, if our suppliers fail to deliver the required commercial quantities of drug substance or drug product on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed, or we could lose potential revenue.

If third party manufacturing issues arise, it could increase product and regulatory approval costs or delay commercialization.

As third parties scale up manufacturing of product candidates and conduct required stability testing, product, packaging, equipment and process-related issues may require refinement or resolution to proceed with any clinical trials and obtain regulatory approval for commercial marketing. We or the manufacturers may identify significant impurities or stability problems, which could cause discontinuation or recall by us or our manufacturers, increased scrutiny by regulatory agencies, delays in clinical programs and regulatory approval, significant increases in our operating expenses, or failure to obtain or maintain approval for product candidates or any approved products.

If we do not succeed in our efforts to develop product candidates, your investment may be lost.

The success of our business depends primarily upon our ability to identify, develop and commercialize drug products, an extremely risky business. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for several reasons, including:

- potential product candidates may have harmful side effects or may have other characteristics that make the products unmarketable or unlikely to receive marketing approval; and

- we or our partners may change their development profiles for potential product candidates or abandon a therapeutic area.

Such events may force us to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could cause us to cease operations. Research programs to identify new product candidates require substantial technical, financial, and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

Because our future commercial success depends on gaining regulatory approval for our products, we cannot generate revenue without obtaining approvals.

Our long-term success and generation of revenue will depend upon the successful development of new products from research and development activities, including those licensed or acquired from third parties. Product development is very expensive and involves a high degree of risk. Only a small number of research and development programs result in the commercialization of a product. For example, the FDA indicates that approximately 70% of drugs proceed past Phase 1 studies, 33% proceed past Phase 2, and just 25%-30% proceed past Phase 3 to Phase 4 which is the final phase in the FDA review and approval process for marketing therapeutic product candidates. The process for obtaining regulatory approval to market product candidates is expensive, usually takes many years, and can vary substantially based on the type, complexity, and novelty of the product candidates involved. Our ability to generate revenues would be adversely affected if we are delayed or unable to successfully develop our products.

We cannot guarantee that any marketing application for our product candidates will be approved. If we do not obtain regulatory approval of our products or we are significantly delayed or limited in doing so, we cannot generate revenue, and we may need to significantly curtail operations.

If we are unable to successfully complete clinical trials of our product candidates or experience significant delays in doing so, our business will be materially harmed.

We intend to invest a significant portion of our efforts and financial resources in the identification and clinical development of pharmaceutical product candidates. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates.

The commercial success of our product candidates will depend on several factors, including:

- identification of viable product candidates and initiation and completion of research and development efforts;
- successful completion of preclinical studies and clinical trials;
- receipt of marketing and pricing approvals from regulatory authorities;
- obtaining and maintaining patent and trade secret protection for product candidates;
- establishing and maintaining manufacturing relationships with third parties or establishing our own manufacturing capability; and
- commercializing our products, if and when approved, whether alone or in collaboration with others.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully complete development of, or to successfully commercialize, our product candidates, which would materially harm our business. Most pharmaceutical products that do overcome the long odds of drug development and achieve commercialization still do not recoup their cost of capital. If we are unable to design and develop each drug to meet a commercial need far in the future, the approved drug may become a commercial failure and our investment in those development and commercialization efforts will have been commercially unsuccessful. In addition, we may be unable to demonstrate safety and efficacy of our product candidates to the satisfaction of regulatory authorities or we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates as a result.

Our product candidates may cause adverse effects or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.

Adverse events ("AEs") or serious adverse events ("SAEs"), that may be observed during clinical trials of our product candidates could cause us, other reviewing entities, clinical trial sites or regulatory authorities to interrupt, delay or halt such trials and could cause denial of regulatory approval. If AEs or SAEs are observed in any clinical trials of our product candidates, including those our partners may develop under alliance agreements, our or our partners' ability to obtain regulatory approval for product candidates may be negatively impacted.

Serious or unexpected side effects caused by an approved product could result in significant negative consequences, including the following:

- regulatory authorities may withdraw prior approval of the product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy ("REMS") which may restrict the manner in which the product can be distributed or administered;
- we may be required to add labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered or conduct additional clinical trials;
- we may decide or be forced to remove the affected product temporarily or permanently from the marketplace;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

These events could prevent us or our partners from achieving or maintaining market acceptance of the affected product and could substantially increase the costs of commercializing our products and impair our ability to generate revenues from the commercialization of these products either by us or by our partners.

Following regulatory approval for a product candidate, we would still face extensive regulatory requirements and the approved product may face future development and regulatory difficulties.

Even if we or our collaboration partners complete clinical trials and obtain regulatory approval in the United States or elsewhere, the applicable regulators may still impose significant restrictions on the indicated uses or marketing of product candidates or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. The following discussion is based on United States law. Similar types of regulatory provisions apply outside of the United States.

The holder of an approved NDA must monitor and report AEs and SAEs and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and other applicable federal and state laws and are subject to FDA review.

Drug product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP, and adherence to commitments made in the NDA. If we, our partners or a regulatory agency discover previously unknown problems with a product such as AEs or SAEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we or our partners fail to comply with regulatory requirements following approval of our product candidates, a regulatory agency may:

- issue a warning letter asserting we are in violation of the law;
- impose a REMS or other restrictions on the manufacturing, marketing or use of the product;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or supplements to an NDA submitted by us;
- seize the product; or
- refuse to allow us to enter into supply contracts, including government contracts.

Our defense of any government investigation of alleged violations of law, or any lawsuit alleging such violations, could require us to expend significant time and resources and could generate negative publicity. Further, the FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates or increase the cost of compliance. The occurrence of any event or penalty described above may prevent or inhibit our ability to commercialize products and generate revenues.

We may not succeed in obtaining or maintaining necessary rights to further drug compounds and processes for our development pipeline through acquisitions and in-licenses.

We may be unable to acquire or in-license any further compositions, methods of use, processes, or other third-party intellectual property rights from third parties we identify. The licensing and acquisition of third-party intellectual property rights is a competitive area, and more established companies are also pursuing strategies to license or acquire third-party intellectual property rights we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

Companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to required third-party intellectual property rights, our business, financial condition, and prospects for growth could suffer.

Because third parties may develop or be developing competitive products without our knowledge, we may later learn that competitive products are superior to our product candidates which may force us to terminate our development efforts of one or more product candidates.

We face potential competition from companies, particularly privately-held companies and foreign companies that may be developing competitive products that are superior to one or more of our product candidates. If in the future, we learn of the existence of one or more competitive products, we may be required to:

- cease our development efforts for a product candidate;
- cause a partner to terminate its support of a product candidate; or
- cause a potential partner to terminate discussions about a potential license.

Any of these events may occur after we have spent substantial sums in connection with the clinical research of one or more product candidates.

Our efforts to identify and develop product candidates are at an early stage. We may be unable to progress our product candidates through clinical trials.

Success in preclinical testing and early clinical trials does not ensure that later clinical trials will succeed, and favorable initial results from a clinical trial do not determine outcomes in subsequent clinical trials. The indications of use for which we pursue development may have clinical effectiveness endpoints not previously reviewed or validated by the FDA or foreign regulatory authorities, which may complicate or delay our effort to obtain marketing approval. We cannot guarantee that any clinical trials we undergo will succeed. In fact, most compounds fail in clinical trials, even at companies far larger and more experienced than us.

We have not commenced clinical trials, obtained marketing approval or commercialized any product candidates. We may not successfully develop a product candidate or design or implement clinical trials required for marketing approval to market our product candidates. If we are unsuccessful in conducting and managing our preclinical development activities or clinical trials or obtaining marketing approvals, we might not be able to commercialize our product candidates, or might be significantly delayed in doing so, which will materially harm our business.

Because of the current inflation affecting the economy, we may be harmed in the future.

Although we currently only have minimal operations, rising prices may have a significant effect on us. In the event, we raise additional capital to ramp up our operations, we may be adversely affected due to increased costs for services from our suppliers. The more active our business is, the more inflation may affect us. As of the date of this Prospectus, we cannot predict how extensive the inflation will be, its duration or the ultimate impact on us.

Risks Related to Our Business Operations and Industry

If we cannot obtain or protect intellectual property rights related to our future products and product candidates, we may not be able to compete effectively in our markets.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our future products and product candidates. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications we own or in-license may fail to result in patents with claims that cover the products in the United States or in other countries. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found; such prior art can invalidate a patent or prevent issuance of a patent based on a pending patent application. Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may cause such patents to be narrowed or invalidated. Even if unchallenged, our patents and patent applications, or those of third-party licensors, may not adequately protect our intellectual property or prevent others from designing around our claims.

If the patent applications we hold or have in-licensed regarding our programs or product candidates fail to issue or if their breadth or strength of protection is threatened, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize products. Patents may not issue and issued patents may be found invalid and unenforceable or challenged by third parties. Since patent applications in the United States and most other countries are confidential for a period after filing, and some remain so until issued, we cannot be certain that we were the first to invent a patent application related to a product candidate. In certain situations, if we and one or more third parties have filed patent applications in the United States and claiming the same subject matter, an administrative proceeding can be initiated to determine which applicant is entitled to the patent on that subject matter. Patents have a limited lifespan. In the United States, the natural expiration of a patent is 20 years after it is filed, although various extensions may be available. The life of a patent, and the protection it affords, is limited. When the patent life has expired for a product, we will become vulnerable to competition from generic medications attempting to replicate that product. Further, if we encounter delays in regulatory approvals, the time during which we will be able to market and commercialize a product candidate under patent protection could be reduced.

In addition to patent protection, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug discovery and development processes that involve proprietary know-how, information or technology not covered by patents. Notwithstanding protective measures we may take, our trade secrets and other confidential proprietary information may be disclosed and competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. In addition, in January 2018 the FDA as part of its Transparency Initiative, launched a voluntary pilot program calling on biopharmaceutical research companies to release clinical study reports summarizing clinical trial data. Following the completion of this pilot program in March 2020, the FDA may consider making release of clinical study reports mandatory and may consider making additional information publicly available on a routine basis in response to concerns expressed by the academic community emphasized by the COVID-19 pandemic, including information we may consider to be trade secrets or other proprietary information. If the FDA takes these measures, we may be forced to disclose propriety information about our product candidates and research, which could materially harm our business.

The laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. We may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

If third-party intellectual property infringement claims are asserted against us, it may prevent or delay our development and commercialization efforts and have a material adverse effect on our business and future prospects.

Our commercial success depends in part on our avoiding infringement on the patents and proprietary rights of third parties. There is substantial litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, and reexaminations and other post-grant proceedings before the U.S. Patent and Trademark Office, and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our partners are pursuing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be patent applications currently pending that may later result in patents that our product candidates may infringe upon. Third parties may obtain patents in the future and claim that use of our technologies infringes on these patents. If any third-party patents were to be held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patents were to be held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making intellectual property claims against us may obtain injunctive or other equitable relief, which could block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, involves substantial litigation expense and diversion of our management's attention from our business. If a claim of infringement against us succeeds, we may have to pay substantial damages, possibly including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

Because of the costs involved in defending patent litigation, we currently lack and may in the future lack the capital to defend our intellectual property rights.

We depend on intellectual property licensed from third parties, and termination of any of these licenses could have a material adverse effect on our business.

We depend on the patents, know-how and other intellectual property, licensed from third parties for the development and, if approved, commercialization of product candidates. If these licenses are terminated, or found to be unenforceable, it could result in the loss of significant rights and could harm our ability to commercialize our future product candidates. For example, on January 4, 2021, Les Laboratories Servier, the licensor under the 2017 Amended and Restated License and Commercialization Agreement pursuant to which we previously had rights for the commercialization of Prestalia®, terminated the license agreement. Prior to the termination, sales by the Company of Prestalia constituted all of our revenue for prior periods, including all of our product revenue during fiscal year 2019.

License agreements impose certain obligations on us, including obligations to use diligent efforts to meet development thresholds, funding requirements and payment obligations. For example, under our license agreement with M1 for the MLR-1023 product, as of February 1, 2023, the Company had not raised the additional $500,000 of capital, commenced API manufacturing, nor completed the Raise Requirement as defined in the MLR-1023 Agreement. In March 2023, the Company obtained a verbal agreement with Melior to extend the terms of the MLR-1023 Agreement until such time that the milestones have been met, including payment of the maintenance costs of the MLR-1023 patent. However, Melior may terminate the license of MLR-1023 at any time due to non-performance of continuing license obligations with a 60-day required notice to cure non-performance. Additionally, under the MLR-1019 license agreement, if the Company fails to get its Common Stock listed on Nasdaq or the NYSE within 12 months after the Company receives a Clinical Trial Authorization from the European Medicines Agency, then the license will terminate.

Further, license agreements are complex, and contain certain provisions which may be susceptible to multiple interpretations. Accordingly, disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including those relating to:

- the scope of rights, if any, granted under the license agreement and other interpretation-related issues;
- whether and to what extent our technology and processes infringe on intellectual property of the licensor that is not subject to the license agreement;
- whether our licensor or its licensor had the right to grant the license agreement;
- whether third parties are entitled to compensation or equitable relief, such as an injunction, for our use of the intellectual property without their authorization;

- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- whether we are complying with our obligations with respect to the use of the licensed technology in relation to our development and commercialization of product candidates;
- our involvement in the prosecution and enforcement of the licensed patents and our licensors' overall patent prosecution and enforcement strategy;
- the allocation of ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and by us and any future partners or collaborators; and
- the amounts of royalties, milestones, or other payments due under the license agreement.

The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement.

We may need to obtain additional licenses to intellectual property rights from third parties.

We may need to obtain additional licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist that might be enforced against our products, resulting in either an injunction prohibiting our sales, or, with respect to our sales and other activities, an obligation on our part to pay royalties and/or other forms of compensation to third parties

The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to develop and commercialize our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. We may not be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding product candidates that we may seek to acquire, in which case our business could be harmed.

We may in the future be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe on patents owned or licensed by us. To counter such infringement or unauthorized use, we or our partners may be required to file infringement claims, or we may be required to defend the validity or enforceability of such patents, which can be expensive and time-consuming. In an infringement proceeding, a court may decide that either one or more of our patents or our licensors' patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue because our patents do not cover that technology. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions regarding our patents or patent applications or those of our partners or licensors. An unfavorable outcome could require us to cease using the related technology or to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may cause us to incur substantial costs and distract the attention of our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Because of the substantial amount of discovery required in intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our Common Stock.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims asserting that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we succeed, litigation could cause substantial cost and be a distraction to our management and other employees.

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

The biotechnology and pharmaceutical industries are intensely competitive. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. Our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. This enables them, among other things, to make greater research and development investments and efficiently utilize their research and development costs. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may cause even more resources being concentrated in our competitors. Additionally, smaller or early-stage companies of which we may not be aware could also prove to be material competitors, particularly through collaborative arrangements with larger, more well-established companies or by competing with us for limited resources and strategic alliances with our current or prospective partners. Competition may increase further because of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may develop, acquire or license drug products that are more effective or less costly than any product candidate we may develop.

Our current or future programs may be targeted toward indications for which there are approved products on the market or product candidates in clinical development. We will face competition from other drugs that are or will be approved for the same therapeutic indications. Our ability to compete successfully will depend largely on our ability to leverage our experience in drug discovery and development to:

- discover and develop therapeutics superior to other products in the market;
- attract and retain qualified scientific, product development and commercial personnel;
- obtain patent and/or other proprietary protection for our technology platform and product candidates;
- obtain required regulatory approvals; and
- successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new therapeutics.

The availability of our competitors' products could limit the demand, and the price we can charge, for any products we may develop and commercialize. We will not achieve our business plan if the acceptance of our products is inhibited by price competition or the reluctance of physicians to switch from existing drug products to our products, or if physicians switch to other new drug products or reserve our products for use in limited circumstances. Additionally, the biopharmaceutical industry is characterized by rapid technological and scientific change, and we may not be able to adapt to these rapid changes to the extent necessary to keep up with competitors or at all. The inability to compete with existing or subsequently introduced drug products would have a material adverse impact on our business, financial condition and prospects.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates less competitive. Any new product that competes with an approved product must typically demonstrate advantages, such as in efficacy, convenience, tolerability or safety, to overcome price competition and to succeed. Our competitors may obtain patent protection, receive approval by FDA and/or foreign regulatory authorities or discover, develop and commercialize product candidates before we do, which would have a material adverse impact on our business.

The commercial success of our product candidates will depend upon the acceptance of these product candidates by the medical community, including physicians, patients and healthcare payors.

Assuming one or more product candidates achieve regulatory approval, and we commence marketing such products, the market acceptance of any product candidates will depend on several factors, including:

- demonstration of clinical safety and efficacy compared to other products;
- the relative convenience, ease of administration and acceptance by physicians, patients and healthcare payors;
- the prevalence and severity of any adverse effects or serious adverse effects;
- limitations or warnings in the label approved by FDA and/or foreign regulatory authorities for such products;
- the timing of market introduction of our products relative to competitive products and the availability of alternative treatments;
- pricing and cost-effectiveness;
- the execution and effectiveness of our or any partners' sales and marketing strategies;
- our ability to obtain hospital formulary approval; and
- our ability to obtain and maintain sufficient third-party payor coverage or reimbursement.

If we obtain regulatory approval for one product candidate, we expect sales to generate substantially all of our product revenues, and as such, the failure of these products to find market acceptance would adversely affect our results of operations. Further, if insurance and/or government coverage and adequate reimbursement are not available for our product candidates, it could impair our ability to achieve and maintain profitability.

Because of the psychotropic properties of MLR-1019, the drug is likely to be designated a controlled substance and subject to classification as a Schedule 1 drug until approval is granted for a medical use.

Schedule 1 drugs, substances, or chemicals are defined as drugs with no currently accepted medical use and a high potential for abuse. Given that MLR1019 has no currently accepted medical use in the USA, the drug is expected to be classified as Schedule 1, until such medical use is granted via an approval from FDA. We can no assurance that even after approval from the FDA that MLR-1019 will be reclassified from a Schedule 1 drug by the Drug Enforcement Division of the U.S. Department of Justice.

We may be subject to increased regulation as well as uncertainty, which may adversely affect our business.

Under the current federal government administration, the FDA, the Centers for Disease Control and other agencies which affect our business may increase their regulatory efforts. At the senior administrative level, new regulators with a regulatory zeal may tighten existing regulations and that approach may also be taken in the routine interactions between staff and our scientists and others. For example, in late calendar year 2021 the White House Office of Management and Budget issued the Fall 2021 Agency Rule List which contains 85 proposed and final rules that the agency plans to issue under the FDA's purview. These rules or other regulatory developments which may occur in the future could have an adverse impact, directly or indirectly, on our operations or on the operations of our collaborators. Increased regulation and enforcement may lead to increased costs and further delays in getting approvals, which may adversely affect our business.

If we lose key management or scientific personnel, cannot recruit qualified employees, directors, officers, or other personnel or experience increases in our compensation costs, our business may materially suffer.

We are highly dependent on our Chief Executive Officer and Interim Chief Scientific Officer, Dr. Zahed Subhan and our Chief Operating Officer and Acting Chief Financial Officer, Andrew Kucharchuk. In addition, services related to our accounting and financial management are being performed by independent contractors. We do not carry "key-man" life insurance on Dr. Subhan. The loss of the services of Dr. Subhan, would leave us without executive and scientific leadership, which could diminish our business and growth opportunities. We will also need to build an executive management team around Dr. Subhan, which could be a time consuming and expensive process and divert management's attention from other pressing matters concerning the Company's operations or growth. The market for highly qualified personnel in this industry is very competitive and we may be unable to attract such personnel in a timely manner, on favorable terms or at all. If we are unable to attract such personnel, our business could be harmed. If we fail to procure the services of additional executive management or implement and execute an effective contingency or succession plan for Dr. Subhan, the loss of Dr. Subhan would significantly disrupt our business.

Other than Dr. Subhan and Mr. Kucharchuk, we have no other officers. Our future success will also depend in part on our ability to identify, hire, and retain additional personnel. We may not be able to attract and retain personnel on acceptable terms, as there is significant competition among numerous pharmaceutical companies for individuals with similar skill sets. Because of this competition, our compensation costs may increase significantly. If we lose key employees or advisors or fail to procure their services on acceptable terms as and when needed, our business may suffer.

If we expand our organization, we may experience difficulties in managing growth, which could disrupt our operations.

As of that date of this Prospectus, we employ one employee and our current Chief Operating Officer. Services related to our accounting and financial management are being performed by independent contractors. As our company matures, we expect to hire employees to increase our managerial, scientific and operational, commercial, financial and other resources and to hire more consultants and contractors. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may cause weaknesses in our infrastructure, and give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as developing additional product candidates. If our management cannot effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to develop and commercialize product candidates and compete effectively will depend, in part, on our ability to manage our future growth.

Because we would face potential product liability if claims are brought against us with respect to any product we commercialize in the future, in such an event we may incur substantial liability and costs.

Any future use of our product candidates in clinical trials or the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. Regardless of merit or eventual outcome, product liability claims may cause:

- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs due to related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- regulatory scrutiny and product recalls, withdrawals or labeling, marketing or promotional restrictions;
- the inability to commercialize our product candidates; and
- decreased demand for our product candidates, if approved for commercial sale.

Insurance coverage is becoming increasingly expensive and we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If we obtain marketing approval for product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. Occasionally, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

If we fail to comply with applicable laws and regulations, including environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes, and the treatment of animals used in research. The research, development and commercialization of drug candidates involve using hazardous and flammable materials, including chemicals and biological materials. These activities also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. If contamination occurs or injury results from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Risks Relating to Ownership of Our Common Stock

We may not be able to satisfy listing requirements of Nasdaq Capital Markets or maintain a listing of our common stock on the OTCQB.

Our common stock is quoted on the OTCQB market operated by OTC Markets Group Inc. We plan to apply for the listing of our common stock on Nasdaq Capital Markets. The closing of an offering is contingent upon our up listing to the Nasdaq Capital Markets unless such condition is waived by the underwriter. In addition, we must meet certain financial and liquidity criteria to maintain the listing of our common stock on Nasdaq Capital Markets. If we fail to meet any listing standards or if we violate any listing requirements, our common stock may be delisted. In addition, our Board of Directors may determine that the cost of maintaining our listing on a national securities exchange outweighs the benefits of such listing. A delisting of our common stock from the Nasdaq Capital Markets may materially impair our stockholders' ability to buy and sell our common stock and could have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock. The delisting of our common stock could significantly impair our ability to raise capital and the value of your investment.

The price of our common stock is volatile, which may cause investment losses for our stockholders.

The market price of our common stock has been and is likely in the future to be volatile. Our common stock price may fluctuate in response to factors such as:

- Announcements by us regarding liquidity, significant acquisitions, equity investments and divestitures, strategic relationships, addition or loss of significant customers and contracts, capital expenditure commitments and litigation;
- Issuance of convertible or equity securities and related warrants for general or merger and acquisition purposes;
- Issuance or repayment of debt, accounts payable or convertible debt for general or merger and acquisition purposes;
- Sale of a significant number of shares of our common stock by stockholders;
- General market and economic conditions;
- Quarterly variations in our operating results;
- Investor and public relation activities;
- Announcements of technological innovations;
- New product introductions by us or our competitors;
- Competitive activities;
- Low liquidity; and
- Additions or departures of key personnel.

These broad market and industry factors may have a material adverse effect on the market price of our common stock, regardless of our actual operating performance. These factors could have a material adverse effect on our business, financial condition, and results of operations.

The sale or conversion of our shares of common stock could depress the price of our common stock.

As of December 31, 2022, we had 3,160,877 shares of common stock issued and outstanding of which 2,471,881 or 78% of the total shares outstanding are restricted and are thus not currently trading. As of December 31, 2022, there were $1.7 million of outstanding convertible promissory notes including accrued interest with various conversion prices and $11.0 million in non-convertible notes including accrued interest, 446,500 additional shares of our common stock that are reserved for issuance under the 2018 Long-Term Incentive Plan, 100 outstanding shares of Series C Preferred Stock convertible into 3,334 shares of common stock, 40 outstanding shares of Series D Preferred Stock convertible into 2,500 shares of common stock, and 267 outstanding shares of Series E Preferred Stock including accrued dividends convertible into 183,346 shares of common stock. On November 16, 2022, a majority of the holders of approximately $8.6 million of the 2019 non-convertible promissory notes including accrued interest, agreed to amend the notes to make them automatically convertible into units consisting of a new series of convertible preferred stock and warrants as defined in the agreement upon an up-listing financing transaction in which the Company's common stock is listed on The Nasdaq Capital Market or the NYSE American in exchange for the Holders agreeing to forbear repayment of their Notes and accrued interest until the up-listing transaction has been completed.

Significant shares of common stock are held by our principal stockholders and other large stockholders. As "affiliates," as defined under Rule 144 under the Securities Act, our principal stockholders, other of our insiders and other large stockholders may only sell their shares of common stock in the public market pursuant to an effective registration statement or in compliance with Rule 144.

These options, warrants, convertible notes payable and convertible preferred stock could result in further dilution to common stockholders and may affect the market price of the common stock.

Future issuance of additional shares of common stock and/or preferred stock could dilute existing stockholders. We have and may issue preferred stock that could have rights that are preferential to the rights of common stock that could discourage potentially beneficial transactions to our common stockholders.

Pursuant to our articles of incorporation, we currently have authorized 180,000,000 shares of common stock and 100,000 shares of preferred stock. To the extent that common shares are available for issuance, subject to compliance with applicable stock exchange listing rules, our Board of Directors has the ability to issue additional shares of common stock in the future for such consideration as the Board of Directors may consider sufficient. The issuance of any additional securities could, among other things, result in substantial dilution of the percentage ownership of our stockholders at the time of issuance, result in substantial dilution of our earnings per share and adversely affect the prevailing market price for our common stock.

An issuance of additional shares of preferred stock could result in a class of outstanding securities that would have preferences with respect to voting rights and dividends and in liquidation over our common stock and could, upon conversion or otherwise, have all of the rights of our common stock. Our Board of Directors' authority to issue preferred stock could discourage potential takeover attempts or could delay or prevent a change in control through merger, tender offer, proxy contest or otherwise by making these attempts more difficult or costly to achieve. The issuance of preferred stock could impair the voting, dividend and liquidation rights of common stockholders without their approval.

Our articles of incorporation allow for our Board to create new series of preferred stock without further approval by our stockholders, which could adversely affect the rights of the holders of our common stock.

Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our board of directors also has the authority to issue preferred stock without further stockholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock, beyond the series of preferred stock that has previously been issued, that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. In addition, our Board of Directors could authorize the issuance of a series of preferred stock that has greater voting power than our common stock or that is convertible into our common stock, which could decrease the relative voting power of our common stock or result in dilution to our existing stockholders.

Future issuances of debt securities, which would rank senior to our common stock upon our bankruptcy or liquidation, and future issuances of preferred stock, which could rank senior to our common stock for the purposes of dividends and liquidating distributions, may adversely affect the level of return you may be able to achieve from an investment in our securities.

In the future, we may attempt to increase our capital resources by offering debt securities. Upon bankruptcy or liquidation, holders of our debt securities, and lenders with respect to other borrowings we may make, would receive distributions of our available assets prior to any distributions being made to holders of our common stock. Moreover, if we issue preferred stock, the holders of such preferred stock could be entitled to preferences over holders of common stock in respect of the payment of dividends and the payment of liquidating distributions. Because our decision to issue debt or preferred stock in any future offering, or borrow money from lenders, will depend in part on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of any such future offerings or borrowings. Holders of our securities must bear the risk that any future offerings we conduct or borrowings we make may adversely affect the level of return, if any, they may be able to achieve from an investment in our securities.

Future capital raises may dilute our existing stockholders' ownership and/or have other adverse effects on our operations.

If we raise additional capital by issuing equity securities, our existing stockholders' percentage ownership will be reduced, and these stockholders may experience substantial dilution. We may also issue equity securities that provide for rights, preferences and privileges senior to those of our common stock. If we raise additional funds by issuing debt securities, these debt securities would have rights senior to those of our common stock and the terms of the debt securities issued could impose significant restrictions on our operations, including liens on our assets. If we raise additional funds through collaborations and licensing arrangements, we may be required to relinquish some rights to our technologies or candidate products, or to grant licenses on terms that are not favorable to us.

We do not anticipate paying any cash dividends on our capital stock in the foreseeable future.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business, and we do not anticipate paying any cash dividends on our capital stock in the foreseeable future. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

If securities industry analysts do not publish research reports on us, or publish unfavorable reports on us, then the market price and market trading volume of our common stock could be negatively affected.

Any trading market for our common stock may be influenced in part by any research reports that securities industry analysts publish about us. We do not currently have and may never obtain research coverage by securities industry analysts. If no securities industry analysts commence coverage of us, the market price and market trading volume of our securities could be negatively affected. In the event we are covered by analysts, and one or more of such analysts downgrade our securities, or otherwise reports on us unfavorably, or discontinues coverage of us, the market price and market trading volume of our securities could be negatively affected.

If our securities become subject to the penny stock rules, it would become more difficult to trade our shares.

The U.S. Securities and Exchange Commission (the "SEC") has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than $5.00, other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. If we do not retain a listing on Nasdaq Capital Markets or another national securities exchange and if the price of our securities is less than $5.00, our securities could be deemed a penny stock. The penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that before effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser's written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our securities, and therefore stockholders may have difficulty selling their securities.

Anti-takeover provisions may limit the ability of another party to acquire our company, which could cause our stock price to decline.

Our articles of incorporation, our bylaws and Delaware law contain provisions that could discourage, delay or prevent a third party from acquiring our company, even if doing so may be beneficial to our stockholders. In addition, these provisions could limit the price investors would be willing to pay in the future for shares of our common stock.

We are authorized to issue "blank check" preferred stock without stockholder approval, which could adversely impact the rights of holders of our securities.

Our articles of incorporation authorize us to issue up to 100,000 shares of blank check preferred stock. Any preferred stock that we issue in the future may rank ahead of our securities in terms of dividend priority or liquidation premiums and may have greater voting rights than our securities. In addition, such preferred stock may contain provisions allowing those shares to be converted into shares of common stock, which could dilute the value of our securities to current stockholders and could adversely affect the market price, if any, of our securities. In addition, the preferred stock could be utilized, under certain circumstances, as a method of discouraging, delaying or preventing a change in control of our company. Although we have no present intention to issue any shares of authorized preferred stock, there can be no assurance that we will not do so in the future.

We effected a reverse stock split of our outstanding common stock on September 30, 2022 at a ratio of 1-for-20.

On September 30, 2022, we filed a Certificate of Amendment to the Certificate of Incorporation with the Delaware Secretary of State to effect a reverse stock split of all outstanding shares of the Company's common stock at a ratio of 1-for-20. The Certificate of Amendment became was effected on October 5, 2022. We expect that the reverse stock split may increase the market price of our common stock while our stock is trading. However, the effect of a reverse stock split upon the market price of our common stock cannot be predicted with certainty, and the results of reverse stock splits by companies in similar circumstances have been varied. It is possible that the market price of our common stock following the reverse stock split will not increase sufficiently for us to be in compliance with the minimum market price requirement of the Nasdaq Capital Market, or if it does, that such price will be sustained. If we are unable to meet the minimum market price requirement, we may be unable to list our shares on the Nasdaq Capital Market, in which case such an offering may not be completed.

Even if the reverse stock split achieves the requisite increase in the market price of our common stock, we cannot assure you that we will be approved for listing on the Nasdaq Capital Market or able to comply with other continued listing standards of the Nasdaq Capital Market.

Even if the reverse stock split achieves the requisite increase in the market price of our common stock to be in compliance with the minimum bid price of Nasdaq, there can be no assurance that the market price of our common stock following the reverse stock split will remain at the level required for continuing compliance with that requirement. It is not uncommon for the market price of a company's common stock to decline in the period following a reverse stock split. If the market price of our common stock declines following the effectuation of the reverse stock split, the percentage decline may be greater than would occur in the absence of a reverse stock split. In any event, other factors unrelated to the number of shares of our common stock outstanding, such as negative financial or operational results, could adversely affect the market price of our common stock and jeopardize our ability to meet or maintain Nasdaq's minimum bid price requirement.

The Nasdaq Capital Market requires that the trading price of its listed stocks remain above one dollar in order for the stock to remain listed. If a listed stock trades below one dollar for more than 30 consecutive trading days, then it is subject to delisting from Nasdaq. In addition, to maintain a listing on Nasdaq, we must satisfy minimum financial and other continued listing requirements and standards, including those regarding director independence and independent committee requirements, minimum stockholders' equity, and certain corporate governance requirements. If we are unable to satisfy these requirements or standards, we could be subject to delisting, which would have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we would expect to take actions to restore our compliance with the listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the minimum bid price requirement, or prevent future non-compliance with the listing requirements.

The reverse stock split may decrease the liquidity of the shares of our common stock.

The liquidity of the shares of our common stock may be affected adversely by the reverse stock split given the reduced number of shares that will be outstanding following the reverse stock split, especially if the market price of our common stock does not increase as a result of the reverse stock split. In addition, the reverse stock split may increase the number of stockholders who own odd lots (less than 100 shares) of our common stock, creating the potential for such stockholders to experience an increase in the cost of selling their shares and greater difficulty effecting such sales.

Following the reverse stock split, the resulting market price of our common stock may not attract new investors, including institutional investors, and may not satisfy the investing requirements of those investors. Consequently, the trading liquidity of our common stock may not improve.

Although we believe that a higher market price of our common stock may help generate greater or broader investor interest, there can be no assurance that the reverse stock split will result in a share price that will attract new investors, including institutional investors. In addition, there can be no assurance that the market price of our common stock will satisfy the investing requirements of those investors. As a result, the trading liquidity of our common stock may not necessarily improve.

We may not receive any additional funds upon the exercise of the warrants.

Each warrant may be exercised by way of a cashless exercise, meaning that the holder may not pay a cash purchase price upon exercise, but instead would receive upon such exercise the net number of shares of our common stock determined according to the formula set forth in the warrant. If a registration statement registering the issuance of the shares of common stock underlying the warrants under the Securities Act is not effective or available and an exemption from registration under the Securities Act is not available for the issuance of such shares, the holder may elect to exercise the warrant through a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the warrant. Accordingly, we may not receive any additional funds upon the exercise of the warrants.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not Applicable.

ITEM 2. PROPERTIES

We do not own or lease any real property or facilities. If we advance our business operations, we may seek to lease facilities of our own in order to support our operational and administrative needs. There can be no assurance that such facilities will be available, or that they will be available on suitable terms. Our inability to obtain such facilities could have a material adverse effect on our future plans and operations.

ITEM 3. LEGAL PROCEEDINGS

From time-to-time, we may become a party to litigation and subject to claims incident to the ordinary course of our business. Although the results of such litigation and claims in the ordinary course of business cannot be predicted with certainty, we believe that due to our lack of capital any litigation will have a material adverse effect on our business, results of operations or financial condition. In addition, litigation can have an adverse impact on us because of defense costs, diversion of management resources and other factors.

ITEM 4. MINE SAFETY DISCLOSURES

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 trades on the OTCQB under the symbol "ATRX". On March 27, 2023, the closing price of our common stock reported by the OTCQB was $0.55 per share.

Holders of record

As of March 31, 2023, there were approximately 172 beneficial holders of record of our common stock. Because many of our shares are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of beneficial holders represented by these record holders.

Dividends

Payment of dividends and the amount of dividends depend on matters deemed relevant by our Board, such as our results of operations, financial condition, cash requirements, future prospects and any limitations imposed by law, credit agreements and debt securities. In addition, convertible note covenants currently limit the Company's ability to issue dividends while the notes are outstanding. To date, we have not paid any cash dividends or stock dividends on our common stock. We currently anticipate that we will not pay any cash dividends on our common stock in the foreseeable future. Furthermore, the terms of the financing arrangements that we have entered into any financing arrangements that we may enter into in the future, may restrict our ability to pay any dividends on our common stock.

Unregistered sales of equity securities

All unregistered sales of our equity securities during the period covered by this Report have been previously reported.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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

Cautionary Note Regarding Forward-Looking Statements

This Report includes forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995, including statements regarding our licenses and the development of product candidates thereunder, our ability to resolve issues with holders of our unsecured note holders, our liquidity and need for and ability to access capital and the expected terms of future financings. The words "believe," "may," "estimate," "continue," "anticipate," "intend," "should," "plan," "could," "target," "potential," "is likely," "will," "expect" and similar expressions, as they relate to us, are intended to identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs.

The results anticipated by any or all of these forward-looking statements might not occur. Important factors, uncertainties and risks that may cause actual results to differ materially from these forward-looking statements include those described in this Report under "Item 1A – Risk Factors" and in our other filings with the Securities and Exchange Commission (the "SEC"). We undertake no obligation to publicly update or revise any forward-looking statements, whether as the result of new information, future events or otherwise. For more information regarding some of the ongoing risks and uncertainties of our business.

Overview

The following Management's Discussion and Analysis of Financial Condition and Results of Operations is intended to provide information necessary to understand our audited consolidated financial statements for each of the two-years in the period ended December 31, 2022, and highlight certain other information which, in the opinion of management, will enhance a reader's understanding of our financial condition, changes in financial condition and results of operations. In particular, the discussion is intended to provide an analysis of significant trends and material changes in our financial position and the operating results of our business during the year ended December 31, 2022, as compared to the year ended December 31, 2021. This discussion should be read in conjunction with our consolidated financial statements for each of the two-years in the period ended December 31, 2022, and related notes included elsewhere in this Report. These historical financial statements may not be indicative of our future performance. This Management's Discussion and Analysis of Financial Condition and Results of Operations contains a number of forward-looking statements, all of which are based on our current expectations and could be affected by the uncertainties and risks described throughout this filing, particularly in "Item 1A. Risk Factors."

Corporate Overview

We are an emerging specialty biotech company with a focus on drug development and commercialization of "small molecule" drugs to treat Parkinson's disease (PD) and Type 1 diabetes. Companies operating in the drug development and biotech sectors typically in-license early-stage inventions or pre-clinical (stage) compounds from universities and other companies and apply their own drug discovery and development expertise and resources to further these drug candidates towards regulatory approval by the Food and Drug Administration (FDA), and potentially other regulatory bodies overseas. The ultimate objectives are to secure regulatory authorizations in the USA and territories internationally, and to generate revenues from marketing activities. Drug candidates may also be licensed (out) to pharmaceutical companies prior to obtaining final regulatory approvals and marketing authorizations for valuable consideration, including upfront payments, milestone payments and royalties.

We utilize a "virtual" drug development model, also prevalent in this industry sector. In this model, Contract Research Organizations (CROs) are typically employed to undertake certain drug discovery and development services on the Company's behalf and under the Company's direct supervision.

On July 28, 2021, we as licensee and MP2 entered into an exclusive license agreement for the development and commercialization of MLR-1019. MLR-1019 is being developed as a new class of therapeutic for PD and is, to the best of our knowledge, the only drug candidate today to address both movement and non-movement aspects of PD. Under the Agreement, we were granted an exclusive license to use MP's patents and know-how related to MLR-1019 to develop products in consideration for cash payments upon meeting certain performance milestones as well as a royalty of 5% of gross sales.

On August 20, 2021, we as licensee entered into an exclusive license agreement regarding the development and commercialization of Melior's MLR-1023 (the "MLR-1023 Agreement") with Melior Pharmaceuticals I, Inc. ("MP1"). In this Annual Report, we refer to MP2 and MP1 as "MP" or "Melior". This second license is for the development and commercialization of MLR-1023, which is being developed as a novel therapeutic for Type 1 diabetes.

On October 20, 2021, we as licensee expanded the exclusive MLR-1023 Agreement with MP1 to include two additional clinical indications, one for Non-Alcoholic Steatohepatitis (NASH) and the other for pulmonary inflammation.

On November 17, 2021, Melior extended the Company's timeline under the MLR-1023 Agreement from 120 days to 180 days from the effective of the MLR-1023 Agreement for the Company to raise $4 million unless, by 180 days Adhera is in the process of completing transactions to complete the fundraising, then an additional 30 days would be provided to allow for the completion of required fundraising. On February 16, 2022, an addendum to the MLR-1023 Agreement dated August 4, 2021 (the "First Addendum"), was executed by the Company and Melior, which extended the requirement by the Company to raise $4 million (the "Raise Requirement") to June 16, 2022.

On July 18, 2022, the Company and Melior entered into the Second Addendum to the License Agreement (the "Second Addendum"). In accordance with the Second Addendum and subject to the terms and conditions therein, the Raise Requirement was extended to February 1, 2023. Pursuant to the Second Addendum, Melior has a right to terminate the MLR-1023 Agreement as a result of the Company's inability to achieve certain milestones, including the requirement to:

(i) raise $500,000 in working capital;
(ii) resume engagement with Davos Pharmaceutical Manufacturing and Maladi Drugs & Pharmaceuticals such that the initial steps of MLR-1019 API manufacture were initiated;
(iii) pay Melior Pharma l, $136,921 as a license payment;
(iv) maintain the full-time employment of the Chief Scientific Officer who was hired pursuant to the First Addendum;
(v) continue to engage with Aegis Capital on activities aimed at providing an up-listing event;
(vi) for the duration of the MLR-1023 Agreement, Adhera will not in-license any additional assets other than those which it has already in-licensed (MLR-1023 and MLR-1019), except for the Taxeme compound (PGT) previously mentioned in the Second Addendum, however, no funds will be expended on discovery or development of the Taxeme compound during this period; and
(vii) fulfill the Raise Requirement defined in the MLR-1023 Agreement which was extended to February 1, 2023.

As of February 1, 2023, the Company had not raised the additional $500,000 of capital, commenced API manufacturing, nor completed the Raise Requirement as defined in the MLR-1023 Agreement. In March 2023, the Company obtained a verbal agreement with Melior to extend the terms of the MLR-1023 Agreement until such time that the milestones have been met, including payment of the maintenance costs of the MLR-1023 patent. However, Melior may terminate our license of MLR-1023 at any time but only in response to non-performance of continuing license obligations and with the required notice to cure non-performance. Any termination or loss of use of MLR-1023 would have a material adverse effect on our business, which would likely result in the Company discontinuing all operations and seeking bankruptcy protection.

To the extent that resources have been available, we have continued to work with our advisors in an effort to restructure our Company and to identify potential strategic transactions, including the Melior transaction described above to enhance the value of the Company. Because of our substantial unpaid debt, if we do not raise substantial additional capital in the immediate future, it is likely that the company will discontinue all operations or seek bankruptcy protection.

Results of Operations

Comparison of the Year Ended December 31, 2022 to the Year Ended December 31, 2021

Operating Expenses

Operating expenses were approximately $1.6 million for the year ended December 31, 2022, a decrease of approximately $924,000 compared to the same period in 2021. The following table summarizes our operating expenses for the years ended December 31, 2022 and 2021:

	Year Ended		
(in thousands)	December 31, 2022	December 31, 2021	Change
Sales and marketing	$ -	$ 17	$ (17)
General and administrative	1,618	657	961
Total operating expenses	$ (1,618)	$ (674)	$ 944

Sales and Marketing

Sales and marketing expenses decreased by approximately $17,000, primarily due to the termination of our commercial operations related to the sale of Prestalia® in December 2019. Sales and marketing expenses for the year ended December 31, 2021, were primarily related to the storage and destruction of Prestalia® inventory. No sales and marketing expenses were incurred for the year ended December 31. 2022.

General and Administrative

General and administrative expenses increased by approximately $961,000 for the year ended December 31, 2022, as compared to the year ended December 31, 2021. The increase was primarily due to a $137,000 licensing payment to Melior I for the MLR-1023 license agreement, an increase in compensation cost of $262,000 including costs related to the hiring a Chief Scientific Officer, a $161,000 increase in fees paid for director and officer insurance and a $401,000 increase in other public company fees including legal expenses, audit fees, and other consulting.

Other Expenses

The following table summarizes other expenses for the year December 31, 2022 and 2021:

	Year Ended		
(in thousands)	December 31, 2022	December 31, 2021	Change Inc/(Dec)
Interest expense	$ (1,344)	$ (1,035)	$ 309
Initial and change in the fair value of derivative liability	2,324	(4,103)	(6,427)
Loss on extinguishment of debt	333	(141)	(474)
Amortization of debt discount	(1,809)	(398)	1,411
Total other expense	$ (496)	$ (5,677)	$ (5,181)

Interest expense for the year ended December 31, 2022, increased by $309,000 compared to the year ended December 31, 2021, primarily due to an increase in outstanding promissory notes. The initial and change in the fair value of the derivative liability as of December 31, 2022, decreased by $6.4 million as a result of a decrease in the fair value of our convertible notes and warrants that were classified as a derivative on our consolidated balance sheet as of December 31, 2022. The gain on extinguishment of debt in 2022 was due to the repayment and conversions of principal and interest on our outstanding convertible notes. The increase of $1.4 million for the amortization of debt discount was due an increase in the amortization of debts discounts as a result of an increase in our promissory notes outstanding.

Liquidity & Capital Resources

Cash Flows

The following table summarizes cash flows for the year ended December 31, 2022 and 2021:

	Year Ended	
(in thousands)	December 31, 2022	December 31, 2021
Net cash used in operating activities	$ (1,415)	$ (665)
Net cash used in investing activities	—	—
Net cash provided by financing activities	1,371	739
Increase/(Decrease) in cash	$ (44)	$ 74

Net cash used in Operating Activities

Net cash used in operating activities was approximately $1.4 million during the year ended December 31, 2022. This was primarily due to our net operating loss of approximately $2.1 million, partially offset by to our derivative income of approximately $2.3 million, non-cash interest expense related to term loans of $1.3 million, non-cash amortization of debt discounts and fees of $1.8 million, gain on extinguishment of debt of approximately $333,000 and other changes in operating assets and liabilities including an increase in operating assets and liabilities of approximately $203,000.

Net cash used in operating activities was approximately $665,000 during the year ended December 31, 2021. This was primarily due to our net operating loss of approximately $6.4 million, partially offset by to our derivative expense of approximately $4.1 million, non-cash interest expense related to term loans of $1.0 million, non-cash amortization of debt discounts of $398,000, loss on extinguishment of debt of approximately $141,000 and other changes in operating assets and liabilities including an increase in prepaid expenses, accounts payable and accrued expenses of approximately $10,000.

Net cash used in Investing Activities

There was no cash used in or provided by investing activities during the years ended December 31, 2022, or 2021.

Net cash provided by Financing Activities

Net cash provided by financing activities of approximately $1.4 million during the year ended December 31, 2022, was primarily due to the issuance of promissory notes with approximately $2.3 million in gross proceeds, partially offset by debt issuance costs of $346,000. In addition, the Company repaid approximately $581,000 of promissory notes during the year-ended December 31, 2022.

Net cash provided by financing activities of approximately $739,000 during the year ended December 31, 2021, was primarily due to the issuance of notes with approximately $840,000 in proceeds, partially offset by debt issuance costs of $101,000.

Working Capital

(in thousands)	December 31, 2022	December 31, 2021	Change
Current assets	$ 79	$ 196	$ (117)
Current liabilities	22,265	25,302	3,037
Working capital (deficiency)	$ (22,186)	$ (25,106)	$ 2,920

Negative working capital as of December 31, 2022, was approximately $22.2 million as compared to negative working capital of approximately $25.1 million as of December 31, 2021. The increase in working capital is primarily related to an decrease in current liabilities of approximately $3.1 million including approximately $5.0 million in accrued dividends as a result of the conversion Series E and Series F Preferred Stock during the period, offset by an increase of $1.3 million of accrued expenses including accrued interest for our promissory notes payable, an increase in our promissory notes payable of $1.9 million net of discounts and a decrease of $1.3 million in the fair value of a derivative liability related to our outstanding convertible notes and warrants.

Liquidity

We will need to raise additional operating capital in 2023 and in future periods in order to maintain our operations, continue our efforts to restructure the Company and pursue our business plan. Without additional sources of cash we will not have the cash resources to continue as a going concern.

Additionally, as of December 31, 2022, we had $12.7 million in outstanding indebtedness including promissory notes and convertible notes and accrued interest on these notes. Approximately, $10.3 million notes including accrued interest are in default.

On November 16, 2022, holders of approximately $8.6 million of outstanding 2019 promissory notes including accrued interest representing a majority of the outstanding principal and accrued interest of the Notes, agreed to amend the Notes to make them automatically convertible into units consisting of a new series of convertible preferred stock and warrants upon an uplisting financing transaction in which the Company's common stock is listed on The Nasdaq Capital Market or the NYSE American, in exchange for the Holders agreeing to forbear repayment of their Notes and accrued interest until the uplisting has been completed.

On January 18, 2023, the Company entered into a Securities Purchase Agreement with an accredited investor pursuant to which the Company issued and sold the investor a non-convertible Original Issue 30% Discount Senior Secured Promissory Note in the principal amount of $285,714 and 452,962 Common Stock Purchase Warrants for total purchase price of $200,000. The Company received total consideration of $173,850 after debt issuance costs.

On February 3, 2023, the Company entered into a Securities Purchase Agreement with an affiliated accredited investor pursuant to which the Company issued and sold the investor a non-convertible Original Issue 30% Discount Senior Secured Promissory Note in the principal amount of $214,286 and 339,722 Common Stock Purchase Warrants for a total purchase price of $150,000. The Company received total consideration of $133,900 after debt issuance costs.

On February 16, 2023, the Company entered into a Securities Purchase Agreement with an affiliated accredited investor pursuant to which the Company issued and sold the investor a non-convertible Original Issue 30% Discount Senior Secured Promissory Note in the principal amount of $214,286 and 339,722 Common Stock Purchase Warrants for a total purchase price of $150,000. The Company received total consideration of $133,850 after debt issuance costs.

We will need to raise substantial additional capital in 2023 in order to satisfy our outstanding indebtedness and mitigate the impact on our balance sheet, and if we are unable to do so we may be forced to cease operations or pursue bankruptcy protection. In order to induce our current lenders to agree to a restructuring, we may be required to issue additional debt or equity securities or submit the Company to restrictive covenants and other terms with the potential to hinder or prevent our planned operations and growth. See "Item 1A. – Risk Factors" of this current report on Form 10-K.

Going Concern

The accompanying consolidated financial statements have been prepared on the basis that we will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business. As of December 31, 2022, we had a significant accumulated deficit of approximately $55.8 million and negative working capital of approximately $22.2 million. For the year ended December 31, 2022, we had a net loss of approximately $2.1 million and negative cash flows from operations. Our operating activities consume the majority of our cash resources. We have incurred recurring losses and negative cash flows from operations since inception we have funded our operating losses through the sale of common stock, preferred stock, warrants to purchase common stock, convertible notes and secured promissory notes.

Off-Balance Sheet Arrangements

As of December 31, 2022, we did not have any significant off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of SEC Regulation S-K.

Critical Accounting Policies and Estimates

In preparing the financial statements, we make estimates and assumptions that have an impact on the assets, liabilities, revenue, and expenses reported. These estimates can also affect supplemental information disclosed by us, including information about contingencies, risk, and financial condition. We believe, given current facts and circumstances, that our estimates and assumptions are reasonable, adhere to GAAP, and are consistently applied. Inherent in the nature of an estimate or assumption is the fact that actual results may differ from the estimates, and estimates may vary as new facts and circumstances arise. Our significant accounting policies are more fully described in the notes to our financial statements included herein for the period ended December 31, 2022.

New and Recently Adopted Accounting Pronouncements

Any new and recently adopted accounting pronouncements are more fully described in Note 2 to our financial statements included herein for the year ended December 31, 2022.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information called for by Item 8 is included following the "Index to Financial Statements" on page F-1 contained in this Report.

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

As previously disclosed on the Company's Current Report on Form 8-K filed on May 5, 2021, on April 28, 2021, the Company's Board of Directors approved the change of the Company's independent registered public accounting firm from Baker Tilly USA, LLP to Salberg& Company, P,A.

ITEM 9A. CONTROLS AND PROCEDURES

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")) that are designed to ensure that information required to be disclosed in our reports under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosures. In designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Any controls and procedures, no matter how well designed and operated, can provide only reasonable, not absolute, assurance of achieving the desired control objectives.

Our internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Our Chief Executive Officer and Chief Operating Officer, who is also serving as our principal accounting and financial officer, has evaluated the effectiveness of our internal control over financial reporting as of December 31, 2022. Based upon that evaluation and subject to the foregoing, our principal executive officer concluded that our internal control over financial reporting were not effective due to the material weakness(es) described below.

Management's Annual Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is a process designed under the supervision of its principal executive and principal financial officer and effected by our Company's Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of its consolidated financial statements for external reporting purposes in accordance with U.S. generally accepted accounting principles.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

Material Weakness in Internal Control over Financial Reporting

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2022, based on the framework established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management has determined that our internal control over financial reporting as of December 31, 2022 was not effective because of certain material weaknesses outlined below.

A material weakness, as defined in the standards established by the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

The ineffectiveness of our internal control over financial reporting was due to the following material weaknesses:

- Inadequate segregation of duties consistent with control objectives, and lack of monitoring controls over the accounting function as the Company has limited accounting staff. ;
- Lack of qualified accounting personnel to prepare and report financial information in accordance with GAAP;
- Lack of a separate Audit Committee of the Board of Directors; and
- Lack of documentation on policies and procedures that are critical to the accomplishment of financial reporting objectives.

Management plans to implement measures designed to ensure that control deficiencies contributing to the material weakness outlined above are remediated at such time as sufficient funds are available to do so. The remediation actions planned include:

- Identifying gaps in our skills base and the expertise of our personnel necessary to meet the financial reporting requirements of a public company;
- Developing written policies and procedures on internal control over financial reporting and monitor the effectiveness of operations on existing controls and procedures; and
- Establishing a separate Audit Committee of the Board of Directors.

We intend to continue to reassess our plans to remedy our internal control deficiencies in light of our personnel structure and our financial condition.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act) during the year ended December 31, 2022, that have materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

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

Not applicable**.**

PART III

The information required by Item 10 (Directors, Executive Officers and Corporate Governance), Item 11 (Executive Compensation), Item 12 (Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters), Item 13 (Certain Relationships and Related Transactions, and Director Independence), and Item 14 (Principal Accounting Fees and Services) is incorporated by reference to the Company's definitive proxy statement for the 2023 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of December 31, 2022.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(1) Financial Statements

Our consolidated financial statements are set forth in Part II, Item 8 of this Annual Report on Form 10-K and are incorporated herein by reference.

(2) Financial Statement Schedules

No financial statement schedules have been filed as part of this Annual Report on Form 10-K because they are not applicable or are not required or because the information is otherwise included herein.

(3) Exhibits required by Regulation S-K

Exhibit No.	Description
3.1	Restated Certificate of Incorporation of the Registrant dated July 20, 2005 (filed as Exhibit 3.1 to our Current Report on Form 8-K dated July 20, 2005, incorporated herein by reference)
3.2	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of the Registrant, dated June 10, 2008 (filed as Exhibit 3.1 to our Current Report on Form 8-K dated June 10, 2008, and incorporated herein by reference)
3.3	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of the Registrant, dated July 21, 2010 (filed as Exhibit 3.1 to our Current Report on Form 8-K dated July 21, 2010, and incorporated herein by reference)
3.4	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of the Registrant, dated July 18, 2011 (filed as Exhibit 3.1 to our Current Report on Form 8-K dated July 14, 2011, and incorporated herein by reference)
3.5	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of the Registrant, dated December 22, 2011 (filed as Exhibit 3.1 to our Current Report on Form 8-K dated December 22, 2011, and incorporated herein by reference)
3.6	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of the Registrant, dated August 1, 2017 (filed as Exhibit 3.1 to our Current Report on Form 8-K dated August 1, 2017, and incorporated herein by reference)
3.7	Certificate of Amendment of the Amended and Restated Certificate of Incorporation of Registrant, dated October 4, 2018 (filed as Exhibit 3.1 to our Current Report on Form 8-K dated October 4, 2018, and incorporated herein by reference)
3.8	Certificate of Designation, Rights and Preferences of Series A Junior Participating Preferred Stock dated January 17, 2007 (filed as Exhibit 3.1 to our Current Report on Form 8-K dated January 19, 2007, incorporated herein by reference)

3.9	Amended Designation, Rights, and Preferences of Series A Junior Participating Preferred Stock, dated June 10, 2008 (filed as Exhibit 3.2 to our Current Report on Form 8-K dated June 10, 2008, and incorporated herein by reference)
3.10	Certificate of Designations or Preferences, Rights and Limitations of Series B Preferred Stock dated December 22, 2011 (filed as Exhibit 3.1 to our Current Report on Form 8-K dated December 22, 2011, incorporated herein by reference)
3.11	Certificate of Designation of Rights, Preferences and Privileges of Series C Convertible Preferred Stock (filed as Exhibit 3.1 to our Current Report on Form 8-K dated March 7, 2014, incorporated herein by reference)
3.12	Certificate of Designation of Rights, Preferences and Privileges of Series D Convertible Preferred Stock (filed as Exhibit 3.1 to our Current Report on Form 8-K dated August 5, 2015, incorporated herein by reference)
3.13	Certificate of Designation of Preferences, Rights and Limitations of the Series E Convertible Preferred Stock of the Registrant (filed as Exhibit 3.1 to our Current Report on Form 8-K dated April 16, 2018, incorporated herein by reference)
3.14	Certificate of Designation of Preferences, Rights and Limitations of the Series F Convertible Preferred Stock of the Registrant (filed as Exhibit 3.1 to our Current Report on Form 8-K dated July 11, 2018, incorporated herein by reference)
3.15	Amended and Restated Bylaws of the Registrant dated August 21, 2012 (filed as Exhibit 3.7 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2011, incorporated herein by reference)
3.16	Certificate of Amendment to the Certificate of Incorporation dated September 30, 2022 (filed as Exhibit 3.1 to our Current Report on Form 8-K dated October 6, 2022, and incorporated herein by reference)
10.1#	License Agreement dated as of March 20, 2009 by and between Novartis Institutes for BioMedical Research, Inc. and the Registrant (filed as Exhibit 10.3 to our Quarterly Report on Form 10-Q/A for the quarter ended March 31, 2009, and incorporated herein by reference)
10.2†	2014 Long-Term Incentive Plan of the Registrant (filed as Exhibit 10.2 to our Current Report on Form 8-K dated September 15, 2014, and incorporated herein by reference)
10.3#	License Agreement dated February 6, 2017 between the Registrant and Lipomedics Inc. (filed as Exhibit 10.5 to our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2017, and incorporated herein by reference)
10.4†	Settlement Agreement, dated April 4, 2019, by and between Adhera Therapeutics, Inc. and Robert C. Moscato, Jr. (filed as Exhibit 10.2 to our Current Report on Form 8-K dated April 4, 2019, and incorporated herein by reference)
10.5	Form of Subscription Agreement used in connection with the offering of the Series F Convertible Preferred Stock of the Registrant (filed as Exhibit 10.34 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, incorporated herein by reference)
10.6	2018 Long-Term Incentive Plan of the Registrant (filed as Exhibit 10.35 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, incorporated herein by reference)
10.7	Security Agreement, dated as of June 26, 2020, among the Registrant, IThena Pharma, Inc., Cequent Pharmaceuticals, Inc., MDRNA Research, Inc., the purchasers of secured promissory notes identified on the signature pages thereto, and Jeff S. Phillips as agent (filed as Exhibit 10.1 to our Current Report on Form 8-K dated June 30, 2020, and incorporated herein by reference)
10.8	Securities Purchase Agreement dated as of February 5, 2020 between the Registrant and the purchasers identified in the signature pages thereto (filed as Exhibit 10.1 to our Current Report on Form 8-K dated February 5, 2020, incorporated herein by reference)
10.9†	Consulting Agreement, dated July 7, 2020, by and between Adhera Therapeutics, Inc. and Andrew Kucharchuk (filed as Exhibit 10.1 to our Current Report on Form 8-K dated July 7, 2020, and incorporated herein by reference)

10.10	License Agreement between Adhera Therapeutics, Inc. and Melior Pharmaceuticals II, LLC dated July 28, 2021 (filed as Exhibit 10.1 to our Current Report on Form 8-K dated August 4, 2021, and incorporated herein by reference)
10.11	License Agreement between Adhera Therapeutics, Inc. and Melior Pharmaceuticals I, LLC dated August 20, 2021 (filed as Exhibit 10.11 to our Form S-1 dated December 2, 2022, and incorporated herein by reference)
10.12	Addendum to License Agreement Adhera Therapeutics, Inc. and Melior Pharmaceuticals I, LLC dated August 20, 2021 dated February 16, 2022 (filed as Exhibit 10.12 to our Form S-1 dated December 2, 2022, and incorporated herein by reference)
10.13	Form of Securities Purchase Agreement issued by Adhera Therapeutics, Inc. to select accredited investors on August 18, 2021 (filed as Exhibit 10.1 to our Current Report on Form 8-K dated August 24, 2021, and incorporated herein by reference)
10.14	Form of Securities Purchase Agreement issued by Adhera Therapeutics, Inc. to select accredited investors on October 8, 2021 (filed as Exhibit 10.1 to our Current Report on Form 8-K dated October 13, 2021, and incorporated herein by reference)
10.15	Form of Securities Purchase Agreement issued by Adhera Therapeutics, Inc. to select accredited investors on October 7, 2021 (filed as Exhibit 4.3 to our Current Report on Form 8-K dated November 12, 2021, and incorporated herein by reference)
10.16	Form of Securities Purchase Agreement issued by Adhera Therapeutics, Inc. to select accredited investors on March 15, 2022 (filed as Exhibit 10.16 to our Form S-1 dated December 2, 2022, and incorporated herein by reference)
10.17	Form of Securities Purchase Agreement dated May 11, 2022 (filed as Exhibit 10.6 on our Quarterly Report on Form 10-Q dated May 16, 2022, and incorporated herein by reference)
10.18	Form of Senior Secured Original Issue Discount Promissory Note dated May 11, 2022 (filed as Exhibit 10.4 on our Quarterly Report on Form 10-Q dated May 16, 2022, and incorporated herein by reference)
10.20	Form of Warrant dated May 11, 2022 (filed as Exhibit 10.5 on our Quarterly Report on Form 10-Q dated May 16, 2022, and incorporated herein by reference)
10.21	Form of Security Agreement dated May 11, 2022 (filed as Exhibit 10.6 on our Quarterly Report on Form 10-Q dated May 16, 2022, and incorporated herein by reference)
10.22	Second Addendum to the License Agreement (filed as Exhibit 10.1 to our Current Report on Form 8-K dated August 4, 2022, and incorporated herein by reference)
10.23	Form of Securities Purchase Agreement issued by Adhera Therapeutics, Inc. to select accredited investors on December 15, 2022 and January 18, 2023 (filed as Exhibit 10.1 on our Current Report on Form 8-K dated January 26, 2023, and incorporated herein by reference)
10.24	Form of Securities Purchase Agreement issued by Adhera Therapeutics, Inc. to select accredited investors on February 16, 2023 (filed as Exhibit 10.1 on our Current Report on Form 8-K dated February 23, 2023, and incorporated herein by reference)
10.25	Form of Securities Purchase Agreement issued by Adhera Therapeutics, Inc. to select accredited investors on March 2, 2023 (filed as Exhibit 10.1 on our Current Report on Form 8-K dated March 8, 2023, and incorporated herein by reference)
10.26†	Employment Agreement with Andrew Kucharchuk dated July 5, 2021 (filed as Exhibit 10.16 to the Amendment to our Annual Report on Form 10-K dated April 29, 2022 and incorporated herein by reference)
10.27†	Agreement with Zahed Subhan dated November 1, 2021 (filed as Exhibit 10.17 to the Amendment to our Annual Report on Form 10-K dated April 29, 2022 and incorporated herein by reference)
10.28	Code of Business Conduct and Ethics (filed as Exhibit 10.18 to the Amendment to our Annual Report on Form 10-K dated April 29, 2022 and incorporated herein by reference)
23.1*	Consent of Salberg & Company, P.A., Independent Registered Public Accounting Firm
31.1*	Certification of Principal Executive Officer pursuant to section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer pursuant to section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification of Principal Executive Officer pursuant to 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 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because iXBRL tags are embedded within the Inline XBRL 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 Labels Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	The Cover Page Interactive Data File, formatted in Inline XBRL (included within the Exhibit 101 attachments)

* Filed herewith.
** Furnished herewith
† Indicates management contract or compensatory plan or arrangement.
# Exhibits and/or Schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company hereby agrees to furnish to the SEC upon request any omitted information.

ITEM 16. FORM 10-K SUMMARY

Not applicable.

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.

ADHERA THERAPEUTICS, INC.

By: */s/ Zahed Subhan*
Zahed Subhan
Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)
Date: March 31, 2023

By: */s/ Andrew Kucharchuk*
Andrew Kucharchuk
Chief Operating Officer (Principal Financial and Accounting Officer)
Date: March 31, 2023

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

By: */s/ Zahed Subhan*
Zahed Subhan
Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)
Date: March 31, 2023

By: */s/ Andrew Kucharchuk*
Andrew Kucharchuk
Chief Operating Officer (Principal Financial and Accounting Officer)
Date: March 31, 2023

By: */s/ Charles L. Rice*
Charles L. Rice
Director
Date: March 31, 2023

By: */s/ Trond K Waerness*
Trond K Waerness
Director
Date: March 31, 2023

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

ADHERA THERAPEUTICS, INC.
CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2022 and 2021

TABLE OF CONTENTS

SALBERG & COMPANY, P.A.
Certified Public Accountants and Consultants

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of:
Adhera Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Adhera Therapeutics, Inc. (the "Company") as of December 31, 2022, and 2021, the related consolidated statements of operations, changes in stockholders' deficit and cash flows for each of the two the years in the period ended December 31, 2022, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2022, and 2021, and the consolidated results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has no revenues and has a net loss and net cash used in operations of approximately $2.1 million and $1.4 million respectively, in 2022 and a working capital deficit, shareholders' deficit and accumulated deficit of $22.2 million, $22.2 million and $55.8 million respectively, at December 31, 2022. These matters raise substantial doubt about the Company's ability to continue as a going concern. Management's Plan in regard to these matters is also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated 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 audits to obtain reasonable assurance about whether the consolidated 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 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 consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

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Member CPAConnect with Affiliated Offices Worldwide • Member AICPA Center for Audit Quality

SALBERG & COMPANY, P.A.
Certified Public Accountants and Consultants

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated 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 consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Derivative Liabilities

As described in Footnote 2 “Fair Value of Financial Instruments”, Footnote 2 “Convertible Debt and Warrant Accounting”, Footnote 4 “Notes Payable and Convertible Promissory Notes” and Footnote 4 “Derivatives Liabilities Pursuant to Convertible Notes and Warrants”, the Company recorded derivative activity during 2022 that resulted primarily in a net aggregate derivative related expense of $2,324 million and derivative liabilities of $6,386 million at December 31, 2022.

We identified the evaluation of instruments and contracts to determine whether there are derivatives to be recorded, the analysis of the accounting treatment and presentation for derivative transactions and the valuation of derivatives as critical audit matters. Auditing management’s analysis of the above critical audit matters was complex and involved a high degree of subjectivity.

The primary procedures we performed to address these critical audit matters included (a) Reviewed and tested management’s conclusions as to whether certain instruments or contracts qualified for derivative treatment by comparing management’s analysis and conclusions to authoritative and interpretive literature, (b) Compared the accounting treatment and presentation to that described by the authoritative and interpretive literature, (c) Tested management’s process for valuing derivatives by comparing it to generally accepted methodologies for valuing derivatives, (d) Tested management’s valuation of the derivatives by testing assumptions and data used in the valuation model including the term, volatility and interest rate, and (e) Recomputed the derivative valuations. We agreed with management’s treatment and valuations.

/s/ Salberg & Company, P.A.

SALBERG & COMPANY, P.A.
We have served as the Company’s auditor since 2021.
Boca Raton, Florida
March 31, 2023

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Member CPAConnect with Affiliated Offices Worldwide • Member AICPA Center for Audit Quality

ADHERA THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(in thousands except share and per share data)

	December 31, 2022	December 31, 2021
ASSETS		
Current assets		
Cash	$ 32	$ 76
Prepaid expenses	47	120
Total current assets	**79**	**196**
Total assets	**$ 79**	**$ 196**
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities		
Accounts payable	$ 2,397	$ 2,309
Due to related parties	26	46
Accrued expenses	4,373	3,110
Accrued dividends	498	5,477
Term loans, net	7,333	5,677
Convertible notes payable, net	1,252	986
Derivative liability	6,386	7,697
Total current liabilities	**22,265**	**25,302**
Total liabilities	**22,265**	**25,302**
Commitments and contingencies (Note 9)		
Stockholders' deficit		
Preferred stock, $0.01 par value; 100,000 shares authorized	—	—
Series C convertible preferred stock, $0.01 par value; 1,200 shares authorized; 100 shares issued and outstanding as of December 31, 2022 and 2021. ($510,000 liquidation preference)	—	—
Series D convertible preferred stock, $0.01 par value; 220 shares authorized; 40 shares issued and outstanding as of December 31, 2022 and 2021 ($12,000 liquidation preference)	—	—
Series E convertible preferred stock, $0.01 par value; 3,500 shares authorized; 267 and 3,326 shares issued and outstanding as of December 31, 2022 and 2021, respectively. ($1,833,453 liquidation preference)	—	—
Series F convertible preferred stock, $0.01 par value; 2,200 shares authorized; zero and 358 shares issued and outstanding as of December 31, 2022 and 2021, respectively.	—	—
Series G convertible preferred stock, $0.01 par value; 6,000 shares authorized; no shares issued and outstanding as of December 31, 2022 and 2021.	—	—
Common stock, $0.006 par value; 180,000,000 shares authorized, 3,160,877 and 853,946 shares issued and outstanding as of December 31, 2022, and 2021, respectively	19	5
Additional paid-in capital	33,548	27,906
Accumulated deficit	(55,751)	(53,017)
Treasury Stock (5,594 shares)	(2)	
Total stockholders' deficit	(22,186)	(25,106)
Total liabilities and stockholders' deficit	**$ 79**	**$ 196**

The accompanying notes are an integral part of these consolidated financial statements.

ADHERA THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands except share and per share data)

	For the Year Ended December 31,	
	2022	**2021**
Operating expenses		
Sales and marketing	$ —	$ 17
General and administrative	1,618	657
Total operating expenses	1,618	674
Loss from operations	(1,618)	(674)
Other income (expense)		
Interest expense, net	(1,344)	(1,035)
Initial and change in fair value of derivative liability	2,324	(4,103)
Gain (loss) on extinguishment of debt	333	(141)
Amortization of debt discount	(1,809)	(398)
Total other income (expense)	(496)	(5,677)
Loss before provision for income taxes	(2,114)	(6,351)
Provision for income taxes	—	—
Net loss	(2,114)	(6,351)
Accrued and deemed dividends	(620)	(2,054)
Net Loss Applicable to Common Stockholders	$ (2,734)	$ (8,405)
Net loss per share - Common Stockholders, basic and diluted	$ (1.18)	$ (12.84)
Weighted average shares outstanding, basic and diluted	2,307,534	654,700

The accompanying notes are an integral part of these consolidated financial statements.

ADHERA THERAPEUTICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' (DEFICIT)
(in thousands, except share and per share amounts)

	Series C Preferred Stock		Series D Preferred Stock		Series E Preferred Stock		Series F Preferred Stock		Common Stock		Additional			
	Number	Par Value	Number	Par Value	Number	Par Value	Number	Par Value	Number	Par Value	Paid-in Capital	Accumulated Deficit	Treasury Stock	Total
Balance as of December 31, 2020	100	-	40	$ -	3,458	-	361	-	560,140	$ 3	$ 29,869	$ (44,612)	$ -	$(14,740)
Accrued and deemed dividend	-	-	-	-	-	-	-	-	-	-	541	(2,054)	-	$ (1,513)
Reclassification of derivative from equity	-	-	-	-	-	-			-	-	(3,462)	-	-	$ (3,462)
Issuance of common stock for cashless exercise of warrants	-	-	-	-	-	-	-	-	10,340	-	(1)	-	-	$ (1)
Issuance of warrants and common stock with convertible notes	-	-	-	-	-	-	-	-	35,764	-	316	-	-	$ 316
Issuance of common stock for convertible note conversions	-	-	-	-	-	-	-	-	168,301	1	534	-	-	$ 535
Issuance of Common Stock for Series E Conversion	-	-	-	-	(132)	-	-	-	1,852	-	3	-	-	$ 3
Issuanceof Common Stock for Series F conversion	-	-	-	-	-	-	(3)	-	77,549	1	106	-	-	$ 107
Net loss	-	-	-	-	-	-	-	-	-	-	-	(6,351)	-	(6,351)
Balance as of December 31, 2021	100	$ -	40	$ -	3,326	$ -	358	$ -	853,946	$ 5	$ 27,906	$ (53,017)	$ -	$(25,106)
Accrued dividend	-	-	-	-	-	-	-	-	-	-	-	(620)	-	$ (620)
Issuance of common stock with convertible notes	-	-	-	-	-	-	-	-	12,500	-	18	-	-	$ 18
Issuance of common stock for convertible note conversions	-	-	-	-	-	-	-	-	12,721	-	28	-	-	$ 28
Issuance of common stock with term loan	-	-	-	-	-	-	-	-	19,231	-	11	-	-	$ 11
Conversion of Series E Preferred to common stock	-	-	-	-	(3,059)	-	-	-	2,035,306	12	5,044	-	-	$ 5,056
Conversion of Series F Preferred to common stock	-	-	-	-	-	-	(358)	-	233,127	2	541	-	-	$ 543
Repurchase of common stock	-	-	-	-	-	-	-	-	(5,954)	-	-	-	(2)	$ (2)
Net loss	-	-	-	-	-	-	-	-	-	-	-	(2,114)	-	$ (2,114)
Balance as of December 31, 2022	100	$ -	40	$ -	267	$ -	-	$ -	3,160,877	$ 19	$ 33,548	$ (55,751)	$ (2)	$(22,186)

The accompanying notes are an integral part of these consolidated financial statements.

ADHERA THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	For the Year Ended December 31,	
	2022	**2021**
Cash Flows Used in Operating Activities:		
Net loss	$ (2,114)	$ (6,351)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of debt discount	1,809	398
Accrued interest expense	1,344	1,035
Derivative (income) expense	(2,324)	4,103
(Gain)/Loss on debt extinguishment	(333)	141
Changes in operating assets and liabilities:		
Prepaid expenses	73	(120)
Accounts payable	68	94
Accrued expenses	62	35
Net Cash Used in Operating Activities	**(1,415)**	**(665)**
Cash Flows Provided by Financing Activities:		
Proceeds from notes payable, net of original issue discounts	2,300	840
Notes payable issuance costs	(346)	(101)
Repurchase of common stock	(2)	-
Repayment of principal and interest on notes payable	(581)	-
Net Cash Provided by Financing Activities	**1,371**	**739**
Net increase (decrease) in cash	(44)	75
Cash – Beginning of Year	76	1
Cash - End of Year	**$ 32**	**$ 76**
Supplementary Cash Flow Information:		
Cash paid for interest	94	-
Cash paid for taxes	-	-
Non-cash Investing and Financing Activities:		
Issuance of common stock for conversion of Series E Preferred	$ 5,056	$ 116
Issuance of common stock for conversion of Series F Preferred	543	3
Debt discounts for issuance costs, warrants and derivatives	20	320
Issuance of common stock for conversion of convertible notes	554	554
Reclassification of derivative liability	-	3,462
Accrued and deemed dividends	620	2,054

The accompanying notes are an integral part of these consolidated financial statements.

Note 1 – Organization and Business Operations

Adhera Therapeutics, Inc. and its wholly-owned subsidiaries, MDRNA Research, Inc. ("MDRNA"), Cequent Pharmaceuticals, Inc. ("Cequent"), Atossa Healthcare, Inc. ("Atossa"), and IThenaPharma, Inc. ("IThena") (collectively "Adhera," we or the "Company"), is an emerging specialty biotech company that, to the extent that resources and opportunities become available, is focused on drug development and commercialization of "small molecule" drugs to treat Parkinson's disease (PD) and Type 1 diabetes.

On July 28, 2021, we as licensee and Melior Pharmaceuticals II, LLC ("Melior II") entered into an exclusive license agreement for the development, commercialization and exclusive license of MLR-1019. MLR-1019 is being developed as a new class of therapeutic and is, to the best of our knowledge, the only drug candidate today to address both movement and non-movement aspects of PD. Under the Agreement, we were granted an exclusive license to use the Melior II Patents and know-how to develop products in consideration for cash payments upon meeting certain performance milestones as well as a royalty of 5% of gross sales.

On August 20, 2021, we as licensee entered into an exclusive license agreement regarding the development and commercialization of Melior's MLR-1023 (the "MLR-1023 Agreement") with Melior Pharmaceuticals I, Inc. ("MP1"). We refer to MP2 and MP1 as "MP" or "Melior". This second license is for the development and commercialization of MLR-1023, which is being developed as a novel therapeutic for Type 1 diabetes.

Under the original terms of the MLR-1023 Agreement, if the Company failed to raise $4.0 million within 120 days of the effective date of the agreement then the MLR-1023 Agreement would immediately terminate unless, by 120 days Adhera was in the process of completing transactions to complete the fundraising then an additional 30 days would be provided to allow for the completion of the raise (the "Raise Requirement").

On October 20, 2021, we as licensee expanded the exclusive licensing agreement with Melior I to include two additional clinical indications for Non-Alcoholic Steatohepatitis (NASH) and pulmonary inflammation.

On November 17, 2021, Melior I extended the Company's timeline from 120 days to 180 days from the effective of the MLR-1023 Agreement for the Raise Requirement, by 180 days Adhera is in the process of completing transactions to complete the fundraising then an additional 30 days shall be provided to allow for the completion of required fundraising.

On February 16, 2022, an addendum to the MLR-1023 Agreement dated August 4, 2021 (the "First Addendum"), was executed by the Company and Melior, which extended the Raise Requirement to June 16, 2022.

On July 20, 2022, the Company and Melior entered into the Second Addendum to the License Agreement (the "Second Addendum"). In accordance with the Second Addendum and subject to the terms and conditions therein, the Raise Requirement was extended to February 1, 2023, in exchange for a $136,921 licensing payment that was made by the Company on July 28, 2022. In addition, the Company was required to hire and retain a Chief Scientific Officer, and raise an additional $500,000 in capital in addition to other requirements set forth in the Second Addendum and MLR-1023 Agreement.

As of February 1, 2023, the Company had not raised the additional $500,000 of capital, commenced API manufacturing, nor completed the Raise Requirement. In March 2023, the Company obtained a verbal agreement with Melior to extend the terms of the MLR-1023 Agreement until such time that the milestones have been met and the Company pays outstanding patent maintenance costs. However, Melior may terminate the license of MLR-1023 at any time due to non-performance of continuing license obligations with a 60-day required notice to cure non-performance.

As of December 31, 2022, no performance milestones requiring cash consideration had been met under the MLR-1023 Agreement

To the extent that resources have been available, the Company has continued to work with its advisors in an effort to restructure our company and to identify potential strategic transactions to enhance the value of our company as such opportunities arise, including potential transactions and capital raising initiatives involving the assets relating to our legacy RNA interference programs, as well as business combination transactions with operating companies. There can be no assurance that the Company will be successful at identifying any such transactions, that it will continue to have sufficient resources to actively attempt to identify such transactions, or that such transactions will be available upon terms acceptable to us or at all. If the Company does not complete any significant strategic transactions, or raise substantial additional capital, in the immediate future, it is likely that the Company will discontinue all operations and seek bankruptcy protection.

Note 2 – Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The summary of significant accounting policies presented below is designed to assist in understanding the Company's consolidated financial statements. Such financial statements and accompanying notes are the representations of Company's management, who is responsible for their integrity and objectivity.

Principles of Consolidation

The consolidated financial statements include the accounts of Adhera Therapeutics, Inc. and the wholly-owned subsidiaries, Ithena, Cequent, MDRNA, and Atossa, and eliminate any inter-company balances and transactions. All wholly-owned subsidiaries of Adhera Therapeutics, Inc. are inactive.

Going Concern and Management's Liquidity Plans

The accompanying consolidated financial statements have been prepared on the basis that the Company will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business. As of December 31, 2022, the Company had cash and cash equivalents of approximately $32,000 and has negative working capital of approximately $22.2 million.

The Company has no revenues and has incurred recurring losses and negative cash flows from operations since inception and has funded its operating losses through the sale of common stock, preferred stock, warrants to purchase common stock, convertible notes and secured promissory notes. The Company incurred a net loss and net cash used in operating activities of approximately $2.1 million and $1.4 million, respectively for the year ended December 31, 2022. The Company had a working capital deficit of approximately $22.2 million a stockholders' deficit of approximately $22.2 million and an accumulated deficit of approximately $55.8 million as of December 31, 2022.

In addition, to the extent that the Company continues its business operations, the Company anticipates that it will continue to have negative cash flows from operations, at least into the near future. However, the Company cannot be certain that it will be able to obtain such funds required for its our operations at terms acceptable to the Company or at all. General market conditions, as well as market conditions for companies in the Company's financial and business position, as well as the ongoing issue arising from the COVID-19 pandemic, the war in Ukraine, federal bank failures or other world-wide events, may make it difficult for the Company to seek financing from the capital markets, and the terms of any financing may adversely affect the holdings or the rights of its stockholders. If the Company is unable to obtain additional financing in the future, there may be a negative impact on the financial viability of the Company. The Company plans to increase working capital by managing its cash flows and expenses, divesting development assets and raising additional capital through private or public equity or debt financing. There can be no assurance that such financing or partnerships will be available on terms which are favorable to the Company or at all. While management of the Company believes that it has a plan to fund ongoing operations, there is no assurance that its plan will be successfully implemented. Failure to raise additional capital through one or more financings, divesting development assets or reducing discretionary spending could have a material adverse effect on the Company's ability to achieve its intended business objectives. These factors raise substantial doubt about the Company's ability to continue as a going concern for a period of twelve months from the issuance date of this Report. The consolidated financial statements do not contain any adjustments that might result from the resolution of any of the above uncertainties.

Reverse Stock-split

On September 30, 2022, the Company filed a Certificate of Amendment to the Certificate of Incorporation with the Delaware Secretary of State to effect a reverse stock split of all outstanding shares of the Company's common stock at a ratio of 1-for-20. On October 5, 2022, the Company effected the 1-for-20 reverse stock split of its common stock. The reverse stock split did not cause an adjustment to the par value or the authorized shares of the common stock. As a result of the reverse stock split, the Company retroactively adjusted all outstanding common stock equivalents including options, warrants, convertible notes and other agreements with third parties.

All disclosures of common shares and per common share data in the accompanying consolidated financial statements and related notes reflect the reverse stock split for all periods presented. As a result of the reverse split the Company recorded a $361,000 adjustment to the par value of common stock which was offset to additional paid-in capital.

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less at the time of purchase to be cash equivalents. As of December 31, 2022, the Company had approximately $32,000 in cash equivalents.

The Company deposits its cash with major financial institutions and may at times exceed the federally insured limit. At December 31, 2022, the Company's cash balance did not exceed the federal deposit insurance limit.

Use of Estimates

The preparation of the accompanying consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reported period. Significant areas requiring the use of management estimates include accruals related to our operating activity including legal and other consulting expenses, the fair value of non-cash equity-based issuances, the fair value of derivative liabilities, and the valuation allowance on deferred tax assets. Actual results could differ materially from such estimates under different assumptions or circumstances.

Fair Value of Financial Instruments

The Company considers the fair value of cash, accounts payable, debt, and accrued expenses not to be materially different from their carrying value. These financial instruments have short-term maturities. We follow authoritative guidance with respect to fair value reporting issued by the Financial Accounting Standards Board ("FASB") for financial assets and liabilities, which defines fair value, provides guidance for measuring fair value and requires certain disclosures. The guidance does not apply to measurements related to share-based payments. The guidance discusses valuation techniques, such as the market approach (comparable market prices), the income approach (present value of future income or cash flow), and the cost approach (cost to replace the service capacity of an asset or replacement cost). The guidance establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three broad levels. The following is a brief description of those three levels:

Level 1: Observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities.

Level 2: Inputs other than quoted prices that are observable for the asset or liability, either directly or indirectly. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

Level 3: Unobservable inputs in which little or no market data exists, therefore developed using estimates and assumptions developed by us, which reflect those that a market participant would use.

As of December 31, 2021, the Company measured conversion features on outstanding convertible notes and warrants as a derivative liability using significant unobservable prices that are based on little or no verifiable market data, which is Level 3 in the fair value hierarchy, resulting in a fair value estimate of approximately $7.7 million. The value of the derivative liability as of December 31, 2021, was determined by using the binomial lattice model using the following inputs: 0.069% to 1.26% risk free rate, volatility of 255% to 399% and time to maturity of 0 - 0.60 years. There were no liabilities or assets measured at fair value on a non-recurring basis as of December 31, 2021.

	Fair Value Measurements at December 31, 2021			
(in thousands)	Quoted Prices in Active Markets for Identical Assets (Level 1)	Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Derivative liability	$ -	$ -	$ 7,697	$ 7,697
Total	$ -	$ -	$ 7,697	$ 7,697

A roll forward of the level 3 valuation financial instruments is as follows:

	Year Ended December 31, 2021		
(In thousands)	**Warrants**	**Notes**	**Total**
Balance at December 31, 2020	$ —	$ —	$ —
Initial valuation of derivative liabilities included in debt discount	—	377	377
Initial valuation of derivative liabilities included in derivative expense	246	1,348	1,594
Reclassification of derivative liabilities gain to loss on debt extinguishment	(52)	(193)	(245)
Reclass from additional paid-in capital	3,107	355	3,462
Change in fair value included in derivative expense	2,035	474	2,509
Balance at December 31, 2021	$ 5,336	$ 2,361	$ 7,697

As of December 31, 2022, the Company measured conversion features on outstanding convertible notes and warrants as a derivative liability using significant unobservable prices that are based on little or no verifiable market data, which is Level 3 in the fair value hierarchy, resulting in a fair value estimate of approximately $6.4 million. The value of the derivative liability as of December 31, 2022, was determined by using the binomial lattice model using the following inputs: 3.99% to 4.73% risk free rate, volatility of 177.51% to 315% and time to maturity of 0 – 1.09 years. There were no liabilities or assets measured at fair value on a non-recurring basis as of December 31, 2022.

	Fair Value Measurements at December 31, 2022			
(in thousands)	Quoted Prices in Active Markets for Identical Assets (Level 1)	Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Derivative liability	$ -	$ -	$ 6,386	$ 6,386
Total	$ -	$ -	$ 6,386	$ 6,386

A roll forward of the level 3 valuation financial instruments is as follows:

	Year Ended December 31, 2022		
(In thousands)	**Warrants**	**Notes**	**Total**
Balance at December 31, 2021	$ 5,336	$ 2,361	$ 7,697
Initial valuation of derivative liabilities included in debt discount	1,202	163	1,365
Initial valuation of derivative liabilities included in derivative expense	83	108	191
Reclassification of derivative liabilities to gain on debt extinguishment	-	(351)	(351)
Change in fair value included in derivative expense	(1,546)	(970)	(2,516)
Balance at December 31, 2022	$ 5,075	$ 1,311	$ 6,386

ASC 825-10 “Financial Instruments” allows entities to voluntarily choose to measure certain financial assets and liabilities at fair value (fair value option). The fair value option may be elected on an instrument-by-instrument basis and is irrevocable unless a new election date occurs. If the fair value option is elected for an instrument, unrealized gains and losses for that instrument should be reported in earnings at each subsequent reporting date. The Company did not elect to apply the fair value option to any outstanding equity instruments.

Convertible Debt and Warrant Accounting

Debt with warrants

In accordance with ASC Topic 470-20-25, when the Company issues debt with warrants, the Company treats the relative fair value of the warrants as a debt discount, recorded as a contra-liability against the debt, and amortizes the balance over the life of the underlying debt as amortization of debt discount expense in the consolidated statements of operations. The offset to the contra-liability is recorded as additional paid in capital in the Company’s consolidated balance sheets if the warrants are not treated as a derivative. The Company determines the fair value of the warrants using the Black-Scholes Option Pricing Model (“Black-Scholes”), the binomial model or the Monte Carlo Method based upon the underlying conversion features of the debt and then computes and records the relative fair value as a debt discount. If the debt is retired early, the associated debt discount is then recognized immediately as amortization of debt discount expense in the consolidated statements of operations.

Convertible debt – derivative treatment

When the Company issues debt with a conversion feature, it first assesses whether the conversion feature meets the requirements to be accounted for as stock settled debt. If it does not meet those requirements then it is assessed on whether the conversion feature should be bifurcated and treated as a derivative liability, as follows: a) one or more underlyings, typically the price of our common stock; b) one or more notional amounts or payment provisions or both, generally the number of shares upon conversion; c) no initial net investment, which typically excludes the amount borrowed; and d) net settlement provisions, which in the case of convertible debt generally means the stock received upon conversion can be readily sold for cash. An embedded equity-linked component that meets the definition of a derivative does not have to be separated from the host instrument if the component qualifies for the scope exception for certain contracts involving an issuer's own equity. The scope exception applies if the contract is both a) indexed to its own stock; and b) classified in stockholders' equity in its statement of financial position.

Recently Issued Accounting Pronouncements

Recently Adopted

In August 2020, the FASB issued ASU No. 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity ("ASU 2020-06"), which will simplify the accounting for certain financial instruments with characteristics of liabilities and equity, including certain convertible instruments and contracts on an entity's own equity. Specifically, the new standard will remove the separation models required for convertible debt with cash conversion features and convertible instruments with beneficial conversion features. It will also remove certain settlement conditions that are currently required for equity contracts to qualify for the derivative scope exception and will simplify the diluted earnings per share calculation for convertible instruments. ASU 2020-06 will be effective January 1, 2022, for the Company and may be applied using a full or modified retrospective approach. Early adoption is permitted, but no earlier than January 1, 2021, for the Company. The Company adopted ASU No. 2020-06 on January 1, 2021. Management determined such adoption did not have a material impact on the overall stockholders' equity (deficit) in the Company's consolidated financial statements.

In May 2021, FASB issued ASU 2021-04: Earnings Per Share (Topic 260), Debt— Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging— Contracts in Entity's Own Equity (Subtopic 815-40), to clarify and reduce diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. The amendments in ASU 2021-04 provide the following guidance for a modification or an exchange of a freestanding equity-classified written call option that is not within the scope of another Topic:

1. An entity should treat a modification of the terms or conditions or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange as an exchange of the original instrument for a new instrument.

2. An entity should measure the effect of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange as follows:

    a. For a modification or an exchange that is a part of or directly related to a modification or an exchange of an existing debt instrument or line-of-credit or revolving-debt arrangements (hereinafter, referred to as a "debt" or "debt instrument"), as the difference between the fair value of the modified or exchanged written call option and the fair value of that written call option immediately before it is modified or exchanged. Specifically, an entity should consider:

        i. An increase or a decrease in the fair value of the modified or exchanged written call option in applying the 10 percent cash flow test and/or calculating the fees between debtor and creditor in accordance with Subtopic 470-50, Debt—Modifications and Extinguishments.

        ii. An increase (but not a decrease) in the fair value of the modified or exchanged written call option in calculating the third-party costs in accordance with Subtopic 470-50.

    b. For all other modifications or exchanges, as the excess, if any, of the fair value of the modified or exchanged written call option over the fair value of that written call option immediately before it is modified or exchanged.

3. An entity should recognize the effect of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange on the basis of the substance of the transaction, in the same manner as if cash had been paid as consideration, as follows:

    a. A financing transaction to raise equity. The effect should be recognized as an equity issuance cost in accordance with the guidance in Topic 340, Other Assets and Deferred Costs.

    b. A financing transaction to raise or modify debt. The effect should be recognized as a cost in accordance with the guidance in Topic 470, Debt, and Topic 835, Interest.

    c. Other modifications or exchanges that are not related to financings or compensation for goods or services or other exchange transactions within the scope of another Topic. The effect should be recognized as a dividend. For entities that present EPS in accordance with Topic 260, that dividend should be an adjustment to net income (or net loss) in the basic EPS calculation.

An entity should recognize the effect of a modification or an exchange of a freestanding equity-classified written call option to compensate for goods or services in accordance with the guidance in Topic 718, Compensation—Stock Compensation. In a multiple-element transaction (for example, one that includes both debt financing and equity financing), the total effect of the modification should be allocated to the respective elements in the transaction.

The amendments in ASU 2021-04 are effective for all entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. An entity should apply the amendments prospectively to modifications or exchanges occurring on or after the effective date of the amendments. Early adoption is permitted for all entities, including adoption in an interim period. If an entity elects to early adopt the amendments in ASU 2021-04 in an interim period, the guidance should be applied as of the beginning of the fiscal year that includes that interim period. The Company adopted ASU No. 2021-04 on January 1, 2022. Management determined such adoption did not have a material impact on the overall stockholders' equity (deficit) in the Company's consolidated financial statements.

Not Yet Adopted

Other accounting standards that have been issued or proposed by FASB that do not require adoption until a future date are not expected to have a material impact on the financial statements upon adoption. The Company does not discuss recent pronouncements that are not anticipated to have an impact on or are unrelated to its financial condition, results of operations, cash flows or disclosures.

Net Loss per Common Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common shares and common stock equivalents outstanding for the period. Common stock equivalents are only included when their effect is dilutive. Potentially dilutive securities which include outstanding warrants, stock options, convertible notes and preferred stock have been excluded from the computation of diluted net loss per share as their effect would be anti-dilutive. For all periods presented, basic and diluted net loss were the same.

The following table presents the computation of net loss per share (in thousands, except share and per share data):

	December 31,	
(in thousands except share and per share data)	2022	2021
Numerator		
Net loss	$ (2114)	$ (6,351)
Preferred stock dividends	(620)	(2,054)
Net Loss allocable to common stockholders	$ (2,734)	$ (8,405)
Denominator		
Weighted average common shares outstanding used to compute net loss per share, basic and diluted	2,307,534	654,700
Net loss per share of common stock, basic and diluted		
Net loss per share, basic and diluted	$ (1.18)	$ (12.84)

The following number of shares have been excluded from diluted net (loss) since such inclusion would be anti-dilutive:

	Year Ended December 31,	
	2021	**2021**
Stock options outstanding	19,000	19,203
Convertible notes	4,286,936	2,434,842
Warrants	6,785,914	3,731,263
Series C Preferred Stock	3,334	3,334
Series D Preferred Stock	2,500	2,500
Series E Preferred Stock	183,346	2,162,076
Series F Preferred Stock	-	227,761
Total	11,281,030	8,580,979

Stock-Based Compensation

The Company applies the provisions of *ASC 718, Compensation—Stock Compensation ("ASC 718")*, which requires the measurement and recognition of compensation expense for all stock-based awards made to employees and non-employees, including stock options, in the statements of operations.

For stock options issued, the Company estimates the grant date fair value of each option using the Black-Scholes option pricing model. The use of the Black-Scholes option pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected life of the option, risk-free interest rates and expected dividend yields of the common stock. For awards subject to service-based vesting conditions, including those with a graded vesting schedule, the Company recognizes stock-based compensation expense equal to the grant date fair value of stock options on a straight-line basis over the requisite service period, which is generally the vesting term. Forfeitures are recorded as they are incurred as opposed to being estimated at the time of grant and revised if and when a forfeiture becomes probable.

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets, including tax loss and credit carry forwards, and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

The Company accounts for income taxes using the asset and liability method to compute the differences between the tax basis of assets and liabilities and the related financial amounts, using currently enacted tax rates.

Note 3 – Prepaid Expenses

As of December 31, 2022, prepaid expenses totaled $47,000 and included prepaid insurance and other prepaid operating expenses. As of December 31, 2021, prepaid expenses totaled approximately $120,000 and included prepaid manufacturing expenses for the Company's clinical development candidate MLR-1019.

Note 4 – Notes Payable and Convertible Promissory Notes

The following table summarizes the Company's outstanding term loans:

(in thousands)	December 31, 2022	December 31, 2021
2019 Term Loan	$ 5,677	$ 5,677
2022 Term Loan	2,365	-
	8,042	5,677
Unamortized discounts and fees	(709)	-
	$ 7,333	$ 5,677

As of December 31, 2021 and 2022, the 2019 Term Loan was in default.

2019 Term Loan

During 2019, the Company entered into term loan subscription agreements with certain accredited investors, pursuant to which the Company issued secured promissory notes in the aggregate principal amount of approximately $5.7 million. The Company paid $707,000 in debt issuance costs which was recorded as a debt discount to be amortized as interest expense over the term of the loan using the straight-line method.

The promissory notes accrued interest at a rate of 12% per annum. Interest is payable quarterly with the first interest payment to be made on December 28, 2019, and each subsequent payment every three months thereafter. On December 28, 2019, the Company defaulted on the initial interest payment on the loan and the interest rate per annum increased to the default rate of 15%.

The unpaid principal balance of the notes, plus accrued and unpaid interest thereon, matured on June 28, 2020. The notes are secured by a first lien and security interest on all the assets of the Company and certain of its wholly owned subsidiaries. On June 28, 2020, the Company defaulted on the maturity date principal payment.

On June 26, 2021, the holders of the 2019 Term Loans agreed to subordinate their lien and security interest in the assets of the Company and its subsidiaries as set forth in the Security Agreement dated June 28, 2019, to the holders of the June 2021 convertible notes.

On April 19, 2022, a majority of the noteholders of the secured non-convertible promissory notes of the Company issued between June 18, 2019, and August 5, 2019, which matured on August 5, 2020, consented to forbear collection efforts until September 30, 2022. Accordingly, the collateral agent for the note holders in consideration of the signed noteholder agreements agreed to forbear all notes outstanding.

On November 16, 2022, holders of outstanding promissory notes representing a majority of the outstanding principal and accrued interest of the Notes, agreed to amend the Notes to make them automatically convertible into units consisting of a new series of convertible preferred stock and warrants upon an uplisting financing transaction in which the Company's common stock is listed on The Nasdaq Capital Market or the NYSE American, in exchange for the Holders agreeing to forbear repayment of their Notes and accrued interest until the Uplisting Transaction has been completed.

The terms for the amendment of the Notes include no less than the following:

- The Notes will automatically convert upon the Uplisting Transaction into the Preferred Stock at 90% of the public offering price;
- In addition, each Holder will receive 0.3 Warrants for every $1.00 of principal on the Holder's original Note;
- The shares of Preferred Stock will be subject to a six-month lock-up period from date of issuance; and
- The Company has agreed to register the Holders' sale of the shares of common stock issuable upon conversion of the Preferred Stock and upon the exercise of the Warrants such that those shares will be freely tradeable following the up-listtTransaction and expiration of the lock-up period.

The shares of the Preferred Stock will be entitled to vote on an as-converted-to-common basis together with the Company's common stock. The shares of the Preferred Stock will automatically convert into shares of common stock upon expiration of the lock-up period at the conversion price of a percentage of a 30-day VWAP of common stock.

The interest on the Notes, as accrued through the date of conversion, will convert into common stock at the offering price for the up-list transaction.

The Company recognized approximately $852,000 in interest expense related to the 2019 Term Loan for the year ended December 31, 2022 and for the year ended December 31, 2021. As of December 31, 2022, the debt discount and issuance costs for this term loan were fully amortized.

As of December 31, 2022, the Company had approximately $2.9 million of accrued interest on the notes included in accrued expenses and remains in default on the repayment of approximately $5.7 million in principal and $2.9 million in accrued interest on the 2019 Term Loan.

2022 Term Loan - May

On May 11, 2022, the Company entered into a Securities Purchase Agreement with investors whereby the Company issued the Purchasers Original Issue Discount Promissory Notes in the aggregate principal amount of $2,222,222, net of an original issue discount of $222,222 for a purchase price of $2,000,000 and warrants to purchase 1,111,112 shares of the Company's common stock, pursuant to the terms and conditions of the SPA and secured by a Security Agreement as described below. In addition, the Company issued 19,231 commons shares to an investment banker as commission on the sale. The Company received total consideration of $1,692,200 after debt issuance costs of $307,800.

The Notes are due on the earliest to occur of (i) the 12-month anniversary of the original issuance date of the Notes, or May 11, 2023, (ii) a financing transaction which results in the Company's common stock being listed on a national securities exchange, and (iii) an event of default. If an event of default occurs before the Company's common stock is listed on a national securities exchange, the event of default would require a repayment of 125% of the outstanding principal, accrued interest and other amounts owing thereon unless the Company is trading on a national securities exchange in which case the repayment would be 100%. The Notes bear interest at 8% per annum, subject to an increase to 15% in case of an event of default as provided for therein. In addition, at any time before the 12-month anniversary of the date of issuance of the Notes, the Company may, upon five days' prior written notice to the Purchaser, prepay all of the then outstanding principal amount of the Notes for cash in an amount equal to the sum of 105% of all amounts due and owing hereunder, including all accrued and unpaid interest.

The Warrants are exercisable for a 66 month period (five years and six months) ending November 11, 2027, at an exercise price of $0.80 per share, subject to certain adjustments.

The Company recorded a total debt discount of $1,693,000 including an original issue discount of $222,222, a discount related to issuance costs of $307,800, a discount related to the issuance of common stock of $11,820, and a $1,151,137 discount related to the initial warrant derivative liability. The discounts are being amortized over the life of the note.

The Company's obligations under the Notes are secured by a first priority lien on all of the assets of the Company and its wholly-owned subsidiaries pursuant to a Security Agreement, dated May 11, 2022 and among the Company, its wholly-owned subsidiaries, the Purchasers, and the lead investor as the collateral agent.

For the year ended December 31, 2022, the Company recognized approximately $1.1 million related to the amortization of debt discounts and fees and approximately $116,000 in interest expense, respectively. No interest expense or debt discount was recognized for the same period of 2021.

As of December 31, 2022, the Company has recorded $2,222,222 of outstanding principal, $116,000 of accrued interest in accrued expenses and approximately $603,000 of unamortized discount and issuance expenses on the 2022 Term Loans.

2022 Term Loan – December

On December 14, 2022, the Company entered into a Securities Purchase Agreement with an accredited investor pursuant to which the Company issued and sold the investor a non-convertible Original Issue Discount Senior Secured Promissory Note in the principal amount of $142,857 and 158,537 Common Stock Purchase Warrants ("Warrants") for total purchase price of $100,000. The Company received total consideration of $82,400 after debt issuance costs of $17,600 and an original issue discount of $42,857.

The Notes are due on the earliest to occur of (i) the 12-month anniversary of the original issuance date of the Notes, or May 11, 2023, (ii) a financing transaction which results in the Company's common stock being listed on a national securities exchange, and (iii) an event of default. If an event of default occurs before the Company's common stock is listed on a national securities exchange, the event of default would require a repayment of 125% of the outstanding principal, accrued interest and other amounts owing thereon unless the Company is trading on a national securities exchange in which case the repayment would be 100%. The Notes bear interest at 8% per annum, subject to an increase to 15% in case of an event of default as provided for therein. In addition, at any time before the 12-month anniversary of the date of issuance of the Notes, the Company may, upon five days' prior written notice to the Purchaser, prepay all of the then outstanding principal amount of the Notes for cash in an amount equal to the sum of 105% of all amounts due and owing hereunder, including all accrued and unpaid interest.

The unpaid principal amount of this Note, together with any interest accrued but unpaid thereon, may, at the sole discretion of the Company, be converted into shares of a new class of convertible preferred stock of the Company on the closing date on which the Company completes a public offering for cash of common stock and/or common stock equivalents which results in the listing of the Company's common stock on a "national securities exchange" as defined in the Securities Exchange Act of 1934 (a "Qualified Financing")

The Warrants are exercisable for a 66 month period (five years and six months) ending June 15, 2028, at an exercise price of $0.82 per share, subject to certain adjustments.

The Company recorded a total debt discount of $111,523 including an original issue discount of $42,857, a discount related to issuance costs of $17,600, and a $51,066 discount related to the initial warrant derivative liability. The discounts are being amortized over the life of the note.

The Company's obligations under the Notes are secured by a first priority lien on all of the assets of the Company and its wholly-owned subsidiaries pursuant to a Security Agreement, dated May 11, 2022 and among the Company, its wholly-owned subsidiaries, the Purchasers, and the lead investor as the collateral agent.

For the year ended December 31, 2022, the Company recognized approximately $5,500 related to the amortization of debt discounts and fees and approximately $563 in interest expense, respectively. As of December 31, 2022 the principal and interest due was $142,857 of principal and $563, respectively. No interest expense or debt discount was recognized for the same period of 2021.

Convertible Promissory Notes

The following table summarizes the Company's outstanding convertible notes as of December 31, 2022, and December 31, 2022:

(in thousands)	December 31, 2022	December 31, 2021
Convertible Notes	$ 1,319	$ 1,516
Unamortized discounts	(67)	(530)
	$ 1,252	$ 986

All convertible notes including accrued interest were in default as of the issuance date of this Report. As of December 31, 2022 accrued interest totaled $442,000.

Secured Convertible Promissory Note – February 2020

On February 5, 2020, the Company entered into a Securities Purchase Agreement with accredited investors and issued the investors, (i) original issue discount Convertible Promissory Notes with a principal of $550,500 issued at a 10% original issue discount, for a total purchase price of $499,950, and (ii) warrants to purchase up to such number of shares of the common stock of the Company as is equal to the product obtained by multiplying 1.75 by the quotient obtained by dividing (A) the principal amount of the Notes by (B) the then applicable conversion price of the Notes.

The Convertible Notes matured on August 5, 2020. Prior to default, interest accrued to the Holders on the aggregate unconverted and then outstanding principal amount of the Notes at the rate of 10% per annum, calculated on the basis of a 360-day year and accrues daily. On June 15, 2020, the Company defaulted on certain covenants in the 2020 term loan and the interest rate reset to the default rate of 18%.

Until the Convertible Notes are no longer outstanding, the Convertible Notes are convertible, in whole or in part, at any time, and from time to time, into shares of Common Stock at the option of the noteholder. The conversion price is the lower of: (i) $10.00 per share of Common Stock and (ii) 70% of the volume weighted average price of the Common Stock on the trading market on which the Common Stock is then listed or quoted for trading for the prior ten (10) trading days (as adjusted for stock splits, stock combinations and similar events); provided, that if the Notes are not prepaid on or before May 5, 2020, then the conversion price shall be the lower of (x) 60% of the conversion price as calculated above or (y) $1.00 (as adjusted for stock splits, stock combinations and similar events). The conversion price of the Convertible Notes shall also be adjusted as a result of subsequent equity sales by the Company, with customary exceptions.

The exercise price of the Warrants shall be equal to the conversion price of the Convertible Notes, provided, that on the date that the Convertible Notes are no longer outstanding, the exercise price shall be fixed at the conversion price of the Convertible Notes on such date, with the exercise price of the Warrants thereafter (and the number of shares of Common Stock issuable upon the exercise thereof) being subject to adjustment as set forth in the Warrants. The warrants have a 5-year term.

The Company recorded a discount related to the Warrants of approximately $322,000, which includes an allocation of original issue discount (“OID”) and issue costs of $30,000 and $53,000 based on the relative fair value of the instruments as determined by using the Monte-Carlo simulation model. The Company also recorded the remaining debt discount related to the convertible debt OID of approximately $21,000 and debt issuance costs of $38,000 using the relative fair value method to be amortized as interest expense over the term of the loan using the straight-line method. Total discounts recorded were approximately $381,000.

On March 19, 2021, the holder of the Convertible Note converted $25,900 of interest into 25,900 shares of common stock.

On July 29, 2021, the holder of the Convertible Note converted $27,500 of interest into 27,500 shares of common stock.

On August 16, 2021, the holder of the Convertible Note converted $25,000 of principal and interest into 25,000 shares of common stock.

On September 13, 2021, the holder of the Convertible Note converted $32,500 of principal and interest into 32,500 shares of common stock.

On October 4, 2021, the holder of the Convertible Note converted $26,250 of principal and interest into 26,250 shares of common stock.

On November 29, 2021, the holder of the Convertible Note converted $31,150 of principal and interest into 31,151 shares of common stock.

The total note principal and interest converted during the year ended December 31, 2021, was $168,300 and 168,294 common shares issued were valued at fair value based on the quoted trading prices on the conversion dates aggregating approximately $554,000 resulting in a loss on debt extinguishment of $386,000. In addition, derivative fair value of $245,000 relating to the portion of the Note converted was settled resulting in gain on extinguishment of approximately $245,000. The net loss on extinguishment was approximately $141,000.

On January 27, 2022, the conversion price of the notes and warrants was adjusted to be the lower of (x) 60% of the conversion price as calculated above or (y) $0.78 as a result of issuance of common stock for a convertible note conversion.

The Company recognized $87,900 in interest expense related to the notes for the year ended December 31, 2022. The Company recognized approximately $96,000 in interest expense related to the notes for the year ended December 31, 2021. As of December 31, 2022, the debt discounts for this Convertible Note were fully amortized.

As of December 31, 2022, the Company had accrued interest on the February 2020 Convertible Note of approximately $189,100.

As of December 31, 2022, the Company remains in default on the repayment of remaining principal of $457,359 and accrued interest on the February 2020 Convertible Notes. Upon demand for repayment at the election of the holder, the holder of the Convertible Note is due 140% of the aggregate of outstanding principal, interest, and other expenses due in respect of this Convertible Note. The 40% premium will be recorded once a demand occurs.

Secured Convertible Promissory Note – June 2020

On June 26, 2020, the Company issued to an existing investor in the Company a 10% original issue discount Senior Secured Convertible Promissory Note with a principal of $58,055, for a purchase price of $52,500, net of the original issue discount of $5,555. The Convertible Note matured on December 26, 2020. Prior to default, interest accrued on the aggregate unconverted and then outstanding principal amount of the Note at the rate of 10% per annum, calculated on the basis of a 360-day year. The Company incurred approximately $14,000 in debt issuance costs. On August 5, 2020, the Company defaulted on certain covenants in the loan and the interest rate reset to the default rate of 18%.

The Note is convertible, in whole or in part, into shares of common stock of the Company at the option of the noteholder at a conversion price of $0.40 (as adjusted for stock splits, stock combinations and similar events); provided, that if an event of default has occurred under the Note, then the conversion price shall be 65% of the lowest closing bid price of the Company's common stock as reported on its principal trading market for the twenty consecutive trading day period ending on (and including) the trading day immediately preceding the date on which the conversion notice was delivered. The conversion price shall also be adjusted for subsequent equity sales by the Company. Because the share price on the commitment date was in excess of the conversion price, the Company recorded a beneficial conversion feature of $50,000 related to this note that was credited to additional paid in capital and reduced the carrying amount. At the commitment date, the actual intrinsic value of the beneficial conversion feature was approximately $203,000. The discount recorded is being amortized to interest expense over the life of the loan using the straight-line method.

The obligations of the Company under the Note are secured by a senior lien and security interest in all of the assets of the Company and certain of its wholly-owned subsidiaries pursuant to the terms and conditions of a Security Agreement dated June 26, 2020 by the Company in favor of the noteholder. In connection with the issuance of the Note, the holders of the secured promissory notes that the Company issued to select accredited investors between June 28, 2019 and August 5, 2019 in the aggregate principal amount of approximately $5.7 million agreed to subordinate their lien and security interest in the assets of the Company and its subsidiaries as set forth in the Security Agreement dated June 28, 2019 that such holders entered into with the Company and its subsidiaries to the security interest granted to the holder of the Note.

On January 27, 2022, the conversion price of the note was adjusted to the lower of 65% of the lowest closing bid price of the Company's common stock as reported on its principal trading market for the twenty consecutive trading day period ending on (and including) the trading day immediately preceding the date on which the conversion notice was delivered or $0.78 as a result of issuance of common shares for a convertible note conversion.

For the year ended December 31, 2022, and December 31, 2021, the Company recognized approximately $10,600 in interest expense related to the notes. As of December 31, 2021, the debt discount and issuance costs for the loan were fully amortized.

As of December 31, 2022, the Company remains in default on the repayment of principal of $58,055 and approximately $26,200 in accrued interest on the notes. Upon demand for repayment at the election of the holder, the holder of the note is due 140% of the aggregate of outstanding principal, interest, and other expenses due in respect of this Note. The 40% premium will be recorded once a demand occurs.

Secured Convertible Promissory Note – October 2020

On October 30, 2020, the Company issued to an existing investor in and lender to the Company a 10% original issue discount senior secured convertible promissory note with a principal of $111,111, for a purchase price of $100,000. The note is convertible into shares of common stock of the Company at the option of the noteholder at a conversion price of $1.40 (as adjusted for stock splits, stock combinations and similar events); provided, that if an event of default has occurred under the Note, then the conversion price shall be 70% of then conversion price. The conversion price of the notes is subject to anti-dilution price protection and on March 19, 2021, the conversion price of the notes was adjusted to $1.00 per share as a result of subsequent equity sales by the Company.

The obligations of the Company under the note are secured by a senior lien and security interest in all of the assets of the Company.

The Company recorded approximately $9,000 in debt issuance cost to be amortized over the life of the loan using the straight-line method.

The interest rate on the note was 10% per annum, calculated on the basis of a 360-day year. On April 30, 2021, the note matured and the Company defaulted on the note and the interest rate on the loan reset to 18%.

Additionally, the Company issued the noteholder 79,366 warrants to purchase the Company's common stock at $1.60 per share subject to certain adjustments as defined in the agreement. Until the Notes are no longer outstanding, the warrants have full-ratchet protection, are exercisable for a period of five years, and contain customary exercise limitations. On March 19, 2021, the exercise price of the warrants was adjusted to $1.00 and the Company issued an additional 47,619 warrants to the note holder. The Company recorded approximately $57,000 as a deemed dividend upon the repricing based upon the change in fair value of the warrants using a binomial valuation model. The Company used a risk-free rate of 0.16%, volatility of 262.27%, and expected term of 0.92 years in calculating the fair value of the warrants.

The Company recorded a discount related to the warrants of approximately $66,000, Including a discount of $6,000 and issuance costs of $5,000 based on the relative fair value of the instruments as determined by using the Black-Scholes valuation model. The Company recorded a beneficial conversion feature of $45,000 related to the note that was credited to additional paid in capital and reduced the carrying amount. The discount recorded is being amortized to interest expense over the life of the loan using the straight-line method. At the commitment date, the actual intrinsic value of the beneficial conversion feature was approximately $69,000. The Company also recorded a debt discount related to the convertible debt of approximately $5,000 and debt issuance cost of $4,000 using the relative fair value method to be amortized as interest expense over the term of the loan using the straight-line method.

On January 27, 2022, the exercise price of the notes and warrants was adjusted from the default conversion price of $0.98 to $0.78 as a result of a convertible note exercise and the Company issued an additional 35,816 warrants to the note holder.

As of December 31, 2022, 162,800 warrants were outstanding that were issued with the October 2020 convertible note at an exercise price of $0.78.

For the year ended December 31, 2022, the Company recognized approximately $20,300 in interest expense. For the year ended December 31, 2021, the Company recognized approximately $17,300 in interest expense. For the year ended December 31, 2021, the Company recognized $79,000 related to the amortization of debt discount including debt issuance costs.

As of December 31, 2022, the Company has outstanding principal of $111,111 and accrued interest on the note of approximately $39,500.

As of December 31, 2022, the Company remains in default on the repayment of principal and interest on the notes. Upon demand for repayment at the election of the holder, the holder of the note is due 125% of the aggregate of outstanding principal, interest, and other expenses due in respect of this Note. The 25% premium will be recorded once a demand occurs.

Secured Convertible Promissory Note – January 2021

On January 31, 2021, the Company issued to an existing investor in and lender to the Company a 10% original issue discounted Senior Secured Convertible Promissory Note with a principal of $52,778, for a purchase price of $47,500, net of original issue discount of $5,278. The Note is convertible into shares of common stock of the Company at the option of the noteholder at a conversion price of $1.40 (as adjusted for stock splits, stock combinations and similar events); provided, that if an event of default has occurred under the Note, then the conversion price shall be 70% of the then conversion price. The conversion price of the notes is subject to anti-dilution price protection and will be adjusted upon subsequent equity sales by the Company.

The obligations of the Company under the Note are secured by a senior lien and security interest in all assets of the Company.

Additionally, the Company issued to the investor 37,699 warrants to purchase the Company's common stock at an exercise price of $1.60 per share subject to certain adjustments as defined in the agreement. Until the Notes are no longer outstanding, the warrants have full-ratchet protection, are exercisable for a period of five years, and contain customary exercise limitations. On March 19, 2021, the exercise price of the warrants was adjusted to $1.00 and the Company issued an additional 22,619 warrants to the note holder. The Company recorded approximately $27,000 as a deemed dividend upon the repricing based upon the change in fair value of the warrants using a binomial valuation model. The Company used a risk-free rate of 0.16%, volatility of 262.27%, and expected term of 0.97 years in calculating the fair value of the warrants.

The Company recorded approximately $2,000 in debt issuance cost to be amortized over the life of the loan using the straight-line method.

The interest rate on the note was 10% per annum, calculated on the basis of a 360-day year. On July 31, 2021, the note matured and the Company defaulted on the note and the interest rate on the loan reset to the default rate of 18% per annum.

The Company recorded a discount related to the warrants of approximately $32,000, which includes an allocated original issue discount, of $3,000 and allocated issuance costs of $1,000 based on the relative fair value of the instruments as determined by using the Black-Scholes valuation model. The assumptions used in the Black-Scholes model were a risk-free rate of 0.45%, volatility of 240.83%, and an expected term of one year in calculating the fair value of the warrants.

The Company also recorded a debt discount related to the convertible debt of approximately $2,000 remaining original issue discount and remaining debt issuance cost of $1,000 using the relative fair value method to be amortized as interest expense over the term of the loan using the straight-line method.

Total discounts recorded including the original issue discount were approximately $35,000.

On January 27, 2022, the exercise price of the notes and warrants was adjusted from the default conversion price of $0.98 to $0.78, as a result of a convertible note exercise and the Company issued an additional 17,012 warrants to the note holder.

As of December 31, 2022, 77,330 warrants were outstanding that were issued with the January 2021 convertible note at an exercise price of $0.78.

For year ended December 31, 2022, the Company recognized approximately $9,600 in interest expense. For year ended December 31, 2021, the Company recognized approximately $6,700 in interest expense. For year ended December 31, 2021, the Company recognized $35,000 related to the amortization of debt discount including the amortization of debt issuance costs. As of December 31, 2022, the debt discount and issuance costs on the note were fully amortized.

As of December 31, 2022, the Company has outstanding principal of $52,778 on the note and has recorded approximately $16,400 of accrued interest included in accrued expenses on the accompanying consolidated balance sheet.

As of December 31, 2022, the Company remains in default on the repayment of principal and accrued interest on the notes. Upon demand for repayment at the election of the holder, the holder of the note is due 125% of the aggregate of outstanding principal, interest, and other expenses due in respect of this Note. The 25% premium will be recorded once a demand occurs

Secured Convertible Promissory Note – April 2021

On April 12, 2021, the Company issued to an accredited investor in and lender to the Company a 10% original issue discounted Senior Secured Convertible Promissory Note with a principal amount of $66,667, for a purchase price of $60,000 net of an original discount of $6,667. Additionally, the Company issued to the investor 40,000 five-year warrants to purchase the Company's common stock at an exercise price of $1.90 per share. The warrants have full ratchet protection.

The note matured on October 12, 2021, Prior to default, interest accrued on the aggregate unconverted and then outstanding principal amount of the note at the rate of 10% per annum, calculated on-the-basis of a 360-day year. On October 12, 2021, the Company defaulted on the note and the interest rate on the note reset to 18% per annum.

The Note is convertible, in whole or in part, at any time, and from time to time, into shares of the common stock of the Company at the option of the noteholder at a conversion price of $1.50 (as adjusted for stock splits, stock combinations and similar events); provided, that if an event of default has occurred under the Note, then the conversion price shall be 70% of the then conversion price. The conversion price shall also be adjusted upon subsequent equity sales by the Company. The obligations of the Company under the Note are secured by a senior lien and security interest in all assets of the Company.

The Company recorded a discount related to the warrants of approximately $34,000, which includes approximately $3,700 of OID discount allocated under the relative fair value method, and a remaining discount related to the OID of $3,000 based on the relative fair value of the instruments. The fair value of the warrants on which the relative fair value is based was determined by using the Black-Scholes valuation model. The assumptions used in the Black-Scholes model were a risk-free rate of 0.89%, volatility of 240.64%, and an expected term of one year in calculating the fair value of the warrants.

On June 25, 2021, the exercise price of the warrants was adjusted to $1.50 and the Company issued an additional 10,667 warrants to the note holder. The Company recorded approximately $11,000 as a deemed dividend upon the repricing based upon the change in fair value of the warrants using a binomial valuation model. The Company used a risk-free rate of 0.92%, volatility of 247.52%, and expected term of 0.96 years in calculating the fair value of the warrants.

On November 4, 2021, the Company issued 7,662 shares of common stock upon a cashless exercise of 12,500 warrants issued with the April 2021 Convertible Note.

On November 30, 2021, the exercise price of the warrants was adjusted to $1.00 based on a note conversion at $1.00 and the Company issued an additional 19,084 warrants to the note holder.

On January 27, 2022, the exercise price of the note and warrants was adjusted from the default conversion price of $1.05 to $0.78 based on a convertible note conversion at $0.78 and the Company issued an additional 16,147 warrants to the note holder.

As of December 31, 2022, 73,398 warrants were outstanding that were issued with the April 2021 convertible note at an exercise price of $0.78.

During the year ended December 31, 2022, the Company repaid $25,000 of principal on the note. The Company recorded approximately $19,500 gain on debt extinguishment resulting from the settlement of the derivative as a result of repayment of the note.

For the year ended December 31, 2022, the Company recognized approximately $10,400 in interest expense for the notes. For the year ended December 31, 2021, the Company recognized approximately $6,100 in interest expense for the notes. For the year ended December 31, 2021, the Company recognized approximately $37,500, related to the amortization of debt discount including debt issuance costs.

As of December 31, 2022, the Company has recorded $41,667 of principal and approximately $16,500 of accrued interest for the note on the accompanying consolidated balance sheet. As of December 31, 2022, the debt discount and issuance costs on the note were fully amortized.

As of December 31, 2022, the Company remains in default on the repayment of principal and accrued interest on the notes. Upon demand for repayment at the election of the holder, the holder of the note is due 125% of the aggregate of outstanding principal, interest, and other expenses due in respect of this Note. The 25% premium will be recorded once a demand occurs.

Secured Convertible Promissory Note – June 2021

On June 25, 2021, the Company issued to an accredited investor in and lender to the Company a 5% original issue discounted Senior Secured Convertible Promissory Note with a principal amount of $66,500, for a purchase price of $63,000, net of an original issue discount of $3,500. Additionally, the Company issued to the investor 40,000 three-year warrants to purchase the Company's common stock at an exercise price of $1.90 per share. Upon subsequent down-round equity sales by the Company, the number of shares issuable upon exercise of the Warrant shall be proportionately adjusted such that the aggregate exercise price of this Warrant shall remain $76,000 which is a full ratchet price protection provision.

The note matures one year from issuance, or such earlier date as the note is required or permitted to be repaid. Interest shall accrue on the aggregate unconverted and then outstanding principal amount of the note at the rate of 10% per annum, calculated on the basis of a 365-day year.

The Note is convertible, in whole or in part, at any time, and from time to time, into shares of the common stock of the Company at the option of the noteholder at a conversion price of $1.50 (as adjusted for stock splits, stock combinations and similar events); provided, however that in the event, the Company's Common Stock trades below $1.60 per share for more than three (3) consecutive trading days, the Holder of this Note is entitled, at its option, to convert all or any amount of the principal face amount of this Note then outstanding into shares of the Company's common stock at a price for each share of Common Stock equal to 65% of the lowest trading price of the Common Stock for the twenty prior trading days including the day upon which a Notice of Conversion is received. The conversion discount, look back period and other terms of the Note will be adjusted on a ratchet basis if the Company offers a more favorable conversion discount, prepayment rate, interest rate, (whether through a straight discount or in combination with an original issue discount), look back period or other more favorable term to another party for any financings while this Note is in effect.

The obligations of the Company under the Note are secured by a senior lien and security interest in all assets of the Company.

The Company incurred approximately $9,300 in debt issuance costs.

The Company also issued 2,377 shares of common stock as a commission fee to the investment banker. The fair value of the common stock which was approximately $5,040 was recorded as debt issuance expense.

Due to the variability in the conversion price of the Note the embedded conversion option has been bifurcated and reflected as a derivative liability with an initial fair value of $102,823 with $87,039 charged to derivative expense and $15,784 recorded as a debt discount.

Total discounts recorded were $66,500. The Company recorded an original issue discount of $3,500, a discount of $9,300 for issuance costs, a discount related to the warrants of approximately $37,916 and a discount related to the derivative of $15,784 based on the relative fair value of the instruments. The warrant fair value on which the relative fair value was based was determined by using a simple binomial lattice model. The assumptions used in the model were a risk-free rate of 0.48%, volatility of 302.11%, and an expected term of 0.60 years in calculating the fair value of the warrants.

On August 11, 2021, the exercise price of the warrants was adjusted to $1.50 and the Company issued an additional 10,667 warrants to the note holder. The Company recorded approximately $25,000 as a deemed dividend upon the repricing based upon the change in fair value of the warrants using a binomial valuation model. The Company used a risk-free rate of 0.81, volatility of 209%, and expected term of 0.57 years in calculating the fair value of the warrants.

On October 27, 2021, the Company and the institutional investor who holds the convertible promissory note agreed to extend the maturity date of the note by six months to December 25, 2022 for no consideration.

On November 30, 2021, the exercise price of the warrants was adjusted to $1.00 based on a note conversion at $1.00 and the Company issued an additional 25,333 warrants to the note holder.

On January 27, 2022, the holder of the June 25, 2021, convertible note converted $9,500 of principal and $421 of interest at $0.78 per share into 12,721 shares of common stock that were valued at fair value based on the quoted trading prices on the conversion dates aggregating approximately $28,000 resulting in a loss on debt extinguishment of $18,000. In addition, derivative fair value of $23,000 relating to the portion of the Note converted was settled resulting in a gain on extinguishment of approximately $23,000. The net gain on extinguishment was approximately $5,000. In addition, the conversion price of the warrants issued with the notes were adjusted to $0.78 per share and the Company issued an additional 21,436 warrants to the holder of the note.

On December 25, 2022, the Company defaulted on the extended maturity date of the note.

As of December 31, 2022, 97,436 warrants were outstanding that were issued with the June 2021 convertible note at an exercise price of $0.78.

For the year ended December 31, 2022, the Company recognized approximately $38,700 related to the amortization of debt discount. For the year ended December 31, 2022, the Company recognized approximately $14,000 in interest expense related to the note. For the year ended December 31, 2021, the Company recognized approximately $27,800 related to the amortization of debt discount. For the year ended December 31, 2021, the Company recognized approximately $5,800 in interest expense related to the note.

At December 31, 2022, the Company has recorded $57,000 of outstanding principal and approximately $19,100 of accrued interest. As of December 31, 2022, the debt discount on the note was fully amortized.

Convertible Promissory Note – August 11, 2021

On August 11, 2021, the Company entered into a Securities Purchase Agreement with an accredited institutional investor pursuant to which the Company issued to the investor its Original Issue Discount Secured Convertible Promissory Note in the principal amount of $220,500 and warrants to purchase 40,000 shares of the common stock of the Company for which the Company received consideration of $210,000 net of an original issue discount of $10,500. In addition, the Company entered into a Registration Rights Agreement with the investor and issued the investor 5,000 common shares as a commitment fee.

The note matured in August 2021 and absent an event of default provides for an interest rate of 10% per annum, payable at maturity, and is convertible into common stock of the Company at a price of $1.50 per share, subject to anti-dilution adjustments in the event of certain corporate events as set forth in the Note, provided that if the average closing price of the Company's common stock during any Nine consecutive trading days is below $1.60, the conversion price shall be reduced to 65% of the lowest trading price during the 20 consecutive trading days immediately preceding the conversion date. On November 9, 2021, the Company defaulted on certain covenants in the note and the interest rate on the note reset to 24% per annum.

In addition to customary anti-dilution adjustments the Note provides, subject to certain limited exceptions, that if the Company issues any common stock or common stock equivalents, as defined in the Note, at a per share price lower than the conversion price then in effect, the conversion price will be reduced to the per share price at which such shares or common share equivalents were sold.

The Warrants are initially exercisable for a period of five years at a price of $1.90 per share, subject to customary anti-dilution adjustments upon the occurrence of certain corporate events as set forth in the Warrant.

The Company incurred approximately $30,000 in debt issuance costs.

The Company also issued 7,000 shares of common stock to the investment banker as a commission on the note.

Due to the variability in the conversion price of the Note the embedded conversion option has been bifurcated and reflected as a derivative liability with an initial fair value of $340,893 with $234,388 charged to derivative expense and $106,505 recorded as a debt discount.

The Company recorded a total debt discount of $220,500 including an original issue discount of $10,500, a discount related to the warrants of approximately $56,454 a discount related to issuance costs of $30,000 and a discount related to the issuance of common stock of approximately $17,041, and a $106,505 discount related to the initial derivative value of the embedded conversion feature on the note all based on the relative fair value of the instruments,

The fair value of the warrants on which the relative fair value was based was determined by using a simple binomial lattice model. The assumptions used in the model were a risk-free rate of 0.81%, volatility of 253%, and an expected term of one year in calculating the fair value of the warrants. The discounts are being amortized over the term of the convertible note.

On November 30, 2021, the exercise price of the warrants was adjusted to $1.00 based on a note conversion at $1.00 and the Company issued an additional 36,000 warrants to the note holder.

On January 27, 2022, the conversion price of the notes was adjusted to the lower of $0.78 per share, or provided that if the average closing price of the Company's common stock during any six consecutive trading days is below $1.60, the conversion price shall be reduced to 65% of the lowest trading price during the 20 consecutive trading days immediately preceding the conversion date. In addition, the exercise price of the warrant was adjusted to $0.78 per share and the Company issued an additional 21,436 warrants to the holder of the note. Both the conversion price of the note and warrants were adjusted as a result of a convertible note exercise at $0.78 per share.

On May 12, 2022, the Company repaid $135,695 of principal and $64,305 of interest including $54,278 of interest due as a result of early redemption on the note. In addition, the holder of the note extended the maturity date on the note to September 30, 2022, when the outstanding balance of principal and interest of $128,502 is due on the note. The Company recorded a $45,200 gain on debt extinguishment as a result of repayment of the note. On September 30, 2022, the Company defaulted on the outstanding balance of principal and interest on the note.

As of December 31, 2022, 97,436 warrants were outstanding that were issued with the August 11, 2021 convertible note at an exercise price of $0.78.

For the year ended December 31, 2022, the Company recognized approximately $134,100 related to the amortization of debt discount. For the year ended December 31, 2022, the Company recognized approximately $97,300 in interest expense related to the note. For the year ended December 31, 2021, the Company recognized approximately $86,400 related to the amortization of debt discount. For the year ended December 31, 2021, the Company recognized approximately $15,800 in interest expense related to the note.

At December 31, 2022, the Company has remaining $84,800 of outstanding principal and approximately $48,800 of accrued interest. As of December 31, 2022, the debt discount on the note was fully amortized.

Convertible Promissory Note – August 17, 2021

On August 17, 2021, the Company entered into a Securities Purchase Agreement with an accredited institutional investor pursuant to which the Company issued to the investor its Original Issue Discount Secured Convertible Promissory Note in the principal amount of $220,500 and warrants to purchase 40,000 shares of the common stock of the Company for which the Company received consideration of $210,000 net of original discount of $10,500. In addition, the Company entered into a Registration Rights Agreement with the investor and issued the investor 5,000 common shares as a commitment fee.

The note matures one year from issuance and provides for an interest rate of 10% per annum, payable at maturity, and is convertible into common stock of the Company at a price of $1.50 per share, subject to anti-dilution adjustments in the event of certain corporate events as set forth in the Note, provided that if the average closing price of the Company's common stock during any three consecutive trading days is below $1.60, the conversion price shall be reduced to 65% of the lowest trading price during the 20 consecutive trading days immediately preceding the conversion date. The embedded conversion option will be treated as a bifurcated derivative liability.

In addition to customary anti-dilution adjustments the Note provides, subject to certain limited exceptions, that if the Company issues any common stock or common stock equivalents, as defined in the Note, at a per share price lower than the conversion price then in effect, the conversion price will be reduced to the per share price at which such shares or common share equivalents were sold.

The Warrants are initially exercisable for a period of five years at a price of $1.90 per share, subject to customary anti-dilution adjustments upon the occurrence of certain corporate events as set forth in the warrant

The Company incurred approximately $30,000 in debt issuance costs. The Company also issued 5,631 shares of common stock to the investment banker as a commission on the note.

Due to the variability in the conversion price of the Note, the embedded conversion option has been bifurcated and reflected as a derivative liability with an initial fair value of $398,404 with $297,833 charged to derivative expense and $100,571 recorded as a debt discount.

The Company recorded a total debt discount of $220,500 including an original issue discount of $10,500, a discount related to the warrants of approximately $62,220 a discount related to issuance costs of $30,000 a discount related to the issuance of common stock of approximately $17,209, and a $100,571 discount related to the initial derivative value of the embedded conversion feature on the Note all based on the relative fair value of the instruments.

The fair value of the warrants on which the relative fair value was based was determined by using a simple binomial lattice model. The assumptions used in the model were a risk-free rate of 0.77%, volatility of 254%, and an expected term of one year in calculating the fair value of the warrants. The discounts are being amortized over the life of the convertible note.

On October 27, 2021, the Company and the institutional investor who holds the promissory note agreed to extend the maturity date the notes by six months to February 17, 2023 for no consideration.

On November 15, 2021, the Company defaulted on certain covenants in the note and the interest rate on the note reset to 24% per annum.

On November 30, 2021, the exercise price of the warrants was adjusted to $1.00 based on a note conversion at $1.00 and the Company issued an additional 36,000 warrants to the note holder.

On January 27, 2022, the conversion price of the notes was adjusted to the lower of $0.78 per share, or provided that if the average closing price of the Company's common stock during any six consecutive trading days is below $1.60, the conversion price shall be reduced to 65% of the lowest trading price during the 20 consecutive trading days immediately preceding the conversion date. In addition, the exercise price of the warrant was adjusted to $0.78 per share and the Company issued an additional 21,436 warrants to the holder of the note. Both the conversion price of the note and warrants were adjusted as a result of a convertible note exercise at $0.78 per share.

As of December 31, 2022, 97,436 warrants were outstanding that were issued with the August 17, 2021 convertible note at an exercise price of $0.78.

For the year ended December 31, 2022, the Company recognized approximately $140,600 related to the amortization of debt discount. For the year ended December 31, 2022, the Company recognized approximately $50,400 in interest expense related to the note. For the year ended December 31, 2021, the Company recognized approximately $62,600 related to the amortization of debt discount. For the year ended December 31, 2021, the Company recognized approximately $15,400 in interest expense related to the note.

At December 31, 2022, the Company has recorded $220,500 of outstanding principal and approximately $65,800 of accrued interest and $17,300 of unamortized discounts. As of December 31, 2022, the debt discount on the note was fully amortized.

Convertible Promissory Note – October 4, 2021

On October 4, 2021, the Company entered into a Securities Purchase Agreement ("SPA") with an institutional investor pursuant to which the Company issued the Buyer a 10% Convertible Redeemable Note in the principal amount of $131,250 and a six-year warrant to purchase 23,810 shares of common stock of the Company for which the Company received proceeds of $110,000. In addition, the Company entered into a Registration Rights Agreement with the investor and issued the investor 2,977 common shares as a commitment fee.

The Note is due October 4, 2022. The Note provides for interest at the rate of 10% per annum, payable in seven equal monthly payments beginning on August 15, 2022 through the maturity date. The Note is convertible into shares of common stock at any time following the date of cash payment at the Buyer's option at a conversion price of $1.50 per share, subject to certain adjustments.

The warrants are exercisable for three-years from October 4, 2021, at an exercise price of $1.90 per share, subject to certain adjustments, which exercise price may be paid on a cashless basis. The aggregate exercise price is $45,238.

The Company incurred approximately $15,000 in debt issuance costs. The Company also issued 2,173 shares of common stock to the investment banker as a commission on the note.

Due to the lack of authorized shares, the embedded conversion option has been bifurcated and reflected as a derivative liability with an initial fair value of $564,943 with $487,052 charged to derivative expense and $77,891 recorded as a debt discount.

The Company recorded a total debt discount of $131,250 including an original issue discount of $6,250, a discount related to issuance costs of $15,000, a discount related to the issuance of common stock of $32,109, and a $77,891 discount related to the initial derivative value of the embedded conversion feature on the Note all based on the relative fair value of the instruments. The discounts are being amortized over the life of the convertible note.

On January 2, 2022, the Company defaulted on certain covenants contained in the October 4, 2021, convertible note and the interest rate reset to 16%.

On January 27, 2022, the exercise price of the note was adjusted to $0.78 based on a convertible note conversion at $0.78.

On May 12, 2022, the Company repaid $83,500 of principal on the note and repurchased 2,977 shares of common stock issued to the holder as an original commitment fee on the note for $1,000. The repurchase was recorded at cost as treasury stock on the accompanying consolidated balance sheet. In addition during the year, the Company repaid an additional $31,042 of principal and $8,905 of interest on the note. The Company recorded approximately $96,000 gain on debt extinguishment resulting from the settlement of the derivative as a result of repayment of the note.

For the year ended December 31, 2022, the Company recognized approximately $99,200 related to the amortization of debt discount. For the year ended December 30, 2022, the Company recognized approximately $6,500 in interest expense related to the note. For the year ended December 31, 2021, the Company recognized approximately $32,000 related to the amortization of debt discount. For the year ended December 31, 2021, the Company recognized approximately $3,200 in interest expense related to the note.

At December 31, 2022, the Company has recorded approximately $16,700 of outstanding principal and approximately $811 of accrued interest. As of December 31, 2022, the debt discount on the note was fully amortized.

Convertible Promissory Note – October 7, 2021

On October 7, 2021, the Company entered into a Securities Purchase Agreement ("SPA") with an institutional investor pursuant to which the Company issued the investor a 10% Convertible Redeemable Note in the principal amount of $131,250 and a three-year warrant to purchase 23,810 shares of common stock of the Company for which the Company received proceeds of $110,000. In addition, the Company entered into a Registration Rights Agreement with the investor and issued the investor 2,977 common shares as a commitment fee and an additional 2,632 shares as a commission to the broker.

The Note is due October 7, 2022. The Note provides for interest at the rate of 10% per annum, payable at maturity. The Note is convertible into shares of common stock at any time following the date of cash payment at the Buyer's option at a conversion price of $1.50 per share, subject to certain adjustments.

The warrants are exercisable for three-years from October 7, 2021, at an exercise price of $1.90 per share, subject to certain adjustments, which exercise price may be paid on a cashless basis. The aggregate exercise price is $45,238.

The Company incurred approximately $15,000 in debt issuance costs.

Due to the lack of authorized shares, the embedded conversion option has been bifurcated and reflected as a derivative liability with an initial fair value of $564,184 with $487,667 charged to derivative expense and $76,517 recorded as a debt discount.

The Company recorded a total debt discount of $131,250 including an original issue discount of $6,250, a discount related to issuance costs of $15,000, a discount related to the issuance of common stock of approximately $33,483, and a $76,517 discount related to the initial derivative value of the embedded conversion feature on the Note all based on the relative fair value of the instruments. The discounts are being amortized over the life of the convertible note.

On January 5, 2022, the Company defaulted on certain covenants contained in the October 7, 2021, convertible note and the interest rate reset to 16%.

On January 27, 2022, the exercise price of the note was adjusted to $0.78 based on a convertible note conversion at $0.78.

On May 12, 2022, the Company repaid $83,500 of principal on the note and repurchased 2,977 shares of common stock issued to the holder as an original commitment fee on the note for $1,000. The repurchase was recorded at cost as treasury stock on the accompanying consolidated balance sheet. In addition, the Company repaid an additional $31,042 of principal and $8,905 of interest on the note during the year ended December 31, 2022. The Company recorded approximately $98,000 gain on debt extinguishment related to the settlement of the derivative liability as a result of repayment of the note.

For the year ended December 31, 2022, the Company recognized approximately $100,300 related to the amortization of debt discounts. For the year ended December 31, 2022, the Company recognized approximately $6,600 in interest expense related to the note. For the year ended December 31, 2021, the Company recognized approximately $30,900 related to the amortization of debt discounts. For the year ended December 31, 2021, the Company recognized approximately $3,100 in interest expense related to the note.

At December 31, 2022, the Company has recorded $16,700 of outstanding principal and approximately $811 of accrued interest. As of December 31, 2022, the debt discount on the note was fully amortized.

Convertible Promissory Note – March 15, 2022

On March 15, 2022, the Company entered into a Securities Purchase Agreement ("SPA") with an institutional investor pursuant to which the Company issued the investor a 10% Convertible Note in the principal amount of $250,000 for a purchase price of $200,000 reflecting a $50,000 original issue discount. The Company received total consideration of $180,000 after debt issuance costs of $20,000. In addition, the Company issued 2,500 shares of common stock as a commitment fee to the investor. The Company also issued 10,000 shares to the broker as a commission on the sale.

The Note provides for guaranteed interest at the rate of 10% per annum for the 12 months from and after the original issue date of the Note for an aggregate guaranteed interest of $25,000, all of which guaranteed interest shall be deemed earned as of the date of the note. The principal amount and the guaranteed interest shall be due and payable in seven equal monthly payments each, $39,285.71, commencing on August 15, 2022, and continuing on the 15th day of each month until paid in full not later than March 15, 2023, the maturity date.

The Note is convertible into shares of common stock at any time following any event of default at the investor's option at a conversion price of ninety percent (90%) per share of the lowest per-share trading price of the Company; stock during the ten trading day periods before the conversion, subject to certain adjustments.

The Company recorded a total debt discount of $250,000 including an original issue discount of $50,000, a discount related to issuance costs of $34,384, a discount related to the issuance of common stock of approximately $3,596, and a $162,020 discount related to the initial derivative value of the embedded conversion feature on the Note all based on the relative fair value of the instruments. The discounts are being amortized over the life of the convertible note.

On September 16, 2022 the Company default on the repayment of the note and the interest rate reset to 18%. In addition, the Company recognized approximately $32,000 of additional interest expense related to default provisions contained in the note.

For the year ended December 31, 2022, the Company repaid $97,176 of principal and $11,396 of interest on the note. The Company recorded approximately $68,600 gain on debt extinguishment resulting from the settlement of the derivative as a result of repayments on the note.

For the year ended December 31, 2022, the Company recognized approximately $200,000 related to the amortization of debt discounts and approximately $30,700 in interest expense related to the note.

As of December 31, 2022, the Company has recorded $202,300 of outstanding principal, $2,000 of accrued interest and $50,000 of unamortized discount and issuance expenses

Derivative Liabilities Pursuant to Convertible Notes and Warrants

In connection with the issuance of the unrelated party convertible notes (collectively referred to as "Notes") and warrants (collectively referred to as "Warrants"), discussed above, the Company determined that the terms of certain Notes and Warrants contain an embedded conversion options to be accounted for as derivative liabilities due to the holder having the potential to gain value upon conversion and provisions which includes events not within the control of the Company. Due to the fact that the number of shares of common stock that may be issuable for warrants and notes with variable conversion features may exceed the Company's authorized share limit as of December 31, 2022, the equity environment was tainted and all convertible debentures and warrants were included in the value of the derivative. Accordingly, for existing embedded conversion options and existing warrants that were not previously accounted for as derivatives, the Company reclassified $3,462,000 from additional paid-in capital to derivative liability on December 31, 2021. In accordance with ASC 815-40 *–Derivatives and Hedging – Contracts in an Entity's Own Stock*, the embedded conversion options contained in the Notes and the Warrants were accounted for as derivative liabilities at the date of issuance or on the reclassification date and shall be adjusted to fair value through earnings at each reporting date. The fair value of the embedded conversion options and the warrants was determined using the Binomial Lattice valuation model. At the end of each period and on note conversion date or repayment or on the warrant exercise date, the Company revalues the derivative liabilities resulting from the embedded option.

During the year ended December 31, 2022, in connection with the issuance of the Notes and Warrants, on the initial measurement dates, the fair values of the embedded conversion options of approximately $1.6 million was recorded as derivative liabilities of which $1.4 million was allocated as a debt discount and $191,000 as derivative expense.

At the end of the period, the Company revalued the embedded conversion option derivative liabilities. In connection with the initial valuations and these revaluations, the Company recorded a loss from the initial and change in the derivative liabilities fair value of approximately $2.3 million for the year ended December 31, 2022.

During the year ended December 31, 2022, the fair value of the derivative liabilities was estimated at issuance and at the December 31, 2022, using the Binomial Lattice valuation model with the following assumptions:

Dividend rate	—%
Term (in years)	0.00 to 1.09 year
Volatility	177.5% to 315%
Risk-free interest rate	1.28% to 4.73%

Other than the effect on the derivative valuation recognized in operations, there was no accounting effect to the ratchet adjustments of certain convertible notes to reduce the conversion price to $0.78 in January 2022 since all of the embedded conversion options in the convertible notes were treated as derivatives.

Note 5 - Licensing Agreements

Les Laboratories Servier

As a result of the Asset Purchase Agreement that the Company entered into with Symplmed Pharmaceuticals LLC in June 2017, Symplmed assigned to the Company an Amended and Restated License and Commercialization Agreement with Les Laboratories Servier, pursuant to which the Company has the exclusive right to manufacture, have manufactured, develop, promote, market, distribute and sell Prestalia® in the U.S. (and its territories and possessions).

On January 4, 2021, the licensor terminated the licensing agreement with the Company for the commercialization of Prestalia®. As of December 31, 2022 and December 31, 2021, the Company had $24,500 recorded as a liability on the accompanying consolidated balance sheet for royalties due under the agreement.

No royalties were incurred for the years ended December 31, 2022 or 2021.

License of DiLA^2 Assets

On March 16, 2018, the Company entered into an exclusive sublicensing agreement for certain intellectual property rights to its DiLA2 delivery system. The agreement included an upfront payment of $200,000 and future additional consideration for sales and development milestones. The upfront fee was contingent upon the Company obtaining a third-party consent to the agreement within ninety days of execution. As of December 31, 2022, and December 31, 2021, the Company had not obtained consent for the sublicense and has classified the upfront payment it had previously recorded as an accrued liability on its balance sheet.

Note 6 - Related Party Transactions

Due to Related Party

The Company and other related entities have had a commonality of ownership and/or management control, and as a result, the reported operating results and/or financial position of the Company could significantly differ from what would have been obtained if such entities were autonomous.

The Company had a Master Services Agreement ("MSA") with Autotelic Inc., a related party that is partly owned by one of the Company's former Board members and executive officers, namely Vuong Trieu, Ph.D., effective November 15, 2016. The MSA stated that Autotelic Inc. would provide business functions and services to the Company and allowed Autotelic Inc. to charge the Company for these expenses paid on its behalf. Dr. Trieu resigned as a director of our company effective October 1, 2018. The Company and Autotelic Inc. agreed to terminate the MSA effective October 31, 2018.

An unpaid balance for previous years services performed under the agreement of approximately $4,000 is included in due to related party in the accompanying consolidated balance sheets at December 31, 2022, and December 31, 2021

In addition, as of December 31, 2022 and December 31, 2021 the Company owed various officers and directors approximately $22,000 and $42,000, respectively for services rendered which is included as due to related party on the accompanying consolidated balance sheet.

Note 7 - Stockholders' Equity

Preferred Stock

Adhera has authorized 100,000 shares of preferred stock for issuance and has designated 1,000 shares as Series B Preferred Stock ("Series B Preferred") and 90,000 shares as Series A Junior Participating Preferred Stock ("Series A Preferred"). No shares of Series A Preferred or Series B Preferred are outstanding. In March 2014, Adhera designated 1,200 shares as Series C Convertible Preferred Stock ("Series C Preferred"). In August 2015, Adhera designated 220 shares as Series D Convertible Preferred Stock ("Series D Preferred"). In April 2018, Adhera designated 3,500 shares of Series E Convertible Preferred Stock ("Series E Preferred"). In July 2018, Adhera designated 2,200 shares of Series F Convertible Preferred Stock ("Series F Preferred"). In December 2019, Adhera designated 6,000 shares of Series G Convertible Preferred Stock ("Series G Preferred"). The Company plans to file a certificate of elimination with respect to the Series A and Series B stock and a certificate of decrease with respect to each of its Series C, D and F Preferred stock. As of December 31, 2022, the Company has not filed the certificate of elimination. Each subsequent authorization of Preferred Stock has liquidation preference over the previous Series.

Series C Preferred

Each share of Series C Preferred has a stated value of $5,000 per share, has a $5,100 liquidation preference per share, has voting rights of 33.33 votes per Series C Preferred share, and is convertible into shares of common stock at a conversion price of $150.00 per share.

As of December 31, 2022, and December 31, 2021, 100 shares of Series C Preferred stock were outstanding.

Series D Preferred

Each share of Series D Preferred has a stated value of $5,000 per share, has a liquidation preference of $300 per share, has voting rights of 62.5 votes per Series D Preferred share and is convertible into shares of common stock at a conversion price of $80.00 per share. The Series D Preferred has a 5% stated dividend rate when, and if declared by the Board of Directors, is not redeemable and has voting rights on an as-converted basis.

As of December 31, 2022, and December 31, 2021, 40 shares of Series D Preferred were outstanding.

Series E Convertible Preferred Stock and Warrants

The Series E Preferred Stock has a stated value of $5,000 per share and accrues 8% dividends per annum that are payable in cash or stock at the Company's discretion. The Series E Preferred has voting rights, dividend rights, liquidation preferences, conversion rights at the option of the holder and anti-dilution rights. Series E Preferred stock is convertible into shares of common stock at $10.00. Anti-dilution price protection on Series E Preferred stock expired on February 10, 2020. Warrants issued with Series E Convertible Preferred Stock have anti-dilution price protection, are exercisable for a period of five years, and contain customary exercise limitations.

On March 19, 2021, the exercise price of the Series E warrants was adjusted from $10.00 to $1.00 per share upon the conversion of $25,900 debt for 25,900 shares common stock. The Company recorded approximately $390,000 as a deemed dividend based upon the change in fair value of the Series E Preferred stock warrants using a binomial valuation model. The Company used a risk-free rate of 0.16%, volatility of 262.27%, and expected term of .41 to .43 years in calculating the fair value of the warrants.

As of May 17, 2021, the three-year anniversary of the closing of the Series E Preferred stock offering, all outstanding Series E Preferred stock may be converted by the Company into common stock upon written notification being provided by the Company to stockholders.

On June 8, 2021, an investor converted 8 shares of Series E Preferred and accrued dividends of approximately $10,000 into 5,051 shares of common stock. In addition, the Company issued 2,679 shares of common stock to the investor for a cashless exercise of 3,750 warrants.

On July 30, 2021, an investor converted 50 shares of Series E Preferred stock with a state value of $250,000 into 25,000 shares of common stock.

On October 4, 2021, the Company issued 12,777 shares of common stock upon the conversion of 20 shares Series E Preferred stock including accrued dividends of $27,770.

On October 5, 2021, the Company issued 19,271 shares of common stock upon the conversion of 30 shares of Series E Preferred stock including accrued dividends of $42,707.

On October 8, 2021, the Company issued 2,571 shares of common stock upon the conversion of 4 shares of Series E Preferred stock including accrued dividends of $5,707.

On October 12, 2021, the Company issued 3,216 shares of common stock upon the conversion of 5 shares of Series E Preferred stock including accrued dividends of $7,156.

On November 23, 2021, the Company issued 9,665 shares of common stock upon the conversion of 15 shares of Series E Preferred stock including accrued dividends of $21,649.

On January 27, 2022, the exercise price of the Series E warrants was adjusted to $0.78 per share as a result of a convertible note exercise at $0.78 per share.

On May 17, 2022, the Company effected the conversion of 3,059 shares of Series E Preferred stock and accrued dividends of approximately $5.1 million into 2,035,306 shares of unregistered common stock at a conversion price of $10.00 per share in accordance with the conversion provisions of the certificate of designation.

As of December 31, 2022, the Company had a total of 1,453,028 warrants issued with Series E Preferred stock outstanding. The warrants expire in 2023 and have an exercise price of $0.78.

The Company had accrued dividends on the Series E Preferred stock of approximately $498,000 and $5.0 million, as of December 31, 2022, and December 31, 2021, respectively.

At December 31, 2022 and December 31, 202, there were 267 and 3,326 Series E shares outstanding, respectively.

Series F Convertible Preferred Shares and Warrants

The Series F Preferred Stock has a stated value of $5,000 per share and accrues 8% dividends per annum that are payable in cash or stock at the Company's discretion. The Series F Preferred has voting rights, dividend rights, liquidation preferences, conversion rights at the holders option and anti-dilution rights. Series F Preferred stock is convertible into shares of common stock at $10.00 Anti-dilution price protection on Series F Preferred stock expired on February 10, 2020. Warrants issued with Series F Convertible Preferred Stock have anti-dilution price protection, are exercisable for a period of five years, and contain customary exercise limitations.

On March 19, 2021, the exercise price of the Series F warrants was adjusted from $10.00 to $1.00 upon the conversion of $25,900 of debt for 25,900 shares of common stock. The Company recorded approximately $31,000 as a deemed dividend based upon the change in fair value of the Series F Preferred stock using a binomial valuation model. The Company used a risk-free rate of 0.16%, volatility of 262.27%, and an expected term of .46 to .53 years in calculating the fair value of the warrants.

On October 15, 2021, the Company issued 1,853 shares of common stock upon the conversion of 3 shares of Series F Preferred stock and including total accrued dividends of $3,521.

As of November 9, 2021, three-year anniversary of the closing of the Series F Preferred stock offering, all outstanding Series F Preferred stock and accrued dividends became convertible by the Company into common stock upon written notification being provided by the Company to stockholders. As of December 31, 2021, the Company has not provided notice of conversion to the holders of the Series F Preferred stock.

On January 27, 2022, the exercise price of the Series F warrants was adjusted to $0.78 per share as a result of a convertible note exercise at $0.78 per share.

On May 17, 2022, the Company effected the conversion of 358 shares of Series F Preferred stock and accrued dividends of approximately $543,000 into 233,127 shares of unregistered common stock at a conversion rate of $10.00 per share in accordance with the conversion provisions of the certificate of designation.

As of December 31, 2022, the Company had a total of 154,425 Series F Preferred stock warrants outstanding. The warrants expire in 2023.

The Company had accrued dividends on the Series F Preferred stock of approximately $448,000, as of December 31, 2021. No dividends were accrued as of December 31, 2022.

At December 31, 2022 and December 31, 2021, there were zero and 358 Series F Preferred shares outstanding, respectively.

Series G Convertible Preferred Shares

The Series G Preferred Stock has a stated value of $5,000 per share and accrues 8% dividends per annum that are payable in cash or stock at the Company's discretion. The Series G Preferred has voting rights, dividend rights, liquidation preferences, conversion rights and anti-dilution rights. Series G Preferred stock is convertible into shares of common stock at $10.00.

As of December 31, 2022 and December 31, 2021, no Series G Preferred Stock has been issued by the Company.

Common Stock

On June 8, 2021, an investor converted 8 shares of Series E Preferred and accrued dividends of approximately $10,000 into 5,051 shares of common stock.

On June 8, 2021, the Company issued 2,679 shares of common stock to the investor for a cashless exercise of 3,750 warrants.

On July 30, 2021, and investor converted 50 shares of Series E Preferred stock with a stated value of $250,000 into 25,000 shares of common stock.

On August 11, 2021, the Company issued 5,000 shares of common stock to a convertible note investor as a commitment fee which was valued at its relative fair value of $56,464.

On August 18, 2021, the Company issued 5,000 shares of common stock to a convertible note investor as a commitment fee which was valued at its relative fair value of $62,220.

On September 22, 2021, the Company issued 15,008 shares of common stock to an investment banker for commissions due under a banking agreement. The shares were recorded at their relative fair value of approximately $39,290.

On October 4, 2021, the Company issued 12,777 shares of common stock upon the conversion of 20 shares Series E Preferred stock including accrued dividends of $27,770.

On October 4, 2021, the Company issued 2,977 shares of common stock to a convertible note investor as a commitment fee which was valued at its relative fair value of $10,859.

On October 5, 2021, the Company issued 19,271 shares of common stock upon the conversion of 30 shares of Series E Preferred stock including accrued dividends of $42,707.

On October 8, 2021, the Company issued 2,571 shares of common stock upon the conversion of 4 shares of Series E Preferred stock including accrued dividends of $5,707.

On October 8, 2021, the Company issued 2,977 shares of common stock to a convertible note investor as a commitment fee which was valued at its relative fair value of $12,233.

On October 12, 2021, the Company issued 3,216 shares of common stock upon the conversion of 5 shares of Series E Preferred stock including accrued dividends of $7,156.

On October 15, 2021, the Company issued 1,853 shares of common stock upon the conversion of 3 shares of Series F Preferred stock including accrued dividends of $3,521.

On November 4, 2021, the Company issued 7,662 shares of common stock upon a cashless exercise of 12,500 warrants issued with the April 2021 Convertible Note.

On November 23, 2021, the Company issued 9,665 shares of common stock upon the conversion of 15 shares of Series E Preferred stock including accrued dividends of $21,649.

On December 6, 2021, the Company issued 4,805 shares of common stock to an investment banker for commissions due under a banking agreement. The shares were recorded at their relative fair value of approximately $18,745.

During the twelve-month period ending December 31, 2021, the company issued 168,294 common shares upon the conversion of $98,141 principal and $70,160 of accrued interest on the February 2020 convertible note. The common shares issued upon conversions of the note for the period ended December 31, 2021, were valued at fair value based on the quoted trading prices on the conversion dates aggregating approximately $554,000 resulting in a loss on debt extinguishment of approximately $386,000.

On January 27, 2022, the Company issued 12,721 shares of common stock upon the conversion of $9,500 principal and $422 of interest on the June 2021 convertible note that were valued at fair value based on the quoted trading prices on the conversion dates aggregating approximately $28,000 resulting in a loss on debt extinguishment of $18,000. In addition, derivative fair value of $23,000 relating to the portion of the Note converted was settled resulting in a gain on extinguishment of approximately $23,000. The net gain on extinguishment was approximately $5,000.

On March 15, 2022, the Company issued 2,500 shares of common stock to a convertible note investor as a commitment fee which was valued at its relative fair value of $3,596.

On March 15, 2022, the Company issued 10,000 shares of common stock to an investment banker for commissions due under a banking agreement for issuance of a convertible note. The shares were recorded at their fair value of approximately $14,384.

On May 11, 2022, the Company issued 19,231 shares of common stock to an investment banker for commissions due under a banking agreement for issuance of a convertible note. The shares were recorded at a fair value of approximately $11,820.

On May 17, 2022, the Company effected the conversion of 3,059 shares of Series E Preferred stock and accrued dividends of approximately $5.1 million into 2,035,306 shares of unregistered common stock at a conversion price of $10.00 per share.

On May 17, 2022, the Company effected the conversion of 358 shares of Series F Preferred stock and accrued dividends of approximately $541,000 into 233,127 shares of unregistered common stock at a conversion rate price $10.00 per share in accordance with the conversion provisions in the certificate of designation.

Treasury Stock

On May 12, 2022, the Company repurchased 5,954 shares of common stock issued to the holders of outstanding notes as an original commitment fee on the notes for $2,000. The repurchase was recorded at cost as treasury stock on the accompanying consolidated balance sheet.

Warrants

As of December 31, 2022, there were 6,785,914 common stock warrants outstanding, with a weighted average exercise price of $0.69 per share, and annual expirations as follows:

Warrants issued with:	Shares	2023	2024	2025	2026	2027 and After
Series E Preferred Stock	1,453,028	1,453,028	-	-	-	-
Series F Preferred Stock	154,425	154,425	-	-	-	-
Bridge Loan	1,269,649	-	-	-	-	1,269,649
Convertible Notes (CVN)	3,824,119	-	145,056	3,333,463	345,600	-
Other	84,693	67,756	1,179	162	-	-
Total Warrants	6,785,914	1,675,209	161,831	3,333,625	345,600	1,269,649

The above table includes 6,720,853 price adjustable warrants including warrants with variable conversion rates and full ratchet protection.

	Shares
Warrants as of December 31, 2021	3,731,263
Issued as a result of price adjustments on convertible notes	133,284
Variable quantity of warrants related to the February 2020 note	1,651,718
Warrants issued with 2022 Bridge Note	1,269,649
Warrants as of December 31, 2022	6,785,914

The intrinsic value of outstanding warrants as of December 31, 2022, was approximately $1.7 million.

As discussed in Note 2 above, the Company has issued convertible notes and warrants with variable conversion provisions. The conversion terms of the convertible notes are variable based on certain factors, such as the future price of the Company's common stock and various default provisions related to the payment of the notes in Company stock. The number of shares of common stock to be issued under the convertible notes and warrants is based on the future price of the Company's common stock. The number of shares of common stock issuable upon conversion of the convertible notes is therefore, indeterminate. Due to the fact that the number of shares of common stock are indeterminable, the equity environment was tainted and all convertible debentures and warrants were included in the value of the derivative as of that date. Pursuant to ASC 815-15 Embedded Derivatives, the fair values of the warrants were recorded as derivative liabilities. On December 31, 2022 and 2021, the Company evaluated all outstanding warrants to determine whether these instruments are tainted and, due to reasons discussed above, all warrants outstanding were considered tainted and were therefore, accounted for as derivative liabilities.

Other than the effect on the derivative valuation recognized in operations, there was no accounting effect to the ratchet adjustments of certain warrants to reduce the conversion price to $0.78 in January 2022 since all of the embedded conversion options in the warrants were treated as derivatives.

Note 8 - Stock Incentive Plans

Stock Options

The following table summarizes stock option activity for the year ended December 31, 2022 and 2021:

	Options Outstanding	
	Shares	Weighted Average Exercise Price
Outstanding, December 31, 2020	19,568	$ 20.00
Options expired / forfeited	(365)	$ 36.60
Outstanding, December 31, 2021	19,203	$ 19.40
Options expired / forfeited	(203)	$ 34.00
Outstanding, December 31, 2022	19,000	$ 19.60
Exercisable, December 31, 2022	19,000	$ 19.60

No stock options were granted during the years ended December 31, 2021 or 2022.

The following table summarizes additional information on the Company's stock options outstanding at December 31, 2022:

	Options Outstanding			Options Exercisable	
Exercise Price	Number Outstanding	Weighted-Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
19.60	19,000	0.33	$ 19.60	19,000	$ 19.60
Totals	19,000	0.33	$ 19.60	19,000	$ 19.60

No stock options were issued by the Company during the year ended December 31, 2022.

As of December 31, 2022, the Company had no unrecognized compensation expense related to unvested stock options. Total expense related to stock options was zero for the years ended December 31, 2022 and 2021, respectively.

As of December 31, 2022, the intrinsic value of options outstanding or exercisable was zero there were no options outstanding with an exercise price less than $0.82, the per share closing market price of our common stock at that date.

Note 9 - Commitments and Contingencies

Litigation

Because of the nature of the Company's business, it is subject to claims and/or threatened legal actions, which arise out of the normal course of business. As of the date of this filing, the Company is not aware of any pending lawsuits against it, its officers or directors.

Leases

The Company does not own or lease any real property or facilities that are material to its current business operations. If the Company continues its business operations, the Company may seek to lease facilities in order to support its operational and administrative needs.

Licensing Agreement – MLR 1019

On July 28, 2021, the Company and Melior II entered into an exclusive license agreement for the development, commercialization and exclusive license of MLR-1019. MLR-1019 is being developed as a new class of therapeutic for Parkinson's disease (PD) and is, to the best of the Company's knowledge, the only drug candidate today to address both movement and non-movement aspects of PD. Under the Agreement, the Company was granted an exclusive license to use Melior II's Patents and know-how to develop products in consideration for cash payments up to approximately $21.8 million upon meeting certain performance milestones, as well as a royalty of 5% of gross sales.

The license agreement terminates upon the last expiration of the patents licensed by the Company, which is presently 2038 subject to any potential extensions and renewals of any of such patents. If the Company fails to have its common stock listed on Nasdaq or the NYSE (an "Uplisting Event") within 12 months after the Company receives a Clinical Trial Authorization from the European Medicines Agency, then the Company's commercial license and rights for using Melior II's data shall terminate. Additionally, if the Company has completed the necessary steps to effect an Uplisting Event, the Company will have the option to purchase all rights held by Melior II on the MLR-1019 licensed products in consideration for 10% of the outstanding shares of the Company's common stock (immediately post Uplisting Event) and 2.5% royalty of future gross product sales.

As of December 31, 2022, no performance milestones requiring cash consideration had been met under the agreement.

Licensing Agreement – MLR 1023

On August 20, 2021, we as licensee entered into the exclusive license agreement regarding the development and commercialization of Melior's MLR-1023 (the "MLR-1023 Agreement") with Melior Pharmaceuticals I, Inc. ("MP1"). We refer to MP2 and MP1 as "MP" or "Melior". This second license is for the development and commercialization of MLR-1023, which is being developed as a novel therapeutic for Type 1 diabetes.

Under the original terms of the MLR-1023 Agreement, if the Company failed to raise $4.0 million within 120 days of the effective date of the agreement then the MLR-1023 Agreement would immediately terminate unless, by 120 days Adhera was in the process of completing transactions to complete the fundraising then an additional 30 days would be provided to allow for the completion of the raise (the "Raise Requirement").

On October 20, 2021, we as licensee expanded the exclusive licensing agreement with Melior I to include two additional clinical indications for Non-Alcoholic Steatohepatitis (NASH) and pulmonary inflammation.

On November 17, 2021, Melior I extended the Company's timeline from 120 days to 180 days from the effective of the MLR-1023 Agreement for the Raise Requirement, by 180 days Adhera is in the process of completing transactions to complete the fundraising then an additional 30 days shall be provided to allow for the completion of required fundraising.

On February 16, 2022, an addendum to the MLR-1023 Agreement dated August 4, 2021 (the "First Addendum"), was executed by the Company and Melior, which extended the Raise Requirement to June 16, 2022.

On July 20, 2022, the Company and Melior entered into the Second Addendum to the License Agreement (the "Second Addendum"). In accordance with the Second Addendum and subject to the terms and conditions therein, the Raise Requirement was extended to February 1, 2023, in exchange for a $136,921 licensing payment that was made by the Company on July 28, 2022. In addition, the Company was required to hire and retain a Chief Scientific Officer, and raise an additional $500,000 in capital in addition to other requirements set forth in the Second Addendum and MLR-1023 Agreement.

As of February 1, 2023, the Company had not raised the additional $500,000 of capital, commenced API manufacturing, nor completed the Raise Requirement. In March 2023, the Company obtained a verbal agreement with Melior to extend the terms of the MLR-1023 Agreement until such time that the milestones have been met and the Company pays outstanding patent maintenance costs. However, Melior may terminate the license of MLR-1023 at any time due to non-performance of continuing license obligations with a 60-day required notice to cure non-performance.

As of December 31, 2022, no performance milestones requiring cash consideration had been met under the MLR-1023 Agreement

On February 16, 2022, an addendum to the MLR-1023 Agreement dated August 4, 2021 (the "First Addendum"), was executed by the Company and Melior, which extended the requirement by the Company to raise $4 million (the "Raise Requirement") to June 16, 2022.

On July 18, 2022, the Company and Melior entered into the Second Addendum to the License Agreement (the "Second Addendum"). In accordance with the Second Addendum and subject to the terms and conditions therein, the Raise Requirement was extended to February 1, 2023, in exchange for a $136,921 licensing payment that was made by the Company on July 28, 2022. In addition, the Company was required to hire and retain a Chief Scientific Officer, and raise an additional $500,000 in capital in addition to other requirements set forth in the Second Addendum and MLR-1023 Agreement.

As of February 1, 2023, the Company had not raised the additional $500,000 of capital, commenced API manufacturing, nor completed the Raise Requirement. In March 2023, the Company obtained a verbal agreement with Melior to extend the terms of the MLR-1023 Agreement until such time that the milestones have been met and the Company pays outstanding patent maintenance costs. However, Melior may terminate the license of MLR-1023 at any time due to non-performance of continuing license obligations with a 60-day required notice to cure non-performance.

As of December 31, 2022, no performance milestones requiring cash consideration had been met under the agreement.

Note 10 - Income Taxes

The Company has identified its federal and Louisiana state tax returns as "major" tax jurisdictions. The periods the Company's income tax returns are subject to examination for these jurisdictions are 2018 through 2022 for federal and 2019 through 2022 for Louisiana. The Company believes its income tax filing positions and deductions will be sustained on audit and does not anticipate any adjustments that would result in a material change to our financial position. Therefore, no liabilities for uncertain income tax positions have been recorded.

At December 31, 2022, the Company had available net operating loss carry-forwards for federal income tax reporting purposes of approximately $320 million and approximately $7.7 million for Louisiana, which are available to offset future taxable income. Portions of these carryforwards will expire through 2037 if not otherwise utilized. Losses from 2018 and onwards will be carryforward indefinitely. The Company has not performed a formal analysis but believes its ability to use such net operating losses and tax credit carryforwards is subject to annual limitations due to change of control provisions under Sections 382 and 383 of the Internal Revenue Code, which significantly impacts its ability to realize these deferred tax assets.

The Company's net deferred tax assets, deferred tax liabilities and valuation allowance as of December 31, 2022, and 2021 are summarized as follows:

	Years Ended December 31,	
(in thousands)	**2022**	**2021**
Deferred tax assets:		
Net operating loss carryforwards	$ 7,658	$ 8,402
R&D tax credits carryforwards	8,522	—
Depreciation and amortization	1,170	1,272
Share based compensation	683	647
Other	1251	613
Total deferred tax assets	19,284	10,935
Valuation allowance	(18,991)	(10,935)
Net deferred tax assets	—	—
Deferred tax liabilities:		
State deferred	293	—
Net deferred tax Assets	$ 0	$ —

The following is the Company's rate reconciliation for the years ended December 31, 2022 and 2021:

	2022		2021	
Pretax Income/(Loss)	$ (2,113,769)		$ (6,351,000)	
Tax @ Statutory Rate (21%)	(443,891)	21.00%	(1,333,710)	21.00%
Permanent Differences:				
Change in Statutory State Tax Rate	(637,312)	30.15%	(808,346)	12.73%
Return To Provision	(6,981,657)	330.29%	515,587	-8.12%
Other Adjustments	133,836	-6.33%	1,095,551	-17.25%
State Tax - Net of Federal Benefit	(125,241)	5.93%	(301,037)	4.74%
Change In Valuation Allowance - State	(1,153,652)	54.58%	932,558	-14.68%
Change In Valuation Allowance - Federal	9,207,918	-435.62%	(100,602)	1.58%
Total	-	0.00%	-	0.00%
Actual Provision	-		-	
Difference	-		-	

The Company records a valuation allowance in the full amount of our net deferred tax assets since realization of such tax benefits has been determined by our management to be less likely than not. The valuation allowance increased $8 million and decreased $42,000 during 2022 and 2021, respectively.

As of the date of this filing, the Company has not filed its 2022 federal and state corporate income tax returns. The Company expects to file the 2022 return by the extension filing date.

Note 11 - Subsequent Events

Repayment of Principal on March 2022 Convertible Note

On February 1, 2023, the Company repaid $15,000 of outstanding principal and interest on the March 2022 convertible note. On February 17, 2023, the Company repaid $32,500 of outstanding principal and interest. On March 13, 2023, the Company repaid $30,000 of outstanding principal and interest.

Default on Convertible Notes

On February 17, 2023, the Company defaulted on the extended maturity date for the August 17, 2021, convertible note.

Conversion of Principal and Interest on Convertible Note

On January 10, 2023, the holder of the March 15, 2022, convertible note converted $3,839 of principal and $1,661 of interest at $0.5599 per share into 17,861 shares of common stock.

Issuance of Promissory Notes

January 18, 2023

On January 18, 2023, the Company entered into a Securities Purchase Agreement with an accredited investor pursuant to which the Company issued and sold the investor a non-convertible Original Issue 30% Discount Senior Secured Promissory Note in the principal amount of $285,714 and 452,962 Common Stock Purchase Warrants for total purchase price of $200,000. The Company received total consideration of $173,850 after debt issuance costs of $26,150.

The Company also agreed to increase the principal amount of prior Original Issue Discount Promissory Notes issued to the investors in May 2022 by 25%. The principal increase in the May 2022 note totaled $277,777.

February 3, 2023

On February 3, 2023, the Company entered into a Securities Purchase Agreement with an affiliated accredited investor pursuant to which the Company issued and sold the investor a non-convertible Original Issue 30% Discount Senior Secured Promissory Note in the principal amount of $214,286 and 339,722 Common Stock Purchase Warrants for a total purchase price of $150,000. The Company received total consideration of $133,900 after debt issuance costs of $16,100. On February 10, 2023, the Company amended the Note and warrant and increased the principal amount of the note to $264,857 and issued an additional 84,930 warrants for no additional consideration.

February 16, 2023

On February 16, 2023, the Company entered into a Securities Purchase Agreement with an affiliated accredited investor pursuant to which the Company issued and sold the investor a non-convertible Original Issue 30% Discount Senior Secured Promissory Note in the principal amount of $214,286 and 339,722 Common Stock Purchase Warrants for a total purchase price of $150,000. The Company received total consideration of $133,850 after debt issuance costs of $16,150.

The Company also agreed to increase the principal amount of prior Original Issue Discount Promissory Notes issued to the investor in May 2022 by 25%. The principal increase in the May 2022 note totaled $69,444.

All of the Warrants issued with promissory notes listed above are exercisable for a 66 month period (five years and six months) at an exercise price of $0.82 per share, subject to certain adjustments.

The Notes are due on the earlier of (i) the 12 month anniversary of the issuance date, and (ii) the date on which the Company completes a public offering for cash of common stock and/or common stock equivalents which results in the listing of the Company's common stock on a "national securities exchange" as defined in the Securities Exchange Act of 1934 (a "Qualified Financing"), provided that unless there is an event of default, the Company may extend the maturity date by six months in its discretion. The Notes bear interest at 8% per annum, payable monthly, subject to an increase to 15% in case of an event of default as provided for therein. Furthermore, at any time before the 12 month anniversary of the date of issuance of a Note, the Company may, after providing written notice to the holder, prepay all of the then outstanding principal amount of the Note for cash in an amount equal to the sum of 105% of the then outstanding principal amount of the Note, accrued but unpaid interest and all liquidated damages and other amounts due in respect of the Note (if any).

The Notes may, at the discretion of the Company, be converted into shares of a new class of convertible preferred stock of the Company (the "Convertible Preferred Stock") on the closing date of the Qualified Financing. In the event of the conversion, the holder will receive a number of shares of Convertible Preferred Stock equal to the quotient obtained by dividing (i) the unpaid principal amount of this Note (together with any interest accrued but unpaid thereon) by (ii) the closing price of the securities issued in the Qualified Financing on the closing date of the Qualified Financing. Upon issuance, the conversion price of the Convertible Preferred Stock will be equal to the closing price of the securities issued in the Qualified Financing, subject to adjustment.

The Company will record a debt discount related to the original issue discount and issuance costs for each note and will evaluate all of the 2023 note terms for derivative accounting treatment.

Licensing Agreement MLR-1023

As of February 1, 2023, the Company had not completed the milestones as defined in the Second Addendum dated July 20, 2022, including raising $500,000 of capital, commenced API manufacturing, nor did the Company complete the $4.0 million Raise Requirement. In March 2023, the Company obtained a verbal agreement with Melior to extend the terms of the MLR-1023 Agreement until such time that the milestones have been met and the Company pays outstanding patent maintenance costs. However, Melior may terminate the license of MLR-1023 at any time due to non-performance of continuing license obligations with a 60-day required notice to cure non-performance.

Exhibit 21.1

List of Subsidiaries

Name	State of Incorporation	Ownership
IthenaPharma Inc.	Delaware	100%
Cequent Pharmaceuticals, Inc.	Delaware	100%
MDRNA Research, Inc.	Delaware	100%
Atossa HealthCare, Inc.	Delaware	100%

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (File No. 333-231219) of Adhera Therapeutics, Inc. of our report dated March 31, 2023, relating to the consolidated financial statements of Adhera Therapeutics, Inc, appearing in the Annual Report on Form 10-K for the year ended December 31, 2022.

/s/ Salberg & Company, P.A.

SALBERG & COMPANY, P.A.
Boca Raton, Florida
March 31, 2023

Exhibit 31.1

ADHERA THERAPEUTICS, INC.
CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302

I, Zahed Subhan, certify that:

1. I have reviewed this Annual Report on Form 10-K of Adhera Therapeutics, Inc. for the year ended December 31, 2022;

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. I am 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. 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.

Date: March 31, 2023

By: */s/ Zahed Subhan*
Name: Zahed Subhan
Title: Chief Executive Officer (Principal Executive Officer)

Exhibit 31.2

ADHERA THERAPEUTICS, INC.
CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302

I, Andrew Kuxharxhuk, certify that:

1. I have reviewed this Annual Report on Form 10-K of Adhera Therapeutics, Inc. for the year ended December 31, 2022;

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. I am 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. 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.

Date: March 31, 2023

By: */s/ Andrew Kucharchuk*
Name: Andrew Kucharchuk
Title: Chief Operating Officer (Principal Accounting and Financial Officer)

Exhibit 32.1

ADHERA THERAPEUTICS, INC.
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 this Annual Report on Form 10-K of Adhera Therapeutics, Inc. (the "Company") for the year ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, in the capacity and on the date indicated below, hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to her knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

Date: March 31, 2023

By: */s/ Zahed Subhan*
Name: Zahed Subhan
Title: Chief Executive Officer (Principal Executive Officer)

Exhibit 32.2

ADHERA THERAPEUTICS, INC.
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 this Annual Report on Form 10-K of Adhera Therapeutics, Inc. (the "Company") for the year ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, in the capacity and on the date indicated below, hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to her knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

Date: March 31, 2023

By: */s/ Andrew Kucharchuk*
Name: Andrew Kucharchuk
Title: Chief Operating Officer (Principal Accounting Officer and Principal Financial Officer)