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

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the fiscal year ended December 31, 2021

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: 001-36357

LIPOCINE INC.
(Exact name of registrant as specified in its charter)

Delaware **(State or Other Jurisdiction of Incorporation or Organization)**	**99-0370688** **(IRS Employer Identification No.)**
675 Arapeen Drive, Suite 202, **Salt Lake City, Utah** **(Address of Principal Executive Offices)**	**84108** **(Zip Code)**

801-994-7383
(Registrant's telephone number, including area code)

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

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, par value $0.0001 per share	**LPCN**	**The NASDAQ Stock Market LLC**

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

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Securities Exchange 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 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 (§220.405 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. ☐

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

Outstanding Shares

The aggregate market value of the common stock held by non-affiliates of the registrant was $120.5 million as of June 30, 2021. For purposes of calculating the aggregate market value of shares of our common stock held by non-affiliates as set forth on the cover page of this Annual Report on Form 10-K, we have assumed that all outstanding shares are held by non-affiliates, except for shares held by each of our executive officers, directors and 10% or greater stockholders. However, this assumption should not be deemed to constitute an admission that all executive officers, directors and 10% or greater stockholders are, in fact, affiliates of our company, or that there are not other persons who may be deemed to be affiliates of our company. Further information concerning shareholdings of our officers, directors and principal stockholders is included or incorporated by reference in Part III, Item 12 of this Annual Report on Form 10-K.

As of March 7, 2022, the registrant had 88,290,650 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the registrant's definitive Proxy Statement for its 2021 Annual Meeting of Stockholders are incorporated by reference into Part III of this Form 10-K.

TABLE OF CONTENTS

FORWARD-LOOKING STATEMENTS

THIS ANNUAL REPORT ON FORM 10-K, IN PARTICULAR "ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION," AND "ITEM 1. BUSINESS," CONTAINS FORWARD-LOOKING STATEMENTS WITHIN THE MEANING OF SECTION 27A OF THE SECURITIES ACT OF 1933, AS AMENDED, AND SECTION 21E OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED, THAT INVOLVE RISKS AND UNCERTAINTIES. FORWARD-LOOKING STATEMENTS PROVIDE CURRENT EXPECTATIONS OF FUTURE EVENTS BASED ON CERTAIN ASSUMPTIONS AND INCLUDE ANY STATEMENT THAT DOES NOT DIRECTLY RELATE TO ANY HISTORICAL OR CURRENT FACT. FORWARD-LOOKING STATEMENTS MAY REFER TO SUCH MATTERS AS PRODUCTS, PRODUCT BENEFITS, PRE-CLINICAL AND CLINICAL DEVELOPMENT TIMELINES, CLINICAL AND REGULATORY EXPECTATIONS AND PLANS, REGULATORY DEVELOPMENTS AND REQUIREMENTS, THE RECEIPT OF REGULATORY APPROVALS, THE EXPECTATIONS FOR AND RESULTS OF CLINICAL TRIALS, PATIENT ACCEPTANCE OF LIPOCINE'S PRODUCTS, MANUFACTURING AND COMMERCIALIZATION OF LIPOCINE'S PRODUCTS, ANTICIPATED FINANCIAL PERFORMANCE, FUTURE REVENUES OR EARNINGS, BUSINESS PROSPECTS, PROJECTED VENTURES, NEW PRODUCTS AND SERVICES, ANTICIPATED MARKET PERFORMANCE, FUTURE EXPECTATIONS FOR LIQUIDITY AND CAPITAL RESOURCES NEEDS AND SIMILAR MATTERS. SUCH WORDS AS "MAY", "WILL", "EXPECT", "CONTINUE", "ESTIMATE", "PROJECT", "INTEND", AND "POTENTIAL" AND SIMILAR TERMS AND EXPRESSIONS ARE INTENDED TO IDENTIFY FORWARD LOOKING STATEMENTS. FORWARD-LOOKING STATEMENTS ARE NOT GUARANTEES OF FUTURE PERFORMANCE AND OUR ACTUAL RESULTS MAY DIFFER SIGNIFICANTLY FROM THE RESULTS DISCUSSED IN THE FORWARD-LOOKING STATEMENTS. FACTORS THAT MIGHT CAUSE SUCH DIFFERENCES INCLUDE, BUT ARE NOT LIMITED TO, THOSE DISCUSSED IN PART I, ITEM 1A "RISK FACTORS" OF THIS FORM 10-K. EXCEPT AS REQUIRED BY APPLICABLE LAW, WE ASSUME NO OBLIGATION TO REVISE OR UPDATE ANY FORWARD-LOOKING STATEMENTS FOR ANY REASON.

There are a number of risks, uncertainties and other important factors that could cause our actual results to differ materially from the forward-looking statements contained in this Annual Report on Form 10-K. Such risks, uncertainties and other important factors include, among others, the risks, uncertainties and factors set forth in "Risk Factors," and the following risks, uncertainties and factors:

- our and our licensee's plans to develop and commercialize any future product candidates;
- our ongoing and planned clinical trials;
- the timing of and our ability to obtain regulatory approvals or fast track or orphan drug designation, breakthrough designation or IND clearance for any future product candidates;
- the effect of the ongoing COVID-19 pandemic on our business;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- the rate and degree of market acceptance and clinical utility of any future product candidates, if approved;
- significant competition in our industry;
- our intellectual property position;
- loss of key members of management;
- failure to successfully execute our strategy; and
- our failure to maintain effective internal controls.

There may be other factors that may cause our actual results to differ materially from the forward-looking statements, including factors disclosed in "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." You should evaluate all forward-looking statements made in this Annual Report on Form 10-K in the context of these risks and uncertainties.

We caution you that the risks, uncertainties and other factors referred to above may not contain all of the risks, uncertainties and other factors that are important to you. In addition, we cannot assure you that we will realize the results, benefits or developments that we expect or anticipate or, even if substantially realized, that they will result in the consequences or affect us or our business in the way expected. All forward-looking statements in this Annual Report on Form 10-K apply only as of the date made and are expressly qualified in their entirety by the cautionary statements included in this Annual Report on Form 10-K. We undertake no obligation to publicly update or revise any forward-looking statements to reflect subsequent events or circumstances.

PART I

ITEM 1. BUSINESS

General

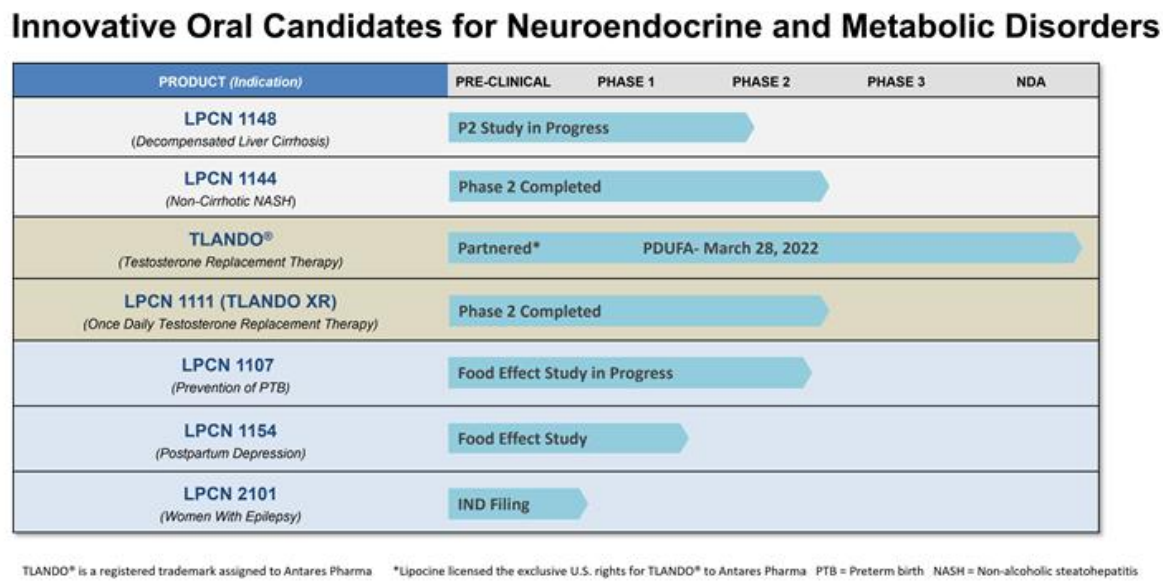
Lipocine Inc. (“Lipocine” or the “Company”) was originally incorporated on June 19, 1997, under the laws of the State of Delaware.

We are a clinical-stage biopharmaceutical company focused on applying our oral drug delivery technology for the development of pharmaceutical products focusing on neuroendocrine and metabolic disorders. Our proprietary delivery technologies are designed to improve patient compliance and safety through orally available treatment options. Our primary development programs are based on oral delivery solutions for poorly bioavailable drugs. We have a portfolio of differentiated innovative product candidates that target high unmet needs for neurological and psychiatric CNS disorders, liver diseases, and hormone supplementation for men and women.

We entered into a license agreement for the development and commercialization our product candidate, TLANDO®, an oral testosterone replacement therapy (“TRT”) comprised of testosterone undecanoate (“TU”). TLANDO is a registered trademark assigned to Antares. On October 14, 2021, we entered into a license agreement (the “Antares License Agreement”) with Antares Pharma, Inc. (“Antares” or our “Licensee”), pursuant to which we granted to Antares an exclusive, royalty-bearing, sublicensable right and license to develop and commercialize, upon final approval of TLANDO from the United States Food and Drug Administration (“FDA”), the TLANDO product for TRT in the U.S. Any FDA required post-marketing studies will also be the responsibility of our licensee, Antares. Prior to entering into the License Agreement, on December 8, 2020, we received tentative approval from the FDA regarding our new drug application (“NDA”) filed in February 2020 for TLANDO as a TRT in adult males for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism. In granting tentative approval, the FDA concluded that TLANDO has met all required quality, safety and efficacy standards necessary for approval. However, TLANDO has not received final approval and is not eligible for final approval to market in the U.S. until the expiration of the exclusivity period previously granted to Clarus Therapeutics, Inc. (“Clarus”) with respect to JATENZO®, which expires on March 27, 2022. The FDA has affirmed to Antares the acceptance of the resubmission of the NDA for TLANDO filed on January 28, 2022. The FDA has designated the NDA as a Class 1 resubmission with a two-month review goal period and set a target action date of March 28, 2022 under the Prescription Drug User Fee Act (PDUFA).

Additional pipeline candidates include: LPCN 1148 comprising a novel prodrug of testosterone, testosterone laurate (“TL”), for the management of decompensated cirrhosis; LPCN 1144, an oral prodrug of androgen receptor modulator for the treatment of non-cirrhotic non-alcoholic steatohepatitis (“NASH”) which has completed phase 2 testing; LPCN 1111 (TLANDO® XR), a next generation oral TRT product comprised of testosterone tridecanoate (“TT”) with the potential for once daily dosing which has completed Phase 2 testing; LPCN 1107, potentially the first oral hydroxy progesterone caproate (“HPC”) product indicated for the prevention of recurrent preterm birth (“PTB”), which has completed a dose finding clinical study in pregnant women and has been granted orphan drug designation by the FDA; and neuroactive steroids (“NAS”) including LPCN 1154 for postpartum depression (PPD) and LPCN 2101 for epilepsy.

The following chart summarizes the status of our product candidate development programs:



Impact of COVID-19 Pandemic

The ongoing COVID-19 pandemic has disrupted and may continue to disrupt our business and delay our preclinical and clinical programs and timelines. The extent to which the COVID-19 pandemic may impact our future operating results and financial condition is uncertain. We initiated our LPCN 1148 Phase 2 trial for the management of cirrhosis in 2021. The COVID-19 surge observed in the fourth quarter of 2021 and the first quarter of 2022 has impacted enrollment in this study. We do not yet know the full extent, if any, of any potential delays or commercial challenges, which could prevent or delay Antares from commercially launching TLANDO. For more information regarding risks related to the ongoing COVID-19 pandemic, please see the risk factor entitled “The ongoing outbreak of coronavirus around the world could adversely impact our business and operating results,” in Part I. Item 1A of this Annual Report on Form 10-K. To the extent the ongoing COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks set forth under “Risk Factors” in this Annual Report on Form 10-K.

Strategy

Our goal is to become a leading biopharmaceutical company focused on applying our proprietary drug delivery technology for the development of pharmaceutical products focusing on neuroendocrine and metabolic disorders. The key components of our strategy are to:

Build a diversified multi-asset pipeline of novel therapies. We intend to employ a value-driven strategy based on our proprietary technology platform to identify and develop product candidates for neuroendocrine and metabolic disorders including Central Nervous System (CNS) disorders and end stage diseases such as decompensated cirrhosis. We intend to focus on product candidates that we believe are differentiated, have attractive profiles, and address a clear unmet medical need that we can advance quickly and efficiently into late-stage development.

Advance LPCN 1148, a unique prodrug of androgen receptor agonist to manage end stage (decompensated) liver cirrhosis disease. We believe LPCN 1148, a novel prodrug of testosterone, could address a significant unmet medical need in patients with decompensated liver cirrhosis accompanied with muscle disorder such as secondary sarcopenia. Sarcopenia in male cirrhotic patients is known to be independently associated with poor outcomes including quality of life, increased decompensation events such as hepatic encephalopathy, increased hospital admissions, and increased mortality rate. We believe LPCN 1148 may be eligible for an orphan drug designation. Enrollment in a multi-center placebo-controlled phase 2 trial is currently ongoing.

Support our licensee in commercialization of our licensed oral TRT option. We believe the TRT market needs a differentiated, convenient oral option. We have exclusively licensed rights to TLANDO to Antares for commercialization of TLANDO in the US. We plan to support our licensee's efforts to effectively enable the availability of TLANDO to patients in a timely manner, in addition to receiving milestone and royalty payments associated with TLANDO commercialization as agreed to in the Antares License Agreement.

Develop partnership(s) to continue the advancement of pipeline assets. We continuously strive to prioritize our resources in seeking co-development partnerships of our pipeline assets. We currently plan to explore partnering of LPCN 1144, our candidate for treatment of non-cirrhotic NASH, LPCN 1107, our candidate for prevention of pre-term birth, and LPCN 1111, a once-a-day therapy candidate for TRT.

LPCN 1148: Oral Product Candidate for the Management of Decompensated Cirrhosis

We are currently evaluating LPCN 1148 comprising testosterone laurate (TL) for the management of decompensated cirrhosis. We believe LPCN 1148 targets unmet needs for cirrhosis subjects including improvement in the quality of life of patients while on the liver transplant waiting list, prevention or reduction in the occurrence of new decompensation events, and improvement in post liver transplant survival, including outcomes and costs.

We are currently conducting a Phase 2 POC study (NCT04874350) in male cirrhotic subjects to evaluate the therapeutic potential of LPCN 1148 for the management of sarcopenia. The ongoing Phase 2 POC study is a prospective, multi-center, randomized, placebo-controlled study in male sarcopenic cirrhotic patients. Subjects will be randomized 1:1 to one of two arms. The treatment arm is an oral dose of LPCN 1148, and the second arm is a matching placebo. The primary endpoint is change in skeletal muscle index at week 24 with key secondary endpoints including change in liver frailty index, rates of breakthrough hepatic encephalopathy, and number of waitlist events, including all-cause mortality. Total treatment is expected to be 52 weeks. We currently expect enrollment in the Phase 2 study to be complete by the end of the second or third quarter of 2022 and top-line 24-week results by the end of 2022 or during the first quarter of 2023.

Key outcomes of interest from the Phase 2 study include clinical outcomes such as overall survival and new decompensation events (including hepatic encephalopathy and/or ascites occurrences), rates of survival to transplant, rates of hospitalizations, infections, etc., muscle changes such as muscle mass, body composition, myosteatosis (muscle fat), functional capacity changes such as liver frailty index (LFI), patient reported outcomes (PROs), and biochemical markers including hematocrit for anemia status, albumin, creatinine/kidney function, etc.

Disease Overview – Cirrhosis

There are over 2 million cases of cirrhosis worldwide, with over 500,000 people living with decompensated cirrhosis in the U.S. and nonalcoholic fatty liver disease is the most rapidly increasing indication for liver transplant. 62% of those on the liver transplant (LT) waitlist are male. The economic burden (approximately $812,500/transplant) is high and continues to increase. Each year about half of the approximately 17,000 people in U.S. on the LT waitlist undergo transplant, while nearly 3000 patients either die or are removed from the list because they were “too sick to transplant.”

Liver cirrhosis is defined as the histological development of regenerative nodules surrounded by fibrous bands. Cirrhotic patients typically have a years-long silent, asymptomatic phase (compensated cirrhosis) until decreasing liver function and increasing portal pressure move the patient into the symptomatic phase (decompensated cirrhosis). Transition to decompensated cirrhosis is marked by clinical events including ascites, encephalopathy, jaundice, and/or variceal hemorrhage. Decompensated subjects survive on average less than 2 years. Common causes of liver cirrhosis include alcoholic liver disease, nonalcoholic fatty liver disease (NAFLD), chronic hepatitis B and C, primary biliary cirrhosis (PBC), primary sclerosing cholangitis (PSC) and cryptogenic.

Common complications in cirrhotic patients may include: compromised liver function, portal hypertension, varices in GI tract with internal bleeding, edema, ascites, hepatic encephalopathy, compromised immunity with post-transplant acute rejection risk, high sodium levels, increased bilirubin, low albumin level, insulin resistance with impaired peripheral uptake of glucose, depression, accelerated muscle disorder in the form of sarcopenia, myosteotosis, and frailty with compromised energetics, bone diseases (e.g., osteoporosis), high alkaline phosphatase (ALP), cachexia, malnutrition, weight loss (>5%), symptoms of hypogonadism such as abnormal hair distribution, anemia, sexual dysfunction, testicular atrophy, muscle wasting, fatigue, osteoporosis, gynecomastia, inflammation with elevated cytokines, and infection risk leading to hospital admissions and possibly death.

Hepatic encephalopathy (“HE”), a significant decompensation event in patient with cirrhosis, is a brain dysfunction caused by liver insufficiency and/or portal systemic shunting. Because the damaged liver cannot function normally (as in cirrhosis), neurotoxins such as ammonia are inadequately removed from systemic circulation and travel to the brain, where they affect neurotransmission. This can cause episodes of HE, which may present as alterations in consciousness, cognition, and behavior that range from minimal to severe. Overt HE occurs in 30% to 40% of patients with cirrhosis at some point during the clinical course of their disease. As the burden of chronic liver disease and cirrhosis is increasing, the frequency of HE is also increasing.

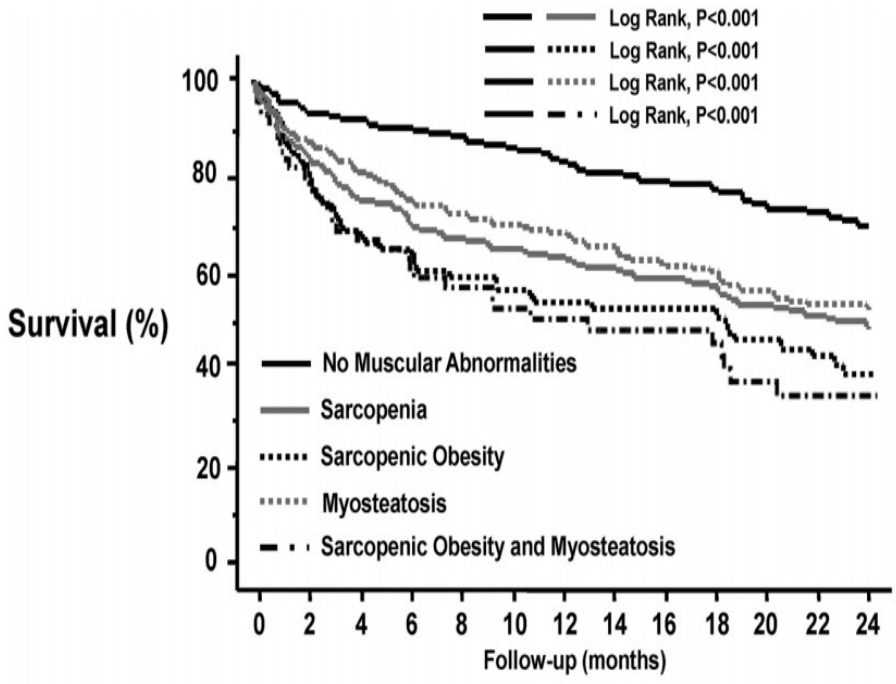
Muscle Disorders and Cirrhosis

Muscle disorders secondary to cirrhosis could be manifested in the form of several inter-related characteristics such as sarcopenia, myosteotosis, and frailty impacting muscle mass, strength, quality, and function. Chronic inflammation and oxidative stress have also been reported to accelerate muscle wasting. Muscle also plays a significant compensatory role in detoxifying ammonia, a neurotoxin and a myotoxin implicated in precipitation of HE in cirrhosis patients.

Sarcopenia and associated frailty affect up to 70% of cirrhotic men and are a leading cause of patients being removed from the LT wait list. Due to the lack of available organs and aging demographics of those on the waitlist, patients that do receive a transplant are “increasingly being described as frail”. The presence of sarcopenia or frailty is associated with increased risk of hospitalization and hepatic decompensation, a two-fold increase in waitlist mortality, poor post-transplant outcomes, and reportedly is equivalent to adding 9-10 points to the Model for End-Stage Liver Disease (MELD) score.

Sarcopenia is typically associated with body composition changes with decreased muscle mass and/or low skeletal muscle index. Change in one or more of appendicular lean mass, total lean mass, fat mass, high VAT (visceral adipose tissue), waist circumference, weight, and/or BMI are notable features. Myosteotosis (fat infiltration in muscles) is indicative of poor muscle quality. Frailty is a state of low energetics accompanied with low physical performance/mobility probably because of poor muscle strength/function and is assessed via various measures such as decreased gait speed, weak hand grip; slow rising from a chair, balance, isometric knee extension peak torque or a composite measure such as liver frailty index (LFI).

Reportedly, as shown in the figure below, muscle disorder such as sarcopenia and myosteotosis in cirrhosis could be a clinically meaningful predictor of survival and mortality with lower survival in cirrhotic patients with accompanying muscle disorders.

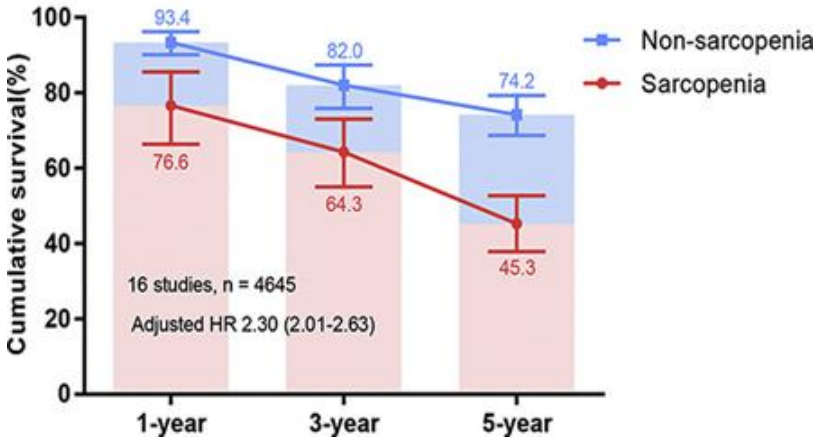


Montano-Loza, J Cachexia Sarcopenia Muscle. 2016 May; 7(2): 126–135

Muscle Disorders and Mortality in Liver Cirrhosis

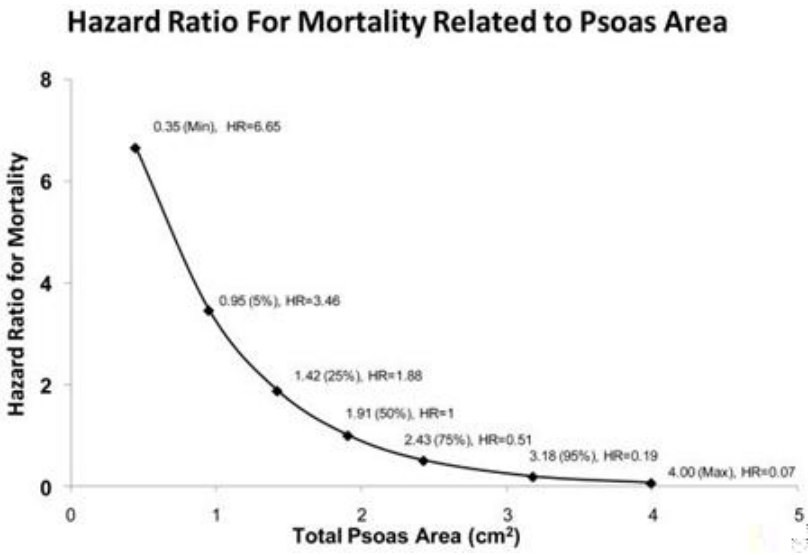
Sarcopenia develops in the majority of male cirrhosis patients. The main mechanisms associated with sarcopenia and decompensated cirrhosis include a catabolic state, progressive immobility, imbalance between muscle breakdown and formation, and hormonal changes. Patients are typically diagnosed with decompensated cirrhosis upon development of cirrhotic symptoms (e.g., jaundice, HE), and the diagnosis is confirmed via various liver function/imaging tests (e.g., MELD score, liver biopsy, CT scan). A variety of clinical evaluations for muscle mass, strength, and function are typically used to diagnose sarcopenia. Sarcopenia in cirrhosis also correlates with decompensation events, particularly HE (sarcopenia is about 2-fold more prevalent in overt HE patients than those without overt HE). Notably, low testosterone in males is associated with sarcopenia, severity of cirrhosis, and mortality.

Reportedly, as shown in figure below, sarcopenia is a predictor for increased mortality in cirrhosis (about 2-fold higher compared to no sarcopenia).



Tantai et al. J. Hepatol. 2022, 76, 588–599

Reportedly, as shown in figure below, pre transplant sarcopenia in liver cirrhosis often produces poor post-transplant outcomes with higher mortality rates. Longer post-transplant hospitalization and rehabilitation can be demanding on the individual, both physically and financially.



Englesbe et al. J Am Coll Surg. 2010 Aug;211(2):271-8

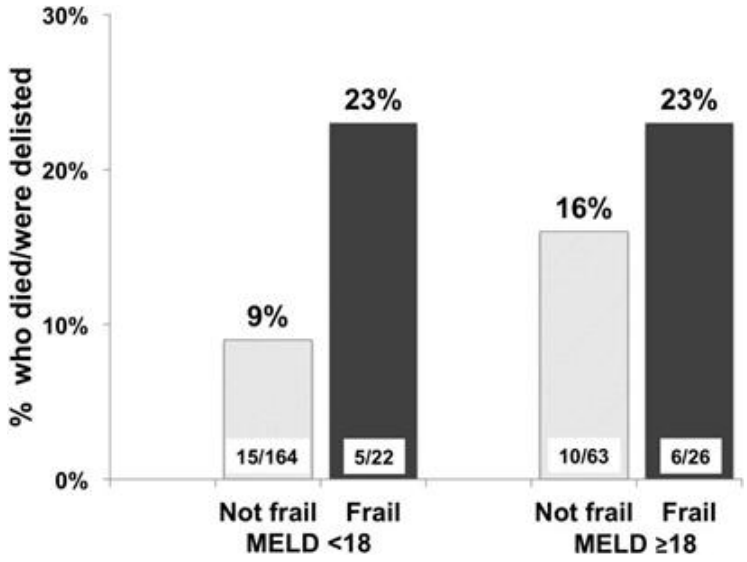
Myosteatosis in cirrhosis

Myosteatosis, fat infiltration in muscles, has been found in many cirrhotic patients undergoing liver transplant evaluation, and studies have associated it with more complications and poor survival. Myosteatosis is characteristically associated with liver steatosis in NAFLD, resulting from ectopic fat accumulation in skeletal muscle. Myosteatosis may affect many individuals who do not meet the anthropometric criteria for sarcopenia or obesity. The accumulation of excess fat in extramyocellular compartments is mostly pathologic. It can be defined as intramuscular (between muscle fibers) or intermuscular (between muscle fascicles) and is associated with lower muscle function and strength, muscle atrophy, and physical disabilities.

Frailty and cirrhosis

Frailty is a state of low energetics accompanied with low physical performance/mobility, usually as a result of poor muscle strength/function and its presence is assessed via various measures such as decreased gait speed, weak hand grip, slow rising from a chair, poor balance, low isometric knee extension peak torque or a composite measure such as liver frailty index (LFI).

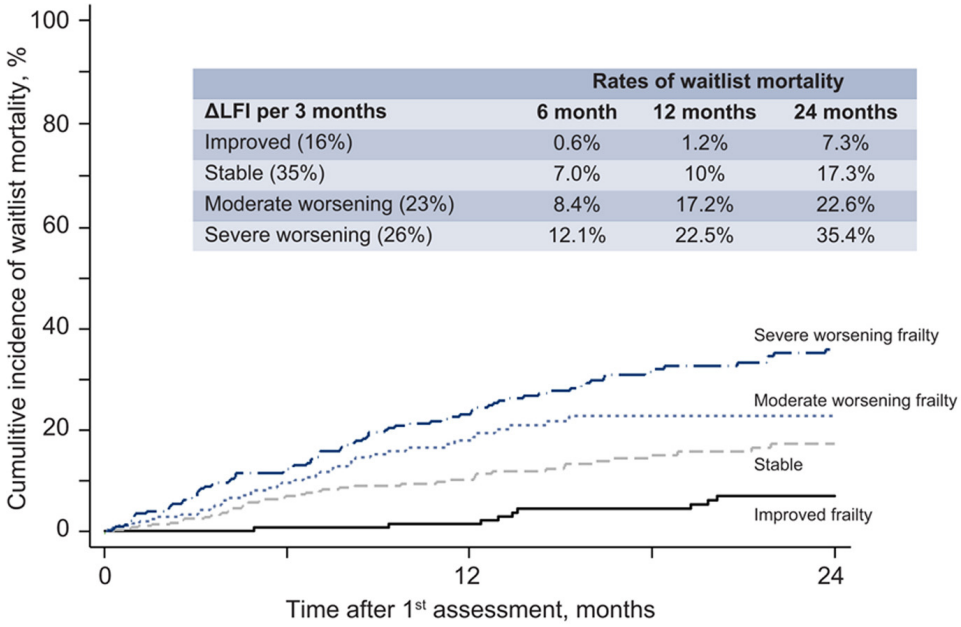
Reportedly, as shown in figure below, frailty predicts LT waitlist mortality among outpatients with cirrhosis regardless of the MELD score.



Lai et al. Am J Transplant. 2014 Aug;14(8):1870-9

The presence of frailty is associated with increased waitlist death/delisting

Moreover, it has also been reported, as shown in figure below, that there is a higher incidence of waitlist mortality as the frailty worsened.



Lai et al. J Hepatol. 2020 Sep;73(3):575-581.

Trajectory of liver frailty and mortality

Currently, there are no FDA approved drugs to treat secondary sarcopenia in cirrhosis. Lipocine is the only clinical-stage company pursuing decompensation in sarcopenic cirrhotic patients, and no regulatory precedent currently exists for the approval of decompensation or sarcopenia-targeted therapies. We believe LPCN 1148 has the potential to aid the management of decompensation events in male sarcopenic cirrhotic patients through the following possible mechanisms of action: myo-augmentation (impact muscle mass and/or quality and/or function) via myostatin inhibition, myosteatosis reduction, anti-catabolic effect, changes in body composition (increase lean mass and/or reduce fat mass) and slowing muscle autophagy; inducing hepato-effective actions with improved key liver injury markers; increase protein synthesis; improve anemia, induce immunomodulation with improvement of immuno-dysregulation, and to lower infection rates; anti-inflammatory/antioxidant effects by lowering undesirable cytokines such as IL-1, IL-6, and TNF-α; and to improve mitochondrial function.(1)

(1) Ref: Leise. Mayo Clin Proc. 2014.; Hudson. Eur J Gastroenterol. 2019.; Bajaj. Clin Gastroenterol Hepatol. 2017.; Bohra. World J Gastroenterol. 2020.; Carey, Hepatology, 2019; Sinclair, Ailment Pharmacol Ther, 2016; Lai, Am J Transplant, 2014; Montano-Loza, Clin Transl Gastroenterol, 2015; Kahn, Clin Transp, 2018; Montano-Loza, J Cach, Sarco, and Musc, 2016.

LPCN 1144: An Oral Prodrug of Bioidentical Testosterone Product Candidate for the Treatment of NASH

We are currently evaluating LPCN 1144, an oral prodrug of bioidentical testosterone comprised of TU, for the treatment of non-cirrhotic NASH.

Disease Overview – NASH

NASH is a more advanced state of non-alcoholic fatty liver disease ("NAFLD") and can progress to a cirrhotic liver or liver failure, require liver transplant, and can result in hepatocellular carcinoma/ liver cancer, and death. Progression of NASH to end stage liver disease will soon surpass all other causes of liver failure requiring liver transplantation. Importantly, beyond these critical conditions, NASH and NAFLD patients additionally suffer heightened cardiovascular risk and, in fact, die more frequently from cardiovascular events than from liver disease. NAFLD/NASH is becoming more common due to its strong correlation with obesity and metabolic syndrome, including components of metabolic syndrome such as diabetes, cardiovascular disease and high blood pressure. Twenty to thirty percent of the U.S. population is estimated to suffer from NAFLD and fifteen to twenty percent of this group progresses to NASH, which is a substantially large population that lacks an effective therapy. NASH is a silent killer that affects millions in the U.S. Diagnoses have been on the rise and are expected to increase dramatically in the next decade. Approximately 50% of NASH patients are in adult males. In men, especially with comorbidities associated with NAFLD/NASH, testosterone deficiency has been associated with an increased visceral adipose tissue and insulin resistance, which could be factors contributing to NAFLD/NASH. There is currently no approved therapy for the treatment of NASH although there are several drug candidates currently under development with many clinical failures to date.

The critical pathophysiologic mechanisms underlying the development and progression of NASH include reduced ability to handle lipids, increased insulin resistance, injury to hepatocytes and liver fibrosis in response to hepatocyte injury. NASH patients have an excessive accumulation of fat in the liver resulting primarily from a caloric intake above and beyond energy needs. A healthy liver contains less than 5% fat, but a liver in someone with NASH can contain more than 20% fat. This abnormal liver fat contributes to the progression to NASH, a liver necro-inflammatory state that can lead to scarring, also known as fibrosis, and, for some, can progress to cirrhosis and liver failure.

Markers of Liver Cell Death

Alanine aminotransferase ("ALT") is an enzyme that is produced in liver cells and is naturally found in the blood of healthy individuals. In liver disease, liver cells are damaged and, as a consequence, ALT is released into the blood, increasing ALT levels above the normal range. Physicians routinely test blood levels of ALT to monitor the health of a patient's liver. ALT level is a clinically important biochemical marker of the severity of liver inflammation and ongoing liver disease. Elevated levels of ALT represent general markers of liver cell death and inflammation without regard to any specific mechanism. Aspartate aminotransferase ("AST") is a second enzyme found in the blood that is produced in the liver and routinely measured by physicians along with ALT. As with ALT, AST is often elevated in liver disease and, like ALT, is considered an overall marker of liver inflammation.

Diagnosis

Most people with NASH are asymptomatic and their disease is often discovered incidentally following a liver imaging procedure, such as an ultrasound, prescribed for other reasons or as part of an investigation for elevated liver enzymes. Once suspected clinically, a liver biopsy is required to definitively diagnose NASH, which necessitates the joint presence of steatosis, ballooning and lobular inflammation. Once pathologically confirmed, the severity of NAFLD and NASH is determined using the histologically validated NAFLD activity score, which grades disease activity on a scale of 0 to 8. The NAFLD activity score is the sum of the individual scores for steatosis (0 to 3), lobular inflammation (0 to 3), and hepatocellular ballooning (0 to 2) but does not include a score for fibrosis. Fibrosis staging (F0-F4) relies on the NASH CRN classification (F0 = no fibrosis; F1 = perisinusoidal or portal/periportal fibrosis (not both); F2 = both perisinusoidal and portal/periportal fibrosis; F3 = bridging fibrosis; F4 = cirrhosis).

Histological diagnosis remains the gold standard for assessment of NASH and fibrosis. However, given that liver biopsy is associated with risks of pain, bleeding and other morbidity, as well as significant cost, the procedure is not practical for general patient screening. Several non-invasive tools such as clinical risk scores and imaging techniques are increasingly used to assess potential NASH patients. Clinical risk scores such as the NAFLD fibrosis score, Fibrosis-4 index, the Enhanced Liver Fibrosis score and vibration-controlled transient elastography ("VCTE"), have been validated and are increasingly used. These tools have an excellent negative predictive value and an acceptable positive predictive value for detection of advanced (≥ F3) fibrosis and are increasingly used in clinical settings. Extensive efforts are also under way to develop non-invasive means to identify patients with NAS ≥ 4 or fibrosis ≥ F2 without a liver biopsy. In draft guidance, the FDA encouraged sponsors to identify biochemical or noninvasive imaging biomarkers that, once characterized and agreed by the FDA, could replace liver biopsies for patient selection and efficacy assessment in clinical trials.

We expect that the validation and subsequent adoption of these new tools will result in an increase in the diagnosis and treatment rates for NASH in the future.

Current Status

We have recently completed the *LiFT* Phase 2 clinical study in biopsy-confirmed non-cirrhotic NASH subjects. The *LiFT* clinical study was a prospective, multi-center, randomized, double-blind, placebo-controlled multiple-arm study in biopsy-confirmed hypogonadal and eugonadal male NASH subjects with grade F1-F3 fibrosis and a target NAFLD Activity Score ≥ 4 with a 36-week treatment period. The *LiFT* clinical study enrolled 56 biopsy confirmed NASH male subjects. Subjects were randomized 1:1:1 to one of three arms (Treatment A is a twice daily oral dose of 142 mg testosterone equivalent, Treatment B is a twice daily oral dose of 142 mg testosterone equivalent formulated with 217 mg of d-alpha tocopherol equivalent, and the third arm is twice daily matching placebo).

The primary endpoint of the *LiFT* clinical study was change in hepatic fat fraction via MRI-PDFF and exploratory liver fat/marker end points post 12 weeks of treatment. Additionally, key secondary endpoints post 36 weeks of treatment included assessment of histological change for NASH resolution and/or fibrosis improvement (biopsy) as well as liver fat data (MRI-PDFF). The *LiFT* clinical study was not powered to assess statistical significance of any of the secondary endpoints. Other important endpoints included the following: change in liver injury markers, anthropomorphic measurements, lipids, insulin resistance and inflammatory/fibrosis markers; as well as patient reported outcomes.

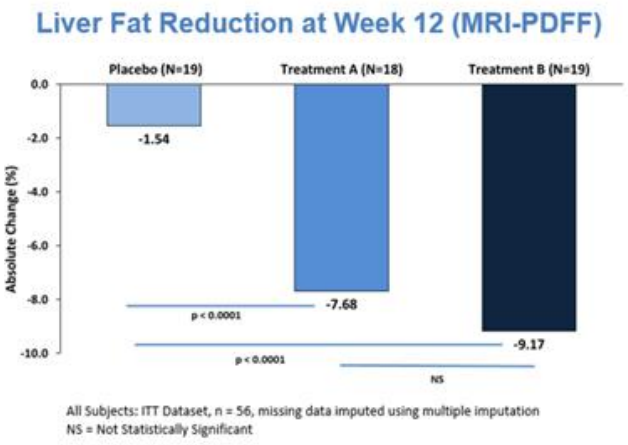
Additionally, subjects have access to LPCN 1144 through an open label extension ("OLE") study. The extension study will enable the collection of additional data on LPCN 1144 for up to a total of 72 weeks of therapy, as well as data for 36 weeks of therapy for those subjects on placebo in the LiFT study. The OLE is currently on-going and has enrolled 25 subjects. We expect topline results from the OLE study mid-2022.

Treatments with LPCN 1144 post 12 weeks of treatment resulted in robust liver fat reduction, assessed by MRI-PDFF, and showed improvement of liver injury markers with no observed tolerability issues.

Liver biopsies were performed at baseline ("BL") and after 36 weeks of treatment ("EOS"). Prespecified biopsy analyses included NASH Clinical Research Network ("CRN") scoring as well as a continuous paired ("Paired Technique") and digital technique ("Digital Technique-Fibronest"). All biopsy analyses were performed on the same slides and the reads for the three techniques were done independently. Analysis sets included the NASH Resolution Set (all subjects that have BL and EOS biopsy with NASH at BL [NAS ≥4 with lobular inflammation score ≥ 1 and hepatocyte ballooning score ≥1 at BL] (n=37)), the Biopsy Set (all subjects with baseline and EOS biopsies (n=44)), and the Safety Set (all randomized subjects (n=56)).

Both LPCN 1144 treatment arms met with statistical significance the pre-specified accelerated approval regulatory endpoint of NASH resolution with no worsening of fibrosis based on NASH CRN scoring. Additionally, both treatment arms showed substantial improvement of the observed NASH activity in steatosis, inflammation, and ballooning.

Key results from the *LiFT* clinical study are presented in the following tables and figures:



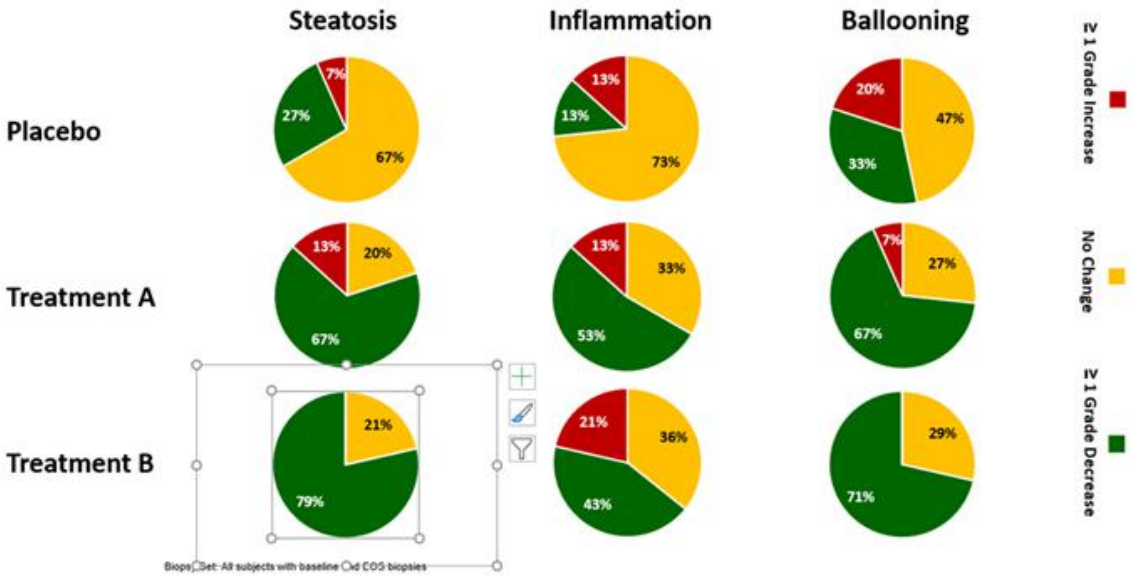
NASH Resolution with No Worsening of Fibrosis[1]

Responders[1], n (%)

	NASH Resolution Set[2]	Safety Set[3]
Placebo	0 (0%)	0 (0%)
Treatment A	6 (46%)*	6 (33%)**
Treatment B	9 (69%)***	9 (47%)***

* p < 0.05; ** p < 0.01 vs placebo, *** p < 0.001 vs placebo

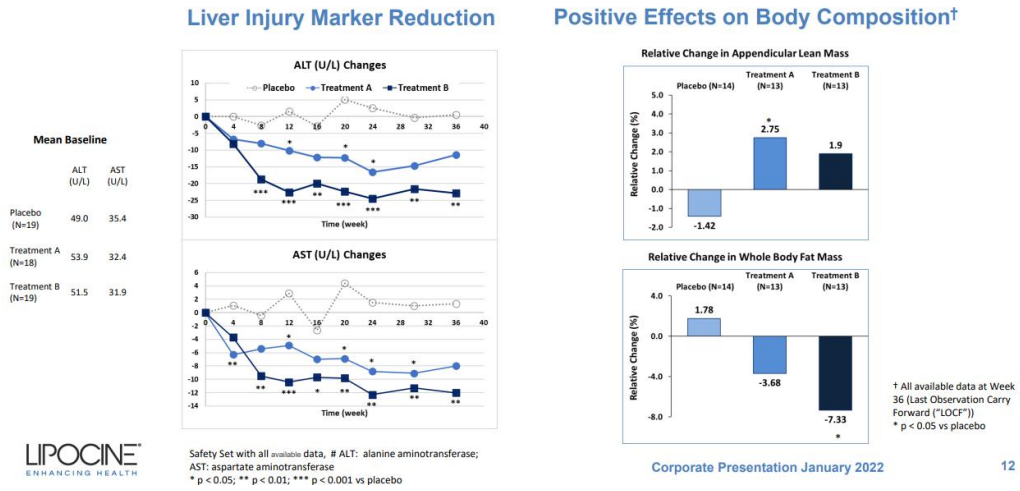
1 NASH resolution is defined per FDA guidance as lobular inflammation score = 0 or 1 and hepatocyte ballo score = 0
2 NASH Resolution Set includes those subjects with baseline and EOS biopsy and with NASH at baseline (N with lobular inflammation score ≥ 1 and hepatocyte ballooning score ≥1) per FDA Phase 3 guidance
3 All randomized subjects (ITT); subjects who were not eligible for NASH resolution evaluation or who were missing EOS biopsies were treated as non-responders



In both treatment arms, substantial reductions in markers of liver injury compared to placebo were observed post four weeks of treatment and were sustained through EOS. Using all available Safety Set data, ALT decreased up to a mean of 23.4 U/L at EOS from all group mean baseline of 51.5 U/L and AST decreased up to a mean of 13.3 U/L at EOS from all group mean baseline of 31.9 U/L.

Positive effects in appendicular lean mass and whole-body fat mass, an indicator overall tissue quality, based on dual-energy X-ray absorptiometry scans were noted in both LPCN 1144 treatment arms.

Finding on liver injury marker and positive effects on body composition can be seen in the following table:



During the 36 weeks of treatment, LPCN 1144 was well tolerated with an overall safety profile comparable to placebo.

In November 2021, the FDA granted Fast Track Designation to LPCN 1144 as a treatment for non-cirrhotic NASH. The Fast Track program is designed to accelerate the development and expedite the review of products, such as LPCN 1144, which are intended to treat serious diseases and for which there is an unmet medical need.

We had a written only response from FDA for a LPCN 1144 Type C meeting with the FDA in January 2022 to discuss the development path forward with LPCN 1144. The FDA acknowledged that the NDA submission of LPCN 1144 would be via 505(b)2 regulatory pathway and agreed that no additional non-clinical studies are needed to support an NDA submission. The FDA recommended to request an end of phase 2 (EOP2) meeting. The FDA acknowledged that in the LiFT study subjects achieved improvements in key components associated with NASH histopathology after 36-weeks of treatment with LPCN 1144 in adult males and agreed that the proposed multicomponent primary surrogate endpoint is acceptable for seeking approval under the accelerated approval pathway. The FDA also recommended either conducting a separate dose–ranging study prior to phase 3 or evaluating multiple doses in phase 3. The FDA agreed that the proposed primary multicomponent surrogate endpoint, NASH resolution with no worsening of fibrosis, is acceptable for seeking approval under the accelerated approval pathway and the FDA recommended a phase 3 trial with a study duration of 72 weeks. The FDA has requested that Lipocine submit an updated Phase 3 protocol for FDA feedback on the study design and our next step will be to request an end-of-phase 2 (EOP2) meeting to discuss the phase 3 and confirmatory trial designs, including the plan for reading liver histopathology.

We are exploring the possibility of licensing LPCN 1144 to a third party, although no licensing agreement has been entered into by the Company. No assurance can be given that any license agreement will be completed, or, if an agreement is completed, that such an agreement would be on acceptable terms.

TLANDO: An Oral Product Candidate for Testosterone Replacement Therapy

As previously described, under the Antares License Agreement, we granted to Antares an exclusive, royalty-bearing, sublicensable right and license to develop and commercialize, upon final approval of TLANDO from the FDA, our TLANDO product for TRT in the U.S. Prior to entering into the Antares License Agreement on December 8, 2020, we received tentative approval from the FDA regarding our NDA filed in February 2020 for TLANDO as a TRT in adult males for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism. In granting tentative approval, the FDA concluded that TLANDO has met all required quality, safety and efficacy standards necessary for approval. However, TLANDO has not received final approval and is not eligible for final approval to market in the U.S. until the expiration of the exclusivity period previously granted to Clarus with respect to JATENZO®, which expires on March 27, 2022. The FDA has affirmed to Antares the acceptance of the resubmission of the NDA for TLANDO. The FDA has designated the NDA as a Class 1 resubmission with a two-month review goal period and set a target action date of March 28, 2022, under the PDUFA. Any FDA requirement to conduct certain post-marketing studies will also be the responsibility of our licensee, Antares.

Proof-of-concept for TLANDO was initially established in 2006, and subsequently TLANDO was licensed in 2009 to Solvay Pharmaceuticals, Inc. which was then acquired by Abbott Products, Inc. (“Abbott”). Following a portfolio review associated with the spin-off of AbbVie Inc. by Abbott in 2011, the rights to TLANDO were reacquired by us. All obligations under the prior license agreement have been completed except that Lipocine will owe Abbott a perpetual 1% royalty on net sales. Such royalties are limited to $1 million in the first two calendar years following product launch, after which period there is not a cap on royalties and no maximum aggregate amount. If generic versions of any such product are introduced, then royalties are reduced by 50%.

Under the Pediatric Research Equity Act (“PREA”), if TLANDO receives full approval, under the terms of the Antares Licensing Agreement, Antares will need to address the PREA requirement to assess the safety and effectiveness of TLANDO in pediatric patients. The FDA may also require certain post-marketing studies to be conducted which will also be the responsibility of our licensee, Antares.

Upon execution of the Antares License Agreement, Antares paid to us an initial payment of $11.0 million. Antares will also make additional payments of $5.0 million to us on each of January 1, 2025, and January 1, 2026, provided that certain conditions are satisfied. We are also eligible to receive milestone payments of up to $160.0 million in the aggregate, depending on the achievement of certain sales milestones in a single calendar year with respect to all products licensed by Antares under the Antares License Agreement. In addition, upon commercialization, we will receive tiered royalty payments at rates ranging from percentages in the mid-teens to up to 20% of net sales of TLANDO in the United States, subject to certain minimum royalty obligations. Further, on October 14, 2021, we assigned our Manufacturing Agreement, dated August 27, 2013, by and between the Company and Encap Drug Delivery (the “Manufacturing Agreement”) to Antares as part of the Antares License Agreement.

LPCN 1111: A Next-Generation Long-Acting Oral Product Candidate for TRT

LPCN 1111: is a next-generation, novel ester prodrug of testosterone comprised of testosterone tridecanoate (TT) which uses the proprietary delivery technology to enhance solubility and improve systemic absorption. We completed a Phase 2b dose finding study in hypogonadal men in the third quarter of 2016. The primary objectives of the Phase 2b clinical study were to determine the starting Phase 3 dose of LPCN 1111 along with safety and tolerability of LPCN 1111 and its metabolites following oral administration of single and multiple doses in hypogonadal men. Good dose-response relationship was observed over the tested dose range in the Phase 2b study. Additionally, the target Phase 3 dose met primary and secondary end points. Overall, LPCN 1111 was well tolerated with no drug-related severe or serious adverse events reported in the Phase 2b study.

In February 2018 we had a meeting with the FDA to discuss these pre-clinical results and to discuss the Phase 3 clinical study and path forward for LPCN 1111. Based on the results of the FDA meeting and additional pre-clinical studies conducted after the FDA meeting, we have proposed a Phase 3 protocol for LPCN 1111 and have solicited FDA feedback. Based on initial FDA feedback, we expect the Phase 3 clinical trial design to follow the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (“ICH”) guidelines and will include at least a three-month efficacy treatment period and a one-year safety component for approximately 100 subjects. We are currently seeking further clarification from FDA with respect to the total subject LPCN 1111 exposure information needed for an NDA filing. We continue to refine the Phase 3 protocol and plan to request FDA approval of the protocol once it is finalized. Additionally, the FDA previously requested that a food effect and a phlebotomy study be completed, and that ambulatory blood pressure monitoring (“ABPM”) be included as part of the Phase 3 clinical study. We are currently transferring the manufacturing of LPCN 1111 to a third-party contract manufacturer and scaling up the formulation after which we anticipate the next steps in developing LPCN 1111 may be to conduct a food effect/phlebotomy study with LPCN 1111. Under the terms of the Antares License Agreement, Antares has been granted an option to license LPCN 1111, exercisable on or before March 31, 2022, for further development and, should LPCN 1111 receive FDA approval, commercialization. If Antares exercises its option to license LPCN 1111, we will be entitled to an additional payment of $4.0 million, as well as development milestone payments of up to $35.0 million in the aggregate and tiered royalty payments at rates ranging from percentages in the mid-teens to 20% of net sales of LPCN 1111 in the United States.

LPCN 1107: An Oral Product Candidate for the Prevention of Preterm Birth

We believe LPCN 1107 has the potential to become the first oral hydroxyprogesterone caproate ("HPC") product indicated for the reduction of risk of PTB (delivery less than 37 weeks) in women with singleton pregnancy who have a history of singleton spontaneous PTB. Prevention of PTB is a significant unmet need as approximately 11.7% of all U.S. pregnancies result in PTB, a leading cause of neonatal mortality and morbidity.

Current Status

We have completed a multi-dose PK dose selection study in pregnant women. The objective of the multi-dose PK selection study was to assess HPC blood levels in order to identify the appropriate LPCN 1107 Phase 3 dose. The multi-dose PK dose selection study was an open-label, four-period, four-treatment, randomized, single and multiple dose PK study in pregnant women with three dose levels of LPCN 1107 and the IM HPC (Makena®). The study enrolled 12 healthy pregnant women (average age of 27 years) with a gestational age of approximately 16 to 19 weeks. Subjects received three dose levels of LPCN 1107 (400 mg BID, 600 mg BID, or 800 mg BID) in a randomized, crossover manner during the first three treatment periods and then received five weekly injections of HPC during the fourth treatment period. During each of the LPCN 1107 treatment periods, subjects received a single dose of LPCN 1107 on Day 1 followed by twice daily administration from Day 2 to Day 8. Following completion of the three LPCN 1107 treatment periods and a washout period, all subjects received five weekly injections of HPC. Results from this study demonstrated that average steady state HPC levels (Cavg0-24) were comparable or higher for all three LPCN 1107 doses than for injectable HPC. Additionally, HPC levels as a function of daily dose were linear for the three LPCN 1107 doses. Also, unlike the injectable HPC, steady state exposure was achieved for all three LPCN 1107 doses within seven days.

A traditional PK/PD based Phase 2 clinical study in the intended patient population is not expected to be required prior to entering into Phase 3. Therefore, based on the results of our multi-dose PK study we had an End-of-Phase 2 meeting and subsequent guidance meetings with the FDA to define a pivotal Phase 2b/3 development plan for LPCN 1107. However, these discussions will need to be updated based on recent developments with Covis' Makena®. We plan to resume our interactions with the FDA to discuss our pivotal clinical trial design and better understand next steps to advance LPCN 1107 after completion of our on-going food-effect study.

We are exploring the possibility of licensing LPCN 1107 to a third party, although no licensing agreement has been entered into by the Company. No assurance can be given that any license agreement will be completed, or, if an agreement is completed, that such an agreement would be on acceptable terms.

The FDA has granted orphan drug designation to LPCN 1107 based on a major contribution to patient care. Orphan designation qualifies Lipocine for various development incentives, including tax credits for qualified clinical testing, and a waiver of the prescription drug user fee when we file our NDA.

Recent Competition Update

On October 5, 2020, the FDA's Center for Drug Evaluation and Research ("CDER") proposed that Makena be withdrawn from the market because the PROLONG trial failed to verify the clinical benefit of Makena and concluded that the available evidence does not show Makena is effective for its approved use.

CDER issued AMAG Pharmaceuticals, the NDA holder at the time, a Notice of Opportunity for Hearing to withdraw approval of Makena, for which AMAG Pharmaceuticals responded by requesting a hearing and providing detail on the company's position, recognizing clinicians' decade-long use of Makena's treatment and the public health implications of withdrawing approval. The FDA Commissioner has recently granted Covis a public hearing although the date of that hearing is not publicly known. During this time, Makena and the approved generics of Makena will remain on the market until the FDA makes a final decision about these products.

Currently, Makena and the approved generics of Makena are the only products approved for the prevention of recurrent preterm birth.

The FDA also indicated that it intends to hold a meeting with experts in obstetrics, neonatal care, and clinical trial design to discuss how to facilitate development of effective and safe therapies to treat preterm birth.

Oral NAS Programs for CNS Disorders

Some preferred endogenous or naturally occurring NAS present in central nervous system (CNS) act as positive allosteric modulators (PAM) of the $GABA_A$ receptor, the major biological target of the inhibitory neurotransmitter γ-aminobutyric acid ($GABA_A$). To improve oral delivery of these modulators, several synthetic NAS derivatives of endogenous $GABA_A$ receptor PAMs, have been developed for therapeutic use in the past few decades.

We believe through utilization of our proprietary technology we may have the ability to enable effective oral delivery of endogenous $GABA_A$ receptor PAMs which historically had been challenging to deliver orally as they were deemed to be not orally bioavailable. We believe these endogenous $GABA_A$ receptor PAMs provide opportunity as a differentiated NAS for treatment of various CNS disorders via the preferred and convenient oral route.

LPCN 1154: Product Candidate for PPD

We are currently evaluating LPCN 1154 comprising an endogenous NAS for PPD. FDA has cleared LPCN 1154 IND (investigational new drug) application to conduct a phase 2 study in PPD. We have completed a PK study with LPCN 1154 post oral administration in which appreciable levels were observed with dose proportionality. We plan to conduct further PK analyses and a food effect PK study.

PPD

PPD (Postpartum depression), a type of major depressive disorder with onset either during pregnancy or within four weeks of delivery, refers to depression persisting up to 12 months after childbirth. PPD can be clinically segmented by the severity of symptoms and presence of a comorbidity, including epilepsy. Approximately 1 in 9 mothers suffers from PPD in the United States alone; this equates to approximately 500,000 women affected by PPD annually.

Disease Overview - PPD

- PPD is distinct from the “baby blues,” a condition that affects up to 70% of all new mother’s experience; “baby blues” tend to be short-lived emotional conditions that do not interfere with daily activities

- Symptoms of PPD include hallmarks of major depression, including, but not limited to, sadness, depressed mood, loss of interest, change in appetite, insomnia, sleeping too much, fatigue, difficulty thinking/concentrating, excessive crying, fear of harming the baby/oneself, and/or thoughts of death or suicide

- During pregnancy, levels of endogenous NAS increase considerably along with levels of progesterone; however, they drop sharply postpartum. It has been hypothesized that the rapid perinatal decrease in circulating levels of endogenous NASs may be involved in the development of PPD. The first and only approved treatment option for PPD is an injectable containing endogenous NAS.

- Depression may persist long after child delivery. Additionally, approximately 40% women relapse in subsequent pregnancies or on other occasions

- Psychiatric comorbidities are common in patients with epilepsy. Patients with epilepsy are at high risk for major depressive disorders and PPD. Reported PPD rates are higher among women with epilepsy than the general population.

Associated Risk Factors

- Genetic: family history and/or previous experience of depression or other mood disorders
- Physiological: rapid changes in sex hormones, stress hormones, and thyroid hormone levels during and after delivery
- Environmental: stressful life events, changes in relationships at home and at work, and/or lack of familial support

Unmet medical need

Approximately, 1 in 9 moms suffers from PPD in the United States alone, which equates to approximately 500,000 women affected by PPD annually. We believe there is considerable unmet need within women with PPD due to lack of convenient and fast-acting oral therapies. Selective Serotonin Reuptake Inhibitors (SSRIs) have been the traditional first-line choice for women with severe PPD requiring weeks for onset of efficacy; therefore, a need for a faster onset of action remains a significant unmet need in treating PPD, especially in women with epilepsy risk wherein psychiatric comorbidity is common and PPD rates are higher than the general population.

Injectable brexanolone (ZulressoTM, Sage Therapeutics) became the first FDA-approved treatment for postpartum depression. However, numerous factors limit the utilization of injectable brexanolone such as method of administration, cost, and safety concerns. Administration of injectable brexanolone requires a 60-hour continuous infusion in a supervised medical setting, a demanding ask for a mother with a newborn. Besides associated privacy concerns and social stigma, hospitalization may also require separation of the mother and child for a few days, which may be difficult to the already strained mother-infant bond and may present breast feeding challenges. Moreover, the pharmacotherapy costs coupled with hospitalization/childcare costs limits its accessibility and affordability to women most in need of the therapy. Finally, due to concerns about the safety of injectable ZulressoTM including excessive sedation or loss of consciousness, Zulresso has a Black Box Warning in its label and is only available through a restricted distribution program (REMS), and sites need significant time to become treatment ready.

We believe the need for a convenient, at-home treatment with faster onset of action which could offer privacy and affordability, independent of socio-economic status, for women with PPD is a significant unmet need. LPCN 1154 targets this unmet need with affordable NAS.

LPCN 2101: NAS for epilepsy

We are currently evaluating an additional NAS candidate, LPCN 2101, for women with epilepsy (“WWE”). We have completed a pre-clinical study for LPCN 2101. We plan to file an IND with the U.S. FDA for LPCN 2101 to conduct a proof-of-concept study for the evaluation of safety, tolerability, and efficacy in adult female subjects of childbearing age diagnosed with epilepsy.

Research and Development

As disclosed in our development pipeline, we continue to build a diversified multi-asset pipeline of novel therapies. In 2021 and 2020, we spent $7.7 million and $9.7 million, respectively, on research and development.

Competition

Cirrhosis Market Overview

Decompensated cirrhosis patients with sarcopenia exhibit significantly shorter overall survival than those without sarcopenia. There are no therapies specifically approved for sarcopenia or decompensated cirrhosis. Currently, the only curative therapy for decompensated cirrhosis is liver transplant; however, liver transplantation is very costly, limited by the supply of available donors, and has a high risk of post-operative complications.

Xifaxan (rifaximin) is the only FDA-approved medicine indicated for the reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults, a decompensation event typically associated with liver cirrhosis.

Currently, there are no FDA approved drugs to treat secondary sarcopenia in decompensated cirrhosis beyond treatment of the underlying conditions. Lipocine is the only clinical-stage company pursuing treatment for subjects with decompensated cirrhosis with sarcopenia, however there are candidates known to be under development for cirrhosis related indication(s).

GB 1211 (by Galecto), an oral galectin-3 inhibitor for advanced liver cirrhosis targeted for directly addressing fibrosis, is in phase 2 development being assessed in patients with moderate-to-severe cirrhosis (Child-Pugh classes B and C) and is anticipated to read out in the second half of 2022.

AXA-1665 (by Axcella Health), an orally active mixture of 8 amino acids in specific ratios designed to maximize anabolic activity and minimize ammonia genesis, is in a Phase 2 study in the secondary prevention of overt HE with a projected completion date of March 2023. While AXA-1665's studies have so far enrolled non-sarcopenic patients, Axcella could pursue cirrhotic sarcopenia with AXA-1665.

Reformulated Rifaximin SSD (by BAUSCH health) is in a phase 3 study for Reduction of Early Decompensation in Cirrhosis with time to first occurrence of hepatic encephalopathy as the Primary endpoint. Reportedly, a new drug application (NDA) planned to be submitted 2026.

NASH Market Overview

There are currently no medications approved for the treatment of NASH. However, various therapeutics are used off-label for the treatment of NASH, including vitamin E (an antioxidant), insulin sensitizers (e.g., metformin, pioglitazone), antihyperlipidemic agents (e.g., gemfibrozil), pentoxifylline and ursodeoxycholic acid. There are several product candidates in Phase 3 or earlier clinical or preclinical development for the treatment of NASH, including *FGF21 stimulants such as BIO89-100 (89bio), Efruxifermin (EFX; Akero Therapeutics), Pegbelfermin (Bristol Myers Squibb/Ambrx Inc.); FGF19 Analog:Aldafermin (NGM Biopharmaceuticals); FXR Agonists: Tropifexor (Novartis), EDP-305 (Enata Pharmaceuticals), PXL007/EYP001 (Poxel/Enyo Pharma:) Glucagon-like Peptide-1 (GLP-1) Agonist: Semaglutide (Novo Nordisk); Peroxisome Proliferator-activated Receptor (PPAR) Regulator: Lanifibranor (Inventiva);THR-β Agonis:t VK2809 (Viking Therapeutics),* and Resmetirom (Madrigal Pharmaceuticals).

Additional pharmaceutical and biotechnology companies with product candidates in development for the treatment of NASH include AstraZeneca plc, Boehringer Ingelheim GmbH, Bristol-Myers Squibb Company, Conatus Pharmaceuticals Inc., CymaBay Therapeutics, Inc., Durect Corporation, Galectin Therapeutics Inc., Galmed Pharmaceuticals Ltd., Immuron Ltd., Ionis Pharmaceuticals, Inc., Islet Sciences, Inc., Madrigal Pharmaceuticals, Inc., MediciNova, Inc., MiNA Therapeutics, NGM Biopharmaceuticals, Inc., Novo Nordisk A/S, NuSirt Sciences Inc., Viking Therapeutics, Inc. and Zydus Pharmaceuticals (USA) Inc.

Testosterone Replacement Therapy Market Overview

The gel-based testosterone replacement products that are currently available include AbbVie's AndroGel®, Lilly's Axiron® Topical Solution and Endo's Testim® and Fortesta® along with their respective authorized generics as well as the equivalent generic versions of each. Transdermal patches include Allergan's Androderm®. Intramuscular forms of testosterone also exist although commercialized mostly in generic forms by multiple companies and in branded form as Aveed® by Endo. Additionally, Endo markets the buccal testosterone replacement therapy Striant® and the Testopel® implantable testosterone pellets, which it acquired from Auxillium in 2015. Antares Pharma, Inc. markets a sub-cutaneous weekly auto-injector testosterone therapy, Xyoste®. Acerus Pharmaceuticals markets an intranasal testosterone therapy, NATESTO®. Finally, Clarus markets an oral TRT, JATENZO®, which received approval in March 2019.

Currently, intramuscular injections have the highest market share in the testosterone replacement market in terms of annual prescriptions. While gels are also a widely used form of TRT, there is a risk of transference; additionally, the gels are messy to apply and have significant compliance issues leading to high rates of discontinuance among patients. Additionally, certain intramuscular injections have the potential to cause pulmonary embolisms as well as cause injection site reactions, scarring, pain and risk of infection in patients. We believe a safe and effective oral therapy could potentially increase patient convenience and compliance, while eliminating the testosterone transference risk associated with gels and injection site reaction of injectables.

The FDA has granted a therapeutic equivalence rating of AB to “generic” versions of approved products which have been approved via a 505(b)(2) NDA. In July 2014, FDA granted the AB rating to Perrigo’s 1% testosterone gel drug product (NDA 203098) approved in January 2013, and a BX rating to Teva’s 1% gel drug product (NDA 202763) approved in February 2012. Each are versions of AbbVie’s AndroGel 1.0% and employed 505(b)(2) submissions citing AndroGel as their reference listed drugs. Teva’s version was found to be bioinequivalent to AndroGel, hence the BX rating. Upsher-Smith Laboratories also received approval for a version of Endo’s Testim (Vogelxo™; NDA 204399) in June 2014 using the same pathway. In January of 2015, the FDA determined that Vogelxo™ is therapeutically equivalent to Testim and received an AB rating. In August 2015, the FDA granted AB rating to Perrigo’s 1.62% testosterone gel drug product (NDA 204268) which also received FDA approval in August 2015. Lilly and Acrux’s Axiron had patent expiry in February 2017. On July 6, 2017, Acrux confirmed that a generic version of Axiron® Topical Solution, 30 mg/1.5 mL (Testosterone Topical Solution, 30 mg/1.5 mL) has been launched in the United States by Perrigo Company plc. Acrux also confirmed the availability of an authorized generic version of Axiron in the United States, through a marketing and distribution agreement between Lilly and Company and a leading authorized generics company

Other TRT Therapies in Development

Recently there has been increased interest in developing oral TRT’s therapies as well as testosterone therapies which are not considered testosterone replacement and as such will need to achieve efficacy endpoints in addition to endpoints related to serum testosterone levels that are required for testosterone replacement therapies.

Marius is developing an oral TU as a testosterone replacement therapy for the treatment of hypogonadism in men as well as in the treatment of Constitutional Delay of Growth and Puberty in adolescent boys (14-17 years of age). Marinus submitted a NDA to the FDA in January 2021 for its product, Kyzatrex™, its novel oral TU soft gelatin capsule for the treatment of hypogonadism in adult men. According to Marius, it was assigned a PDUFA date of October 31, 2021, for KYZATREX®. However, no updates have been provided by Marius post the October 31, 2021, PDUFA date for KYZATREX®.

We believe there remains a significant unmet need in TRT for a once-a-day convenient oral option. LPCN 1111 is targeted to meet this unmet need.

Hydroxyprogesterone caproate, or HPC, Preterm Birth, or PTB, Market Overview

PTB is defined as delivery before 37 weeks of gestation. The only approved therapy for prevention of PTB in women with a prior history of at least one preterm birth (approximately 180,000 pregnancies annually) is a weekly intramuscular injection of HPC, marketed by Covis under the brand name Makena®. The FDA granted a 7-year orphan drug exclusivity to Makena in February 2011 because the product is intended to treat “rare diseases or conditions” defined as a condition that affects fewer than 200,000 persons in the United States; exclusivity expired in February 2018. Generic versions of the intramuscular injection of Makena became available during 2018. In order to protect market share, Covis also developed a subcutaneous auto-injector for Makena that received FDA approval on February 14, 2018. Treatment with Makena is initiated in pregnant women between week 16 and week 20 of pregnancy and is continued until up to delivery or week 37, whichever is earlier. The intramuscular injection is administered by a healthcare provider using a 21-gauge needle into the gluteus muscle, alternating sides each week. The intramuscular injections are associated with significant pain, discomfort and associated injection site reactions. The subcutaneous auto-injector for Makena eliminates the need to travel weekly to a healthcare provider to have the injection administered. Covis has disclosed that the completed confirmatory trial for Makena did not demonstrate a statistically significant difference between the treatment and placebo arms for the co-primary endpoints of reducing the risk of recurrent preterm birth or improving neonatal mortality and morbidity. On October 29, 2019 a Meeting of the Bone, Reproductive and Urologic Drugs Advisory Committee (“BRUDAC”) was held to consider the trial’s findings and the sNDA in the context of AMAG Pharmaceuticals’ confirmatory study obligation. While the committee discussed multiple questions, in a mixed vote on the key question, nine advisory committee members voted to recommend that the FDA pursue withdrawal of approval for Makena and seven committee members voted to leave the product on the market under accelerated approval and require a new confirmatory trial. Among the clinicians on the advisory committee, five of the six who practice obstetrics voted to keep Makena on the market and generate more data. On October 5, 2020, the FDA’s CDER proposed that Makena be withdrawn from the market because the PROLONG trial failed to verify the clinical benefit of Makena and concluded that the available evidence does not show Makena is effective for its approved use.

CDER issued AMAG, the NDA holder at the time, a NOOH to withdraw approval of Makena, for which AMAG Pharmaceuticals responded by requesting a hearing and providing detail on the company's position, recognizing clinicians' decade-long use of Makena's treatment and the public health implications of withdrawing approval. The FDA Commissioner granted a hearing, and the process is expected to take months. During this time, Makena and the approved generics of Makena will remain on the market until the FDA makes a final decision about these products.

Neuroactive Steroids Market overview

The unique potential mechanism of action (MOA) of NAS presents an opportunity to treat variety of CNS disorders. Accordingly, multiple NAS as $GABA_A$ receptor PAMs are in active development for varied indications. Some companies engaged in development include SAGE Therapeutics, Inc., Marinus Pharmaceuticals, Praxis Precision Medicines, and Eliem Therapeutics.

Postpartum Depression

Sage Therapeutics is currently marketing an injectable version of an endogenous neuroactive steroid, brexanolone, under tradename of ZULRESSO, as first and only FDA approved product (approval on 03/19/2019) for treatment in postpartum depression (PPD).

SAGE therapeutics is also currently developing an oral synthetic derivative of an endogenous NAS, SAGE-217 (Zuranolone), a $GABA_A$ receptor PAM, and is in phase 3 development for postpartum depression. Zuranolone (oral) received Breakthrough Therapy Designation for the treatment of MDD in February 2018.

Marinus Pharmaceuticals has also reported clinical development of Ganaxolone, a synthetic $GABA_A$ receptor PAM in PPD that been studied in two Phase 2 trials, one investigating IV +/- oral administration (Magnolia part 1 and 2) and one oral administration (Amaryllis). Additional assets of the same MOA are indicated for MDD (PRAX-114 and ETX-155) but could be pivoted to a PPD indication.

Intellectual Property

Drug Delivery Technologies for Lipophilic Drug Substances

Our patent portfolio is directed to various types of compositions and methods for delivery of lipophilic drugs, which are drugs that are soluble in lipids. Our licensed product, TLANDO, is an oral formulation of the lipophilic prodrug TU, utilizing our proprietary technology for improved delivery of lipophilic therapeutic agents. As of March 7, 2022, our intellectual property patent portfolio is as follows:

- 15 issued patents in the US related to Oral TU with 2029-2030 expiration dates;
- 1 issued patent in the US related to Oral TU with 2031 expiration date;
- 4 U.S. patent applications related to Oral TU with potential expiration dates, if issued, in 2029;
- 5 U.S. patent applications related to Oral TU with potential expiration dates, if issued, in 2030;
- 6 U.S. patent applications related to Oral TU with potential expiration dates, if issued, in 2035-2040;
- 3 issued U.S. patents related to LPCN 1111 with expiration dates in 2035-2037;
- 5 U.S. patent applications related to LPCN 1111, with potential expiration dates, if issued, in 2029-2037;
- 7 U.S. patents related to LPCN 1107 with expiration dates in 2031;
- 3 U.S. patent applications related to LPCN 1107 with potential expiration dates, if issued, in 2031-2036;
- 1 issued patent related to Oral TU in the following countries: India, Mexico, Japan, Canada and Australia that expires in 2030;
- 1 issued patent related to Oral TU in the following countries: Australia, Canada and Japan that expires in 2024;
- 1 issued patent related to Oral TU in in the following countries: Australia, Canada, and New Zealand that expires in 2026;
- 1 issued patent related to Oral TU in the following country: Canada that expires in 2034
- 1 patent application related to Oral TU in the following countries: Europe, Brazil, and Hong Kong, that if issue, will expire in 2030;
- 1 patent application related to Oral TU in the following countries: China and Russia, that if issue, will expire in 2035;
- 1 patent application related to Oral TU in the following countries: Europe and Japan, that if issue, will expire in 2037;
- 1 patent application related to LPCN 1111 in the following countries: Europe and Japan, that if issue, will expire in 2037;
- 1 issued patents or applications related to LPCN 1111 in the following countries: Argentina, Australia, Brazil, Canada, China, Europe, Israel, India, Japan, South Korea, Mexico, New Zealand, Russia, Uruguay, Paraguay, Venezuela, and South Africa, that expires or will expire, if issued, in 2030;
- 1 patent application related to LPCN 1111 in the following countries: Australia, Brazil, Canada, China, Europe, India, Indonesia, Israel, Japan, Mexico, New Zealand, Russia, South Korea and South Africa, that, if issued, will expire in 2035;
- 1 issued patent or application related to LPCN 1107 in the following countries: Australia, Brazil, Canada, China, Europe, Israel, India, Japan, South Korea, Mexico, New Zealand, Russia, and South Africa that expires, or will expire if issued, in 2032;
- 1 patent application related to LPCN 1107 in the following countries: Australia, Brazil, China, Europe, Indonesia, Israel, Japan, Mexico, New Zealand, Philippines and South Africa that will expire, if issued in 2036;
- 6 U.S. Patent applications related to LPCN 1144/1148 and one Patent Cooperation Treaty ("PCT") application; and
- A U.S. patent related to progesterone formulations that expires in 2031.

We also hold license rights in fields other than cough and cold, to 2 U.S. patents and 1 U.S. application (and related foreign patents and applications) that we previously assigned to Spriaso LLC, which could be possibly used with future product candidates.

Additionally, we have 6 U.S. patents that we plan to list in the FDA Orange Book for TLANDO that are expected to expire in 2029 and 2030. If we or our licensee are marketing the TLANDO product at the time the patents expire and have no other issued U.S. patents covering the product, then we will lose certain advantages that come with FDA Orange Book listing of patents and will no longer be able to prevent others in the U.S. from practicing the inventions claimed by the 6 patents.

We expect to file new patent applications in the future in an attempt to further cover to various aspects of our products and product development.

See Item 3 – Legal Proceedings, for a discussion of intellectual property related legal proceedings.

Government Regulation

The Regulatory Process for Drug Development

The production and manufacture of our product candidates and our research and development activities are subject to regulation by various governmental authorities around the world. In the United States, drugs and products are subject to regulation by the FDA. There are other comparable agencies in Europe and other parts of the world. Regulations govern, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of products. Applicable law requires licensing and registration of manufacturing and contract research facilities, carefully controlled research and testing of products, governmental review and/or approval of results prior to marketing therapeutic products. Additionally, adherence to good laboratory practices, or GLP, good clinical practices, or GCP, during clinical testing and current good manufacturing practices, or cGMP, during production is required. The system of new drug approval in the United States is generally considered to be the most rigorous in the world and is described in further detail below under “United States Pharmaceutical Product Development Process.”

United States Pharmaceutical Product Development Process

In the United States, the FDA regulates pharmaceutical products under the Federal Food, Drug and Cosmetic Act and implementing regulations. The testing, production, sale, and promotion of pharmaceutical products are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

It takes many years for a typical experimental drug to go from concept to approval. The process required by the FDA before a pharmaceutical product may be marketed in the United States generally includes the following:

- Completion of preclinical laboratory tests and animal studies. The latter often conducted according to GLPs or other applicable regulations, as well as synthesis and drug formulation development leading ultimately to clinical drug supplies manufactured according to cGMPs;
- Submission to the FDA of an IND, which must be submitted to the FDA and become effective before human clinical trials may begin in the United States;
- Performance of adequate and well-controlled human clinical trials according to the FDA’s current GCPs, to establish the safety and efficacy of the proposed pharmaceutical product for its intended use;
- Submission to the FDA of an NDA for a new pharmaceutical product;
- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the pharmaceutical product is produced to assess compliance with the FDA’s cGMP to assure that the facilities, methods and controls are adequate to preserve the pharmaceutical product’s identity, strength, quality and purity;
- Potential FDA audit of the preclinical and clinical trial sites that generated the data in support of the NDA; and
- FDA review and approval of the NDA.

The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations require the expenditure of substantial resources and FDA approval is inherently uncertain.

Preclinical Studies: Prior to preclinical studies, a research phase takes place which involves demonstration of target and function, design, screening and synthesis of agonists or antagonists. Preclinical studies include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to evaluate efficacy and activity, toxic effects, PKs and metabolism of the pharmaceutical product candidate and to provide evidence of the safety, bioavailability and activity of the pharmaceutical product candidate in animals. The conduct of the preclinical safety evaluations must comply with federal regulations and requirements including GLPs. The results of the formal IND-enabling preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature as well as the comprehensive descriptions of proposed human clinical studies, are then submitted as part of the IND application to the FDA.

The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the IND on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a pharmaceutical product candidate at any time before or during clinical trials due to safety concerns or non-compliance. Accordingly, we cannot be certain that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such clinical trial.

Clinical Trials: Clinical trials involve the administration of the pharmaceutical product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by the sponsor. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety. Each protocol must be submitted to the FDA if conducted under a U.S. IND. Clinical trials must be conducted in accordance with the FDA's GCP requirements. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, or ethics committee at or servicing each institution at which the clinical trial will be conducted. An IRB or ethics committee is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB or ethics committee also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

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

Phase 1 Clinical Trials: Phase 1 clinical trials are usually first-in-man trials, take approximately one to two years to complete and are generally conducted on a small number of healthy human subjects to evaluate the drug's activity, schedule and dose, PKs and pharmacodynamics. However, in the case of life-threatening diseases, such as cancer, the initial Phase 1 testing may be done in patients with the disease. These trials typically take longer to complete and may provide insights into drug activity.

Phase 2 Clinical Trials: Phase 2 clinical trials can take approximately one to three years to complete and are carried out on a relatively small to moderate number of patients (as compared to Phase 3) in a specific indication. The pharmaceutical product is evaluated to preliminarily assess efficacy, to identify possible adverse effects and safety risks, and to determine optimal dose, regimens, PKs, pharmacodynamics and dose response relationships. This phase also provides additional safety data and serves to identify possible common short-term side effects and risks in a larger group of patients. Phase 2 clinical trials sometimes include randomization of patients.

Phase 3 Clinical Trials: Phase 3 clinical trials take approximately two to five years to complete and involve tests on a much larger population of patients (several hundred to several thousand patients) suffering from the targeted condition or disease. These studies usually include randomization of patients and blinding of both patients and investigators at geographically dispersed test sites (multi-center trials). These trials are undertaken to further evaluate dosage, clinical efficacy and safety and are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of an NDA or foreign authorities for approval of marketing applications.

Post-approval studies, or Phase 4 clinical trials, may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication and may be required by the FDA as a condition of approval.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events or for any finding from tests in laboratory animals that suggests a significant risk for human subjects. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or, if used, its data safety and monitoring board may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB or ethics committee can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's or ethics committee's requirements or if the pharmaceutical product has been associated with unexpected serious harm to patients.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the pharmaceutical product, as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the pharmaceutical product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final pharmaceutical product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the pharmaceutical product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Pharmaceutical Review and Approval Process

New Drug Application: Upon completion of pivotal Phase 3 clinical studies, the sponsor assembles all the product development, preclinical and clinical data along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the pharmaceutical product, proposed labeling and other relevant information, and submits it to the FDA as part of an NDA. The submission or application is then reviewed by the regulatory body for approval to market the product. This process typically takes eight months to one year to complete. The FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. If a product receives regulatory approval, the approval may be limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs 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 United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States 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. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

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 to market the same drug for the same indication, except in very limited circumstances, for seven years. Orphan drug exclusivity, however, could also block the approval of one of our products for seven years if a competitor obtains approval of the same drug as defined by the FDA or if our drug candidate is determined to be contained within the competitor's product for the same indication or disease.

Post-Approval Requirements

Any pharmaceutical products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with the FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, prohibitions on promoting pharmaceutical products for uses or in patient populations that are not described in the pharmaceutical product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities and promotional activities involving the internet. Failure to comply with the FDA requirements can have negative consequences, including adverse publicity, enforcement letters from the FDA, mandated corrective advertising or communications with doctors and civil or criminal penalties.

The FDA also may require post-marketing testing, known as Phase 4 testing, risk evaluation and mitigation strategies and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product.

21st Century Cures Act

The 21st Century Cures Act (Public Law No. 144-255) was enacted on December 13, 2016. This sweeping legislation makes significant changes to the way that FDA approves new drugs and medical devices. Among other things, the legislation calls on FDA to consider new types of data, such as patient experience data, in its drug approval process. The legislation also permits drug manufacturers to utilize new types of clinical trial designs in order to collect data in the drug approval process. The intent of many of the statute's provisions are to speed the approval of new drugs and medical devices. Whether the 21st Century Cures Act realizes these goals will depend on the adoption of new FDA regulations, policy guidance and FDA approval practices, many of which the agency has not yet proposed or issued.

Other Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including, but not limited, to the Centers for Medicare and Medicaid Services and other divisions of the United States government, including the U.S. Federal Communications Commission, the Department of Health and Human Services, the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice, and state and local governments. For example, if a drug product is reimbursed by Medicare, Medicaid, or other federal or state healthcare programs, our Company, including our sales, marketing and scientific/educational grant programs, among others, must comply with federal healthcare laws, including, but not limited to, the federal Anti-Kickback Statute, false claims laws, civil monetary penalties laws, healthcare fraud and false statement provisions and data privacy and security provisions under the Health Insurance Portability and Accountability Act, or HIPAA, the Physician Payment Sunshine Act, and any analogous state laws. If a drug product is reimbursed by Medicare or Medicaid, pricing and rebate programs must comply with, as applicable, the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 ("OBRA"), and the Medicare Prescription Drug Improvement and Modernization Act of 2003. Among other things, OBRA requires drug manufacturers to pay rebates on prescription drugs to state Medicaid programs and empowers states to negotiate rebates on pharmaceutical prices, which may result in prices for our future products that will likely be lower than the prices we might otherwise obtain. Additionally, the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, "ACA") substantially changes the way healthcare is financed by both governmental and private insurers. Among other cost containment measures, ACA establishes: an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents; a new Medicare Part D coverage gap discount program; and a new formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program. There may continue to be additional proposals relating to the reform of the U.S. healthcare system, in the future, some of which could further limit coverage and reimbursement of drug products. If drug products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements may apply.

Additionally, to the extent that any of our products 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 fraud and abuse, privacy and transparency laws.

Pharmaceutical Coverage, Pricing and Reimbursement

In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of coverage and adequate reimbursement from third-party payers, including government health administrative authorities, managed care providers, private health insurers and other organizations. In the United States, private health insurers and other third-party payers often provide reimbursement for products and services based on the level at which the government (through the Medicare or Medicaid programs) provides reimbursement for such treatments. Third-party payers are increasingly examining the medical necessity and cost-effectiveness of medical products and services in addition to their safety and efficacy and, accordingly, significant uncertainty exists as to the coverage and reimbursement status of newly approved therapeutics. In particular, in the United States, the European Union and other potentially significant markets for our product candidates, government authorities and third-party payers are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. Further, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of insurers and managed care organizations, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general. As a result, coverage and adequate third-party reimbursement may not be available for our products to enable us to realize an appropriate return on our investment in research and product development.

The market for our product candidates for which we may receive regulatory approval will depend significantly on access to third-party payers' drug formularies or lists of medications for which third-party payers provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payers may refuse to include a particular branded drug in their formularies or may otherwise restrict patient access to a branded drug when a less-costly generic equivalent or other alternative is available. In addition, because each third-party payer individually approves coverage and reimbursement levels, obtaining coverage and adequate reimbursement is a time-consuming and costly process. We would be required to provide scientific and clinical support for the use of any product to each third-party payer separately with no assurance that approval would be obtained, and we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. This process could delay the market acceptance of any of our product candidates for which we may receive approval and could have a negative effect on our future revenues and operating results. We cannot be certain that our product candidates will be considered cost-effective. If we are unable to obtain coverage and adequate payment levels for our product candidates from third-party payers, physicians may limit how much or under what circumstances they will prescribe or administer them, and patients may decline to purchase them. This in turn could affect our ability to successfully commercialize our products and impact our profitability, results of operations, financial condition, and future success.

The United States Orphan Drug Act encourages the development of orphan drugs, which are intended to treat “rare diseases or conditions” within the meaning of this Act (i.e., those that affect fewer than 200,000 persons in the United States). The provisions of the Act are intended to stimulate the research, development and approval of products that treat rare diseases. Orphan Drug Designation provides a sponsor with several potential benefits: (1) sponsors may be granted seven years of marketing exclusivity after approval of the orphan-designated indication for the drug product; (2) sponsors are granted U.S. tax incentives for clinical research; (3) the FDA’s office of orphan products development coordinates research study design assistance for sponsors of drugs for rare diseases; and (4) grant funding can be obtained to defray costs of qualified clinical testing.

Priority Review

Priority Review is a designation for an NDA after it has been submitted to the FDA for review. Reviews for NDAs are designated as either “Standard” or “Priority.” A Standard designation sets the target date for completing all aspects of a review and the FDA taking an action on 90% of applications (i.e., approve or not approve) at 12 months after the date it was submitted for drugs considered new molecular entities and at 10 months after the date it was submitted for drugs considered non-new molecular entities. A Priority designation sets the target date for the FDA action on 90% of applications at eight months after submission submitted for drugs considered new molecular entities and at 6 months after submission for drugs considered non-new molecular entities. A Priority designation is intended for those products that address unmet medical needs.

Accelerated Approval

Accelerated Approval or Subpart H Approval is a program described in the NDA regulations that is intended to make promising products for life threatening diseases available on the basis of evidence of effect on a surrogate endpoint prior to formal demonstration of patient benefit. A surrogate marker is a measurement intended to substitute for the clinical measurement of interest, usually prolongation of survival in oncology that is considered likely to predict patient benefit. The approval that is granted may be considered a provisional approval with a written commitment to complete clinical studies that formally demonstrate patient benefit.

Related Party Transaction

On July 23, 2013, we entered into assignment/license and services agreements with Spriaso, an entity that is majority-owned by Mahesh V. Patel, Gordhan Patel, John W. Higuchi, Dr. William I. Higuchi, and their affiliates. Mahesh V. Patel is our President and Chief Executive Officer and Chairman of our Board of Directors. Mr. Higuchi is a member of our Board of Directors and Gordhan Patel and Dr. Higuchi, former Board members, were each members of our Board of Directors at the date the license and agreements were entered into.

Under the assignment agreement, we assigned and transferred to Spriaso all of our rights, title and interest in our intellectual property for the cough and cold field. In addition, Spriaso was assigned all rights and obligations under our product development agreement with a co-development partner. In exchange, we would be entitled to receive a potential cash royalty of 20% of the net proceeds received by Spriaso, up to a maximum of $10 million. Spriaso also granted back to us an exclusive license to such intellectual property to develop products outside of the cough and cold field. The assignment agreement will expire upon the expiration of all of Spriaso’s payment obligations thereunder and the expiration of all of the licensed patents thereunder. Spriaso has the right to terminate the assignment agreement with 30 days written notice. We have the right to terminate the assignment agreement upon the complete liquidation or dissolution of Spriaso, unless the assignment agreement is assigned to an affiliate or successor of Spriaso.

Under the services agreement, we agreed to provide facilities and up to 10% of the services of certain employees to Spriaso for a period of time. The agreement to provide services expired in 2021; however, it may be extended upon written agreement of Spriaso and us. Additionally, Spriaso filed its first NDA in 2014, and as an affiliated entity of Lipocine, it used up the one-time waiver of user fees for a small business submitting its first human drug application to FDA.

Employees

As of December 31, 2021, we had 13 full time employees and we also utilize the services of consultants on a regular basis. Eight employees are engaged in drug development activities and five are in general and administration functions and all of our employees work out of our Salt Lake City facility. The Company continually evaluates the business need and opportunity and balances in house expertise and capacity with outsourced expertise and capacity. Currently, we outsource substantial clinical trial work to clinical research organizations and certain drug manufacturing to contract manufacturers. None of our employees are represented by labor unions or covered by collective bargaining agreements and we consider our relations with our employees to be good.

We strive toward having a diverse team of employees and are committed to equality, inclusion and workplace diversity.

Available Information

Our website address is www.lipocine.com. We make available free of charge on the Investor Relations portion of our website, ir.lipocine.com, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission. The SEC maintains an internet website that contains reports, proxy and information statements, and other information that we file electronically, which can be found at http://www.sec.gov.

ITEM 1A. RISK FACTORS

We have identified the following risks and uncertainties that may have a material adverse effect on our business, financial condition, results of operations and future growth prospects. Our business could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should also refer to the other information contained in this Annual Report on Form 10-K, including our consolidated financial statements and related notes.

Risk Factors Summary

Our business operations are subject to numerous risks, factors and uncertainties, including those outside of our control, that could cause our actual results to be harmed, including risks regarding the following:

Risks Relating to Our Business and Industry

- the timelines of our clinical trials;
- the early stage of development of LPCN 1148, LPCN 1114, LPCN 1111, LPCN 1107 and neuro active steroids;
- the early stage of development of our research and development programs and processes and the risk of competition;
- the regulation requirements for our product candidates;
- the regulatory approval, success, and commercialization of our licensed product candidate, TLANDO;
- the possibility that T-replacement therapies could be found to create, or could be perceived to create, health risks;
- any possible failure to obtain adequate healthcare reimbursement for our products;
- competition in the TRT market, including the entrance of generic T-gels into the market;
- our licensee's ability to commercialize TLANDO may be limited;
- successful commercialization of our product candidates internally or through collaborators;
- the possibility that we may never receive regulatory approval to market our products outside the United States;
- the stringent government regulations concerning the clinical testing of our products;
- the market's acceptance of our products;
- physicians and patients using other products may not switch to our product;
- the possibility that regulatory agencies could find that we have improperly promoted off-label uses;
- any possible failure to comply with federal and state healthcare laws;
- the ongoing outbreak of coronavirus around the world;
- our ability to retain our chief executive officer and other key executives and to attract, retain and motivate qualified personnel;
- difficulties in managing the growth of the Company;
- re-importation of drugs from foreign countries into the United States by our competitors;
- any product liability claims;
- any failure to comply with the Controlled Substances Act;
- the defense and resolution of any litigation;
- cyber security risks;

Risks Related to Our Dependence on Third Parties

- our reliance on third-party contractors and service providers for the execution of some aspects of our development programs;
- our reliance on contract research organizations or other third parties to assist us in conducting clinical trials;
- our reliance on suppliers for the active and inactive ingredients for our products;
- our ability to establish successful collaborations for our products;

Risks Related to Ownership of Our Common Stock

- our stock price's reaction to the results and timing of clinical trials, regulatory and other decisions;
- the effectiveness of our internal control over financial reporting;
- the cost and expense to comply with the requirements of being a public company;
- the volatility of our share price;
- fluctuations in the value of our warrants outstanding from the November 2019 Offering;
- the possibility of delisting of our securities from the Nasdaq Capital Market;
- anti-takeover provisions in our amended and restated certificate of incorporation and our amended and restated bylaws, as well as provisions of Delaware law and our stockholder rights plan;
- the right of the holders of the common warrants issued in the November 2019 Offering to receive the Black Scholes value of the warrants in the event of a fundamental transaction;
- our decision not to pay dividends on our common stock;
- our management and directors' ability to exert influence over our affairs;
- volatility in the trading price of our common stock;
- any failure of securities or industry analysts to publish accurate research about our business;

Risks Relating to Our Financial Position and Capital Requirements

- our need for and ability to obtain substantial additional capital in the future;
- the covenants in our loan agreement or our failure to comply with such covenants;
- our ability to generate sufficient cash flow to satisfy our significant debt service obligations;
- potential dilution to our existing stockholders from raising any additional capital;
- our inability to predict when we will generate product revenues or achieve profitability;
- our incurrence of significant operating losses;
- any fluctuation in our operating results;
- limited shares available for issuance to raise capital;

Risks Relating to Our Intellectual Property

- our ability to protect our intellectual property;
- our ability to obtain additional protection under the Drug Price Competition and Patent Term Restoration Act;
- the possibility of incurring substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights, or our inability to protect our rights to our products and technology;
- the cost and expense, and any unfavorable outcomes, resulting from any claims for infringing intellectual property rights of third parties;
- the fact that we do not have patent protection for our product candidates in a significant number of countries;
- our ability to comply with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies; and
- the possibility that we may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Risks Relating to Our Business and Industry

The timelines of our clinical trials may be impacted by numerous factors and any delays may adversely affect our ability to execute our current business strategy.

Our expectations regarding the success of our product candidates, including our clinical candidates and lead compounds, and our business are based on projections which may not be realized for many scientific, business or other reasons. We therefore cannot assure investors that we will be able to adhere to our current schedule. We set goals that forecast the accomplishment of objectives material to our success: selecting clinical candidates, product candidates, failures in research, the inability to identify or advance lead compounds, identifying target patient groups or clinical candidates, the timing and completion of clinical trials, and anticipated regulatory approval. The actual timing of these events can vary dramatically due to factors such as slow enrollment of subjects in studies, uncertainties in scale-up, manufacturing and formulation of our compounds, failures in research, the inability to identify clinical candidates, failures in our clinical trials, requirements for additional clinical trials and uncertainties inherent in the regulatory approval process and regulatory submissions. Decisions by our partners or collaborators may also affect our timelines and delays in achieving manufacturing capacity. The length of time necessary to complete clinical trials and to submit an application for marketing approval by applicable regulatory authorities may also vary significantly based on the type, complexity and novelty of the product candidate involved, as well as other factors.

LPCN 1148 is in a very early stage of development and is currently undergoing phase 2 clinical evaluation in a proof-of-concept study for management of liver cirrhosis in male patients and while there are no therapies specifically approved by the FDA for sarcopenia or cirrhosis beyond treatment of underlying conditions, there are candidates know to be under development for cirrhosis related indication(s).

LPCN 1148 is in a very early stage of development and consequently the risk that we may fail to commercialize LPCN 1148 and related products is high. This development program is susceptible to technical failures in ongoing and future clinical studies, regulatory hurdles for further testing and/or meeting FDAs needs for NDA filing or approval. The results of the current phase 2 clinical evaluation may not support continued development or regulatory approval. While we believe there is a potential to gain Orphan Drug Designation for an indication or condition in male liver cirrhosis, the FDA may not grant such designation which could adversely impact development or the commercial potential of LPCN 1148.

LPCN 1144 is in a very early stage of development and may not be further developed for a variety of reasons.

LPCN 1144 is in a very early stage of development and consequently the risk that we fail to commercialize LPCN 1144 and related products is high. In particular, we have only recently announced topline primary and key secondary endpoint results from our Phase 2 *LiFT* clinical study.

Although our results from the *LiFT* clinical study results were positive for NASH resolution with no worsening of fibrosis, these results may not be indicative of ultimate success in a larger Phase 2/3 clinical study with required FDA endpoints and populations needed for regulatory approval of LPCN 1144 for the treatment of NASH.

In addition, a number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials, even after achieving positive results in early-stage development. The FDA currently insists on histopathology endpoint for diagnosis and assessment of efficacy in a pivotal trial. Accordingly, our results from our *LiFT* study may not be predictive of the results we may obtain from further studies and trials.

Several factors could significantly affect the prospects for LPCN 1144, including factors relating to the regulatory approval, competitive landscape and clinical development challenges for LPCN 1144. The anticipated Phase 3 programs for an NDA filing for LPCN 1144 will be very long and resource intensive.

LPCN 1111 is in a very early stage of development and may not be further developed for a variety of reasons.

LPCN 1111 is in a very early stage of development. We have completed a Phase 2a and Phase 2b study in hypogonadal men. Future studies may not have clinical results that support continued develop and/or a path towards regulatory approval and commercialization.

In addition, the active ingredient in LPCN 1111 has only been manufactured on a small scale. Scaling up into larger batches could be challenging and our ability to procure adequate material in a timely manner to further develop LPCN 1111 is uncertain. We also may not be able to engage a manufacturer who can supply adequate quantities of the drug substance in compliance with cGMP.

Several factors could significantly affect the prospects for LPCN 1111, including Antares' option to license LPCN 1111 (TLANDO XR) as such option is available to them under the Antares License Agreement, and factors relating to the regulatory approval and clinical development challenges for LPCN 1111 discussed above. The anticipated phase 3 program for an NDA filing for LPCN 1111, however, could be very long and expensive.

LPCN 1107 is in a very early stage of development and may not be further developed for a variety of reasons.

LPCN 1107 is in a very early stage of development and consequently the risk that we fail to commercialize LPCN 1107 and related products is high. In particular, we have only conducted three phase 1 clinical studies with this product candidate. Two of the studies were in healthy pregnant women and one was in healthy women. Although these studies demonstrated oral absorption of LPCN 1107 is possible, we may not be able to match Cavg blood levels shown with the intramuscular injection comparator product over a longer duration. Furthermore, our completed phase 1 clinical studies may not be predictive of safety concerns that may arise in pregnant women or demonstrate that LPCN 1107 has an adequate safety profile to warrant further development. The FDA may also require further preclinical studies. All of these factors can impact the timing of and our ability to continue development of LPCN 1107.

In addition, a number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials, even after achieving positive results in early-stage development. Accordingly, our results from our Phase 1a, our Phase 1b and our multi-dose PK dose selection studies may not be predictive of the results we may obtain from further studies and trials.

A traditional PK/PD based phase 2 clinical study in the intended patient population may not be required prior to entering into Phase 3. Therefore, based on the results of our multi-dose PK study results, we had an end-of-phase 2 meeting with the FDA in the second quarter of 2016, as well as subsequent guidance meetings to agree on a pivotal Phase 2b/3 development plan for LPCN 1107. However, these discussions will need to be updated based on recent developments with Covis' Makena®. We plan to resume our interactions with the FDA to discuss our pivotal Phase 2b/3 clinical trial design and better understand next steps to advance LPCN 1107 after completion of our ongoing food effect study. Once the pivotal Phase 2b/3 clinical trial is started, the anticipated Phase 2b/3 program for an NDA filing for LPCN 1107 will be very long and expensive.

The FDA has concluded that Makena, based on Makena's failed definitive PROLONG study, a competing product with the same active ingredient and similar target indication, is ineffective and has proposed that it be withdrawn from the market, but the final decision is still pending. It is entirely possible that any pivotal study may require a placebo-controlled trial design. Therefore, given the uncertainly of the status of the current standard of care, Makena and its generics, Lipocine may face significant challenges in patient recruitment for a placebo-controlled trial, be faced with significant resource investment to conduct additional trials, and face potential perceived risk of efficacy failure in a pivotal study resulting in no further development of LPCN 1107.

LPCN 1154 and LPCN 2101 a very early stage of development and may not be further developed for a variety of reasons.

Our oral NAS comprising programs (LPCN 1154 and LPCN 2101) are in a very early stage of development and consequently the risk that we may fail to commercialize LPCN 1154, LPCN 2101, and related products is high. We have not conducted clinical studies of these programs and the ultimate regulatory or technical success of each of the neuroactive steroids under investigation in these programs is uncertain. The current limited pre-clinical results we have observed may not be replicated in larger studies, future PK phase 2, or pivotal studies with a potential "to be marketed formulation". We may not be able get IND clearance in a timely manner or may be unable to further test in-clinic due to other regulatory hurdles.

In addition, our oral NAS product candidates may not be effective in treating PPD or WWE or may not have differentiation from competitive products on the market or in development. We may expend significant resources before determining that these programs are not viable candidates for regulatory approval and commercialization.

Our research and development programs and processes are at an early stage of development, which makes it difficult to evaluate our business and prospects or predict if or when we will successfully commercialize our product candidates.

Our operations to date have primarily been limited to conducting research and development activities under license and collaboration agreements. Our current portfolio consists of product candidates at various clinical stages of development in addition to our out-licensed product TLANDO. We have never marketed or commercialized a drug product. Consequently, any predictions about our future performance may not be as accurate as they could be if we were further along our commercialization path. In addition, as a pre-commercial stage business, we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors.

Our clinical product candidates are at an early stage of development and will require significant further investment and regulatory approvals prior to marketing and commercialization. As such, our product development processes for oral neuro active steroids, LPCN 1148, LPCN 1111, LPCN 1144, and LPCN 1107 are very risky and uncertain, and our product candidates may fail to advance beyond the current study. Even if we obtain required financing, we cannot ensure successful product development or that we will obtain regulatory approval or successfully commercialize any of our product candidates and generate product revenues.

All of our clinical candidates will be subject to extensive regulation which can be costly and time consuming, cause delays or prevent approval of the products for commercialization.

Our clinical development of oral neuro active steroids, LPCN 1148, LPCN 1111, LPCN 1144, and LPCN 1107 and any future product candidates is subject to extensive regulations by the FDA. Product development is a very lengthy and expensive process and can vary significantly based upon the product candidate's novelty and complexity. Regulations are subject to change and regulatory agencies have significant discretion in the approval process.

Numerous statutes and regulations govern human testing and the manufacture and sale of human therapeutic products in the United States. Such legislation and regulation bears upon, among other things, the approval of protocols and human testing, the approval of manufacturing facilities, safety of the product candidates, testing procedures and controlled research, review and approval of manufacturing, preclinical and clinical data prior to marketing approval including adherence to cGMP during production and storage as well as regulation of marketing activities including advertising and labeling.

In order to obtain regulatory clearance for the commercial sale of any of our product candidates, we must demonstrate through preclinical studies and clinical trials that the potential product is safe and efficacious for use in humans for each target indication. Obtaining approval of any of our product candidates is an extensive, lengthy, expensive and uncertain process, and the FDA may delay, limit or deny approval for many reasons, including:

- we may not be able to demonstrate that the product candidate is safe and effective to the satisfaction of the FDA;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA for marketing approval;

- the FDA may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the contract research organization that we retain to manage our clinical trials may take actions outside of our control that materially adversely impact our clinical trials;
- the FDA may not find the data from preclinical studies and clinical trials sufficient to demonstrate that a particular product candidate's clinical and other benefits outweigh its safety risks;
- the FDA may disagree with our interpretation of data from our preclinical studies and clinical trials or may require that we conduct additional trials;
- the FDA may not accept data generated at our clinical trial sites;
- if our NDA once submitted is reviewed by an Advisory Committee, the FDA may have difficulties scheduling an Advisory Committee meeting in a timely manner or the Advisory Committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the FDA may require development of a REMS as a condition of approval;
- the FDA may require longer or additional duration of stability data on the clinical lots prior to initiation of further clinical trials;
- the FDA may identify deficiencies in the formulation or stability of our product candidates or products, or relating to our manufacturing processes or facilities, or in the processes and facilities of the contract manufacturing organization ("CMO"), our suppliers, or other third parties that may be utilized in the production supply chain of our products; and
- with respect to TLANDO and LPCN 1111, the FDA may not grant a three-year exclusivity as the active is a Testosterone prodrug.

Preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain FDA approval for their products.

No assurance can be given that current regulations relating to regulatory approval will not change or become more stringent. The FDA may also require that we amend clinical trial protocols and/or run additional trials in order to provide additional information regarding the safety, efficacy or equivalency of any compound for which we seek regulatory approval. Moreover, any regulatory approval of a drug which is eventually obtained may entail limitations on the indicated uses for which that drug may be marketed. Furthermore, product approvals may be withdrawn or limited in some way if problems occur following initial marketing or if compliance with regulatory standards is not maintained. The FDA could become more risk averse to any side effects or set higher standards of safety and efficacy prior to reviewing or approving a product. This could result in a product not being approved

We are substantially dependent on the success of our licensed product candidate, TLANDO, for which we received tentative approval from the FDA and which may not receive final regulatory approval or be successfully commercialized.

TLANDO is currently our only product candidate that has completed Phase 3 clinical trials. In October 2021, we entered into the Antares License Agreement with Antares, pursuant to which we granted Antares an exclusive, royalty-bearing, sublicensable right and license to develop and commercialize, upon final approval of TLANDO from the FDA, our TLANDO product with respect to TRT in the U.S. None of our other products have been approved for sale. Therefore, at this stage, our ability to realize revenue depends on TLANDO's successful regulatory approval and commercialization, if final approval is obtained. The commercial success of TLANDO depends almost entirely on Antares' commercialization efforts and we have very limited ability to influence Antares' efforts, including the amount and timing of resources they devote, if any, to the commercialization of TLANDO.

On December 8, 2020, the FDA informed us that it granted tentative approval to TLANDO for testosterone replacement therapy in adult males indicated for conditions associated with a deficiency or absence of endogenous testosterone: primary hypogonadism (congenital or acquired) and hypogonadotropic hypogonadism (congenital or acquired). In granting tentative approval, the FDA concluded that TLANDO has met all required quality, safety and efficacy standards necessary for approval, but TLANDO has not received final approval and is not eligible for final approval and marketing in the U.S. until the expiration of the exclusivity period previously granted to Clarus with respect to JATENZO®, which expires on March 27, 2022. Antares will not be able to market TLANDO in the U.S. until that time. Any delay in receiving final FDA approval could adversely affect Antares's commercialization efforts and ability to compete with other TRT products and have a material adverse effect on our business.

Under the PREA, if TLANDO receives full approval, our licensing partner, Antares, will need to address the PREA requirement to assess the safety and effectiveness of TLANDO in pediatric patients. The FDA has also required us to conduct certain post-marketing studies including: (i) conduct an appropriately designed label comprehension and knowledge study that assesses patient understanding of key risk messages in the Medication Guide for TLANDO and (ii) conduct an appropriately designed one-year trial to evaluate development of adrenal insufficiency with chronic TLANDO therapy. The timetables for these post-marketing requirements will be established at the time of full approval of TLANDO. Antares will be responsible for any required studies after approval of TLANDO.

Even if final regulatory approval of TLANDO is obtained, the success of TLANDO, and our ability to realize royalty revenue, will depend on the commercialization efforts of Antares. If Antares is not able to successfully commercialize TLANDO, we may not realize any royalty revenue under the Antares License Agreement and our business could be adversely affected.

In the event that we seek regulatory approval of TLANDO outside the United States, such markets have requirements for approval of drug candidates with which we must comply prior to marketing. Obtaining regulatory approval for marketing of TLANDO in one country does not ensure we will be able to obtain regulatory approval in other countries but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries.

Any regulatory approval of TLANDO, once obtained, including the FDA's tentative approval, may be withdrawn. Ultimately, the failure to obtain and maintain regulatory approvals would prevent TLANDO from being marketed and would have a material adverse effect on our business.

If T-replacement therapies are found, or are perceived, to create health risks, our ability to realize any revenue from TLANDO and LPCN 1111 could be materially adversely affected, and our business could be harmed. Even if our TLANDO and our LPCN 1111 are approved, physicians and patients may be deterred from prescribing and using T-replacement therapies, which could depress demand for TLANDO and LPCN 1111 and compromise the successful commercialization of TLANDO and LPCN 1111, if final approval is obtained.

Certain publications have suggested potential health risks associated with T-replacement therapy, such as increased cardiovascular disease risk, including increased risk of heart attack or stroke, fluid retention, sleep apnea, breast tenderness or enlargement, increased red blood cells, development of clinical prostate disease, including prostate cancer, and the suppression of sperm production. These potential health risks are described in various articles, including the following publications:

- a 2014 publication in PLOS ONE, which found that, compared to the one year prior to beginning T-replacement therapy, the risk of heart attack doubled 90 days after the start of T deficiency treatment in older men regardless of their history of heart disease and was two to three times higher in men younger than 65 with a history of heart disease;

- a 2013 publication in the *Journal of the American Medical Association*, which reported that hypogonadal men receiving T-replacement therapy developed a 30% increase in the risk of stroke, heart attack and death; and

- a 2013 publication in BMC Medicine, which concluded that exogenous T increased the risk of cardiovascular-related events, particularly in trials not funded by the pharmaceutical industry.

Prompted by these events, the FDA announced on January 31, 2014, that it will investigate the risk of stroke, heart attack, and death in men taking FDA-approved testosterone products and that the FDA would hold a T-class Advisory Committee meeting on September 17, 2014, to discuss this topic further. The FDA has also asked health care professionals and patients to report side effects involving prescription testosterone products to the agency.

Following the FDA's announcement, the Endocrine Society, a professional medical organization, released a statement in February 2014 in support of further studies regarding the risks and benefits of FDA-approved T-replacement products for men with age-related T deficiency. Specifically, the Endocrine Society noted that large-scale randomized controlled trials are needed to determine the risks and benefits of T-replacement therapy in older men. In addition, the Endocrine Society recommended that patients should be informed of the potential cardiovascular risks in middle-aged and older men associated with T-replacement therapies. Also following the FDA's announcement, Public Citizen, a consumer advocacy organization, petitioned the FDA to add a "black box" warning about the increased risks of heart attacks and other cardiovascular dangers to the product labels of all T-replacement therapies. In addition, this petition urged the FDA to delay its decision date on approving Aveed, a long-acting T-injectable developed by Endo, which was subsequently approved by the FDA in March 2014. In July 2014, the FDA responded to the Public Citizen petition and denied the petition. Additionally, in June 2014 the FDA announced that it would require the manufacturers of testosterone drugs to update the warning label to include blood clots including deep vein thrombosis and pulmonary embolism.

At the T-class Advisory Committee meeting held on September 17, 2014, the Advisory Committee discussed (i) the identification of the appropriate patient population for whom T-replacement therapy should be indicated and (ii) the potential risk of major adverse cardiovascular events, defined as non-fatal stroke, non-fatal myocardial infarction and cardiovascular death associated with T-replacement therapy. At the meeting, 16 of the 21 members of the Advisory Committee voted that the FDA should require sponsors of testosterone products to conduct a post marketing study (e.g. observational study or controlled clinical trial) to further assess the potential cardiovascular risk. Further, 12 of these voted that such post marketing study be required only if the T-replacement therapy is also approved for age-related hypogonadism.

The Advisory Committee also held a meeting on September 18, 2014, to evaluate the safety and efficacy of JATENZO® (previously Rextoro), an oral TU submitted to the FDA by Clarus for the proposed indication of T-replacement therapy. 18 of the 21 members of the Advisory Committee voted that the overall benefit/risk profile of JATENZO® was not acceptable to support approval for T-replacement therapy. The Advisory Committee agreed that an oral TU as a T-replacement therapy is promising and that it would be of great value to patients to have an oral treatment option, but they did not believe the current JATENZO® data supported approval.

On March 3, 2015, the FDA issued a safety announcement addressing the Advisory Committee's recommendations and communicated its expectations related to label revisions and additional clinical requirements.

The FDA's safety assessment recommended the following label modifications/restrictions in the indicated population for T-replacement therapy:

- limiting use of T-replacement products to men who have low testosterone caused by certain medical conditions;
- prior to initiating use of T-replacement products, confirm diagnosis of hypogonadism by ensuring that serum testosterone has been measured in the morning on at least two separate days and that these concentrations are below the normal range;
- adding cautionary language stating that the safety and efficacy of TRT products with age-related hypogonadism have not been established; and
- adding cautionary language stating that some studies have shown an increased risk of myocardial infarction and stroke associated with use of T-replacement products.

Additionally, the FDA stated that it will require manufacturers of approved T-replacement products to conduct a well-designed clinical trial to more clearly address the question of whether an increased risk of heart attack or stroke exists among users of T-replacement products. The FDA encouraged manufacturers to work together on conducting a clinical trial, although the FDA will allow manufacturers to work separately if they so choose.

On December 8, 2020, the FDA tentatively approved TLANDO. As part of their approval, the FDA has required us to include certain warnings and precautions in our labeling for TLANDO, including a "black box warning," including warnings relating to blood pressure increases and an indication that the safety and efficacy of TLANDO in males less than 18 years has not been established. These warnings may deter physicians and patients from using TLANDO after it has received final approval, which could adversely affect our business.

The FDA has also required us to conduct certain post-marketing studies to (i) assess patient understanding of key risks relating to TLANDO and (ii) evaluate development of adrenal insufficiency with chronic TLANDO therapy. Antares is responsible for conducting these post-marketing studies. Negative outcomes from such studies could adversely affect the ability of Antares to successfully commercialize TLANDO, which would adversely affect our ability to realize royalty revenue under the Antares License Agreement.

If we fail to obtain adequate healthcare reimbursement for our products, our revenue-generating ability will be diminished and there is no assurance that the anticipated market for our products will be sustained.

We believe that there could be many different applications for products successfully derived from our technologies and that the anticipated market for products under development could continue to expand. However, due to competition from existing or new products, potential changes to the class TRT label by the FDA and the yet to be established commercial viability of our products, no assurance can be given that these beliefs will prove to be correct. Physicians, patients, formularies, payors or the medical community in general may not accept or utilize any products that we or our collaborative partners may develop. Other drugs may be approved during our clinical testing which could change the accepted treatments for the disease targeted and make our compound obsolete.

Our ability to commercialize our products with success may depend, in part, on the extent to which coverage and adequate reimbursement to patients for the cost of such products and related treatment will be available from governmental health administration authorities, private health coverage insurers and other organizations, as well as the ability of private payors to pay for or afford our drugs. Adequate third-party coverage may not be available to patients to allow us to maintain price levels sufficient for us to realize an appropriate return on our investment in product development.

Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payers can be critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Additionally, current manufacturers of drug products may have agreements with payors that may limit the ability of new products to get on formulary or require a step edit with an existing product before reimbursement or a new product will occur. Even if we obtain coverage for our products, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are less likely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Payers may require a more arduous prior authorization process as a condition to payment for TRT therapy. This could adversely affect the market for TRT products.

In the United States and in many other countries, pricing and/or profitability of some or all prescription pharmaceuticals and biopharmaceuticals are subject to varying degrees of government control. Healthcare reform and controls on healthcare spending may limit the price we charge for any products and the amounts thereof that we can sell. In particular, in the United States, the federal government and private insurers have changed and have considered ways to change, the manner in which healthcare services are provided. In March 2010, ACA became law in the United States. ACA substantially changes the way healthcare is financed by both governmental and private insurers and significantly affects the healthcare industry. The provisions of ACA of importance to our potential product candidates include the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers’ Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals beginning in 2014 and by adding new mandatory eligibility categories for certain individuals with specified income levels, thereby potentially increasing manufacturers’ Medicaid rebate liability;

- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;

- new requirements to report annually certain financial arrangements with physicians, certain other healthcare professionals, and teaching hospitals;

- a new requirement to annually report drug samples that manufacturers and distributors provide to licensed practitioners, pharmacies of hospitals and other healthcare entities; and

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since ACA was enacted. On August 2, 2011, the Budget Control Act of 2011, created, among other things, measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015 was signed into law on April 16, 2015 and implemented the most significant change in Medicare reimbursement since the ACA was enacted. This 2015 law authorizes a new Medicare pay –for-performance reimbursement system for physicians, which will reward physicians for performance on metrics related to quality of care, resource use, meaningful use of electronic medical records, and clinical practice improvement activities. The Bipartisan Budget Act was enacted on November 2, 2015, and among provisions, restricts the types of facilities that may receive hospital reimbursement under Medicare. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

We anticipate that ACA will result in additional downward pressure on the reimbursement we may receive for any approved and covered product and could seriously harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payers. In the future, the U.S. government may institute further controls and different reimbursement schemes and limits on Medicare and Medicaid spending or reimbursement that may affect the payments we could collect from sales of any products in the United States.

The Department of Health and Human Services Office of Inspector General issued final regulations on November 30, 2020 to eliminate safe harbor protection under the anti-kickback statute for drug price reductions that pharmaceutical manufacturers pay to Medicare and Medicaid plan sponsors and their pharmacy benefit managers. The proposal reflects a clear intent to substantially alter many of the current drug discount and services compensation practices among pharmaceutical manufacturers and Medicare and Medicaid managed care organizations and their pharmacy benefit managers. The proposal also reflects a skepticism that current drug discount and compensation practices among manufacturers and pharmacy benefit managers are sufficiently transparent to health plans to ensure that all appropriate cost reductions and value is passed through to health plans and reflected in lower health plans costs and lower premiums for beneficiaries. The Biden Administration has delayed the effective date of this rule until January 1, 2023, and a lawsuit initiated by the Pharmaceutical Care Management Administration has challenged this final rule. If the regulation becomes effective, it could result in lower prices for pharmaceutical products in general.

The Centers for Medicare and Medicaid Services issued an interim final rule on November 20, 2020, that would tie prices for certain drugs under Medicare Part B to the lowest price for those drugs available in certain countries that are members of the Organization for Economic Co-operation and Development. This "most favored nation" drug pricing rule is also the subject of lawsuits, and a federal court has placed an injunction on the implementation of the rule. This rule, if finalized, could also result in lower prices for pharmaceutical products in general.

The Biden Administration will have the opportunity to address these regulations as well as drug pricing, health care access, and other health care reform issues. Any further legislative or administrative action to reduce reimbursement or health benefits to beneficiaries under the Medicare or Medicaid program could affect the payment we could collect from sale of any product in the United States.

There is substantial competition in the TRT market, which may result in others discovering, developing or commercializing products before or more successfully than us or our licensing partner.

We expect to face significant competition for any of our product candidates, if approved. In particular, once final approval is obtained, TLANDO would compete in the T-replacement therapies market, which is competitive and currently dominated by the sale of T-gels and T-injectables. Receipt of future potential payments under our licensing agreement will depend, in large part, on our licensing partner's ability to obtain an adequate share of the market. Potential competitors in North America, Europe and elsewhere include major pharmaceutical companies, specialty pharmaceutical companies, biotechnology firms, universities and other research institutions and government agencies. Other pharmaceutical companies may develop oral T-replacement therapies that compete with TLANDO. For example, because TU is not a patented compound and is commercially available to third parties, it is possible that competitors may design methods of TU administration that would be outside the scope of the claims of either our issued patents or our patent applications. This would enable their products to effectively compete with TLANDO, which could have a negative effect on potential payments under our licensing agreement.

The following T-replacement therapies currently on the market in the United States would compete with TLANDO:

- Oral-T, such as Jatenzo;
- T-gels, such as AndroGel (marketed by Abbvie) and Perrigo's AB-rated 1% generic of AndroGel, Teva's 1% generic of AndroGel, Testim and its generics (marketed by Endo Health Solutions, or Endo), and Fortesta and its generics (marketed by Endo);
- T-injectables, including a subcutaneous auto-injector, XYOSTED, marketed by Antares Pharma, Inc.;
- Branded, longer-acting injectables, such as Aveed (marketed by Endo);
- T-nasals, such as Natesto (marketed by Acerus);
- methyl-T, such as Methitest (marketed by Impax) and Testred (marketed by Valeant);
- transdermal patches, such as Androderm (marketed by Allergan);
- buccal patches, such as Striant (marketed by Endo);
- generic testosterone enanthate intra-muscular injectables;
- authorized generic and generic T-gels; and
- subcutaneous injectable pellets, such as Testopel (marketed by Endo).

On March 27, 2019, Clarus' product JATENZO®, an oral TU product, was approved by the FDA and also received three years of marketing exclusivity. On February 10, 2020, Clarus announced that JATENZO® has been launched and is commercially available. Based on the FDA's tentative approval of TLANDO, the marketing of TLANDO cannot begin until after March 27, 2022, the expiration of the exclusivity period granted to Clarus with respect to JATENZO®.

We are also aware of other pharmaceutical companies that have T-replacement therapies or testosterone therapies in development that may be approved for marketing in the United States or outside of the United States.

Based on publicly available information, we believe that several other T-replacement therapies that would be competitive with TLANDO are in varying stages of development, some of which may be approved, marketed and/or commercialized prior to TLANDO. These therapies include T-gels, oral-T, an aromatase inhibitor, a new class of drugs called Selective Androgen Receptor Modulators and hydroalcoholic gel formulations of DHT.

In light of the competitive landscape above, TLANDO will not be the only oral TRT to market, which may significantly affect the market acceptance and commercial success of TLANDO.

Furthermore, many of our potential competitors have substantially greater financial, technical, and human resources than we do and significantly greater experience in the discovery and development of drug candidates, obtaining FDA and other marketing approvals of products and the commercialization of those products. Accordingly, our competitors may be more successful than we may be in obtaining FDA approval for drugs and achieving widespread market acceptance. Our competitors' drugs may be more effective, or more effectively marketed and sold, than our products and may render our products obsolete or non-competitive before we can recover the expenses of developing and commercializing them. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available. Failure to successfully compete in this market would materially and negatively impact our business and operations.

Even if TLANDO is approved by the FDA, our licensee's ability to commercialize TLANDO may be limited.

Our licensee partner's ability to commercialize TLANDO, should it receive final approval, is uncertain. Our licensee's ability to commercially launch TLANDO is contingent upon numerous factors including, among other things, receipt of final FDA approval, the completion of post-marketing studies, the availability of commercial launch supplies, the impact of COVID-19, commercial acceptance by patients, the medical community, and third-party payors, and the resources that our licensee devotes to the commercialization of TLANDO. If our licensee is unable to successfully launch TLANDO commercially at scale, our business and operations could be adversely affected.

We will not be able to successfully commercialize our product candidates without establishing sales, marketing and market access capabilities internally or through collaborators.

We currently do not have a sales, marketing and market access staff. If and when any of our product candidates are commercialized, we may not be able to find suitable sales and marketing staff and collaborators for our product candidates. The outside collaborators we work with, including Antares under the Antares License Agreement with respect to TLANDO, may not be adequate or successful and any collaborators could terminate or materially reduce the effort they direct to our products. The development of collaborations or an internal sales force and marketing, market access and sales capability will require significant capital, management resources and time. The cost of establishing such a sales force may exceed any potential product revenues and our marketing, market access and sales efforts may be unsuccessful. If we are unable to develop an internal marketing, market access and sales capability or if we are unable to enter into a marketing and sales arrangement with a third party on acceptable terms, we may be unable to successfully commercialize our product candidates.

Even if we receive marketing approval in the United States, we may never receive regulatory approval to market our products outside the United States, which could reduce the size of our potential markets and have a material adverse impact on our business.

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy.

Approval procedures vary among countries and can involve additional product candidate testing and additional administrative review periods. The time required to obtain approvals in other countries might differ from that required to obtain FDA approval. The marketing approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States as well as other risks. In particular, in many countries outside of the United States, products must receive pricing and reimbursement approval before the product can be commercialized. This can result in substantial delays in such countries. Marketing approval in one country does not ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one country may have a negative effect on the regulatory process in others. Failure to obtain marketing approval in other countries or any delay or setback in obtaining such approval would impair our ability to market our products in such foreign markets. Any such impairment would reduce the size of our potential markets, which could have an adverse impact on our business, results of operations and prospects.

We are subject to stringent government regulations concerning the clinical testing of our products and will continue to be subject to government regulation of any product that receives regulatory approval.

Numerous statutes and regulations govern human testing and the manufacture and sale of human therapeutic products in the United States and other countries where we intend to market our products. Such legislation and regulation bears upon, among other things, the approval of clinical study protocols and human testing of our products, the approval of manufacturing facilities, testing procedures and controlled research, the review and approval of manufacturing, preclinical and clinical data prior to marketing approval, including adherence to cGMP during production and storage, and marketing activities including advertising and labeling.

Clinical trials may be delayed or suspended at any time by us or by the FDA or by other similar regulatory authorities if it is determined at any time that patients may be or are being exposed to unacceptable health risks, including the risk of death, or if compounds are not manufactured under acceptable cGMP conditions or with acceptable quality. Current regulations relating to regulatory approval may change or become more stringent. The agencies may also require additional clinical trials to be run in order to provide additional information regarding the safety, efficacy or equivalency of any compound for which we seek regulatory approval. Moreover, any regulatory approval of a drug which is eventually obtained may entail limitations on the indicated uses for which that drug may be marketed. Furthermore, product approvals may be withdrawn or limited in some way if problems occur following initial marketing or if compliance with regulatory standards is not maintained. Regulatory agencies could become more risk adverse to any side effects or set higher standards of safety and efficacy prior to reviewing or approving a product. This could result in a product not being approved.

If we, or any future marketing collaborators or CMOs, fail to comply with applicable regulatory requirements, we may be subject to sanctions including fines, product recalls or seizures and related publicity requirements, injunctions, total or partial suspension of production, civil penalties, suspension or withdrawals of previously granted regulatory approvals, warning or untitled letters, refusal to approve pending applications for marketing approval of new products or of supplements to approved applications, import or export bans or restrictions, and criminal prosecution and penalties. Any of these penalties could delay or prevent the promotion, marketing or sale of our products.

The successful commercialization of our product candidates and ability to generate significant revenue will depend on achieving market acceptance.

Even if our product candidates are successfully developed and receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payers such as private insurers or governments and other funding parties and the medical community. The degree of market acceptance for our products, if approved, will depend on a number of factors, including:

- the relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies;
- the prevalence and severity of any adverse side effects;
- limitations or warnings contained in the labeling approved by the FDA;
- availability of alternative treatments, including a number of competitive therapies already approved or expected to be commercially launched in the near future;
- distribution and use restrictions imposed by the FDA or agreed to by us as part of a mandatory REMS or voluntary risk management plan;

- pricing and cost effectiveness;
- the effectiveness of our or any future collaborators' sales and marketing strategies;
- our ability to increase awareness of our products through marketing efforts;
- our ability to obtain sufficient third-party coverage or reimbursement; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage.

If our product candidates are approved but do not achieve an adequate level of acceptance by physicians, healthcare payors and patients, we may not generate sufficient revenue from our products and we may never become or remain profitable. In addition, our efforts to educate the medical community and third-party payors on the benefits of our products may require significant resources and may never be successful.

Even if we obtain marketing approval for our products, physicians and patients using existing products may choose not to switch to our products.

Physicians often show a reluctance to switch their patients from existing drug products even when new and potentially more effective and convenient treatments enter the market. Also, physicians may be reluctant to switch patients if adequate reimbursement for new products is not available. In addition, patients often acclimate to the brand or type of drug product that they are currently taking and do not want to switch unless their physicians recommend switching products or they are required to switch drug treatments due to lack of reimbursement for existing drug treatments and only if the new product has adequate reimbursement. The existence of either or both of physician or patient reluctance in switching to our products would have an adverse effect on our operating results and financial condition.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. If we are found to have improperly promoted off-label uses, we may become subject to significant liability.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our product candidates. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. The FDA may impose further requirements or restrictions on the distribution or use of our product candidates as part of a REMS plan, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. If we receive marketing approval for our product candidates, physicians may nevertheless prescribe our products to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability, including potential liability under federal civil and criminal false claims acts. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

If we fail to comply with federal and state healthcare laws, including fraud and abuse and health information privacy and security laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected.

As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payers, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which constrains our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual or the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;
- HIPAA, which among other things created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the federal Physician Payments Sunshine Act, which, among other things, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under certain federal healthcare programs to report annually information related to "payments or other transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and ownership and investment interests held by certain healthcare professionals and their immediate family members;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and its implementing regulations, which imposes certain requirements relating to the privacy, security, breach notification, and transmission of individually identifiable health information; and
- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exceptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. To the extent that any of our product candidates is ultimately sold in countries other than the United States, we may be subject to similar laws and regulations in those countries. If we or our operations are found to be in violation of any of

the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, exclusion from participating in government healthcare programs, contractual damages, reputational harm and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could materially adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

The Department of Health and Human Services Office of Inspector General proposed new regulations on February 6, 2019 to eliminate safe harbor protection under the anti-kickback statute for drug price reductions that pharmaceutical manufacturers pay to Medicare and Medicaid plan sponsors and their pharmacy benefit managers. The proposal reflects a clear intent to substantially alter many of the current drug discount and services compensation practices among pharmaceutical manufacturers and Medicare and Medicaid managed care organizations and their pharmacy benefit managers. The proposal also reflects a skepticism that current drug discount and compensation practices among manufacturers and pharmacy benefit managers are sufficiently transparent to health plans to ensure that all appropriate cost reductions and value is passed through to health plans and reflected in lower health plans costs and lower premiums for beneficiaries. If the proposal is finalized, it could result in lower prices for pharmaceutical products in general. The Biden Administration has delayed the effective date of this rule until January 1, 2023, and a lawsuit initiated by the Pharmaceutical Care Management Administration has challenged this final rule. If the regulation becomes effective, it could result in lower prices for pharmaceutical products in general.

The Biden Administration will have the opportunity to address these regulations as well as drug pricing, health care access, and other health care reform issues. Any further legislative or administrative action to reduce reimbursement or health benefits to beneficiaries under the Medicare or Medicaid program could affect the payment we could collect from sale of any product in the United States.

The ongoing outbreak of coronavirus around the world could adversely impact our business and operating results.

In December 2019, a novel strain of coronavirus, SARS-CoV-2, was reported to have surfaced in Wuhan, China. Since then, SARS-CoV-2, and the resulting disease COVID-19, has spread to multiple countries, including the United States and all of the primary markets where we conduct business.

The duration and extent of COVID-19's impact on our business may be difficult to assess or predict. The widespread pandemic has resulted, and may continue to result for an extended period, in significant disruption of global financial markets, reducing our ability to access capital, which would negatively affect our liquidity. Further, quarantines or government reaction or shutdowns for COVID-19 could disrupt our operations and harm our business, financial condition and results of operations. Our key personnel and other employees could also be affected by COVID-19, potentially reducing their availability, and an outbreak such as COVID-19 or the procedures we take to mitigate its effect on our workforce could reduce the efficiency of our operations or prove insufficient. We may delay or reduce certain capital spending and certain projects until the travel and logistical impacts of COVID-19 are lifted, which will delay the completion of such projects.

In addition, the conduct of clinical trials and studies required to obtain regulatory approvals for our products have been and we expect may continue to be affected by the COVID-19 pandemic. As hospital resources are prioritized for the COVID-19 outbreak and quarantines impede patient movement or interrupt healthcare services, clinical studies may continue to be disrupted. If we are unable to successfully complete our clinical studies, our business and operating results will be harmed. Further, we believe that subject drop-out rates and the number of subjects that ultimately complete clinical studies could be negatively impacted by COVID-19. Interruptions caused by COVID-19 may also limit our ability to collect data from clinical studies. If we are unable to complete or effectively collect data from clinical studies, our business and operating results will be harmed.

The global outbreak of COVID-19 continues to rapidly evolve. The ultimate impact of the COVID-19 outbreak is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business or the global economy as a whole. However, these effects have harmed our business, financial condition and results of operations in the near term and could have a continuing material impact on our operations, sales and ability to continue as a going concern.

Our future success depends on our ability to retain our chief executive officer and other key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on Dr. Mahesh V. Patel and the other principal members of our executive team. Employment with our executives and other employees are “at will”, meaning that there is no mandatory fixed term and their employment with us may be terminated by us or by them for any or no reason. The loss of the services of any of our executives or other key employees might impede the achievement of our research, development and commercialization objectives. Recruiting and retaining qualified scientific personnel, and accounting personnel will also be critical to our success. We may not be able to attract and retain qualified personnel on acceptable terms, or at all, given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific personnel from universities and research institutions. Failure to succeed in clinical trials may make it more challenging to recruit and retain qualified scientific personnel.

In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

We will need to grow our Company, and we may encounter difficulties in managing this growth, which could disrupt our operations.

As of December 31, 2021, we had 13 employees. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, and give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects. If our management is unable to effectively manage our future growth, our expenses may increase more than expected, our ability to generate revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Federal legislation and actions by state and local governments may permit re-importation of drugs from foreign countries into the United States, including foreign countries where the drugs are sold at lower prices than in the United States, which could materially adversely affect our operating results.

Our licensing partner may face competition for TLANDO, if final approval is received, from lower priced T-replacement therapies from foreign countries that have placed price controls on pharmaceutical products. The Medicare Prescription Drug Improvement and Modernization Act of 2003 contains provisions that may change U.S. importation laws and expand pharmacists’ and wholesalers’ ability to import lower priced versions of an approved drug and competing products from Canada, where there are government price controls. These changes to U.S. importation laws will not take effect unless and until the Secretary of Health and Human Services certifies that the changes will pose no additional risk to the public’s health and safety and will result in a significant reduction in the cost of products to consumers. The Secretary of Health and Human Services has not yet announced any plans to make this required certification.

A number of federal legislative proposals have been made to implement the changes to the U.S. importation laws without any certification and to broaden permissible imports in other ways. Even if the changes do not take effect, and other changes are not enacted, imports from Canada and elsewhere may continue to increase due to market and political forces, and the limited enforcement resources of the FDA, U.S. Customs and Border Protection and other government agencies. For example, Pub. L. No. 111-83, which was signed into law in October 2009, provides appropriations for the Department of Homeland Security for the 2010 fiscal year, expressly prohibits U.S. Customs and Border Protection from using funds to prevent individuals from importing from Canada less than a 90-day supply of a prescription drug for personal use, when the drug otherwise complies with the Federal Food, Drug, and Cosmetic Act. Further, several states and local governments have implemented importation schemes for their citizens, and, in the absence of federal action to curtail such activities, we expect other states and local governments to launch importation efforts.

The importation of foreign products that compete with our products could have an adverse effect on our revenue and profitability.

We may become subject to the risk of product liability claims.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. Human therapeutic products involve the risk of product liability claims and associated adverse publicity. Currently, the principal risks we face relate to patients in our clinical trials, who may suffer unintended consequences. Claims might be made by patients, healthcare providers or pharmaceutical companies or others. We may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale.

For example, to our knowledge, HPC has not been administered orally in a published clinical trial in any pregnant woman for the prevention of PTB. We cannot be certain of the safety profile upon single oral or multiple oral administration of LPCN 1107 to the patient or the fetus and its long term side effects on the mother as well as the child because (i) oral performance of LPCN 1107 may be substantially different from efficacy and/or safety standpoint compared to FDA approved and commercialized intramuscular HPC, Makena, and (ii) oral delivery of HPC could have a very different PK and/or pharmacodynamic profile that has never been experienced with non-oral administration of HPC, thus having its own significant liability exposure independent of known safety of non-oral HPC in humans.

Any product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates, if approved. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management’s time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenues from product sales; and
- the inability to commercialize any of our product candidates, if approved.

We may not have or be able to obtain or maintain sufficient and affordable insurance coverage, and without sufficient coverage any claim brought against us could have a materially adverse effect on our business, financial condition or results of operations. We run clinical trials through investigators that could be negligent through no fault of our own and which could affect patients, cause potential liability claims against us and result in delayed or stopped clinical trials. We are required in many cases by contractual obligations, to indemnify collaborators, partners, third party contractors, clinical investigators and institutions. These indemnifications could result in a material impact due to product liability claims against us and/or these groups. We currently carry $3.0 million in product liability insurance, which we believe is appropriate for our clinical trials. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Testosterone is a Schedule III substance under the Controlled Substances Act and any failure to comply with this Act or its state equivalents would have a negative impact on our business.

Testosterone is listed by the U.S. Drug Enforcement Agency, or DEA, as a Schedule III substance under the Controlled Substances Act of 1970. The DEA classifies substances as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. Scheduled substances are subject to DEA regulations relating to manufacturing, storage, distribution and physician prescription procedures. For example, all regular Schedule III drug prescriptions must be signed by a physician and may not be refilled more than six months after the date of the original prescription or more than five times unless renewed by the physician.

Entities must register annually with the DEA to manufacture, distribute, dispense, import, export and conduct research using controlled substances. In addition, the DEA requires entities handling controlled substances to maintain records and file reports, follow specific labeling and packaging requirements, and provide appropriate security measures to control against diversion of controlled substances. Failure to follow these requirements can lead to significant civil and/or criminal penalties and possibly even lead to a revocation of a DEA registration. Individual states also have controlled substances laws. State controlled substances laws often mirror federal law, however because the states are separate jurisdictions, they may schedule products separately. While some states automatically schedule a drug when the DEA does so, in other states there must be rulemaking or legislative action, which could delay commercialization.

Products containing controlled substances may generate public controversy. As a result, these products may have their marketing approvals withdrawn. State and Federal legislatures and administrative agencies may take additional action to combat a perceived misuse or overuse of such products.

We may have to dedicate resources to the defense and resolution of litigation.

Securities legislation in the United States makes it relatively easy for stockholders to sue. This can lead to frivolous lawsuits which take substantial time, money, resources and attention or force us to settle such claims rather than seek adequate judicial remedy or dismissal of such claims. Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. Biotechnology and pharmaceutical companies, including us, have experienced significant stock price volatility in recent years, increasing the risk of such litigation. As we defend the class action lawsuits or future patent infringement actions should they be filed, or if we are required to defend additional actions brought by other shareholders, we may be required to pay substantial litigation costs and managerial attention and financial resources may be diverted from business operations even if the outcome is in our favor. In addition, while our insurance carrier may cover the costs of settling claims, the Company's capital resources are critical to its continued operations, and the payment of litigation settlements and associated legal fees diverts these capital resources away from our operations, even if such amounts do not have a material impact on our financial statements.

On November 14, 2019, the Company and certain of its officers were named as defendants in a purported shareholder class action lawsuit, *Solomon Abady v. Lipocine Inc. et al*., 2:19-cv-00906-PMW, filed in the United District Court for the District of Utah. The complaint alleges that the defendants made false and/or misleading statements and/or failed to disclose that our filing of the NDA for TLANDO to the FDA contained deficiencies and as a result the defendants' statements about our business and operations were false and misleading and/or lacked a reasonable basis in violation of federal securities laws. The lawsuit seeks certification as a class action (for a purported class of purchasers of the Company's securities from March 27, 2019 through November 8, 2019), compensatory damages in an unspecified amount, and unspecified equitable or injunctive relief. We have insurance that covers claims of this nature.

Defendants intend to vigorously defend themselves against these allegations, but doing so may result in substantial litigation costs and managerial attention and financial resources may be diverted from business operations even if outcome is in favor of our current and former officers and directors and the Company.

Additionally on April 2, 2019, we filed a lawsuit against Clarus in the United States District Court in Delaware alleging that Clarus's JATENZO® product infringes six of Lipocine's issued U.S. patents: 9,034,858; 9,205,057; 9,480,690; 9,757,390; 6,569,463; and 6,923,988. Clarus has answered the complaint and asserted counterclaims of non-infringement and invalidity. We answered Clarus's counterclaims on April 29, 2019. On February 11, 2020, we voluntarily dismissed allegations of patent infringement for expired U.S. Patent Nos. 6,569,463 and 6,923,988 in an effort to streamline the issues and associated costs for dispute. The Court held a scheduling conference on August 15, 2019, a claim construction hearing on February 11, 2020 and a summary judgment hearing on January 15, 2021. In May 2021, the Court granted Clarus' motion for Summary Judgment, finding the asserted claims of Lipocine's U.S. patents 9,034,858; 9,205,057; 9,480,690; and 9,757,390 invalid for failure to satisfy the written description requirement of 35 U.S.C. § 112. Clarus still had remaining claims before the Court. On July 13, 2021, we entered into a Global Agreement with Clarus which resolved all outstanding claims of this litigation. Under the terms of the settlement, we agreed to pay Clarus $4.0 million, payable as follows: $2.5 million immediately, $1.0 million on July 13, 2022 and $500,000 on July 13, 2023. The payment of this and other settlement payments diverts capital resources away from our operations, which may adversely affect our business.

Cyber security risks and the failure to maintain the integrity of company, employee or guest data could expose us to data loss, litigation and liability, and our reputation could be significantly harmed.

We collect and third parties collaborating on our clinical trials collect and retain large volumes of data, including personally identifiable information regarding clinical trial participants and others, for business purposes, including for regulatory, research and development and commercialization purposes, and our collaborators' various information technology systems enter, process, summarize and report such data. We also maintain personally identifiable information about our employees. The integrity and protection of our Company, employee and clinical data is critical to our business. We are subject to significant security and privacy regulations, as well as requirements imposed by government regulation. Maintaining compliance with these evolving regulations and requirements could be difficult and may increase our expenses. In addition, a penetrated or compromised data system or the intentional, inadvertent or negligent release or disclosure of data could result in theft, loss or fraudulent or unlawful use of company, employee or clinical data which could harm our reputation, disrupt our operations, or result in remedial and other costs, fines or lawsuits.

Risks Related to Our Dependence on Third Parties

We may enter into license agreements and/or collaborations with third parties for the development and commercialization of our drug candidates. If those collaborations, including, without limitation, our license arrangement with Antares for the development and commercialization of TLANDO, are not successful, we may not be able to capitalize on the market potential of these drug candidates and may have to alter our development and commercialization plans for our products.

Our drug development programs for our product candidates will require substantial additional cash to fund expenses. We have not yet established any collaborative arrangements relating to the development or commercialization of LPCN 1111, LPCN 1144, LPCN 1148, LPCN 1107 or our oral NAS. We have entered into the Antares License Agreement for TLANDO with respect to TRT in the U.S. We intend to continue to develop our other product candidates in the United States without a partner although our ability to advance these product candidates will depend on our capital resources. However, in order to commercialize our product candidates in the United States, we have partnered with Antares with respect to TLANDO and we will likely look to establish a partnership or co-promotion arrangement with an established pharmaceutical company that has a sales force, collaborate on the establishment of an internal sales force or build an internal sales force on our own with respect to our other product candidates. We may also seek to enter into collaborative arrangements to develop and commercialize our product candidates outside the United States. We will face significant competition in seeking appropriate collaborators and these collaborations are complex and time-consuming to negotiate and document. We may not be able to negotiate collaborations on acceptable terms or in a timely manner, or at all. If that were to occur, we may have to curtail the development or delay commercialization of our product candidates in certain geographies, reduce the scope of our sales or marketing activities, reduce the scope of our commercialization plans, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities either inside or outside of the United States on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all.

To the extent we have, and if we do enter into any further such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our partners dedicate to the development or commercialization of our product candidates. On October 14, 2021, we entered into the Antares License Agreement with Antares, pursuant to which we granted to Antares an exclusive, royalty-bearing, sublicensable right and license to develop and commercialize, upon final approval of TLANDO from the FDA, our TLANDO product with respect to TRT in the U.S. The Antares License Agreement also provides Antares with an option, exercisable on or before March 31, 2022, to license TLANDO XR. Consequently, our ability to generate any revenues from TLANDO with respect to TRT in the U.S. depends on the efforts of Antares to commercialize TLANDO, once final FDA approval is obtained. We have very limited control over the amount and timing of resources that Antares will dedicate to these efforts.

Our ability to generate revenues from this and other collaborative arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions agreed to with them in these arrangements. License agreements and/or collaborations involving our drug candidates, such as our agreement with Antares, pose numerous risks to us, including the following:

- partners have significant discretion in determining the efforts and resources that they will apply to these efforts and may not perform their obligations as expected;
- partners may de-emphasize or not pursue development and commercialization of our drug candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the partners' strategic focus, including as a result of a sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- partners may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a drug candidate, repeat or conduct new clinical trials or require a new formulation of a drug candidate for clinical testing;
- partners could independently develop, or develop with third parties, products that compete directly or indirectly with our products or drug candidates if the partners believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- partners may not be able to acquire and maintain supplier and manufacturer relationships necessary to successfully commercialize our products;
- a partner with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product relative to other products;
- partners may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings;
- disputes may arise between our partners and us that result in the delay or termination of the research, development or commercialization of our products or drug candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- agreements may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable drug candidates;
- agreements may not lead to development or commercialization of drug candidates in the most efficient manner or at all; and
- if a partner of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

If our license arrangements with Antares, or any future license or collaboration we may enter into, if any, are not successful, our business, financial condition, results of operations, prospects and development and commercialization efforts may be adversely affected. Any termination or expiration of the Antares License Agreement, or any future license or collaboration we may enter into, if any, could adversely affect us financially or harm our business reputation, development and commercialization efforts.

We rely upon third-party contractors and service providers for the execution of some aspects of our development programs. Failure of these collaborators to provide services of a suitable quality and within acceptable timeframes may cause the delay or failure of our development programs.

We outsource certain functions, tests and services to contract research organizations ("CROs"), medical institutions and collaborators; and also outsource manufacturing to collaborators and/or contract manufacturers ("CMO's"). We also rely on third parties for quality assurance, clinical monitoring, clinical data management and regulatory expertise. We may also engage a CRO to run all aspects of a clinical trial on our behalf. There is no assurance that such individuals or organizations will be able to provide the functions, tests, drug supply or services as agreed upon or in a quality fashion. Any failure to do so could cause us to suffer significant delays in the development of our products or processes.

Due to our reliance on CROs or other third parties to assist us or who have historically assisted us in conducting clinical trials, we will be unable to directly control all aspects of our clinical trials.

We engaged a CRO to conduct our SOAR, DV and DF Phase 3 clinical studies for TLANDO, as well as the ABPM study for TLANDO. Additionally, we utilized a CRO for the Phase 2 *LiFT* clinical study for LPCN 1144 and are utilizing a CRO for the on-going Phase 2 clinical study for LPCN 1148. As a result, we have less direct control over the conduct of our clinical trials, the timing and completion of the trials and the management of data developed through the trials than if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties, including CROs, may:

- have staffing difficulties or disruptions;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities or may become financially distressed;
- form relationships with other entities, some of which may be our competitors; or
- manufacturing capacity limitations.

These factors may materially adversely affect their willingness or ability to conduct our trials in a manner acceptable to us. We may experience unexpected cost increases that are beyond our control.

Moreover, the FDA requires us to comply with GCP's for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements.

Problems with the timeliness or quality of the work of a CRO may lead us to seek to terminate the relationship and use an alternative service provider. However, making this change may be costly and may delay our trials, and contractual restrictions may make such a change difficult or impossible. If we must replace any CRO that is conducting our clinical trials, our trials may have to be suspended until we find another CRO that offers comparable services. The time that it takes us to find alternative organizations may cause a delay in the commercialization of our product candidates or may cause us to incur significant expenses to replicate data that may be lost. Although we do not believe that any CRO on which we may rely will offer services that are not available elsewhere, it may be difficult to find a replacement organization that can conduct our trials in an acceptable manner and at an acceptable cost. Any delay in or inability to complete our clinical trials could significantly compromise our ability to secure regulatory approval of our product candidates and preclude our ability to commercialize them, thereby limiting or preventing our ability to generate revenue from their sales.

We and our licensee rely on a single supplier for our supply of testosterone esters, the active pharmaceutical ingredient of TLANDO, LPCN 1111, LPCN 1148, and LPCN 1144, and the loss of this supplier could harm our business.

We and our licensee rely on a single third-party supplier for our supply of testosterone esters, the active pharmaceutical ingredient of TLANDO, LPCN 1111, LPCN 1148, and LPCN 1144. Since there are only a limited number of testosterone esters suppliers in the world, if this supplier ceases to provide us with testosterone esters, we may be unable to procure testosterone esters on commercially favorable terms and/or may not be able to obtain testosterone esters in a timely manner. Furthermore, the limited number of suppliers of testosterone esters may provide such companies with greater opportunity to raise their prices. If we or our licensee are unable to obtain testosterone esters in a timely manner and/or in sufficient quantities, our ability to develop, and potentially commercialize, LPCN 1111, LPCN 1148, and LPCN 1144 may be adversely affected. In addition, any increase in price for testosterone esters will likely reduce our potential gross margins for LPCN 1111, LPCN 1148 and LPCN 1144.

We rely on limited suppliers for our supply of NAS, the active pharmaceutical ingredient of LPCN 1154 and LPCN 2101 and the loss of these limited suppliers could harm our business.

We rely on a limited third-party supplier for our supply NAS, the active pharmaceutical ingredient of LPCN 1154 and LPCN 2101. Since there are only a limited number of NAS suppliers in the world, if a supplier ceases to provide us with NAS, we may be unable to procure NAS on developmental or commercially favorable terms. Furthermore, the limited number of suppliers of NAS may provide such suppliers with a greater opportunity to raise their prices. If we are unable to obtain NAS in a timely manner and/or in sufficient quantities, our ability to develop NAS may be adversely affected.

If we do not establish successful collaborations, we may have to alter our development and commercialization plans for our products.

Our drug development programs for our product candidates will require substantial additional cash to fund expenses. We have not yet established any collaborative arrangements relating to the development or commercialization of LPCN 1148, LPCN 1114, LPCN 1111, LPCN 1107 or oral neuroactive steroids. We intend to continue to develop our product candidates in the United States without a partner although our ability to advance these product candidates will depend on our capital resources. However, in order to commercialize our product candidates in the United States, we will likely look to establish a partnership or co-promotion arrangement with an established pharmaceutical company that has a sales force, collaborate on the establishment of an internal sales force or build an internal sales force on our own. We may also seek to enter into collaborative arrangements to develop and commercialize our product candidates outside the United States. We will face significant competition in seeking appropriate collaborators and these collaborations are complex and time-consuming to negotiate and document. We may not be able to negotiate collaborations on acceptable terms or in a timely manner, or at all. If that were to occur, we may have to curtail the development or delay commercialization of our product candidates in certain geographies, reduce the scope of our sales or marketing activities, reduce the scope of our commercialization plans, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities either inside or outside of the United States on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all.

If we are successful in entering into collaborative arrangements and any of our collaborative partners does not devote sufficient time and resources to a collaboration arrangement with us, we may not realize the potential commercial benefits of the arrangement, and our results of operations may be materially adversely affected. In addition, if any future collaboration partner were to breach or terminate its arrangements with us, the development and commercialization of our product candidates could be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue development and commercialization of our product candidates on our own in such locations.

Risks Related to Ownership of Our Common Stock

Our stock price could decline significantly based on the results and timing of clinical trials, and/or regulatory and other decisions affecting our product candidates.

Results of clinical trials and preclinical studies of our current and potential product candidates may not be viewed favorably by us or third parties, including the FDA or other regulatory authorities, investors, analysts and potential collaborators. The same may be true of how we design the clinical trials of our product candidates and regulatory decisions affecting those clinical trials. Pharmaceutical company stock prices have declined significantly when such results and decisions were unfavorable or perceived negatively or when a product candidate did not otherwise meet expectations. The final results from our clinical development programs may be negative, may not meet expectations or may be perceived negatively. The designs of our clinical trials (which may change significantly and be more expensive than currently anticipated depending on our clinical results and regulatory decisions) may also be viewed negatively by third parties. We may not be successful in completing these clinical trials on our projected timetable, if at all. In addition, we may never achieve FDA approval for any of our product candidates, which could cause our stock price to decline significantly and have other significant adverse effects on our business.

If we do not maintain effective internal controls over financial reporting in the future, the accuracy and timeliness of our financial reporting may be adversely affected.

The Sarbanes-Oxley Act requires, among other things, that we assess the effectiveness of our internal control over financial reporting annually and disclosure controls and procedures quarterly. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. If material weaknesses are identified in the future or we are not able to comply with the requirements of Section 404 in a timely manner, our reported financial results could be materially misstated, we could receive an adverse opinion regarding our internal controls over financial reporting from our accounting firm, and we could be subject to investigations or sanctions by regulatory authorities, which would require additional financial and management resources, and the market price of our stock could decline.

We incur significant expenses in order to comply with the requirements of being a public company in the United States.

As a public company, we incur significantly more legal, accounting and other expenses than as a private company. In addition, the Sarbanes-Oxley Act of 2002 and rules subsequently implemented by the SEC and U.S. stock exchanges impose numerous requirements on public companies, including requiring changes in corporate governance practices. Also, the Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. Our management and other personnel will need to devote a substantial amount of time to compliance with these laws and regulations. These requirements have increased and will continue to increase our legal, accounting, and financial compliance costs and have made and will continue to make some activities more time consuming and costly.

Our share price is expected to be volatile and may be influenced by numerous factors that are beyond our control.

A low share price and low market valuation may make it difficult to raise sufficient additional cash due to the significant dilution to current stockholders. Market prices for shares of biotechnology and biopharmaceutical companies such as ours are often volatile. The market price of our common stock may fluctuate significantly in response to a number of factors, most of which we cannot control, including:

- commercial launch of TLANDO, if approved;
- plans for, progress of and results from clinical trials of our product candidates;
- the failure of the FDA to approve our product candidates;
- regulatory uncertainty in the TRT class;
- FDA Advisory Committee meetings and related recommendations including meetings convened on the TRT class or on similar companies;
- announcements by the FDA that may impact on-going clinical studies related to safety or efficacy of TRT products;
- product approval and potential FDA required labeling language and/or Phase 4 study commitments;
- announcements of new products, technologies, commercial relationships, acquisitions or other events by us or our competitors;
- our ability to license our products to third parties;
- failure to engage with collaborators or build an internal sales force to commercialize our products should a product candidate receive FDA approval;
- the success or failure of other TRT products or non-testosterone based testosterone therapy products;
- failure of our products, if approved, to achieve commercial success;
- fluctuations in stock market prices and trading volumes of similar companies;
- general market conditions and overall fluctuations in U.S. equity markets;
- variations in our quarterly operating results;
- changes in our financial guidance or securities analysts' estimates of our financial performance;
- changes in accounting principles;
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders;
- additions or departures of key personnel;
- discussion of us or our stock price by the press and by online investor communities;
- our cash balance; and
- other risks and uncertainties described in these risk factors.

In recent years, the stock of other biotechnology and biopharmaceutical companies has experienced extreme price fluctuations that have been unrelated to the operating performance of the affected companies. There can be no assurance that the market price of our shares of common stock will not experience significant fluctuations in the future, including fluctuations that are unrelated to our performance. These fluctuations may result due to macroeconomic and world events, national or local events, general perception of the biotechnology industry or to a lack of liquidity. In addition, other biotechnology companies or our competitors' programs could have positive or negative results that impact their stock prices and their results, or stock fluctuations could have a positive or negative impact on our stock price regardless of whether such impact is direct or not.

Stockholders may not agree with our business, scientific, clinical, commercial, or financial strategy, including additional dilutive financings, and may decide to sell their shares or vote against shareholder proposals. Such actions could materially impact our stock price. In addition, portfolio managers of funds or large investors can change or change their view on us and decide to sell our shares. These actions could have a material impact on our stock price. In order to complete a financing, or for other business reasons, we may elect to consolidate our shares of common stock. Investors may not agree with these actions and may sell our shares. We may have little or no ability to impact or alter such decisions.

The stock prices of many companies in the biotechnology industry have experienced wide fluctuations that have often been unrelated to the operating performance of the companies. Following periods of volatility in the market price of a company's securities, securities class action litigation often has been initiated against a company. For example, on July 1, 2016, the Company and certain of its officers were named as defendants in a purported shareholder class action lawsuit, *David Lewis v. Lipocine Inc., et al*., filed in the United States District Court for the District of New Jersey. This initial action was followed by additional lawsuits also filed in the District of New Jersey. David Lewis v Lipocine Inc., et al. was ultimately settled. Additionally on November 14, 2019, the Company and certain of its officers were named as defendants in a purported shareholder class action lawsuit, *Solomon Abady v. Lipocine Inc. et al*., 2:19-cv-00906-PMW, filed in the United District Court for the District of Utah. This initial action was followed by additional lawsuits also filed in the United States District Court for the District of Utah. These current class action lawsuits and any future class action litigation that may be initiated against us may result in us incurring substantial costs and our management's attention may be diverted from our operations, which could significantly harm our business. In addition, such litigation could lead to increased volatility in our share price.

The value of our warrants outstanding from the November 2019 Offering is subject to potentially material increases and decreases based on fluctuations in the price of our common stock.

In November 2019, we completed a public offering of common stock and warrants to purchase common stock (the "November 2019 Offering"). Gross proceeds from the November 2019 Offering were approximately $6.0 million. In the November 2019 Offering, the Company sold (i) 10,450,000 Class A Units, with each Class A Unit consisting of one share of common stock and a common stock warrant to purchase one share of common stock, and (ii) 1,550,000 Class B Units, with each Class B Unit consisting of one pre-funded warrant to purchase one share of a common stock and one common stock warrant to purchase one share of common stock at a price of $0.50 per Class A Unit and $0.4999 per Class B Unit. The pre-funded warrants were issued in lieu of common stock in order to ensure the purchaser did not exceed certain beneficial ownership limitations. The pre-funded warrants were immediately exercisable at an exercise price of $.0001 per share, subject to adjustment. Additionally, the common stock warrants were immediately exercisable at an exercise price of $0.50 per share and expire on November 17, 2024.

We account for the common stock warrants as a derivative instrument, and changes in the fair value of the warrants are included under other income (expense) in the Company's statements of operations for each reporting period. As of December 31, 2021, the aggregate fair value of the warrant liability included in the Company's consolidated balance sheet was $796,000. We use the Black-Scholes option pricing model to determine the fair value of the warrants. As a result, the option-pricing model requires the input of several assumptions, including the stock price volatility, share price and risk-free interest rate. Changes in these assumptions can materially affect the fair value estimate. While the liability may only result from a change of control at a point in time, we ultimately may incur amounts significantly different than the carrying value of the liability.

We may not be able to maintain our listing on the NASDAQ Capital Market, which would adversely affect the price and liquidity of our common stock.

As a small capitalization pharmaceutical company, the price of our common shares has been, and is likely to continue to be, highly volatile. Any announcements concerning us or our competitors, clinical trial results, quarterly variations in operating results, introduction of new products, delays in the introduction of new products or changes in product pricing policies by us or our competitors, acquisition or loss of significant customers, partners and suppliers, changes in earnings estimates or our ratings by analysts, regulatory developments, or fluctuations in the economy or general market conditions, among other factors, could cause the market price of our common shares to fluctuate substantially. There can be no assurance that the market price of our common shares will not decline below its current price or that it will not experience significant fluctuations in the future, including fluctuations that are unrelated to our performance.

Currently our common stock is quoted on the NASDAQ Capital Market under the symbol "LPCN". We must satisfy certain minimum listing maintenance requirements to maintain the NASDAQ Capital Market quotation, including certain governance requirements and a series of financial tests relating to stockholders' equity or net income or market value, public float, number of market makers and stockholder, market capitalization, and maintaining a minimum bid price of $1.00 per share. For example, on January 14, 2022, we received a notice from the Listing Qualifications Department of The NASDAQ Stock Market stating that we are no longer in compliance with the requirement to have a majority independent board, audit committee and compensation committee for continued listing on The NASDAQ Capital Market under NASDAQ Listing Rule 5605. In accordance with NASDAQ Listing Rules 5605(b)(1)(A), 5605(c)(4) and 5605(d)(4) we are entitled to a cure period to regain compliance.

Anti-takeover provisions in our amended and restated certificate of incorporation and our amended and restated bylaws, as well as provisions of Delaware law and our stockholder rights plan, might discourage, delay or prevent a change in control of our Company or changes in our Board of Directors or management and, therefore, depress the trading price of our common stock.

Our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law contain provisions that may depress the market price of our common stock by acting to discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares of our common stock. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove members of our Board of Directors or our management. Our corporate governance documents include provisions:

- limiting the ability of our stockholders to call and bring business before special meetings and to take action by written consent in lieu of a meeting;
- requiring advance notice of stockholder proposals for business to be conducted at meetings of our stockholders and for nominations of candidates for election to our Board of Directors;
- authorizing blank check preferred stock, which could be issued with voting, liquidation, dividend and other rights superior to our common stock; and
- limiting the liability of, and providing indemnification to, our directors and officers.

As a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock from engaging in certain business combinations with us. Any provision of our amended and restated certificate of incorporation, amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Additionally, on November 5, 2021, we adopted an amended and restated stockholder rights plan that would cause substantial dilution to, and substantially increase the costs paid by, a stockholder who attempts to acquire us on terms not approved by our board. The intent of the stockholder rights plan is to protect our stockholders' interests by encouraging anyone seeking control of our Company to negotiate with our board. However, our stockholder rights plan could make it more difficult for a third party to acquire us without the consent of our board, even if doing so may be beneficial to our stockholders. This plan may discourage, delay or prevent a tender offer or takeover attempt, including offers or attempts that could result in a premium over the market price of our common stock. This plan could reduce the price that stockholders might be willing to pay for shares of our common stock in the future. Furthermore, the anti-takeover provisions of our stockholder rights plan may entrench management and make it more difficult to replace management even if the stockholders consider it beneficial to do so.

The common warrants issued in the November 2019 Offering include a right to receive the Black Scholes value of the warrants in the event of a fundamental transaction, which payment would be senior to our common stock.

The common warrants issued in the November 2019 Offering provide that, in the event of a "fundamental transaction," including, among other things, a merger or consolidation of the Company or sale of all or substantially all of the Company's assets, the holders of such warrants have the option to require the Company to pay to such holders an amount of cash equal to the Black Scholes value of the warrants. Such amount would be payable prior to any payments to holders of our common stock. The payment of such amount could result in common stockholders and other warrant holders not receiving any consideration if we were to liquidate, dissolve or wind up, either voluntarily or involuntarily. In addition, the existence of such right may reduce the value of our common stock, make it harder for us to sell shares of common stock in offerings in the future, or prevent or delay a change of control.

We have no current plans to pay dividends on our common stock and investors must look solely to stock appreciation for a return on their investment in us.

We do not anticipate paying any cash dividends on our common stock in the foreseeable future. We currently intend to retain all future earnings to fund the development and growth of our business. Any payment of future dividends will be at the discretion of our board of directors and will depend on, among other things, our earnings, financial condition, capital requirements, level of indebtedness, statutory and contractual restrictions applying to the payment of dividends and other considerations that the board of directors deems relevant. Investors may need to rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize a return on their investment. Investors seeking cash dividends should not purchase our common stock.

Our management and directors will be able to exert influence over our affairs.

As of December 31, 2021, our executive officers and directors beneficially owned approximately 5.3% of our common stock. These stockholders, if they act together, may be able to influence our management and affairs and all matters requiring stockholder approval, including significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control and might affect the market price of our common stock.

The market price of our common stock has been volatile over the past year and may continue to be volatile.

The market price and trading volume of our common stock has been volatile over the past year, and it may continue to be volatile. During 2021, our common stock has traded as low as $0.994 and as high as $2.28 per share. We cannot predict the price at which our common stock will trade in the future, and it may decline. The price at which our common stock trades may fluctuate significantly and may be influenced by many factors, including our financial results; developments generally affecting our industry; general economic, industry and market conditions; the depth and liquidity of the market for our common stock; investor perceptions of our business; reports by industry analysts; announcements by other market participants, including, among others, investors, our competitors, and our customers; regulatory action affecting our business; and the impact of other "Risk Factors" discussed herein and in our Annual Report. In addition, changes in the trading price of our common stock may be inconsistent with our operating results and outlook. The volatility of the market price of our common stock may adversely affect investors' ability to purchase or sell shares of our common stock.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. We currently only have limited securities and industry analysts providing research coverage of our Company and may never obtain additional research coverage by securities and industry analysts. If no additional securities or industry analysts commence coverage of our Company or if current securities analyst coverage of our Company ceases, the trading price for our stock could be negatively impacted. If the analysts downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If analysts cease coverage of us or fail to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

Risks Relating to Our Financial Position and Capital Requirements

We will need substantial additional capital in the future. If additional capital is not available, we will have to delay, reduce or cease operations.

We will need to raise additional capital to continue to fund our operations. Our future capital requirements may be substantial and will depend on many factors including:

- current and future clinical trials for our product candidates, including for oral neuroactive steroids, LPCN 1148 and LPCN 1144;
- regulatory actions of the FDA;
- the scope, size, rate of progress, results and costs of completing ongoing clinical trials and development plans with our product candidates;
- the cost, timing and outcomes of our efforts to obtain marketing approval for our product candidates in the United States;
- payments received under any current or future license agreements, strategic partnerships or collaborations;
- the cost of filing, prosecuting and enforcing patent claims;
- the costs associated with commercializing our product candidates if we receive marketing approval, including the cost and timing of developing internal sales and marketing capabilities or entering into strategic collaborations to market and sell our products;
- the costs of on-going and future litigation;
- covenants in the Securities Purchase Agreements entered into in the February 2020 Offering and the November 2019 Offering restricting our ability to enter into variable rate transactions; and
- funding additional product line expansions.

We believe that our existing capital resources, together with interest thereon, will be sufficient to meet our projected operating requirements through at least March 31, 2023. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. While we believe we have sufficient liquidity and capital resources to fund our projected operating requirements through at least March 31, 2023, we will need to raise additional capital at some point through the equity or debt markets or through out-licensing activities, either before or after March 31, 2023, to support our operations, on-going clinical study for LPCN 1148, on-going litigation, and compliance with regulatory requirements. If the Company is unsuccessful in raising additional capital, its ability to continue as a going concern will become a risk. Further, our operating plan may change, and we may need additional funds to meet operational needs and capital requirements for product development, regulatory compliance, and clinical trial activities sooner than planned. In addition, our capital resources may be consumed more rapidly if we pursue additional clinical studies for our oral neuroactive steroids, LPCN 1148, LPCN 1111, LPCN 1144, and LPCN 1107. Conversely, our capital resources could last longer if we reduce expenses, reduce the number of activities currently contemplated under our operating plan or if we terminate or suspend on-going clinical studies.

Funding may not be available to us on favorable terms, or at all. Also, market conditions and the number of authorized shares we have available may prevent us from accessing the debt and equity capital markets, including sales of our common stock through the ATM Offering (as defined below). If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend one or more of our clinical studies, research and development programs or, if any of our product candidates receive approval from the FDA, commercialization efforts. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, including the ATM Offering, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. These arrangements may not be available to us or available on terms favorable to us. To the extent that we raise additional capital through marketing and distribution arrangements, other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences, warrants or other terms that adversely affect our stockholders' rights or further complicate raising additional capital in the future. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable, for any reason, to raise needed capital, we will have to reduce costs, delay research and development programs, liquidate assets, dispose of rights, commercialize products or product candidates earlier than planned or on less favorable terms than desired, or reduce or cease operations.

Our loan agreement contains covenants which may adversely impact our business; the failure to comply with such covenants could cause our outstanding debt to become immediately payable.

On January 5, 2018, we entered into a Loan and Security Agreement (the "Loan and Security Agreement") with Silicon Valley Bank ("SVB") pursuant to which SVB lent us $10.0 million. The principal borrowed under the Loan and Security Agreement bears interest at a rate equal to the Prime Rate plus one percent per annum, which interest is payable monthly. The loan matures on June 1, 2022. In addition, as TLANDO was not approved by the FDA by May 31, 2018, we were required to maintain $5.0 million of cash collateral at SVB until such time as TLANDO's approval by the FDA. However, on February 16, 2021, we and SVB amended the Loan and Security Agreement to, among other things, remove the financial trigger and financial trigger release event provisions requiring us to maintain a minimum cash collateral value and collateral pledge thereof. The Loan Agreement includes a number of restrictive covenants, including restrictions on incurring additional debt, transactions with affiliates, disposing of property, business combinations or acquisitions, paying dividends and making other distributions or payments on our capital stock, subject to limited exceptions. Collectively, these covenants could constrain our ability to grow our business through acquisitions or engage in other transactions. In addition, the Loan Agreement includes covenants requiring, among other things, that we provide financial statements, comply with all laws, pay all taxes and maintain insurance. If we are not able to comply with these covenants, the amounts outstanding under the Loan Agreement could become immediately due and payable and could have a material adverse effect on our liquidity, financial condition, operating results, business, and prospects and cause the price of our common stock to decline.

We may be unable to generate sufficient cash flow to satisfy our significant debt service obligations, which would adversely affect our financial condition and results of operations.

Our ability to make principal and interest payments on and to refinance our indebtedness will depend on our ability to generate cash in the future. This, to a certain extent, is subject to general economic, financial, competitive, legislative, regulatory and other factors that are beyond our control. If our business does not generate sufficient cash flow from operations, in the amounts projected or at all, or if future borrowings are not available to us under our variable funding notes in amounts sufficient to fund our other liquidity needs, our financial condition and results of operations may be adversely affected. If we cannot generate sufficient cash flow from operations to make scheduled principal amortization and interest payments on our debt obligations in the future, we may need to refinance all or a portion of our indebtedness on or before maturity, sell assets, delay capital expenditures or seek additional equity. If we are unable to refinance any of our indebtedness on commercially reasonable terms, or at all, or to affect any other action relating to our indebtedness on satisfactory terms, or at all, our business may be harmed.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations, or require us to relinquish rights.

We may seek additional capital through a combination of private and public equity offerings, debt financings collaborations and strategic and licensing arrangements. To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, current stockholders' ownership interest in the Company will be diluted. In addition, the terms may include liquidation or other preferences that materially adversely affect their rights as a stockholder. Debt financing, if available, would increase our fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration, strategic alliance and licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, our intellectual property, future revenue streams or grant licenses on terms that are not favorable to us.

We cannot predict when we will generate product revenues and may never achieve or maintain profitability.

Our ability to become profitable depends upon our ability to generate revenue from product sales and/or licensing agreements. To date, we have not generated any revenue from product sales of TLANDO or our other drug candidates in the current pipeline, and we do not know when, or if, we will generate any revenue from product sales. We do not expect to generate significant revenue unless or until we obtain marketing approval of, and begin to sell, any of our product candidates. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- obtain U.S. and foreign marketing approval for our product candidates;
- commercialize our product candidates by developing a sales force and/or entering into licensing agreements or collaborations with partners/third parties, either before or after obtaining marketing approval for our product candidates; and
- achieve market acceptance of our product candidates in the medical community and with third-party payors.

Even if our product candidates are approved for commercial sale, we expect to incur significant costs as we prepare to commercialize them. Even if we receive FDA approval for our product candidates, they may not be commercially successful drugs. We may not achieve profitability soon after generating product sales, if ever. If we are unable to generate product revenue, we will not become profitable and may be unable to continue operations without continued funding.

Accordingly, the likelihood of our success must be evaluated in light of many potential challenges and variables associated with an early-stage drug development company, many of which are outside of our control, and past operating or financial results should not be relied on as an indication of future results. If one or more of our product candidates is approved for commercial sale and we retain commercial rights, we anticipate incurring significant costs associated with commercializing any such approved product candidate. Therefore, even if we are able to generate revenues from the sale of any approved product, we may never become profitable. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to predict the timing or amount of expenses and when we will be able to achieve or maintain profitability, if ever.

We have incurred significant operating losses in most years since our inception and anticipate that we will incur continued losses for the foreseeable future.

We have focused a significant portion of our efforts on developing TLANDO and more recently on our oral neuroactive steroids, LPCN 1148, and LPCN 1144. We have funded our operations to date through sales of our equity securities, debt, and payments received under our license and collaboration arrangements. We have incurred losses in most years since our inception. As of December 31, 2021, we had an accumulated deficit of $172.7 million. Substantially all of our operating losses resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. These losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital. We expect our research and development expenses to significantly increase in connection with clinical trials associated with our oral neuroactive steroids, LPCN 1148, LPCN 1111, LPCN 1144, and LPCN 1107, if initiated. As a result, we expect to continue to incur significant operating losses for the foreseeable future as we evaluate further clinical development of our oral neuroactive steroids, LPCN 1148, LPCN 1111, LPCN 1144, and LPCN 1107 and our other programs and continued research efforts. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

Our operating results may fluctuate significantly, and any failure to meet financial expectations may disappoint securities analysts or investors and result in a decline in the price of our securities.

We have a history of operating losses. Our operating results have fluctuated in the past and are likely to do so in the future. These fluctuations could cause our share price to decline. Due to fluctuations in our operating results, we believe that period-to-period comparisons of our results are not indicative of our future performance. It is possible that in some future quarter or quarters, our operating results will be above or below the expectations of securities analysts or investors. In this case, the price of our securities could decline.

We have limited shares available for issuance to raise capital to fund our operations and grant stock-based incentive awards to employees, directors, and consultants. If we are unable to increase the number of shares of common stock available for issuance, our business will be adversely affected.

Currently, we have 100,000,000 authorized shares of common stock. As of March 07, 2022, we had 88,290,650 shares of common stock outstanding. After taking into account the 4,438,013 shares reserved for issuance upon the exercise of outstanding options and 1,934,366 reserved for issuance upon the exercise of outstanding warrants, as of March 07, 2022, we have a limited number of shares available for issuance. If we are not able to obtain shareholder approval to increase the number of shares of common stock available for issuance, including, for example, through an amendment to our certificate of incorporation or a reverse stock split, we will have limited shares available for issuance to raise capital to fund our operations, make grants of stock-based incentive awards, or take such other actions requiring available capital stock needed to operate our business. Delays in securing, or the failure to secure, shareholder approval of such actions, if needed, may prevent us from executing a capital raising transaction, which may have a material adverse effect on our business and financial condition.

Risks Relating to Our Intellectual Property

Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

Our commercial success will depend in large part on obtaining and maintaining patent, trademark and trade secret protection of our product candidates, their respective formulations, methods used to manufacture them and methods of treatment, as well as successfully defending these patents against third party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell, or importing our product candidates, once commercialized, is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

The patent positions of pharmaceutical, biopharmaceutical and related companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in patents in these fields has emerged to date in the United States. There have been changes regarding how patent laws are interpreted, and both the United States Patent and Trademark Office (“PTO”) and Congress have enacted radical changes to the patent system. We cannot accurately predict future changes in the interpretation of patent laws or changes to patent laws which might be enacted into law. Those changes may materially affect our patents, our ability to obtain patents and/or the patents and applications of our collaborators and licensors. The patent situation in these fields outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in the patents we own or which we license or third-party patents.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep a competitive advantage. For example:

- others may be able to make or use compounds that are the same or similar to the pharmaceutical compounds used in our product candidates but that are not covered by the claims of our patents;
- the Active Pharmaceutical Ingredients (“APIs”) in our licensed product TLANDO and current product candidates LPCN 1144 and LPCN 1107 are, or may soon become, commercially available in generic drug products, and no patent protection may be available without regard to formulation or method of use;
- we may not be able to detect infringement against our owned or licensed patents, which may be especially difficult for manufacturing processes or formulation patents;
- we might not have been the first to make the inventions covered by our issued patents or pending patent applications or those we license;
- we might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our pending patent applications or those of our licensor will not result in issued patents;

- it is possible that there are dominating patents to any of our product candidates of which we are not aware;
- it is possible that there are prior public disclosures that could invalidate our patents, or parts of our patents, of which we are not aware;
- it is possible that others may circumvent our owned or licensed patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;
- the laws of foreign countries may not protect our proprietary rights to the same extent as the laws of the United States;
- the claims of our owned or licensed issued patents or patent applications, if and when issued, may not cover our product candidates;
- our issued patents or those of our licensor may not provide us with any competitive advantages, or may be narrowed in scope, be held invalid or unenforceable as a result of legal challenges by third parties;
- our licensor or licensees as the case may be, who have access to our patents, may attempt to enforce our owned or licensed patents, which if unsuccessful, may result in narrower scope of protection of our owned or licensed patents or our owned or licensed patents becoming invalid or unenforceable;
- we may not develop additional proprietary technologies for which we can obtain patent protection; or
- the patents of others may have an adverse effect on our business.

We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect, and we have limited control over the protection of trade secrets used by our collaborators and suppliers. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods, and know-how. If our confidential or proprietary information is divulged to or acquired by third parties, including our competitors, our competitive position in the marketplace will be harmed and our ability to successfully penetrate our target markets could be severely compromised.

If any of our owned or licensed patents are found to be invalid or unenforceable, or if we are otherwise unable to adequately protect our rights, it could have a material adverse impact on our business and our ability to commercialize or license our technology and products. Additionally, we currently do not have patent protection for our product candidates in many countries, including large territories such as India, Russia, and China, and we will be unable to prevent patent infringement in those countries unless we can file patent applications and obtain patents in those countries that cover our product candidates. Likewise, our United States patents covering certain technology used in our product candidates, including TLANDO, are expected to expire on various dates from 2023 through 2037. Upon the expiration of these patents, we will lose the right to exclude others from practicing these inventions to the extent that at those times we have no additional issued patents to protect our product candidates, including TLANDO. Additionally, if these are our only patents listed in the FDA Orange Book, should we have an FDA-approved and marketed product at that time, their expiration will mean that we lose certain advantages that come with Orange Book listing of patents. The expiration of these patents could also have a similar material adverse effect on our business, results of operations, financial condition and prospects. Moreover, if we are unable to commence or continue any action relating to the defense of our patents, we may be unable to protect our product candidates.

If we do not obtain additional protection under the Drug Price Competition and Patent Term Restoration Act and similar foreign legislation by extending the patent terms and obtaining data exclusivity for our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or competitor's prior product launch or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our ability to generate revenues could be materially adversely affected.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights, and we may be unable to protect our rights to our products and technology.

If we or our collaborators choose to go to court to stop a third party from using the inventions claimed in our owned or licensed patents, that third party may ask a court to rule that the patents are invalid and should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources, including financial resources, even if we were successful in stopping the infringement of these patents. In addition, there is a risk that a court will decide that these patents are not valid or not enforceable and that we do not have the right to stop others from using the inventions.

There is also the risk that, even if the validity of these patents is not challenged or is upheld, the court will refuse to stop the third party on the ground that such third-party's activities do not infringe on our owned or licensed patents. In addition, the U.S. Supreme Court has changed some standards relating to the granting of patents and assessing the validity of patents. As a consequence, issued patents may be found to contain invalid claims according to the newly revised standards. Some of our owned or licensed patents may be subject to challenge and subsequent invalidation or significant narrowing of claim scope in a reexamination or other proceeding before the USPTO, or during litigation, under the revised criteria which make it more difficult to obtain or maintain patents.

While our in-licensed patents and applications are not currently used in our product candidates, should we develop other product candidates that are covered by this intellectual property, we will rely on our licensor to file and prosecute patent applications and maintain patents and otherwise protect the intellectual property we license from them. Our licensor has retained the first right, but not the obligation, to initiate an infringement proceeding against a third-party infringer of the intellectual property licensed to us, and enforcement of our in-licensed patents or defense of any claims asserting the invalidity or unenforceability of these patents would also be subject to the control or cooperation of our licensor. It is possible that our licensor's defense activities may be less vigorous than had we conducted the defense ourselves.

We also license our patent portfolio, including U.S. and foreign patents and patent applications that cover TLANDO and our other product candidates, to third parties for their respective products and product candidates. Under our agreements with our licensees, we have the right, but not the obligation, to enforce our current and future licensed patents against infringers of our licensees. In certain cases, our licensees may have primary enforcement rights and we have the obligation to cooperate. In the event of an enforcement action against infringers of our licensees, our licensees might not have the interest or resources to successfully preserve the patents, the infringers may countersue, and as a result our patents may be found invalid or unenforceable or of a narrower scope of coverage and leave us with no patent protection for TLANDO and our other product candidates.

We may be subject to a third-party pre-issuance submission of prior art to the PTO, or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our owned or licensed patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our owned or licensed patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates and impair our ability to raise needed capital.

If we are required to defend patent infringement actions brought by other third parties, or if we sue to protect our own patent rights or otherwise to protect our proprietary information and to prevent its disclosure, we may be required to pay substantial litigation costs and managerial attention and financial resources may be diverted from business operations even if the outcome is in our favor.

If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields relating to our product candidates. As the biotechnology, pharmaceutical, and related industries expand and more patents are issued, the risk increases that others may assert that our product or product candidates infringe the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their formulations or methods of use. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product, product candidates, technology, or methods. For example, on November 2, 2015, Clarus filed a complaint against us in the United States District Court for the District of Delaware alleging that TLANDO will infringe the Clarus 428 Patent, and the complaint sought damages, declaratory and injunctive relief. On October 6, 2016, United States District Court of the District of Delaware granted our motion to dismiss the lawsuit filed by Clarus, because at the time there was no actionable infringement on Clarus' 428 patent.

In addition, there may be issued patents of third parties of which we are currently unaware, that are infringed or are alleged to be infringed by our product candidates or proprietary technologies. Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our or our licensor's issued patents or our pending applications, or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our owned or licensed patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to those owned or licensed by us, we may have to participate in an interference proceeding declared by the PTO to determine priority of invention in the United States. If another party has an allowed reason to question the validity of our owned or licensed U.S. patents, the third party can request that the PTO reexamine the patent claims, which may result in a loss of scope of some claims or a loss of the entire patent. In addition to potential infringement claims, interference and reexamination proceedings, we may become a party to patent opposition proceedings in the European Patent Office or post-grant proceedings in the United States where either our patents are challenged, or we are challenging the patents of others. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, for example if the other party had independently arrived at the same or similar invention prior to our invention, resulting in a loss of our U.S. patent position with respect to such inventions. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and/or proprietary technologies infringe their intellectual property rights. These lawsuits are costly and could adversely affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we or our commercialization partners are infringing the third party's patents and would order us or our partners to stop the activities covered by the patents. In addition, there is a risk that a court will order us or our partners to pay the other party damages for having violated the other party's patents.

If a third-party's patent was found to cover our product candidates, proprietary technologies or their uses, we or our collaborators could be enjoined by a court and required to pay damages and could be unable to commercialize any one or more of our product candidates or use our proprietary technologies unless we or they obtained a license to the patent. A license may not be available to us or our collaborators on acceptable terms, if at all. In addition, during litigation, the patent holder could obtain a preliminary injunction or other equitable relief which could prohibit us from making, using or selling our products, technologies or methods pending a trial on the merits, which could be years away.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology, pharmaceutical, and related industries generally. If a third-party claims that we or our collaborators infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product at issue infringes on or violates the third party's rights, and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from selling or licensing the product unless the third party licenses its product rights to us, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and/or grant cross-licenses to intellectual property rights for our products; and
- redesigning our products or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or otherwise have a material adverse effect on our business, results of operations, financial condition, and prospects.

Although we own worldwide rights to our product candidates, we do not have patent protection for the product candidates in a significant number of countries, and we will be unable to prevent infringement in those countries.

Our patent portfolio related to our product candidates includes patents in the United States and other foreign countries. The covered technology and the scope of coverage varies from country to country. For those countries where we do not have granted patents, we have no ability to prevent the unauthorized use of our intellectual property, and third parties in those countries may be able to make, use, or sell products identical to, or substantially similar to our product candidates.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on our owned or licensed patents are due to be paid to the PTO in several stages over the lifetime of the patents. Future maintenance fees will also need to be paid on other patents which may be issued to us. We have systems in place to remind us to pay these fees, and we employ outside firms to remind us to pay annuity fees due to foreign patent agencies on our pending foreign patent applications. We have even less control over our in-licensed patents and applications, for which our licensor retains responsibility. The PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

We also may rely on trade secrets and confidentiality agreements to protect our technology and know-how, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect, and we have limited control over the protection of trade secrets used by our collaborators and suppliers. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators, and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods, and know-how. If our confidential or proprietary information is divulged to or acquired by third parties, including our competitors, our competitive position in the marketplace will be harmed and our ability to successfully generate revenues from our product candidates, if approved by the FDA or other regulatory authorities, could be adversely affected.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology, pharmaceutical and related industries, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management, which would adversely affect our financial condition.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our corporate headquarters are located in a leased facility in Salt Lake City, Utah. Our lease expires on February 28, 2023. We believe that our existing facility is suitable and adequate and that we have sufficient capacity to meet our current anticipated needs.

ITEM 3. LEGAL PROCEEDINGS

On April 2, 2019, we filed a lawsuit against Clarus in the United States District Court for the District of Delaware alleging that Clarus's JATENZO® product infringes six of Lipocine's issued U.S. patents: 9,034,858; 9,205,057; 9,480,690; 9,757,390; 6,569,463; and 6,923,988. However, on February 11, 2020, we voluntarily dismissed allegations of patent infringement for expired U.S. Patent Nos. 6,569,463 and 6,923,988 in an effort to streamline the issues and associated costs for dispute. Clarus answered the complaint and asserted counterclaims of non-infringement and invalidity. We answered Clarus's counterclaims on April 29, 2019. The Court held a scheduling conference on August 15, 2019, a claim construction hearing on February 11, 2020, and a summary judgment hearing on January 15, 2021. In May 2021, the Court granted Clarus' motion for summary judgment, finding the asserted claims of Lipocine's U.S. patents 9,034,858; 9,205,057; 9,480,690; and 9,757,390 invalid for failure to satisfy the written description requirement of 35 U.S.C. § 112. Clarus still had remaining claims before the Court. On July 13, 2021, we entered into the Global Agreement with Clarus which resolved all outstanding claims of this litigation as well as the on-going United States Patent and Trademark Office ("USPTO") Interference No. 106,128 between the parties. Under the terms of the Global Agreement, Lipocine agreed to pay Clarus $4.0 million payable as follows: $2.5 million immediately, $1.0 million on July 13, 2022, and $500,000 on July 13, 2023. No future royalties are owing from either party. On July 15, 2021, the Court dismissed with prejudice Lipocine's claims and Clarus' counterclaims.

On November 14, 2019, we and certain of our officers were named as defendants in a purported shareholder class action lawsuit, *Solomon Abady v. Lipocine Inc. et al*., 2:19-cv-00906-PMW, filed in the United District Court for the District of Utah. The complaint alleges that the defendants made false and/or misleading statements and/or failed to disclose that our filing of the NDA for TLANDO to the FDA contained deficiencies and as a result the defendants' statements about our business and operations were false and misleading and/or lacked a reasonable basis in violation of federal securities laws. The lawsuit seeks certification as a class action (for a purported class of purchasers of the Company's securities from March 27, 2019, through November 8, 2019), compensatory damages in an unspecified amount, and unspecified equitable or injunctive relief. We have insurance that covers claims of this nature. The retention amount payable by us under our policy is $1.25 million. We filed a motion to dismiss this class action lawsuit on July 24, 2020. In response, the plaintiffs filed their response to the motion to dismiss the class action lawsuit on September 22, 2020, and we filed our reply to our motion to dismiss on October 22, 2020. A hearing on the motion to dismiss occurred on January 12, 2022. We intend to vigorously defend ourselves against these allegations and have not recorded a liability related to this shareholder class action lawsuit as the outcome is not probable nor can an estimate be made of loss, if any.

On March 13, 2020, we filed U.S. patent application serial number 16/818,779 (the "Lipocine '779 Application") with the USPTO. On October 16 and November 3, 2020, we filed suggestions for interference with the USPTO requesting that a patent interference be declared between the Lipocine '779 Application and US patent application serial number 16/656,178 to Clarus Therapeutics, Inc. (the "Clarus '178 Application"). Pursuant to our request, the Patent Trial and Appeal Board ("PTAB") at the USPTO declared the interference on January 4, 2021, to ultimately determine, as between us and Clarus, who is entitled to the claimed subject matter. The interference number is 106,128, and we were initially declared Senior Party. A conference call with the PTAB was held on January 25, 2021, to discuss proposed motions. On February 1, 2021, the PTAB issued an order authorizing certain motions and setting the schedule for the preliminary motions phase. On July 13, 2021, we entered into the Global Agreement with Clarus to resolve interference No. 106,128 among other items. On July 26, 2021, the PTAB granted our request for adverse judgment in interference No. 106,128 in accordance with the Global Agreement.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is quoted on The NASDAQ Capital Market under the symbol "LPCN".

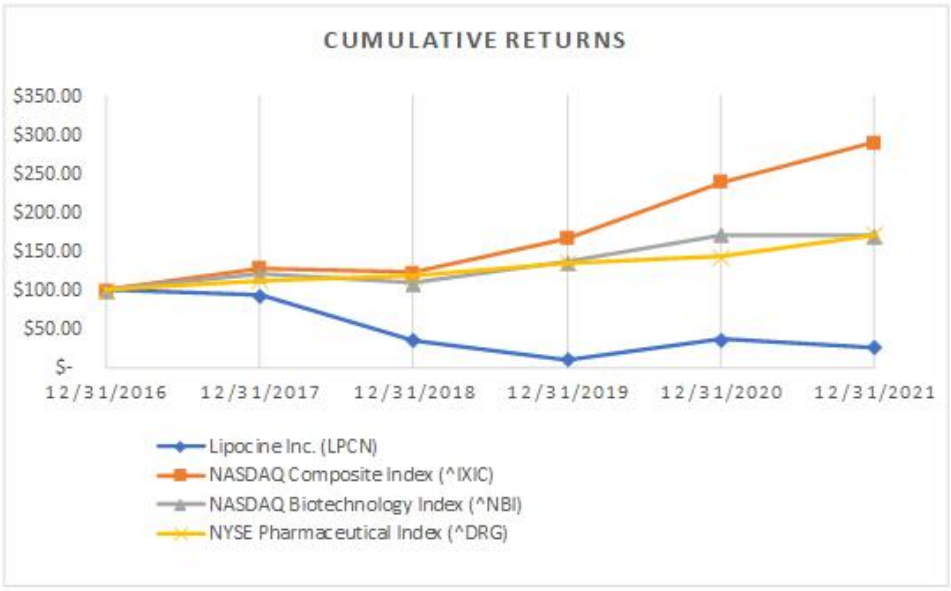
Holders

As of March 7, 2022, there were approximately 96 holders of record of our common stock. This number does not include an undetermined number of stockholders whose stock is held in "street" or "nominee" name.

Performance Graph and Table

The following graph shows a comparison from December 31, 2016 through December 31, 2021 of the cumulative total return for (i) our ordinary shares, (ii) the NASDAQ Composite Index, (iii) the NASDAQ Biotechnology Index and (iv) the NYSE Pharmaceutical Index.

The graph assumes an initial investment of $100 on December 31, 2016. The comparisons in the graph are required by the SEC and are not intended to forecast or be indicative of possible future performance of our ordinary shares.



Cumulative Returns

	12/31/2016	12/31/2017	12/31/2018	12/31/2019	12/31/2020	12/31/2021
Lipocine Inc. (LPCN)	$ 100.00	$ 93.48	$ 35.33	$ 10.46	$ 36.96	$ 26.93
NASDAQ Composite Index (^IXIC)	100.00	128.24	123.26	166.68	239.42	290.63
NASDAQ Biotechnology Index (^NBI)	100.00	121.06	109.77	136.56	171.64	170.55
NYSE Pharmaceutical Index (^DRG)	100.00	113.16	118.12	135.74	143.17	171.79

The foregoing graph and table are furnished solely with this report, and are not filed with this report, and shall not be deemed incorporated by reference into any other filing under the Securities Act of 1933, as amended, or the Securities Act, or the Securities Exchange Act of 1934, as amended, whether made by us before or after the date hereof, regardless of any general incorporation language in any such filing, except to the extent we specifically incorporate this material by reference into any such filing.

Dividends

We do not anticipate paying any cash dividends on our common stock in the foreseeable future. We intend to retain any future earnings to finance growth and development and therefore do not anticipate paying cash dividends in the foreseeable future.

ITEM 6. RESERVED

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

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the related notes thereto and other financial information included elsewhere in this report.

As used in the discussion below, "we," "our," and "us" refers to the historical financial results of Lipocine.

Forward Looking Statements

This section and other parts of this report contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that involve risks and uncertainties. Forward-looking statements provide current expectations of future events based on certain assumptions and include any statement that does not directly relate to any historical or current fact. Forward-looking statements may refer to such matters as products, product benefits, pre-clinical and clinical development timelines, clinical and regulatory expectations and plans, anticipated financial performance, future revenues or earnings, business prospects, projected ventures, new products and services, anticipated market performance, future expectations for liquidity and capital resources needs and similar matters. Such words as "may", "will", "expect", "continue", "estimate", "project", and "intend" and similar terms and expressions are intended to identify forward looking statements. Forward-looking statements are not guarantees of future performance and our actual results may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such differences include, but are not limited to, those discussed in Part I, Item 1A (Risk Factors) of this Form 10-K. Except as required by applicable law, we assume no obligation to revise or update any forward-looking statements for any reason.

Overview of Our Business

We are a clinical-stage biopharmaceutical company focused on applying our oral drug delivery technology for the development of pharmaceutical products focusing on neuroendocrine and metabolic disorders. Our proprietary delivery technologies are designed to improve patient compliance and safety through orally available treatment options. Our primary development programs are based on oral delivery solutions for poorly bioavailable drugs. We have a portfolio of differentiated innovative product candidates that target high unmet needs for neurological and psychiatric CNS disorders, liver diseases, and hormone supplementation for men and women.

We entered into a license agreement for the development and commercialization our product candidate, TLANDO®, an oral testosterone replacement therapy ("TRT") comprised of testosterone undecanoate ("TU"). TLANDO is a registered trademark assigned to Antares. On October 14, 2021, we entered into a license agreement (the "Antares License Agreement") with Antares Pharma, Inc. ("Antares" or our "Licensee"), pursuant to which we granted to Antares an exclusive, royalty-bearing, sublicensable right and license to develop and commercialize, upon final approval of TLANDO from the United States Food and Drug Administration ("FDA"), the TLANDO product for TRT in the U.S. Any FDA required post-marketing studies will also be the responsibility of our licensee, Antares. Prior to entering into the License Agreement, on December 8, 2020, we received tentative approval from the FDA regarding our new drug application ("NDA") filed in February 2020 for TLANDO as a TRT in adult males for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism. In granting tentative approval, the FDA concluded that TLANDO has met all required quality, safety and efficacy standards necessary for approval. However, TLANDO has not received final approval and is not eligible for final approval to market in the U.S. until the expiration of the exclusivity period previously granted to Clarus Therapeutics, Inc. ("Clarus") with respect to JATENZO®, which expires on March 27, 2022. The FDA has affirmed to Antares the acceptance of the resubmission of the NDA for TLANDO filed on January 28, 2022. The FDA has designated the NDA as a Class 1 resubmission with a two-month review goal period and set a target action date of March 28, 2022 under the Prescription Drug User Fee Act (PDUFA).

Additional pipeline candidates include: LPCN 1148 comprising a novel prodrug of testosterone, testosterone laurate ("TL"), for the management of decompensated cirrhosis; LPCN 1144, an oral prodrug of androgen receptor modulator for the treatment of non-cirrhotic non-alcoholic steatohepatitis ("NASH") which has completed phase 2 testing; LPCN 1111 (TLANDO® XR), a next generation oral TRT product comprised of testosterone tridecanoate ("TT") with the potential for once daily dosing which has completed Phase 2 testing; LPCN 1107, potentially the first oral hydroxy progesterone caproate ("HPC") product indicated for the prevention of recurrent preterm birth ("PTB"), which has completed a dose finding clinical study in pregnant women and has been granted orphan drug designation by the FDA; and neuroactive steroids ("NAS") including LPCN 1154 for postpartum depression (PPD) and LPCN 2101 for epilepsy.

To date, we have funded our operations primarily through the sale of equity securities, debt and convertible debt and through up-front payments, research funding and royalty and milestone payments from our license and collaboration arrangements. We have not generated any revenues from product sales and while we expect to generate royalties from our licensee's sales of TLANDO, we do not expect to generate revenue from product sales unless from our other product candidates unless and until approval.

We have incurred losses in most years since our inception. As of December 31, 2021, we had an accumulated deficit of $172.7 million. Income and losses fluctuate year to year, primarily depending on the nature and timing of research and development occurring on our product candidates. Our net loss was $634,000 for the year ended December 31, 2021, compared to $21.0 million for the year ended December 31, 2020. Substantially all of our operating losses resulted from expenses incurred in connection with our product candidate development programs, our research activities and general and administrative costs, including on-going litigation, associated with our operations.

We expect to continue to incur significant expenses and operating losses for the foreseeable future as we:

- conduct further development of our other product candidates, including LPCN 1148 and LPCN 1144;
- continue our research efforts;
- research new products or new uses for our existing products;
- maintain, expand and protect our intellectual property portfolio; and
- provide general and administrative support for our operations, including on-going litigation.

To fund future long-term operations, including the potential commercialization of any of our product candidates, we will need to raise additional capital. The amount and timing of future funding requirements will depend on many factors, including capital market conditions, regulatory requirements and outcomes related to TLANDO, regulatory requirements related to our other product development programs, the timing and results of our ongoing development efforts, the potential expansion of our current development programs, potential new development programs, our ability to license our products to third parties, the pursuit of various potential commercial activities and strategies associated with our development programs and related general and administrative support. We anticipate that we will seek to fund our operations through public or private equity or debt financings or other sources, such as potential license, partnering and collaboration agreements. We cannot be certain that anticipated additional financing will be available to us on favorable terms, in amounts sufficient to fund our operations, or at all. Although we have previously been successful in obtaining financing through public and private equity securities offerings and our license and collaboration agreements, there can be no assurance that we will be able to do so in the future.

Corporate Strategy

Our goal is to become a leading biopharmaceutical company focused on applying our proprietary drug delivery technology for the development of pharmaceutical products focusing on neuroendocrine and metabolic disorders. The key components of our strategy are to:

Build a diversified multi-asset pipeline of novel therapies. We intend to employ a value-driven strategy based on our proprietary technology platform to identify and develop product candidates for neuroendocrine and metabolic disorders including Central Nervous System (CNS) disorders and end stage diseases such as decompensated cirrhosis. We intend to focus on product candidates that we believe are differentiated, have attractive profiles, and address a clear unmet medical need that we can advance quickly and efficiently into late-stage development.

Advance LPCN 1148, a unique prodrug of androgen receptor agonist to manage end stage (decompensated) liver cirrhosis disease. We believe LPCN 1148, a novel prodrug of testosterone, could address a significant unmet medical need in patients with decompensated liver cirrhosis accompanied with muscle disorder such as secondary sarcopenia. Sarcopenia in male cirrhotic patients is known to be independently associated with poor outcomes including quality of life, increased decompensation events such as hepatic encephalopathy, increased hospital admissions, and increased mortality rate. We believe LPCN 1148 may be eligible for an orphan drug designation. Enrollment in a multi-center placebo-controlled phase 2 trial is currently ongoing.

Support our licensee in commercialization of our licensed oral TRT option. We believe the TRT market needs a differentiated, convenient oral option. We have exclusively licensed rights to TLANDO to Antares for commercialization of TLANDO in the US. We plan to support our licensee's efforts to effectively enable the availability of TLANDO to patients in a timely manner, in addition to receiving milestone and royalty payments associated with TLANDO commercialization as agreed to in the Antares License Agreement.

Develop partnership(s) to continue the advancement of pipeline assets. We continuously strive to prioritize our resources in seeking co-development partnerships of our pipeline assets. We currently plan to explore partnering of LPCN 1144, our candidate for treatment of non-cirrhotic NASH, LPCN 1107, our candidate for prevention of pre-term birth, and LPCN 1111, a once-a-day therapy candidate for TRT.

Financial Operations Overview

Revenue

To date, we have not generated any revenues from product sales and do not expect to do so until one of our product candidates receives approval from the FDA. Revenues to date have been generated substantially from license fees, royalty and milestone payments and research support from our licensees. Since our inception through December 31, 2021, we have generated $44.2 million in revenue under our various license and collaboration arrangements and from government grants. We have entered into the Antares license agreement with the potential for revenue from future milestones and royalties, but we may never generate revenues from any of our clinical or preclinical development programs or licensed products as we may never succeed in obtaining regulatory approval or commercializing any of these product candidates.

Research and Development Expenses

Research and development expenses consist primarily of salaries, benefits, stock-based compensation and related personnel costs, fees paid to external service providers such as contract research organizations and contract manufacturing organizations, contractual obligations for clinical development, clinical sites, manufacturing and scale-up for late-stage clinical trials, formulation of clinical drug supplies, and expenses associated with regulatory submissions. Research and development expenses also include an allocation of indirect costs, such as those for facilities, office expense, travel, and depreciation of equipment based on the ratio of direct labor hours for research and development personnel to total direct labor hours for all personnel. We expense research and development expenses as incurred. Since our inception, we have spent approximately $128.5 million in research and development expenses through December 31, 2021.

On December 8, 2020, we received tentative approval from the FDA regarding our NDA filed in February 2020 for TLANDO as a TRT in adult males for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism. In granting tentative approval, the FDA concluded that TLANDO has met all required quality, safety and efficacy standards necessary for approval. However, TLANDO has not received final approval and is not eligible for final approval to market in the U.S. until the expiration of the exclusivity period previously granted to Clarus with respect to JATENZO®, which expires on March 27, 2022. On October 14, 2021, we entered into the Antares License Agreement with Antares, pursuant to which we granted to Antares an exclusive, royalty-bearing, sublicensable right and license to develop and commercialize, upon final approval of TLANDO from the FDA, our TLANDO product with respect to TRT in the U.S. The Antares License Agreement also provides Antares with an option, exercisable on or before March 31, 2022, to license TLANDO XR. Under the terms of the Antares License Agreement, all future research and development activities for TLANDO will be conducted and paid for by Antares. Any further expenditures, if needed, are subject to numerous uncertainties regarding timing and cost to completion.

We expect to continue to incur significant costs as we develop our product candidates: ongoing phase 2 study with LPCN 1148, LPCN 1144, LPCN 1111, LPCN 1107 and NAS including LPCN 1154 and LPCN 2101.

In general, the cost of clinical trials may vary significantly over the life of a project as a result of uncertainties in clinical development, including, among others:

- the number of sites included in the trials;
- the length of time required to enroll suitable subjects;
- the duration of subject follow-ups;
- the length of time required to collect, analyze and report trial results;
- the cost, timing and outcome of regulatory review; and
- potential changes by the FDA in clinical trial and NDA filing requirements.

We have also incurred significant manufacturing costs to prepare launch supplies for TLANDO. However, any additional expenditures required to prepare for a commercial launch of TLANDO, should it be approved, will be paid by Antares.

Future research and development expenditures are subject to numerous uncertainties regarding timing and cost to completion, including, among others:

- the timing and outcome of regulatory filings and FDA reviews and actions for product candidates;
- our dependence on third-party manufacturers for the production of satisfactory finished product for registration and launch should regulatory approval be obtained on any of our product candidates;
- the potential for future license or co-promote arrangements for our product candidates, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our future plans and capital requirements; and
- the effect on our product development activities of actions taken by the FDA or other regulatory authorities.

A change of outcome for any of these variables with respect to our product development candidates could mean a substantial change in the costs and timing associated with these efforts, will require us to raise additional capital, and may require us to reduce operations.

Given the stage of clinical development and the significant risks and uncertainties inherent in the clinical development, manufacturing and regulatory approval process, we are unable to estimate with any certainty the time or cost to complete the development of LPCN 1148, LPCN 1144, LPCN 1111, LPCN 1107, NAS including LPCN 1154 and LPCN 2101 and other product candidates. Clinical development timelines, the probability of success and development costs can differ materially from expectations and results from our clinical trials may not be favorable. If we are successful in progressing NAS, LPCN 1148, LPCN 1111, LPCN 1144, LPCN 1107, or other product candidates into later stage development, we will require additional capital. The amount and timing of our future research and development expenses for these product candidates will depend on the preclinical and clinical success of both our current development activities and potential development of new product candidates, as well as ongoing assessments of the commercial potential of such activities.

Summary of Research and Development Expense

We are conducting on-going clinical and regulatory activities with most of our product candidates. Additionally, we incur costs for our other research programs. The following table summarizes our research and development expenses:

	Years Ended December 31,	
	2021	**2020**
External service provider costs:		
LPCN 1154	$ 1,499,837	$ -
LPCN 1148	891,647	-
TLANDO	116,419	1,192,532
LPCN 1111	97,119	72,515
LPCN 1144	1,693,397	5,331,092
LPCN 1107	468,467	8,860
Total external service provider costs	4,766,886	6,604,999
Internal personnel costs	2,157,218	2,354,530
Other research and development costs	741,455	788,940
Total research and development	$ 7,665,559	$ 9,748,469

We expect research and development expenses to increase in the future as we complete on-going clinical studies, including the *LiFT* Phase 2 OLE clinical study with LPCN 1144 and the Phase 2 study with LPCN 1148, and as we conduct future clinical studies with LPCN 1107 and our oral neuroactive steroids. However, if we are unable to raise additional capital, we may need to reduce research and development expenses in order to extend our ability to continue as a going concern.

Summary of General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation related to our executive, finance, business development, and support functions. Other general and administrative expenses include rent and utilities, travel expenses, professional fees for auditing, tax and legal services, litigation settlement and market research and market analytics.

General and administrative expenses also include expenses for the cost of preparing, filling and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims, including the patent interference and patent infringement lawsuits against Clarus.

We expect that general and administrative expenses will decrease in the future as we expect to incur decreased legal fees due to the global settlement agreement (“Global Agreement”) with Clarus. We expect that such decreases will be offset by other increases as we mature as a public company, including legal and consulting fees, accounting and audit fees, director fees, increased directors’ and officers’ insurance premiums, fees for investor relations services and enhanced business and accounting systems, litigation costs, professional fees and other costs. However, if we are unable to raise additional capital, we may need to further reduce general and administrative expenses in order to extend our ability to continue as a going concern.

Summary of Other Expense (Income), Net

Other expense (income), net consists primarily of interest income earned on our cash, cash equivalents and marketable investment securities and interest expense incurred on our outstanding Loan and Security Agreement and losses (gains) on our warrant liability.

Results of Operations

Comparison of the Years Ended December 31, 2021 and 2020

The following table summarizes our results of operations for the years ended December 31, 2021 and 2020:

	Years Ended December 31,		
	2021	**2020**	**Variance**
Revenue	$ 16,140,838	$ -	$ 16,140,838
Research and development expenses	7,665,559	9,748,469	(2,082,910)
General and administrative expenses	5,329,776	8,247,795	(2,918,019)
Interest and investment income	(67,700)	(75,650)	7,950
Interest expense	203,292	386,618	(183,326)
Unrealized (gain) loss on warrant liability	(355,890)	2,892,189	3,248,079
Litigation settlement	4,000,000	-	4,000,000
Gain on extinguishment of debt	-	(234,802)	234,802
Income tax expense	200	200	-

Revenue

We recognized license revenue of $16.1 million during the year ended December 31, 2021, compared to no license revenue during the year ended December 31, 2020. License revenue in 2021 primarily related to licensing fees, minimum royalties and the sale of finished goods inventory we received in accordance with the Antares Licensing Agreement for TLANDO which was signed on October 14, 2021. Additionally, we recognized $55,000 in license revenue in 2021 related to payments received from Spriaso under a licensing agreement in the cough and cold field.

Research and Development Expenses

We recorded research and development expenses of $7.7 million and $9.7 million, respectively, for the years ended December 31, 2021, and 2020. The decrease in research and development expenses during the year ended December 31, 2021 was primarily due to a $3.6 million decrease in contract research organization expense and outside consulting costs related to the LPCN 1144 *LiFT* Phase 2 clinical study in NASH subjects, a $1.1 million decrease in costs associated with TLANDO and a $197,000 net decrease in personnel expense which was mainly due to a decrease in bonus and stock compensation expense offset by increases in salaries partially due to headcount increases, as well as decreases in other R&D expenses of 37,000. These decreases were offset by a $1.5 million increase in costs related to LPCN 1154, a $892,000 increase in costs associated with LPCN 1148 and a $460,000 increase in costs for LPCN 1107.

General and Administrative Expenses

We recorded general and administrative expenses of $5.3 million and $8.2 million, respectively, for the years ended December 31, 2021, and 2020. The decrease in general and administrative expenses during the year ended December 31, 2021 was primarily due to a $2.5 million decrease in legal costs in 2021 as compared to 2020 relating to a decrease in the following legal activities: lawsuit filed against Clarus Therapeutics Inc. for patent infringement in April 2019 and the on-going class action lawsuit defense; and, a decrease of $584,000 in personnel costs mainly due a reduction in bonus and stock compensation expense. These decreases were offset by a $153,000 increase in corporate insurance expenses and a $10,000 increase in other general and administrative expenses.

Interest and Investment Income

The decrease in interest and investment income during the year ended December 31, 2021 was due to lower interest rates in 2021 compared to 2020, despite higher cash and marketable investment securities balances.

Interest Expense

The decrease in interest expense during the year ended December 31, 2021 is due to a decrease in interest expense on our Loan and Security Agreement with SVB, mainly as a result of lower principal balances in 2021 compared to 2020.

Unrealized Loss (Gain) on Warrant Liability

We recorded a $356,000 gain and a $2.9 million loss, respectively, on warrant liability during the years ended December 31, 2021 and 2020 related to the change in the fair value of outstanding common stock warrants issued in the November 2019 Offering. The gain in 2021 was attributable to a decrease in the value of warrants outstanding as of December 31, 2021 as compared to December 31, 2020 due to a small decrease in the number of warrants outstanding, a decrease in our stock price, and a shorter term remaining on the outstanding warrants. The loss in 2020 was mainly attributable to an increase in the value of both warrants exercised during the year and warrants outstanding as of December 31, 2020 as compared to December 31, 2019 due to an increase in our stock price. There were 10,000 and 10,895,970 common stock warrants from the November 2019 Offering exercised during 2021 and 2020, respectively. The warrants are classified as a liability due to a provision contained within the warrant agreement which allows the warrant holder the option to elect to receive an amount of cash equal to the value of the warrants as determined in accordance with the Black-Scholes option pricing model with certain defined assumptions upon a change of control. The warrant liability will continue to fluctuate in the future based on inputs to the Black-Scholes model including our current stock price, the remaining life of the warrants, the volatility of our stock price, the risk-free interest rate and the number of common stock warrants outstanding.

Litigation Settlement

We recorded an expense of $4.0 million and zero, respectively, on litigation settlement during 2021 and 2020 related to the Global Agreement with Clarus to resolve all outstanding claims in the on-going intellectual property litigation between the two companies as well as the on-going interference proceeding between the two companies. Under the terms of the settlement, we agreed to pay Clarus $4.0 million payable as follows: $2.5 million immediately, $1.0 million on July 13, 2022 and $500,000 on July 13, 2023. No future royalties are owing from either party. Under the terms of the Global Agreement, Lipocine and Clarus have agreed to dismiss the Lipocine Inc. v Clarus Therapeutics, Inc., No 19-cv-622 (WCB) litigation presently pending in the U.S. District Court for the District of Delaware. Also, both parties have reached an agreement on the interference proceedings captioned Clarus Therapeutics, Inc. v. Lipocine Inc., Interference No. 106,128 presently pending in the U.S. Patent and Trademark Office.

Liquidity and Capital Resources

Since our inception, our operations have been primarily financed through sales of our equity securities, debt and payments received under our license and collaboration arrangements. We have devoted our resources to funding research and development programs, including discovery research, preclinical and clinical development activities. We have incurred operating losses in most years since our inception and we expect to continue to incur operating losses into the foreseeable future as we advance clinical development of LPCN 1111, LPCN 1144, LPCN 1148, LPCN 1107, oral neuroactive steriods and any other product candidate, including continued research efforts.

As of December 31, 2021, we had $46.6 million of unrestricted cash, cash equivalents and marketable investment securities compared to $19.7 million at December 31, 2020. Additionally, as of December 31, 2020 we had $5.0 million of restricted cash, which was required to be maintained as cash collateral under the SVB Loan and Security Agreement until TLANDO is approved by the FDA. However, on February 16, 2021, we amended the Loan and Security Agreement with SVB to, among other things, remove the cash collateral requirement.

On October 14, 2021, we entered into the Antares License Agreement with Antares, pursuant to which we granted to Antares an exclusive, royalty-bearing, sublicensable right and license to develop and commercialize, upon final approval of TLANDO from the FDA, our TLANDO product with respect to TRT in the U.S. The Antares License Agreement also provides Antares with an option, exercisable on or before March 31, 2022, to license TLANDO XR. Upon execution of the Antares License Agreement, Antares paid to us an initial payment of $11.0 million. Antares has also agreed to make certain minimum royalty payments in the future and, since these future minimum royalties are variable consideration deemed to be probable, $4 million in revenue has been recognized in 2021 for the minimum royalties to be received in the future. In addition, Antares agreed to purchase finished goods manufactured by Lipocine in anticipation of commercial scale-up for approximately $1 million. Antares will also make additional payments of $5.0 million to us on each of January 1, 2025 and January 1, 2026, provided that certain conditions are satisfied. We are also eligible to receive milestone payments of up to $160.0 million in the aggregate, depending on the achievement of certain sales milestones in a single calendar year with respect to all products licensed by Antares under the Antares License Agreement. In addition, upon commercialization, we will receive tiered royalty payments at rates ranging from percentages in the mid-teens to up to 20% of net sales of TLANDO in the United States, subject to certain minimum royalty obligations. If Antares exercises its option to license TLANDO XR, we will be entitled to an additional payment of $4.0 million, as well as development milestone payments of up to $35.0 million in the aggregate and tiered royalty payments at rates ranging from percentages in the mid-teens to 20% of net sales of TLANDO XR in the United States. Our ability to realize benefits from the Antares License Agreement, including milestone and royalty payments, is subject to a number of risks. We may not realize milestone or royalty payments in anticipated amounts, or at all.

On January 28, 2021, we completed a public offering of securities registered under an effective registration statement filed pursuant to the Securities Act of 1933, as amended ("January 2021 Offering"). The gross proceeds from the January 2021 Offering were approximately $28.7 million, before deducting underwriter fees and other offering expenses of $1.9 million. In the January 2021 Offering, we sold 16,428,571 shares of our common stock.

On April 21, 2020, we entered into a loan (the "Loan") from SVB in the aggregate amount of $234,000, pursuant to the Paycheck Protection Program (the "PPP") under Division A, Title I of the CARES Act, which was enacted March 27, 2020. The Loan, which was in the form of a note dated April 21, 2020, originally matured on April 21, 2022, and bears interest at a rate of 1.0% per annum, payable monthly commencing on November 21, 2020. Under the terms of the PPP, certain amounts of the Loan may be forgiven if they are used for qualifying expenses as described in the CARES Act. On November 2, 2020, we were notified by the Small Business Administration that our PPP Loan had been forgiven.

On February 27, 2020, we completed a registered direct offering of securities registered under an effective registration statement filed pursuant to the Securities Act of 1933, as amended ("February 2020 Offering"). The gross proceeds from the February 2020 Offering were approximately $6.0 million, before deducting placement agent fees and other offering expenses of $347,000. In the February 2020 Offering, the Company sold 10,084,034 Class A Units, with each Class A Unit consisting of one share of common stock and a one-half of one common warrant to purchase one share of common stock, at a price of $0.595 per Class A Unit. The common stock warrants were immediately exercisable at an exercise price of $0.53 per share, subject to adjustment, and expire on February 27, 2025. By their terms, however, the common stock warrants cannot be exercised at any time that the common stock warrant holder would beneficially own, after such exercise, more than 4.99% (or, at the election of the holder, 9.99%) of the shares of common stock then outstanding after giving effect to such exercise.

On January 5, 2018, we entered into the Loan and Security Agreement with SVB pursuant to which SVB agreed to lend us $10.0 million. The principal borrowed under the Loan and Security Agreement bears interest at a rate equal to the Prime Rate, as reported in money rates section of The Wall Street Journal or any successor publication representing the rate of interest per annum then in effect, plus one percent per annum, which interest is payable monthly. Additionally on April 1, 2020, we entered into a Deferral Agreement with SVB. Under the Deferral Agreement, principal repayments were deferred by six months and we were only required to make monthly interest payments during the deferral period. The Loan matures on June 1, 2022. Previously, we were only required to make monthly interest payments until December 31, 2018, following which we also made equal monthly payments of principal and interest until the signing of the Deferral Agreement. We will also be required to pay an additional final payment at maturity equal to $650,000 (the "Final Payment Charge"). At our option, we may prepay all amounts owed under the Loan and Security Agreement (including all accrued and unpaid interest and the Final Payment Charge). In connection with the Loan and Security Agreement, we granted to SVB a security interest in substantially all of our assets now owned or hereafter acquired, excluding intellectual property and certain other assets. In addition, as TLANDO was not approved by the FDA by May 31, 2018, we were required to maintain $5.0 million of cash collateral at SVB until such time as TLANDO is approved by the FDA. However, on February 16, 2021, we amended the Loan and Security Agreement with SVB to, among other things, remove the financial trigger and financial trigger release event provisions requiring us to maintain a minimum cash collateral value and collateral pledge thereof. While any amounts are outstanding under the Loan and Security Agreement, we are subject to a number of affirmative and negative covenants, including covenants regarding dispositions of property, business combinations or acquisitions, incurrence of additional indebtedness and transactions with affiliates, among other customary covenants. The credit facility also includes events of default, the occurrence and continuation of which could cause interest to be charged at the rate that is otherwise applicable plus 5.0% and would provide SVB, as collateral agent, with the right to exercise remedies against us and the collateral securing the credit facility, including foreclosure against the property securing the credit facilities, including our cash. These events of default include, among other things, any failure by us to pay principal or interest due under the credit facility, a breach of certain covenants under the credit facility, the Company's insolvency, a material adverse change, and one or more judgments against us in an amount greater than $100,000 individually or in the aggregate.

On March 6, 2017, we entered into the Sales Agreement with Cantor Fitzgerald & Co. ("Cantor") pursuant to which we may issue and sell, from time to time, shares of our common stock having an aggregate offering price of up to the amount we have registered on an effective registration statement pursuant to which the offering is being made. We currently have registered up to $50.0 million for sale under the Sales Agreement, pursuant to our Registration Statement on Form S-3 (File No. 333-250072) (the "Form S-3"), through Cantor as our sales agent. Cantor may sell our common stock by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) of the Securities Act of 1933, as amended, including sales made directly on or through the NASDAQ Capital Market or any other existing trade market for our common stock, in negotiated transactions at market prices prevailing at the time of sale or at prices related to prevailing market prices, or any other method permitted by law. Cantor uses its commercially reasonable efforts consistent with its normal trading and sales practices and applicable law and regulations to sell these shares. We pay Cantor 3.0% of the aggregate gross proceeds from each sale of shares under the Sales Agreement. We have also provided Cantor with customary indemnification rights.

The shares of our common stock sold under the Sales Agreement are sold and issued pursuant to our Form S-3, which was previously declared effective by the Securities and Exchange Commission, and the related prospectus and one or more prospectus supplements.

We are not obligated to make any sales of our common stock under the 2020 Sales Agreement. The offering of our common stock pursuant to the 2020 Sales Agreement will terminate upon the termination of the 2020 Sales Agreement as permitted therein. We and Cantor may each terminate the 2020 Sales Agreement at any time upon ten days' prior notice.

During the year ended December 31, 2021, we sold 1,811,238 shares of our common stock pursuant to our current Registration Statement on Form S-3 (File No. 333-250072), resulting in net proceeds of approximately $3.4 million under the sales agreement which is net of $112,000 in expenses consisting of commissions paid to Cantor in connection with these sales and other offering and accounting costs. As of December 31, 2021, we had $41.2 million available for sale under the Sales Agreement.

We believe that our existing capital resources, together with interest thereon, will be sufficient to meet our projected operating requirements through at least March 31, 2023 which include on-going clinical studies for LPCN 1148, LPCN 1154, LPCN 2101, and future clinical studies for LPCN 1144, LPCN 1107 and possible other oral neuroactive steroids, compliance with regulatory requirements, and satisfaction of our obligations under the settlement agreement with Clarus. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect if additional activities are performed by us including new clinical studies for LPCN 1111, LPCN 1144, LPCN 1148, LPCN 1107 and oral neuroactive steroids. While we believe we have sufficient liquidity and capital resources to fund our projected operating requirements through at least March 31, 2023, we will need to raise additional capital at some point through the equity or debt markets or through additional out-licensing activities, either before or after March 31, 2023, to support our operations. If we are unsuccessful in raising additional capital, our ability to continue as a going concern will be limited. Further, our operating plan may change, and we may need additional funds to meet operational needs and capital requirements for product development, regulatory compliance and clinical trial activities sooner than planned. In addition, our capital resources may be consumed more rapidly if we pursue additional clinical studies for LPCN 1111, LPCN 1144, LPCN 1148, LPCN 1107 and oral neuroactive steroids. Conversely, our capital resources could last longer if we reduce expenses, reduce the number of activities currently contemplated under our operating plan or if we terminate, modify or suspend on-going clinical studies. We can raise capital pursuant to the Sales Agreement but may choose not to issue common stock if our market price is too low to justify such sales in our discretion. In addition, we currently have 5,223,779 unissued and unreserved shares available for issuance at December 31, 2021. Without sufficient shares available for issuance, our ability to raise capital through sales of equity, including under the Sales Agreement, is limited. There are numerous risks and uncertainties associated with the development and, subject to approval by the FDA, commercialization of our product candidates. There are numerous risks and uncertainties impacting our ability to enter into collaborations with third parties to participate in the development and potential commercialization of our product candidates, and the potential benefits to us of such arrangements, including the Antares License Agreement. Licensees of our product candidates, including Antares, may not successfully commercialize our products and, as a result, we may not receive anticipated royalty or other payments under such arrangements. Additionally, TLANDO is not eligible for final FDA approval until March 28, 2022 and, therefore, we do not expect to receive any royalty or milestone payments until after such time, if any such payments will be received at all. We are unable to precisely estimate the amounts of increased capital outlays and operating expenditures associated with our anticipated or unanticipated clinical studies and ongoing development efforts. All of these factors affect our need for additional capital resources. To fund future operations, we will need to ultimately raise additional capital and our requirements will depend on many factors, including the following:

- the scope, rate of progress, results and cost of our clinical studies, preclinical testing and other related activities for all of our product candidates, including LPCN 1111, LPCN 1144, LPCN 1148, LPCN 1107 and oral neuroactive steriods;
- the cost of manufacturing clinical supplies, and establishing commercial supplies, of our product candidates and any products that we may develop;
- the cost and timing of establishing sales, marketing and distribution capabilities, if any;
- the terms and timing of any collaborative, licensing, settlement and other arrangements that we may establish;
- the number and characteristics of product candidates that we pursue;
- the cost, timing and outcomes of regulatory approvals;
- the timing, receipt and amount of sales, profit sharing or royalties, if any, from our potential products;
- the cost of preparing, filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the extent to which we acquire or invest in businesses, products or technologies, although we currently have no commitments or agreements relating to any of these types of transactions; and
- the extent to which we grow significantly in the number of employees or the scope of our operations.

Funding may not be available to us on favorable terms, or at all. Also, market conditions may prevent us from accessing the debt and equity capital markets, including sales of our common stock through the Sales Agreement. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend one or more of our clinical studies, research and development programs or, if any of our product candidates receive approval from the FDA, commercialization efforts. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, including the Sales Agreement, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. These arrangements may not be available to us or available on terms favorable to us. To the extent that we raise additional capital through marketing and distribution arrangements, other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences, warrants or other terms that adversely affect our stockholders' rights or further complicate raising additional capital in the future. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable, for any reason, to raise needed capital, we will have to reduce costs, delay research and development programs, liquidate assets, dispose of rights, commercialize products or product candidates earlier than planned or on less favorable terms than desired or reduce or cease operations.

Sources and Uses of Cash

The following table provides a summary of our cash flows for the years ended December 31, 2021 and 2020:

	Years ended December 31,	
	2021	**2020**
Cash used in operating activities	$ (4,411,303)	$ (15,303,098)
Cash provided by (used in) investing activities	(43,780,397)	3,892,703
Cash provided by financing activities	26,924,870	20,899,254

Net Cash Used in Operating Activities

During the year ended December 31, 2021 and 2020, net cash used in operating activities was $4.4 million and $15.3 million, respectively.

Net cash used in operating activities during 2021 and 2020 was primarily attributable to cash outlays to support on-going operations, including research and development expenses and general and administrative expenses. During 2021 and 2020, we were performing activities related to the LPCN 1144 *LiFT* Phase 2 paired biopsy clinical study. During 2021, we were also conducting a Phase 2 clinical trial with LPCN 1148 and we entered into the Global Agreement with Clarus. During 2020, we were also performing activities around the submission of the TLANDO NDA.

Net Cash Used In/Provided by Investing Activities

During the years ended December 31, 2021, net cash used in investing activities was $43.8 million compared to cash provided by investing activities in 2020 of $3.9 million.

Net cash used in investing activities during 2021 was primarily the result of purchasing marketable investment securities, net, of $43.8 million. Net cash provided by investing activities in 2020 was primarily the result of utilizing marketable securities, net, of $3.9 million. There were $8,000 and zero capital expenditures for the years ended December 31, 2021, and 2020, respectively.

Net Cash Provided by Financing Activities

During the years ended December 31, 2021, and 2020, net cash provided by financing activities was $26.9 million and $20.9 million, respectively.

Net cash provided by financing activities during 2021 was attributable to the net proceeds from the sale of 16,428,571 shares of common stock pursuant to January 2021 Offering resulting in net proceeds of $26.8 million and $3.4 million in proceeds from the sale of 1,811,238 shares of common stock pursuant to the Sales Agreement with Cantor, offset by $3.3 million in debt principal repayments under the SVB Loan and Security Agreement.

Net cash provided by financing activities during 2020 was primarily attributable to $9.0 million in proceeds from the sale of 6,576,300 shares of commons stock pursuant to the ATM Offering, $7.7 million in proceeds from the exercise of warrants, $5.7 million in proceeds from the sale of 10,084,034 shares of common stock pursuant to the February 2020 Offering and $234,000 in loan proceeds under the Payment Protection Program, offset by $1.7 million in debt principal repayments under the SVB Loan and Security Agreement.

Employee stock option exercises provided approximately $7,000 of cash during 2021 and there were no employee stock option exercises during 2020. Proceeds from the exercise of employee stock options vary from period to period based upon, among other factors, fluctuations in the market price of our common stock relative to the exercise price of such options.

Contractual Commitments and Contingencies

Long-Term Debt Obligations and Interest on Debt

On January 5, 2018, we entered into a Loan and Security Agreement with SVB pursuant to which SVB agreed to lend us $10.0 million. The principal borrowed under the Loan and Security Agreement bears interest at a rate equal to the Prime Rate plus one percent per annum, which interest is payable monthly. The loan matures on June 1, 2022 and we are required to make equal monthly payments of principal and interest for the remaining term of the loan beginning on November 1, 2020 although there was a principal deferment period of six months beginning on April 1, 2020 through October 31, 2020 due to COVID-19. We will also be required to pay the $650,000 Final Payment Charge at maturity.

Purchase Obligations

We enter into contracts and issue purchase orders in the normal course of business with clinical research organizations for clinical trials and clinical and commercial supply manufacturing and with vendors for preclinical research studies, research supplies and other services and products for operating purposes. These contracts generally provide for termination on notice and are cancellable obligations.

Operating Leases

In August 2004, we entered into an agreement to lease our facility in Salt Lake City, Utah consisting of office and laboratory space which serves as our corporate headquarters. On January 24, 2022, we modified and extended the lease through February 28, 2023.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements which we have prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). In preparing our financial statements, we are required to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. We have identified the following accounting policies that we believe require application of management's most subjective judgments, often requiring the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. Our actual results could differ from these estimates and such differences could be material.

While our significant accounting policies are described in more detail in Note 2 of our annual financial statements included in this filing, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers (Topic 606)* with amendments in 2015 (ASU 2015-14) and 2016 (ASU 2016-8, ASU 2016-10, ASU 2016-12 and ASU 2016-20). The updated standard is a new comprehensive revenue recognition model that requires revenue to be recognized in a manner that depicts the transfer of goods or services to a customer at an amount that reflects the consideration expected to be received in exchange for those goods or services. The guidance also requires disclosures regarding the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. We adopted this pronouncement effective January 1, 2017. We recognized revenue of $16.1 million in 2021 under agreements with Antares Pharma, Inc. and Spriaso LLC, and no revenue in 2020.

We may provide research and development services under collaboration arrangements to advance the development of jointly owned products. We record the expenses incurred and reimbursed on a net basis in research and development expense.

As of December 31, 2021, we do not have any active collaboration agreements except for an agreement to provide joint research and development services through January 23, 2015. This agreement was assigned to Spriaso as is further described in Note 12 “Agreement with Spriaso, LLC” of this form 10-K.

Accrued Research and Development Expenses

We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on the facts and circumstances known to us at that time. Our expense accruals for contract research, contract manufacturing and other contract services are based on estimates of the fees associated with services provided by the contracting organizations. Payments under some of the contracts we have with such parties depend on factors such as successful enrollment of patients, site initiation and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If possible, we obtain information regarding unbilled services directly from these service providers. However, we may be required to estimate these services based on other information available to us. If we underestimate or overestimate the activity or fees associated with a study or service at a given point in time, adjustments to research and development expenses may be necessary in future periods. Subsequent changes in estimates may result in a material change in our accruals.

Stock-Based Compensation

We recognize stock-based compensation expense for grants of stock option awards, restricted stock units and restricted stock under our Incentive Plan to employees, nonemployees and nonemployee members of our board of directors based on the grant-date fair value of those awards. The grant-date fair value of an award is generally recognized as compensation expense over the award’s requisite service period. In addition, we have granted performance-based stock option awards and restricted stock grants, which vest based upon our satisfying certain performance conditions. Potential compensation cost, measured on the grant date, related to these performance options will be recognized only if, and when, we estimate that these options will vest, which is based on whether we consider the options’ performance conditions to be probable of attainment. Our estimates of the number of performance-based options that will vest will be revised, if necessary, in subsequent periods.

We use the Black-Scholes model to compute the estimated fair value of stock option awards. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of our common stock price, (ii) the periods of time over which employees and members of the board of directors are expected to hold their options prior to exercise (expected term), (iii) expected dividend yield on the common stock, and (iv) risk-free interest rates. Stock-based compensation expense also includes an estimate, which is made at the time of grant, of the number of awards that are expected to be forfeited. This estimate is revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

As of December 31, 2021, there was $1.4 million of total unrecognized compensation cost related to unvested share-based compensation arrangements granted under the Company’s stock option plan.

Warrant Liability

In connection with the November 2019 public offering, we issued warrants to purchase common stock. The warrants require us to pay such holders an amount of cash in the event of a fundamental transaction, as defined in the warrant agreement. As the cash payment is at the option of the warrant holder, we account for the common stock warrants as a liability, which is adjusted to fair value each reporting period as well as upon exercise of such warrants. The Company estimates the fair value of the warrant liability based on a hypothetical payout associated with a fundamental transaction. The fair value estimate utilizes a pricing model and unobservable inputs. Unlike the fair value of other assets and liabilities which are readily observable and therefore more easily independently corroborated, the warrants are not actively traded, and fair value is determined based on significant judgments regarding models, unobservable inputs and valuation methodologies.

As of December 31, 2021 and 2020, the warrant liability was $796,000 and $1.2 million, respectively.

Accounting Standards Issued Not Adopted

Refer to Note 13 in “Notes to Consolidated Financial Statements” for a discussion of new accounting standards.

Off-Balance Sheet Arrangements

None.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to various market risks, which include potential losses arising from adverse changes in market rates and prices, such as interest rates. We do not enter into derivatives or other financial instruments for trading or speculative purposes.

Interest Rate Risk. Our interest rate risk exposure results from our investment portfolio. Our primary objectives in managing our investment portfolio are to preserve principal, maintain proper liquidity to meet operating needs and maximize yields. The securities we hold in our investment portfolio are subject to interest rate risk. At any time, sharp changes in interest rates can affect the fair value of the investment portfolio and its interest earnings. After a review of our marketable investment securities, we believe that in the event of a hypothetical ten percent increase in interest rates, the resulting decrease in fair value of our marketable investment securities would be insignificant to the consolidated financial statements. Currently, we do not hedge these interest rate exposures. We have established policies and procedures to manage exposure to fluctuations in interest rates. We place our investments with high quality issuers and limit the amount of credit exposure to any one issuer and do not use derivative financial instruments in our investment portfolio. We invest in highly liquid, investment-grade securities and money market funds of various issues, types and maturities. These securities are classified as available-for-sale and, consequently, are recorded on the balance sheet at fair value with unrealized gains or losses reported as accumulated other comprehensive income as a separate component in stockholders' deficit unless a loss is deemed other than temporary, in which case the loss is recognized in earnings.

Additionally in January 2018, we entered into the Loan and Security Agreement with SVB for $10.0 million. A one percent increase in the prime rate would result in a $5,000 increase in interest expense, while a one percent decrease in the prime rate would result in a $5,000 decrease in interest expense.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTAL DATA

LIPOCINE INC.
INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders
Lipocine Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Lipocine Inc. and subsidiaries (the Company) as of December 31, 2021 and 2020, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for the years then ended, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2021 and 2020, and the consolidated results of its operations and its cash flows for years then ended, in conformity with accounting principles generally accepted in the United States of America.

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 audit 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 its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the 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.

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.

Warrant Liability

In connection with a November 2019 public offering, the Company issued warrants to purchase common stock. The warrants require the Company to pay such warrant holders an amount of cash in the event of a fundamental transaction, as defined in the warrant agreement. As the cash payment is at the option of the holder, the Company accounts for the common stock warrants as a liability, which is adjusted to fair value each reporting period as well as upon exercise of such warrants. The Company estimates the fair value of the warrant liability based on a hypothetical payout associated with a fundamental transaction. The fair value estimate utilizes a pricing model and unobservable inputs. Unlike the fair value of other assets and liabilities which are readily observable and therefore more easily independently corroborated, the warrants are not actively traded, and fair value is determined based on significant judgments regarding models, unobservable inputs and valuation methodologies.

We identified the valuation of the warrant liability as a critical audit matter because of the unobservable inputs used to estimate fair value. The valuations involve a high degree of auditor judgment and an increased extent of effort, including the need to audit and evaluate the appropriateness of the pricing model and inputs.

Our audit procedures for auditing the fair value of the warrant liability included the following procedures, among others:

- We evaluated the reasonableness of management's valuation methodology and estimates.
- We developed valuation estimates, using externally sourced inputs and models, and compared to management's recorded value and investigated differences.
- We compared management's assumptions utilized within management's models to external sources.

Revenue Recognition

The Company entered into a license agreement during 2021 that includes a license fee, guaranteed minimum royalties, ongoing sales royalties, milestone payments and transfer of materials.

Management is required to determine the transaction price and allocate the transaction price to the performance obligations in the license agreement. Management is also required to make estimates of when achievement of a particular milestone becomes probable. Milestone payments are included in the transaction price when it becomes probable that such inclusion would not result in a significant revenue reversal.

We identified revenue recognition as a critical audit matter because of the significant judgment by management in determining the transaction price and allocating the transaction price to the performance obligations. This in turn led to a high degree of auditor judgment and effort in performing procedures and evaluating audit evidence related to the judgments made by management.

Our audit procedures for auditing revenue included the following procedures, among others:

- We obtained and read the material license and royalty agreements
- We tested management's determination of the transaction price and the allocation of the transaction price to the performance obligations
- We evaluated the reasonableness of management's judgments and estimates

/s/ Tanner LLC

We have served as the Company's auditor since 2018
Salt Lake City, Utah
March 9, 2022

LIPOCINE INC. AND SUBSIDIARIES
Consolidated Balance Sheets
December 31, 2021 and 2020

	2021	2020
Assets		
Current assets:		
Cash and cash equivalents	$ 2,950,552	$ 19,217,382
Restricted cash	-	5,000,000
Marketable investment securities	41,667,405	449,992
Accrued interest income	247,253	391
Prepaid and other current assets	1,514,465	661,258
Total current assets	46,379,675	25,329,023
Marketable investment securities	2,021,800	-
Contract asset	4,050,000	-
Property and equipment, net of accumulated depreciation of $1,144,077 and $1,143,697 respectively	7,211	-
Other assets	23,753	23,753
Total assets	$ 52,482,439	$ 25,352,776
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,289,342	$ 1,597,220
Accrued expenses	1,016,458	1,653,178
Debt - current portion	2,310,825	3,333,333
Litigation settlement liability - current portion	1,000,000	-
Total current liabilities	5,616,625	6,583,731
Debt - non-current portion	-	2,257,075
Warrant liability	795,796	1,170,051
Litigation settlement liability - non-current portion	500,000	-
Total liabilities	6,912,421	10,010,857
Commitments and contingencies (notes 5, 8 and 11)		
Stockholders' equity:		
Preferred stock, par value $0.0001 per share, 10,000,000 shares authorized; zero issued and outstanding	-	-
Common stock, par value $0.0001 per share, 100,000,000 shares authorized; 88,296,360 and 70,041,967 issued and 88,290,650 and 70,036,257 outstanding	8,830	7,005
Additional paid-in capital	218,286,323	187,407,634
Treasury stock at cost, 5,710 shares	(40,712)	(40,712)
Accumulated other comprehensive loss	(18,016)	-
Accumulated deficit	(172,666,407)	(172,032,008)
Total stockholders' equity	45,570,018	15,341,919
Total liabilities and stockholders' equity	$ 52,482,439	$ 25,352,776

See accompanying notes to consolidated financial statements

LIPOCINE INC. AND SUBSIDIARIES
Consolidated Statements of Operations and Comprehensive Loss
Years Ended December 31, 2021 and 2020

	2021	2020
Revenues	$ 16,140,838	$ -
Operating expenses:		
Research and development	7,665,559	9,748,469
General and administrative	5,329,776	8,247,795
Total operating expenses	12,995,335	17,996,264
Operating income (loss)	3,145,503	(17,996,264)
Other income (expense)		
Interest and investment income	67,700	75,650
Interest expense	(203,292)	(386,618)
Gain on extinguishment of debt	-	234,802
Unrealized gain (loss) on warrant liability	355,890	(2,892,189)
Litigation settlement	(4,000,000)	-
Total other expense, net	(3,779,702)	(2,968,355)
Loss before income tax expense	(634,199)	(20,964,619)
Income tax expense	(200)	(200)
Net loss	$ (634,399)	$ (20,964,819)
Basic loss per share attributable to common stock	$ (0.01)	$ (0.38)
Weighted average common shares outstanding, basic	86,934,618	55,688,085
Diluted loss per share attributable to common stock	$ (0.01)	$ (0.38)
Weighted average common shares outstanding, diluted	86,934,618	55,688,085
Comprehensive loss:		
Net loss	$ (634,399)	$ (20,964,819)
Unrealized net gain (loss) on available-for-sale securities	(18,016)	38
Comprehensive loss	$ (652,415)	$ (20,964,781)

See accompanying notes to consolidated financial statements

LIPOCINE INC. AND SUBSIDIARIES
Consolidated Statements of Changes in Stockholders' Equity
Years Ended December 31, 2021 and 2020

	Common Stock		Treasury Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Number of Shares	Amount	Number of Shares	Amount				
Balances at December 31, 2019	37,649,465	$ 3,766	5,710	$ (40,712)	$ 157,391,969	$ (38)	$ (151,067,189)	6,287,796
Net loss	-	-	-	-	-	-	(20,964,819)	(20,964,819)
Unrealized net gain on marketable investment securities	-	-	-	-	-	38	-	38
Common stock sold through equity offering	10,084,034	1,008	-	-	5,652,132	-	-	5,653,140
Common stock issued for warrant exercises	15,097,651	1,510	-	-	7,673,366	-	-	7,674,876
Stock-based compensation	-	-	-	-	1,373,182	-	-	1,373,182
Settlement of warrant liability on warrant exercises	-	-	-	-	6,313,338	-	-	6,313,338
Vesting of restricted stock units	628,807	63	-	-	(63)	-	-	-
Common stock sold through ATM offering	6,576,300	658	-	-	9,003,710	-	-	9,004,368
Balances at December 31, 2020	70,036,257	7,005	5,710	(40,712)	187,407,634	-	(172,032,008)	15,341,919
Net loss	-	-	-	-	-	-	(634,399)	(634,399)
Unrealized net loss on marketable investment securities	-	-	-	-	-	(18,016)	-	(18,016)
Stock-based compensation	-	-	-	-	603,946	-	-	603,946
Option exercises	4,584	-			6,693	-	-	6,693
Common stock sold through equity offering	16,428,571	1,643	-	-	26,838,814	-	-	26,840,457
Common stock issued for warrant exercises	10,000	1	-	-	4,999	-	-	5,000
Settlement of warrant liability on warrant exercises	-	-	-	-	18,365	-	-	18,365
Common stock sold through ATM offering	1,811,238	181	-	-	3,405,872	-	-	3,406,053
Balances at December 31, 2021	88,290,650	$ 8,830	5,710	$ (40,712)	$ 218,286,323	$ (18,016)	$ (172,666,407)	$ 45,570,018

See accompanying notes to consolidated financial statements

LIPOCINE INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows
Years Ended December 31, 2021 and 2020

	2021	2020
Cash flows from operating activities:		
Net loss	$ (634,399)	$ (20,964,819)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation expense	380	3,554
Stock-based compensation expense	603,946	1,373,182
Non-cash interest expense	53,750	109,335
Non-cash gain on extinguishment of debt	-	(234,802)
Non-cash loss (gain) on change in fair value of warrant liability	(355,890)	2,892,189
Amortization of premium/discount on marketable investment securities	515,577	(2,616)
Changes in operating assets and liabilities:		
Accrued interest income	(246,862)	16,131
Prepaid and other current assets	(4,903,207)	(115,371)
Accounts payable	(307,878)	414,979
Accrued expenses	(636,720)	1,205,140
Litigation settlement liability	1,500,000	-
Cash used in operating activities	(4,411,303)	(15,303,098)
Cash flows from investing activities:		
Purchases of fixed assets	(7,591)	-
Purchases of marketable investment securities	(48,422,806)	(6,315,297)
Maturities of marketable investment securities	4,650,000	10,208,000
Cash provided by (used in) investing activities	(43,780,397)	3,892,703
Cash flows from financing activities:		
Proceeds from debt	-	233,537
Debt repayments	(3,333,333)	(1,666,667)
Proceeds from stock option exercises	6,693	-
Proceeds from sale of common stock sold in equity offering	26,840,457	5,653,140
Proceeds from exercise of warrants	5,000	7,674,876
Net proceeds from sale of common stock through ATM	3,406,053	9,004,368
Cash provided by financing activities	26,924,870	20,899,254
Net increase (decrease) in cash and cash equivalents	(21,266,830)	9,488,859
Cash, cash equivalents and restricted cash at beginning of period	24,217,382	14,728,523
Cash, cash equivalents and restricted cash at end of period	$ 2,950,552	$ 24,217,382
Supplemental disclosure of cash flow information:		
Interest paid	149,543	276,019
Income taxes paid	200	200
Supplemental disclosure of non-cash investing and financing activities:		
Settlement of warrant liability on warrant exercises	18,365	6,313,338
Unrealized net gain (loss) on marketable investment securities	(18,016)	38
Accrued final payment charge on debt	53,750	109,335

See accompanying notes to consolidated financial statements

(1) Description of Business

Lipocine Inc. ("Lipocine" or the "Company"), a clinical-stage biopharmaceutical company focused on metabolic and endocrine disorders, is engaged in research and development for the delivery of drugs using its proprietary delivery technology. The Company's principal operation is to provide oral delivery solutions for existing drugs. Lipocine develops its own drug candidates or it develops drug candidates on behalf of or in collaboration with corporate partners. The Company has funded operating costs primarily through collaborative license, milestone and research arrangements, through federal grants, through the sale of equity securities and through debt. The Company is incorporated under the laws of the State of Delaware.

(2) Summary of Significant Accounting Policies

(a) Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles 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 revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant items subject to such estimates and assumptions include those related to stock-based compensation; income tax uncertainties; the fair value of the warrant liability and the useful lives of property and equipment.

(b) Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities to the Company of three months or less to be cash equivalents. Although the Company may deposit its cash and cash equivalents with multiple financial institutions, its deposits, at times, may exceed federally insured limits. Cash and cash equivalents were $3.0 million and $19.2million at December 31, 2021 and 2020.

(c) Receivables

Accounts receivable are recorded at the invoiced amount and do not bear interest.

The Company maintains an allowance for doubtful accounts for estimated losses. In establishing the allowance, management considers historical losses adjusted to take into account current market conditions and their customers' financial condition, the amount of receivables in dispute, and the current receivables aging and current payment patterns. The Company had no write-offs in 2021 and 2020 and the Company did not record an allowance for doubtful accounts as of December 31, 2021 and 2020 as there were no accounts receivable outstanding. The Company does not have any off-balance-sheet credit exposure related to its customers.

(d) Revenue Recognition

The Company generates most of its revenue from license and royalty arrangements. At inception of each contract, the Company identifies the goods and services that have been promised to the customer and each of those that represent a distinct performance obligation, determines the transaction price including any variable consideration, allocates the transaction price to the distinct performance obligations and determines whether control transfers to the customer at a point in time or over time. Variable consideration is included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. The Company reassess its reserves for variable consideration at each reporting date and makes adjustments, if necessary, which may affect revenue and earnings in periods in which any such changes become known.

(2) Summary of Significant Accounting Policies – (continued)

Disaggregation of Revenue. In the following tables, revenues reported for the year ended December 31, 2021, under Topic 606, is disaggregated by type of revenue.

Type of Revenue		
Licensing	$	11,000,000
Sales-based royalties		54,994
Minimum guaranteed royalties		4,050,000
Materials		1,035,844
	$	16,140,838

Under Topic 606, all revenue has been recognized as point in time for the year ended December 31, 2021.

See Note 4 for a description of the license agreement with Antares Pharma, Inc. See Note 12 for a description of the agreement with Spriaso.

License Fees. For distinct license performance obligations, upfront license fees are recognized when the Company satisfies the underlying performance obligation. This generally occurs upon transfer of the right to use the Company's licensed technology to the customer. In addition, license arrangements may include contingent milestone payments, which are due following achievement by our licensee of specified sales or regulatory milestones and the licensee and/or Company will fulfill its performance obligation prior to achievement of these milestones. Because of the uncertainty of the milestone achievement, and/or the dependence on sales of our licensee, variable consideration for contingent milestones is fully constrained and is not recognized as revenue until the milestone is achieved by our licensee, to the extent collectability is reasonably certain.

Royalties. Royalties revenue consists of sales-based and minimum royalties earned under licenses agreements for our products. Performance obligations under these licenses, which consist of the right to use the Company's proprietary technology, are satisfied at a point in time corresponding with delivery of the underlying technology rights to the licensee, which is generally upon transfer of the licensed technology/product to the customer. Sales-based royalties revenue represents variable consideration under the license agreements and is recognized in the period a customer sells products incorporating the Company's licensed technologies/products. The Company estimates sales-based royalties revenue earned but unpaid at each reporting period using information provided by the licensee. The Company's license arrangements may also provide for minimum royalties, which the Company recognizes upon the satisfaction of the underlying performance obligation, which generally occurs with delivery of the underlying technology rights to the licensee.Sales-based and minimum royalties are generally due within 45 days after the end of each quarter in which they are earned.

Contract Assets

Contract assets consist of minimum royalty revenue earned in relation to the license agreement but not yet payable based on the terms of the contract. The contract asset as of December 31, 2021 is related to the Antares License Agreement.

Revenue Concentration

A major customer is considered to be one that comprises more than 10% of the Company's total revenues. There was one major customer for the year ended December 31, 2021 which accounted for 99.7% of total revenue. There was no revenue recognized for the year ended December 31, 2020.

(2) Summary of Significant Accounting Policies – (continued)

(e) Property and Equipment

Property and equipment are recorded at cost, less accumulated depreciation. Maintenance and repairs that do not extend the life or improve the asset are expensed in the year incurred.

Depreciation is computed using the straight-line method over the estimated useful lives of the assets, which are five years for laboratory and office equipment, three years for computer equipment and software, and seven years for furniture and fixtures.

(f) Accounting for Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets held and used is measured by a comparison of the carrying amount of an asset to future net cash flows (undiscounted) expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets held for sale are reported at the lower of the carrying amount, or fair value, less costs to sell.

(g) Income Taxes

Income taxes are accounted for under the asset and liability method. 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 and operating loss and tax credit carryforwards. Deferred tax assets 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. A valuation allowance is provided against net deferred tax assets if, based upon the available evidence, it is more likely than not that some or all of the net deferred tax assets will not be realized.

The Company recognizes the effect of income tax positions only if those positions are more likely than not of being sustained. Recognized income tax positions are measured at the largest amount that is greater than 50 percent likely of being realized. Changes in recognition or measurement are reflected in the period in which the change in judgment occurs. The Company records interest and penalties related to unrecognized tax benefits as a component of its income tax expense.

(h) Share Based Payments

The Company recognizes stock-based compensation expense for grants of stock option awards, restricted stock units and restricted stock under the Company's Incentive Plan to employees, nonemployees and nonemployee members of the Company's board of directors based on the grant-date fair value of those awards. The grant-date fair value of an award is generally recognized as compensation expense over the award's requisite service period. In addition, the Company has granted performance-based stock option awards and restricted stock units, which vest based upon the Company satisfying certain performance conditions. Potential compensation cost, measured on the grant date, related to these performance options will be recognized only if, and when, the Company estimates that these options or units will vest, which is based on whether the Company considers the performance conditions to be probable of attainment. The Company's estimates of the number of performance-based options or units that will vest will be revised, if necessary, in subsequent periods.

(2) Summary of Significant Accounting Policies – (continued)

The Company uses the Black-Scholes model to compute the estimated fair value of stock option awards. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of the Company's Common Stock price, (ii) the periods of time over which employees, nonemployees and members of the board of directors are expected to hold their options prior to exercise (expected term), (iii) expected dividend yield on the Common Stock, and (iv) risk-free interest rates. Stock-based compensation expense also includes an estimate, which is made at the time of grant, of the number of awards that are expected to be forfeited. This estimate is revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Stock-based compensation cost that has been expensed in the statements of operations amounted to $604,000 and $1.4 million for the years ended December 31, 2021 and 2020, allocated as follows:

	Year Ended	
	2021	2020
Research and development	$ 280,186	$ 583,212
General and administrative	323,760	789,970
	$ 603,946	$ 1,373,182

The Company issued 1,106,000 stock options and 1,360,000 stock options during the years ended December 31, 2021 and 2020, respectively.

Key assumptions used in the determination of the fair value of stock options granted are as follows:

Expected Term: The expected term represents the period that the stock-based awards are expected to be outstanding. Due to limited historical experience of similar awards, the expected term was estimated using the simplified method in accordance with the provisions of Staff Accounting Bulletin ("SAB") No. 107, *Share-Based Payment,* for awards with stated or implied service periods. The simplified method defines the expected term as the average of the contractual term and the vesting period of the stock option. For awards with performance conditions, and that have the contractual term to satisfy the performance condition, the contractual term was used.

Risk-Free Interest Rate: The risk-free interest rate used was based on the implied yield currently available on U.S. Treasury issues with an equivalent remaining term.

Expected Dividend: The expected dividend assumption is based on management's current expectation about the Company's anticipated dividend policy. The Company does not anticipate declaring dividends in the foreseeable future.

Expected Volatility: The volatility factor is based solely on the Company's trading history.

(2) Summary of Significant Accounting Policies – (continued)

For options granted in 2021 and 2020, the Company calculated the fair value of each option grant on the respective dates of grant using the following weighted average assumptions:

	2021	2020
Expected term	5.83 years	5.83 years
Risk-free interest rate	1.04%	0.93%
Expected dividend yield	—	—
Expected volatility	102.18%	100.32%

FASB Accounting Standards Codification ("ASC") 718, *Stock Compensation*, requires the Company to recognize compensation expense for the portion of options that are expected to vest. Therefore, the Company applied estimated forfeiture rates that were derived from historical employee termination behavior. If the actual number of forfeitures differs from those estimated by management, additional adjustments to compensation expense may be required in future periods.

As of December 31, 2021, there was $1.4 million of total unrecognized compensation cost related to unvested share-based compensation arrangements granted under the Company's stock option plan. That cost is expected to be recognized over a weighted average period of 2.3 years and will be adjusted for subsequent changes in estimated forfeitures. The weighted average fair value of share-based compensation awards granted during the years ended December 31, 2021 and 2020 was approximately $0.97 per share and $0.72 per share, respectively.

(i) Fair Value

The Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. The Company determines fair value based on assumptions that market participants would use in pricing an asset or liability in the principal or most advantageous market. When considering market participant assumptions in fair value measurements, the following fair value hierarchy distinguishes between observable and unobservable inputs, which are categorized in one of the following levels:

- Level 1 Inputs: Quoted prices for identical instruments in active markets.
- Level 2 Inputs: Quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, and model-derived valuation in which all significant inputs and significant value drivers are observable in active markets.
- Level 3 Inputs: Valuations derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable.

(2) Summary of Significant Accounting Policies – (continued)

All of the Company's financial instruments are valued using quoted prices in active markets or based on other observable inputs. For accrued interest income, prepaid and other current assets, accounts payable, and accrued expenses, the carrying amounts approximate fair value because of the short maturity of these instruments. The following table presents the placement in the fair value hierarchy of assets and liabilities that are measured at fair value on a recurring basis at December 31, 2021 and 2020:

	December 31, 2021	Fair value measurements at reporting date using		
		Level 1 inputs	Level 2 inputs	Level 3 inputs
Assets:				
Cash equivalents - money market funds	$ 2,089,751	$ 2,089,751	$ -	$ -
Government treasury bills	5,515,920	5,515,920		
Commercial paper	15,385,634	-	15,385,634	-
Corporate bonds and notes	22,787,651		22,787,651	
	$ 45,778,956	$ 7,605,671	$ 38,173,285	$ -
Liabilities:				
Warrant liability	$ 795,796	-	-	795,796
	$ 46,574,752	$ 7,605,671	$ 38,173,285	$ 795,796

	December 31, 2020	Fair value measurements at reporting date using		
		Level 1 inputs	Level 2 inputs	Level 3 inputs
Assets:				
Cash equivalents - money market funds	$ 18,399,585	$ 18,399,585	$ -	$ -
Commercial paper	449,992	-	449,992	-
	$ 18,849,577	$ 18,399,585	$ 449,992	$ -
Liabilities:				
Warrant liability	$ 1,170,051	-	-	1,170,051
	$ 20,019,628	$ 18,399,585	$ 449,992	$ 1,170,051

(2) Summary of Significant Accounting Policies – (continued)

The following methods and assumptions were used to determine the fair value of each class of assets and liabilities recorded at fair value in the balance sheets:

Cash equivalents: Cash equivalents primarily consist of highly rated money market funds and treasury bills with original maturities to the Company of three months or less and are purchased daily at par value with specified yield rates. Cash equivalents related to money market funds and treasury bills are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices or broker or dealer quotations for similar assets.

Government bonds and notes: The Company uses a third-party pricing service to value these investments. United States bonds and notes are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices for identical assets and reportable trades.

Corporate bonds, notes, and commercial paper: The Company uses a third-party pricing service to value these investments. Corporate bonds, notes and commercial paper are classified within Level 2 of the fair value hierarchy because they are valued using broker/dealer quotes, bids and offers, benchmark yields and credit spreads and other observable inputs.

Warrant liability: The warrant liability (which relates to warrants to purchase shares of common stock) is marked-to-market each reporting period with the change in fair value recorded to other income (expense) in the accompanying statements of operations until the warrants are exercised, expire or other facts and circumstances lead the warrant liability to be reclassified to stockholders' equity. The fair value of the warrant liability is estimated using a Black-Scholes option-pricing model. The significant assumptions used in preparing the option pricing model for valuing the warrant liability as of December 31, 2021, include (i) volatility of 100%, (ii) risk free interest rate of 0.97%, (iii) strike price of $0.50, (iv) fair value of common stock of $.99, and (v) expected life of 2.9 years. The significant assumptions used in preparing the option pricing model for valuing the warrant liability as of December 31, 2020, include (i) volatility of 100%, (ii) risk free interest rate of 0.27%, (iii) strike price of $0.50, (iv) fair value of common stock of $1.36, and (v) expected life of 3.9 years.

The Company's accounting policy is to recognize transfers between levels of the fair value hierarchy on the date of the event or change in circumstances that caused the transfer. There were no transfers into or out of Level 1, Level 2 or Level 3 for the years ended December 31, 2021 and 2020.

(j) Earnings (Loss) per Share

Basic earnings (loss) per share is calculated by dividing net income (loss) available to common shareholders by the weighted average number of common shares outstanding during the period.

Diluted earnings (loss) per share is based on the weighted average number of common shares outstanding plus, where applicable, the additional potential common shares that would have been outstanding related to dilutive options, warrants, and unvested restricted stock units to the extent such shares are dilutive.

(2) Summary of Significant Accounting Policies – (continued)

The following table sets forth the computation of basic and diluted earnings (loss) per share of common stock for the years ended December 31, 2021 and 2020.

	Year Ended December 31,	
	2021	**2020**
Basic loss per share attributable to common stock:		
Numerator		
Net loss	$ (634,399)	$ (20,964,819)
Denominator		
Weighted avg. common shares outstanding	86,934,618	55,688,085
Basic loss per share attributable to common stock	$ (0.01)	$ (0.38)
Diluted loss per share attributable to common stock:		
Numerator		
Net loss	$ (634,399)	$ (20,964,819)
Denominator		
Weighted avg. common shares outstanding	86,934,618	55,688,085
Diluted loss per share attributable to common stock	$ (0.01)	$ (0.38)

The computation of diluted earnings per share for the years ended December 31, 2021 and 2020 does not include the following stock options or warrants to purchase shares in the computation of diluted earnings per share because these instruments were antidilutive:

	December 31,	
	2021	**2020**
Stock options	4,551,205	3,564,458
Warrants	1,934,366	1,944,366

(2) Summary of Significant Accounting Policies – (continued)

(k) Segment Information

The Company is a single reportable segment engaged in research and development for the delivery of drugs using its proprietary delivery technology. Operating segments are identified as components of an enterprise for which separate discrete financial information is available for evaluation by the chief operating decision maker in making decisions regarding resource allocation and assessing performance. The chief operating decision maker made such decisions and assessed performance at the company level, as one segment.

(l) Principles of Consolidation

The consolidated financial statements include the accounts of the Company and all subsidiaries. The Company eliminates all intercompany accounts and transactions in consolidation.

(3) Marketable Investment Securities

The Company has classified its marketable investment securities as available-for-sale securities, all of which are debt securities. These securities are carried at fair value with unrealized holding gains and losses, net of the related tax effect, included in accumulated other comprehensive income (loss) in stockholders' equity until realized. Gains and losses on investment security transactions are reported on the specific-identification method. Dividend income is recognized on the ex-dividend date and interest income is recognized on an accrual basis. The amortized cost, gross unrealized holding gains, gross unrealized holding losses, and fair value for available-for-sale securities by major security type and class of security at December 31, 2021 and 2020 were as follows:

December 31, 2021	Amortized Cost	Gross unrealized holding gains	Gross unrealized holding losses	Aggregate fair value
Government treasury bills	$ 5,526,122	$ -	$ (10,202)	$ 5,515,920
Corporate bonds, notes and commercial paper	38,181,099	-	(7,814)	38,173,285
	$ 43,707,221	$ -	$ (18,016)	$ 43,689,205

December 31, 2020	Amortized Cost	Gross unrealized holding gains	Gross unrealized holding losses	Aggregate fair value
Commercial paper	$ 449,992	-	-	$ 449,992
	$ 449,992	$ -	$ -	$ 449,992

(3) Marketable Investment Securities - (continued)

Maturities of debt securities classified as available-for-sale securities at December 31, 2021 are as follows:

December 31, 2021	Amortized Cost	Aggregate fair value
Due within one year	$ 41,680,635	$ 41,667,405
Due after one year through two years	2,026,586	2,021,800
	$ 43,707,221	$ 43,689,205

There were no sales of marketable investment securities during the years ended December 31, 2021 and 2020 and therefore no realized gains or losses. Additionally, $4.7 million and $10.2 million of marketable investment securities matured during the years ended December 31, 2021 and 2020, respectively. The Company determined there were no other-than-temporary impairments for the years ended December 31, 2021 and 2020.

(4) Contractual Agreements

(a) Abbott Products, Inc.

On March 29, 2012, the Company terminated its collaborative agreement with Solvay Pharmaceuticals, Inc. (later acquired by Abbott Products, Inc.) for TLANDO. As part of the termination, the Company reacquired the rights to the intellectual property from Abbott. All obligations under the prior license agreement have been completed except that Lipocine will owe Abbott a perpetual 1% royalty on net sales. Such royalties are limited to $1.0 million in the first two calendar years following product launch, after which period there is not a cap on royalties and no maximum aggregate amount. If generic versions of any such product are introduced, then royalties are reduced by 50%. The Company did not incur any royalties owed during the years ended December 31, 2021 and 2020.

(b) Antares Pharma, Inc.

On October 14, 2021, the Company entered into a license agreement (“License Agreement”) with Antares Pharma, Inc. (“Antares”) pursuant to which the Company granted to Antares an exclusive, royalty-bearing, sublicensable right and license to develop and commercialize, upon final approval of TLANDO® from the U.S. Food and Drug Administration (“FDA”), the Company’s TLANDO product with respect to testosterone replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone, as indicated in NDA No. 208088, treatment of Klinefelter syndrome, and pediatric indications relating to testosterone replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone (the “Field”), in each case within the United States. The Antares License Agreement also provides Antares with an option, exercisable on or before March 31, 2022, to license TLANDO XR, the Company’s potential once-daily oral product candidate for testosterone replacement therapy. Upon execution of the Antares License Agreement, Antares paid to the Company an initial payment of $11.0 million. Antares will also make additional payments of $5.0 million to the Company on each of January 1, 2025, and January 1, 2026, provided that certain conditions are satisfied. The Company is also eligible to receive milestone payments of up to $160.0 million in the aggregate, depending on the achievement of certain sales milestones in a single calendar year with respect to all products licensed by Antares under the Antares License Agreement. In addition, upon commercialization, the Company will receive tiered royalty payments at rates ranging from percentages in the mid-teens to up to 20% of net sales of TLANDO in the United States, subject to certain minimum royalty obligations. If Antares exercises its option to license TLANDO XR, the Company will be entitled to an additional payment of $4.0 million, as well as development milestone payments of up to $35.0 million in the aggregate and tiered royalty payments at rates ranging from percentages in the mid-teens to 20% of net sales of TLANDO XR in the United States. The Company retains development and commercialization rights in the rest of the world, and with respect to applications outside of the Field inside or outside the United States. Antares will also purchase certain existing inventory of licensed products from the Company, subject to testing and acceptance procedures. Finally, pursuant to the terms of the Antares License Agreement, Antares is generally responsible for expenses relating to the development (including the conduct of any clinical trials) and commercialization of licensed products in the Field in the United States, while the Company is generally responsible for expenses relating to development activities outside of the Field and/or the United States. The Company recognized revenue under the Antares Licensing Agreement of $16.1 million and zero during the years ended December 31, 2021 and 2020.

(4) Contractual Agreements – (continued)

(c) Contract Research and Development

The Company has entered into agreements with various contract organizations that conduct preclinical, clinical, analytical and manufacturing development work on behalf of the Company as well as a number of independent contractors, primarily clinical researchers, who serve as advisors to the Company. The Company incurred expenses of $4.9 million and $6.8 million under these agreements in 2021 and 2020 and has recorded these expenses in research and development expenses.

(5) Loan and Security Agreement

Silicon Valley Bank Loan

On January 5, 2018, the Company entered into a Loan and Security Agreement (the "Loan and Security Agreement") with Silicon Valley Bank ("SVB") pursuant to which SVB agreed to lend the Company $10.0 million. The principal borrowed under the Loan and Security Agreement bears interest at a rate equal to the Prime Rate, as reported in the money rates section of The Wall Street Journal or any successor publication representing the rate of interest per annum then in effect, plus one percent per annum (4.25% as of December 31, 2021), which interest is payable monthly. Additionally on April 1, 2020, the Company entered into a Deferral Agreement with SVB. Under the Deferral Agreement, principal repayments were deferred by six months and the Company was only required to make monthly interest payments. The loan matures on June 1, 2022. Previously, the Company only made monthly interest payments until December 31, 2018, following which the Company also made equal monthly payments of principal and interest until the signing of the Deferral Agreement. The Company will also be required to pay an additional final payment at maturity equal to $650,000 (the "Final Payment Charge"). The Final Payment Charge will be due on the scheduled maturity date and to date approximately $644,000 has been recognized as an increase to the principal balance with a corresponding charge to interest expense with the remaining final payment charge to be recognized over the term of the facility using the effective interest method. At its option, the Company may prepay all amounts owed under the Loan and Security Agreement (including all accrued and unpaid interest and the Final Payment Charge).

In connection with the Loan and Security Agreement, the Company granted to SVB a security interest in substantially all of the Company's assets now owned or hereafter acquired, excluding intellectual property and certain other assets. On September 9, 2021, SVB consented to the Antares Licensing Agreement which among other things provides Antares a license to certain intellectual property as well as assigns Antares the TLANDO® trademark. In addition, as TLANDO was not approved by the United States Food and Drug Administration ("FDA") prior to May 31, 2018, the Company maintained $5.0 million of cash collateral at SVB as required under the Loan and Security Agreement until such time as TLANDO is approved by the FDA. However on February 16, 2021, the Company amended the Loan and Security Agreement with SVB to, among other things, remove the financial trigger and financial trigger release event provisions requiring the Company to maintain a minimum cash collateral value and collateral pledge thereof.

While any amounts are outstanding under the Loan and Security Agreement, the Company is subject to a number of affirmative and negative covenants, including covenants regarding dispositions of property, business combinations or acquisitions, incurrence of additional indebtedness and transactions with affiliates, among other customary covenants. The credit facility also includes events of default, the occurrence and continuation of which could cause interest to be charged at the rate that is otherwise applicable plus 5.0% and would provide SVB, as collateral agent, with the right to exercise remedies against the Company and the collateral securing the credit facility, including foreclosure against the property securing the credit facilities, including its cash. These events of default include, among other things, any failure by the Company to pay principal or interest due under the credit facility, a breach of certain covenants under the credit facility, the Company's insolvency, a material adverse change, and one or more judgments against the Company in an amount greater than $100,000 individually or in the aggregate.

(5) Loan and Security Agreement – (continued)

Future maturities of principal payments on the Loan and Security Agreement at December 31, 2021 (excluding accrued final payment fee) are as follows:

Years Ending December 31,	Amount (in thousands)
2022	1,667
Thereafter	—
	$ 1,667

Payroll Protection Program Loan
In April 2020, the Company was granted a loan from SVB in the aggregate amount of $233,537, pursuant to the Paycheck Protection Program (the "PPP") under Division A, Title I of the CARES Act. On November 2, 2020, we were notified by the Small Business Administration that our PPP loan had been forgiven.

(6) Property and Equipment

Property and equipment consisted of the following:

	December 31, 2021	December 31, 2020
Computer equipment and software	$ 43,361	$ 43,361
Lab and office equipment	1,056,523	1,048,932
Furniture and fixtures	51,404	51,404
	1,151,288	1,143,697
Less accumulated depreciation	(1,144,077)	(1,143,697)
	$ 7,211	$ -

Depreciation expense for the years ended December 31, 2021 and 2020 was approximately $400 and $4,000, respectively.

(7) Income Taxes

(a) Income Tax Expense

Income tax expense consists of:

	December 31,	
	2021	**2020**
U.S. federal	$ -	$ -
State and local	200	200
Deferred	-	-
Total	$ 200	$ 200

(b) Tax Rate Reconciliation

Income tax expense was $200 and $200, respectively, for the years ended December 31, 2021 and 2020 and differed from the amounts computed by applying the U.S. federal income tax rate of 21% for 2021 and 2020, respectively, to pretax income from continuing operations as a result of the following:

	December 31,	
	2021	**2020**
Computed “expected” tax benefit	$ (133,182)	$ (4,402,570)
Increase (reduction) in income taxes resulting from:		
Change in valuation allowance	476,431	4,248,002
State and local income taxes, net of federal income tax benefit	158	158
Stock expense	97,697	86,209
Research and development tax credits	(352,163)	(485,254)
Orphan drug tax credit	(14,025)	(4,797)
Warrant liability	(74,737)	607,360
Other, net	21	(48,908)
	$ 200	$ 200

(7) Income Taxes – (continued)

(c) Significant Components of Deferred Taxes

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and deferred tax liabilities at December 31, 2021 and 2020 are presented below.

	December 31,	
	2021	**2020**
Deferred tax assets:		
Stock-based compensation	$ 1,687,480	$ 1,651,482
Net operating loss carryforwards	34,759,890	35,102,326
Employee benefits	56,009	54,108
Research and development tax credits	4,935,609	4,472,003
Orphan drug tax credits	1,186,582	1,168,828
Plant and equipment	-	959
Other deductible tempory differences	394,636	5,386
Total gross deferred tax assets	43,020,206	42,455,092
Deferred tax assets:		
Plant and equipment	(1,871)	-
Total gross deferred tax liabilities	(1,871)	-
Net deferred tax liabilities	$ (1,871)	$ -
Deferred tax asset/deferred tax liability	43,018,335	42,455,092
Less valuation allowance	(43,018,335)	(42,455,092)
Net deferred tax assets	$ -	$ -

The valuation allowance for deferred tax assets as of December 31, 2021 and 2020 was $43.0 million and $42.5 million. The net change in the valuation allowance was an increase of $0.5 million in 2021 and an increase of $5.2 million in 2020. A valuation allowance has been provided for the full amount of the Company's net deferred tax assets as the Company believes it is more likely than not that these benefits will not be realized. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities (including the impact of available carryback and carryforward periods), projected future taxable income, and tax planning strategies in making this assessment.

(7) Income Taxes – (continued)

During the year ended December 31, 2013, the Company experienced a change in ownership, as defined by the Internal Revenue Code, as amended (the "Code") under Section 382. A change of ownership occurs when ownership of a company increases by more than 50 percentage points over a three-year testing period of certain stockholders. As a result of this ownership change, we determined that our annual limitation on the utilization of our federal net operating loss ("NOL") and credit carryforwards is approximately $1.1 million per year. We will only be able to utilize $20.2 million of our pre-ownership change NOL carryforwards and will forgo utilizing $5.5 million of our pre-ownership change NOL carryforwards and $1.2 million of our pre-change credit carryforwards as a result of this ownership change. We do not account for forgone NOL and credit carryovers in our deferred tax assets and only account for the NOL and credit carryforwards that will not expire unutilized as a result of the restrictions of Code Section 382.

As of December 31, 2021, we had NOL and research and development credit carryforwards for U.S. federal income tax reporting purposes of approximately $135.6 million and $3.5 million, respectively. Approximately $24.6 million of the NOL will expire between 2023 and 2033 and $70.8 million of the NOL will expire 2034 through 2037. Pursuant to the Tax Cuts and Jobs Act of 2017, NOL's generated in 2018 and subsequent years have an unlimited carryforward therefore the 2020, 2019 and 2018 NOL of $40.2 million can be carried forward indefinitely. The research and development credits will begin to expire in 2033 through 2041. We have orphan drug credit carry forwards of approximately $1.2 million which will expire if unused through 2041.

We also have state NOL and research and development credit carry forwards of approximately $127.1 million and $1.4 million, respectively. None of the Company's state NOL expires in 2022, $34.8 million expires between 2022 and 2029, and $92.3 million will expire in 2030 through 2036. The state research and development credits expire in 2023 through 2035.

The Company's federal and state income tax returns for December 31, 2018 through 2021 are open tax years.

A reconciliation of the beginning and ending amount of total unrecognized tax contingencies, excluding interest and penalties, for the years ended December 31, 2021 and 2020 are as follows:

	December 31,	
	2021	2020
Balance, beginning of year	$ -	$ -
Balance, end of year	$ -	$ -

(8) Leases

On August 6, 2004, the Company assumed a non-cancelable operating lease for office space and laboratory facilities in Salt Lake City, Utah. On May 6, 2014, the Company modified and extended the lease through February 28, 2018, on February 8, 2018, the Company extended the lease through February 28, 2019, on January 2, 2019, the Company extended the lease through February 29, 2020, on February 24, 2020, the Company extended the lease through February 28, 2021, on March 3, 2021, the Company extended the lease through February 28, 2022 and on January 24, 2022, the Company extended the lease through February 28, 2023.

(8) Leases – (continued)

Future minimum lease payments under non-cancelable operating leases as of December 31, 2021 are:

	Operating leases
Year ending December 31:	
2022	$ 341,429
2023	$ 57,273
Total minimum lease payments	$ 398,702

The Company's rent expense was $330,000 for each of the years ended December 31, 2021 and 2020, respectively.

(9) Stockholders' Equity

(a) Issuance of Common Stock

On January 28, 2021, the Company completed a public offering of securities registered under an effective registration statement filed pursuant to the Securities Act of 1933, as amended ("January 2021 Offering"). The gross proceeds from the January 2021 Offering were approximately $28.7 million, before deducting underwriter fees and other offering expenses of $1.9 million. In the January 2021 Offering, the Company sold 16,428,571 shares of its common stock.

On February 27, 2020, the Company completed a registered direct offering of securities registered under an effective registration statement filed pursuant to the Securities Act of 1933, as amended ("February 2020 Offering"). The gross proceeds from the February 2020 Offering were approximately $6.0 million, before deducting placement agent fees and other offering expenses of $347,000. In the February 2020 Offering, the Company sold 10,084,034 Class A Units at an offering price of $0.595 per unit, with each Class A Unit consisting of one share of its common stock and one-half of a common warrant to purchase one share of common stock at an exercise price of $0.53 per share of common stock. Additionally, the common stock warrants were immediately exercisable and expire on February 27, 2025. By their terms, however, the common stock warrants cannot be exercised at any time that the common stock warrant holder would beneficially own, after such exercise, more than 4.99% (or, at the election of the holder, 9.99%) of the shares of common stock then outstanding after giving effect to such exercise.

On November 18, 2019, the Company completed a public offering of securities registered under an effective registration statement filed pursuant to the Securities Act of 1933, as amended ("November 2019 Offering"). The gross proceeds from the November 2019 Offering were approximately $6.0 million, before deducting placement agent fees and other offering expenses of $404,000. In the November 2019 Offering, the Company sold (i) 10,450,000 Class A Units, with each Class A Unit consisting of one share of its common stock and a common warrant to purchase one share of its common stock, and (ii) 1,550,000 Class B Units, with each Class B Unit consisting of one pre-funded warrant to purchase one share of its common stock and a common warrant to purchase one share of its common stock, at a price of $0.50 per Class A Unit and $0.4999 per Class B Unit. The pre-funded warrants, which were exercised for common stock in December 2019, were issued in lieu of common stock in order to ensure the purchaser did not exceed certain beneficial ownership limitations. The pre-funded warrants were immediately exercisable at an exercise price of $.0001 per share, subject to adjustment. Additionally, the common stock warrants were immediately exercisable at an exercise price of $0.50 per share, subject to adjustment, and expire on November 17, 2024. By their terms, however, neither the pre-funded warrants nor the common stock warrants can be exercised at any time that the pre-funded warrant holder or the common stock warrant holder would beneficially own, after such exercise, more than 4.99% (or, at the election of the holder, 9.99%) of the shares of common stock then outstanding after giving effect to such exercise. On the date of the November 2019 Offering, the Company allocated approximately $768,000 and $4.8 million to common stock/additional paid-in capital and warrant liability, respectively.

(9) Stockholders' Equity – (continued)

On March 6, 2017, the Company entered into the Sales Agreement with Cantor Fitzgerald & Co. ("Cantor") pursuant to which the Company may issue and sell, from time to time, shares of its common stock having an aggregate offering price of up to the amount the Company registered on an effective registration statement pursuant to which the offering is being made. The Company currently has registered up to $50.0 million for sale under the Sales Agreement, pursuant to the Registration Statement on Form S-3 (File No. 333-250072) through Cantor as the Company's sales agent. Cantor may sell the Company's common stock by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) of the Securities Act, including sales made directly on or through the Nasdaq Capital Market or any other existing trade market for our common stock, in negotiated transactions at market prices prevailing at the time of sale or at prices related to prevailing market prices, or any other method permitted by law. Cantor uses its commercially reasonable efforts consistent with its normal trading and sales practices and applicable law and regulations to sell these shares. The Company pays Cantor 3.0% of the aggregate gross proceeds from each sale of shares under the Sales Agreement. In addition, the Company has also provided Cantor with customary indemnification rights.

The shares of the Company's common stock sold under the Sales Agreement are sold and issued pursuant to the Registration Statement on Form S-3 (File No. 333-250072) (the "Form S-3"), which was previously declared effective by the Securities and Exchange Commission, and the related prospectus and one or more prospectus supplements.

The Company is not obligated to make any sales of its common stock under the Sales Agreement. The offering of common stock pursuant to the Sales Agreement will terminate upon the termination of the Sales Agreement as permitted therein. The Company and Cantor may each terminate the Sales Agreement at any time upon ten days' prior notice.

As of December 31, 2021, we had sold an aggregate of 15,023,073 shares at a weighted-average sales price of $2.19 per share under the Sales Agreement for aggregate gross proceeds of $32.9 million and net proceeds of $31.7 million, after deducting sales agent commission and discounts and our other offering costs. During the year ended December 31, 2021, the Company sold 1,811,238 shares of our common stock pursuant to the current Registration Statement on Form S-3 (File No. 333-250072) at a weighted-average sales price of $1.95 per share, resulting in net proceeds of approximately $3.4 million under the Sales Agreement which is net of $112,000 in expenses. During the year ended December 31, 2020, the Company sold 3,746,300 shares of our common stock pursuant to the current Registration Statement on Form S-3 (File No. 333-250072) at a weighted average sales price of $1.41 per share, in net proceeds of approximately $5.1 million under the Sales Agreement which is net of $148,000 in expenses. Additionally, during the year ended December 31, 2020, the Company sold 2,830,000 shares of our common stock pursuant to the prior Registration Statement on Form S-3 (File No. 333-220942) at a weighted average sales price of $1.43 per share under the ATM for aggregate gross proceeds of $3.9 million which is net of $165,000 in expenses. As of December 31, 2021, the Company had $41.2 million available for sale under the Sales Agreement.

(b) Rights Agreement

On November 13, 2015, the Company and American Stock Transfer & Trust Company, LLC, as Rights Agent, entered into a Rights Agreement. Also on November 12, 2015, the board of directors of the Company authorized and the Company declared a dividend of one preferred stock purchase right (each a "Right" and collectively, the "Rights") for each outstanding share of common stock of the Company. The dividend was payable to stockholders of record as of the close of business on November 30, 2015 and entitles the registered holder to purchase from the Company one one-thousandth of a fully paid non-assessable share of Series A Junior Participating Preferred Stock of the Company at a price of $63.96 per one-thousandth share (the "Purchase Price"). The Rights will generally become exercisable upon the earlier to occur of (i) 10 business days following a public announcement that a person or group of affiliated or associated persons has become an Acquiring Person (as defined below) or (ii) 10 business days (or such later date as may be determined by action of the board of directors prior to such time as any person or group of affiliated or associated persons becomes an Acquiring Person) following the commencement of, or announcement of an intention to make, a tender offer or exchange offer the consummation of which would result in the beneficial ownership by a person or group of 15% or more of the outstanding common stock of the Company. Except in certain situations, a person or group of affiliated or associated persons becomes an "Acquiring Person" upon acquiring beneficial ownership of 15% or more of the outstanding shares of common stock of the Company.

(9) Stockholders' Equity – (continued)

In general, in the event a person becomes an Acquiring Person, then each Right not owned by such Acquiring Person will entitle its holder to purchase from the Company, at the Right's then current exercise price, in lieu of shares of Series A Junior Participating Preferred Stock, common stock of the Company with a market value of twice the Purchase Price. In addition, if after any person has become an Acquiring Person, (a) the Company is acquired in a merger or other business combination, or (b) 50% or more of the Company's assets, or assets accounting for 50% or more of its earning power, are sold, leased, exchanged or otherwise transferred (in one or more transactions), proper provision shall be made so that each holder of a Right (other than the Acquiring Person, its affiliates and associates and certain transferees thereof, whose Rights became void) shall thereafter have the right to purchase from the acquiring corporation, for the Purchase Price, that number of shares of common stock of the acquiring corporation which at the time of such transaction would have a market value of twice the Purchase Price.

The Company will be entitled to redeem the Rights at $0.001 per Right at any time prior to the time an Acquiring Person becomes such. The terms of the Rights are set forth in the Rights Agreement, which is summarized in the Company's Current Report on Form 8-K dated November 13, 2015. The rights plan was originally set to expire on November 12, 2018; however, on November 5, 2018 our Board of Directors approved an Amended and Restated Rights Agreement pursuant to which the expiration date was extended to November 5, 2021 and again on November 1, 2021, the Company adopted a Second Amended and Restated Rights Agreement pursuant to which the expiration date was extended to November 1, 2024, unless the rights are earlier redeemed or exchanged by the Company.

(c) Stock Option Plan

In April 2014, the board of directors adopted the 2014 Stock and Incentive Plan ("2014 Plan") subject to shareholder approval which was received in June 2014. The 2014 Plan provides for the granting of nonqualified and incentive stock options, stock appreciation rights, restricted stock units, restricted stock and dividend equivalents. An aggregate of 1,000,000 shares are authorized for issuance under the 2014 Plan. Additionally, 271,906 remaining authorized shares under the 2011 Equity Incentive Plan ("2011 Plan") were issuable under the 2014 Plan at the time of the 2014 Plan adoption. Upon receiving shareholder approval in June 2016, the 2014 Plan was amended and restated to increase the authorized number of shares of common stock of the Company issuable under all awards granted under the 2014 Plan from 1,271,906 to 2,471,906. Additionally, upon receiving shareholder approval in June 2018, the 2014 Plan was further amended and restated to increase the authorized number of shares of common stock of the Company issuable under all awards granted under the 2014 Plan from 2,471,906 to 3,221,906. Finally, upon receiving shareholder approval in June 2020, the 2014 Plan was further amended and restated to increase the authorized number of shares of common stock of the Company issuable under all awards granted under the 2014 Plan from 3,221,906 to 5,721,906. The board of directors, on an option-by-option basis, determines the number of shares, exercise price, term, and vesting period. Options granted generally have a ten-year contractual life. The Company issues shares of common stock upon the exercise of options with the source of those shares of common stock being either newly issued shares or shares held in treasury. An aggregate of 5,721,906 shares are authorized for issuance under the 2014 Plan, with 857,459 shares remaining available for grant as of December 31, 2021.

(9) Stockholders' Equity – (continued)

A summary of stock option activity is as follows:

	Outstanding stock options	
	Number of shares	Weighted average exercise price
Balance at December 31, 2020	3,564,458	$ 3.36
Options granted	1,105,500	1.23
Options exercised	(4,584)	1.46
Options forfeited	-	-
Options cancelled	(114,169)	4.51
Balance at December 31, 2021	4,551,205	2.82
Options exercisable at December 31, 2021	2,799,979	3.84

The following table summarizes information about stock options outstanding and exercisable at December 31, 2021:

Options outstanding				Options exercisable			
Number outstanding	Weighted average remaining contractual life (Years)	Weighted average exercise price	Aggregate intrinsic value	Number exerciseable	Weighted average remaining contractual life (Years)	Weighted average exercise price	Aggregate intrinsic value
4,551,205	6.66	$ 2.82	$ 315,330	2,799,979	5.01	$ 3.84	$ 201,966

The intrinsic value for stock options is defined as the difference between the current market value and the exercise price. The total intrinsic value of stock options exercised during the years ended December 31, 2021 and 2020 was $2,000 and zero. There were 4,584 and zero stock options exercised during the years ended December 31, 2021 and 2020, respectively.

(9) Stockholders' Equity – (continued)

(d) Common Stock Warrants

The Company accounts for its common stock warrants under ASC 480, *Distinguishing Liabilities from Equity*, which requires any financial instrument, other than an outstanding share, that, at inception, embodies an obligation to repurchase the issuer's equity shares, or is indexed to such an obligation, and requires or may require the issuer to settle the obligation by transferring assets, to be classified as a liability. In accordance with ASC 480, the Company's outstanding warrants from the November 2019 Offering are classified as a liability. The liability is adjusted to fair value at each reporting period, with the changes in fair value recognized as gain (loss) on change in fair value of warranty liability in the Company's consolidated statements of operations. The warrants issued in the November 2019 Offering allow the warrant holder, if certain change in control events occur, the option to receive an amount of cash equal to the value of the warrants as determined in accordance with the Black-Scholes option pricing model with certain defined assumptions upon a fundamental transaction.

As of December 31, 2021, the Company had 1,094,030 warrants outstanding from the November 2019 Offering to purchase an equal number of shares of common stock. The fair value of these warrants on November 18, 2019 (closing date of November 19 Offering) and December 31, 2021 and 2020 was determined using the Black-Scholes option pricing model with the following Level 3 inputs (as defined in the November 2019 Offering):

	December 31, 2021	December 31, 2020	December 31, 2019	November 18, 2019
Expected life in years	2.88	3.88	4.88	5.00
Risk-free interest rate	0.97%	0.27%	1.69%	1.63%
Dividend yield	—	—	—	—
Volatility	100.00%	100.00%	225.93%	224.47%
Stock price	$ 0.99	$ 1.36	$ 0.39	$ 0.41

During the year ended December 31, 2021, the Company recorded a non-cash gain of $356,000 from the change in fair value of the November 2019 Offering warrants and during the year ended December 31, 2020, the Company recorded a non-cash loss of $2.9 million from the change in fair value of the November 2019 Offering warrants. The following table is a reconciliation of the warrant liability measured at fair value using level 3 inputs:

	Warrant Liability
Balance at December 31, 2020	$ 1,170,051
Settlement of liabilty on warrant exercise	(18,365)
Change in fair value of common stock warrants	(355,890)
Balance at December 31, 2021	$ 795,796

Additionally, in the February 2020 Offering, the Company issued 5,042,017 common stock warrants. However, the February 2020 Offering warrants do not provide the warrant holder the option to receive an amount of cash equal to the Black-Scholes value of the warrants upon a fundamental transaction. Therefore, the Company has not recorded a warrant liability with respect to the warrants issued in the February 2020 Offering.

(9) Stockholders' Equity – (continued)

The following table summarizes the number of common stock warrants outstanding and the weighted average exercise price:

	Warrants	Weighted Average Exercise Price
Outstanding at December 31, 2020	1,944,366	$ 0.51
Issued	-	-
Exercised	(10,000)	0.50
Expired	-	-
Cancelled	-	-
Forfeited	-	-
Balance at December 31, 2021	1,934,366	$ 0.51

During the years ended December 31, 2021 and 2020, 10,000 and 15.1 million common stock warrants to purchase one share of our common stock were exercised, respectively, resulting in proceeds of approximately $5,000 and $7.7 million, respectively.

The following table summarizes information about common stock warrants outstanding at December 31, 2021:

Warrants outstanding			
Number exercisable	Weighted average remaining contractual life (Years)	Weighted average exercise price	Aggregate intrinsic value
1,934,366	3.00	$ 0.51	$ 922,629

(10) 401(k) Plan

On January 1, 2002, the Company adopted a tax qualified employee savings and retirement plan (the "401(k) Plan") covering eligible employees. Pursuant to the 401(k) Plan, employees may elect to reduce current compensation by a percentage of eligible compensation, not to exceed legal limits, and contribute the amount of such reduction to the 401(k) Plan. Beginning April 1, 2014, the 401(k) Plan was amended to require matching contributions to the 401(k) Plan by the Company on behalf of the participants of 100 percent Company match on up to four percent of an employee's compensation computed on a per pay period basis. The Company contributed $81,000 and $67,000, respectively, to the 401(k) Plan during the years ended December 31, 2021 and 2020.

(11) Commitments and Contingencies

Litigation

The Company is involved in various lawsuits, claims and other legal matters from time to time that arise in the ordinary course of conducting business. The Company records a liability when a particular contingency is probable and estimable.

On April 2, 2019, the Company filed a lawsuit against Clarus in the United States District Court for the District of Delaware alleging that Clarus's JATENZO® product infringes six of Lipocine's issued U.S. patents: 9,034,858; 9,205,057; 9,480,690; 9,757,390; 6,569,463; and 6,923,988. However, on February 11, 2020, the Company voluntarily dismissed allegations of patent infringement for expired U.S. Patent Nos. 6,569,463 and 6,923,988 in an effort to streamline the issues and associated costs for dispute. Clarus answered the complaint and asserted counterclaims of non-infringement and invalidity. The Company answered Clarus's counterclaims on April 29, 2019. The Court held a scheduling conference on August 15, 2019, a claim construction hearing on February 11, 2020, and a summary judgment hearing on January 15, 2021. In May 2021, the Court granted Clarus' motion for Summary Judgment, finding the asserted claims of Lipocine's U.S. patents 9,034,858; 9,205,057; 9,480,690; and 9,757,390 invalid for failure to satisfy the written description requirement of 35 U.S.C. § 112. Clarus still had remaining claims before the Court. On July 13, 2021, the Company entered into the Global Agreement with Clarus which resolved all outstanding claims of this litigation as well as the on-going United States Patent and Trademark Office ("USPTO") Interference No. 106,128 between the parties. Under the terms of the Global Agreement, the Company agreed to pay Clarus $4.0 million payable as follows: $2.5 million immediately, $1.0 million on July 13, 2022 and $500,000 on July 13, 2023. No future royalties are owing from either party. On July 15, 2021, the Court dismissed with prejudice the Company's claims and Clarus' counterclaims.

On November 14, 2019, the Company and certain of our officers were named as defendants in a purported shareholder class action lawsuit, *Solomon Abady v. Lipocine Inc. et al*., 2:19-cv-00906-PMW, filed in the United District Court for the District of Utah. The complaint alleges that the defendants made false and/or misleading statements and/or failed to disclose that the Company's filing of the NDA for TLANDO to the FDA contained deficiencies and as a result the defendants' statements about our business and operations were false and misleading and/or lacked a reasonable basis in violation of federal securities laws. The lawsuit seeks certification as a class action (for a purported class of purchasers of the Company's securities from March 27, 2019 through November 8, 2019), compensatory damages in an unspecified amount, and unspecified equitable or injunctive relief. The Company has insurance that covers claims of this nature. The retention amount payable by us under our policy is $1.25 million. The Company filed a motion to dismiss this class action lawsuit on July 24, 2020. In response, the plaintiffs filed their response to the motion to dismiss the class action lawsuit on September 22, 2020, and the Company filed its reply to the motion to dismiss on October 22, 2020. A hearing on the motion to dismiss occurred on January 12, 2022. The Company intends to vigorously defend ourselves against these allegations and have not recorded a liability related to this shareholder class action lawsuit as the outcome is not probable nor can an estimate be made of loss, if any.

On March 13, 2020, the Company filed U.S. patent application serial number 16/818,779 (the "Lipocine '779 Application") with the USPTO. On October 16 and November 3, 2020, the Company filed suggestions for interference with the USPTO requesting that a patent interference be declared between the Lipocine '779 Application and US patent application serial number 16/656,178 to Clarus Therapeutics, Inc. (the "Clarus '178 Application"). Pursuant to our request, the Patent Trial and Appeal Board ("PTAB") at the USPTO declared the interference on January 4, 2021 to ultimately determine, as between the Company and Clarus, who is entitled to the claimed subject matter. The interference number is 106,128, and we were initially declared Senior Party. A conference call with the PTAB was held on January 25, 2021 to discuss proposed motions. On February 1, 2021, the PTAB issued an order authorizing certain motions and setting the schedule for the preliminary motions phase. On July 13, 2021, the Company entered into the Global Agreement with Clarus to resolve interference No. 106,128 among other items. On July 26, 2021, the PTAB granted the Company's request for adverse judgment in interference No. 106,128 in accordance with the Global Agreement.

Beyond *Solomon Abady v. Lipocine Inc. et al*., 2:19-cv-00906-PM, management does not currently believe that any other matter, individually or in the aggregate, will have a material adverse effect on our financial condition, liquidity or results of operations.

(11) Commitments and Contingencies (continued)

Guarantees and Indemnifications

In the ordinary course of business, the Company enters into agreements, such as lease agreements, licensing agreements, clinical trial agreements, and certain services agreements, containing standard guarantee and / or indemnifications provisions. Additionally, the Company has indemnified its directors and officers to the maximum extent permitted under the laws of the State of Delaware.

(12) Agreement with Spriaso, LLC

The Company has a license and a services agreement with Spriaso, a related-party that is majority-owned by certain current and former directors of Lipocine Inc. and their affiliates. Under the license agreement, the Company assigned and transferred to Spriaso all of the Company's rights, title and interest in its intellectual property to develop products for the cough and cold field. In addition, Spriaso received all rights and obligations under the Company's product development agreement with a third-party. In exchange, the Company will receive a royalty of 20 percent of the net proceeds received by Spriaso, up to a maximum of $10.0 million. Spriaso also granted back to the Company an exclusive license to such intellectual property to develop products outside of the cough and cold field. The Company also agreed to continue providing up to 10 percent of the services of certain employees to Spriaso for a period of time. The agreement to provide services expired in 2021; however, it may be extended upon written agreement of Spriaso and the Company. The Company did not receive any reimbursements from Spriaso for the years ended December 31, 2021 and 2020, respectively. Additionally, during the years ended December 31, 2021 and 2020, the Company received $55,000 and zero, respectively, in royalty revenue from Spriaso. Spriaso filed its first NDA and as an affiliated entity of the Company, it used up the one-time waiver for user fees for a small business submitting its first human drug application to the FDA. Spriaso is considered a variable interest entity under the FASB ASC Topic 810-10, *Consolidations*, however the Company is not the primary beneficiary and has therefore not consolidated Spriaso.

(13) Accounting Pronouncements

Accounting Pronouncements Issued Not Yet Adopted

In 2016, the FASB issued Accounting Standards Update ("ASU") 2016-13, *Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). This standard replaces the incurred loss impairment methodology in current GAAP with a methodology that reflects expected credit losses on instruments within its scope, including trade receivables, and requires entities to measure all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions and reasonable and supportable forecasts. The original effective date for ASU 2016-13 was for annual and interim periods beginning after December 15, 2019.

However, in October 2019, the FASB issued ASU 2019-10, *Financial Instruments - Credit Losses, Derivatives and Hedging, and Leases: Effective Dates*, which deferred the effective date of ASU 2016-13 for certain entities, including those that are eligible to be smaller reporting companies. A company's determination about whether it is eligible for the deferral is a one-time assessment as of November 15, 2019 based on its most recent determination of its small reporting company eligibility as of the last business day of the most recently completed second quarter. Based on this determination, the Company qualifies as a smaller reporting entity and is therefore eligible for the deferral of adoption of ASU 2016-13, resulting in a new effective date of January 1, 2023. The Company has historically not had credit losses on financial instruments and is currently evaluating the impact the adoption of ASU 2016-13 will have on its consolidated financial statements.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures" within the meaning of Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Our disclosure controls and procedures ("Disclosure Controls") are designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act, such as this Annual Report on Form 10-K, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Our Disclosure Controls include, without limitation, controls and procedures designed to ensure that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

As of the end of the period covered by this Annual Report on Form 10-K, we evaluated the effectiveness of the design and operation of our Disclosure Controls, which was done under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer. Based on the controls evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the date of their evaluation, our Disclosure Controls were effective as of December 31, 2021.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control system was designed to provide our management and board of directors reasonable assurance regarding the reliability of financial reporting and preparation of financial statements for external purposes in accordance with GAAP. Internal control over financial reporting has inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements will not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Our management has assessed the effectiveness of internal control over financial reporting as of December 31, 2021. In making this assessment, we used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control-Integrated Framework (2013)*. Based on our assessment we believe that, as of December 31, 2021, our internal control over financial reporting is effective based on those criteria.

Change in Internal Control over Financial Reporting

During the quarter ended December 31, 2021, there have been no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that have materially affected, or 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

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Certain of the information required by this item will be contained in our definitive Proxy Statement with respect to our 2022 Annual Meeting of Stockholders, under the captions “Election of Directors,” and “Compliance with Section 16(a) of the Exchange Act” and is incorporated into this item by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item will be contained in our definitive Proxy Statement with respect to our 2022 Annual Meeting of Stockholders, under the captions “Executive Compensation”, “Compensation Committee Interlocks and Insider Participation”, and “Compensation Committee Report” and is incorporated into this item by reference.

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

The information required by this item will be contained in our definitive Proxy Statement with respect to our 2022 Annual Meeting of Stockholders, under the captions “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information” and is incorporated into this item by reference.

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

The information required by this item will be contained in our definitive Proxy Statement with respect to our 2022 Annual Meeting of Stockholders under the captions “Certain Relationships and Related Transactions” and “Independence of the Board” and is incorporated into this item by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item will be contained in our definitive Proxy Statement with respect to our 2022 Annual Meeting of Stockholders, under the caption “Principal Accountant Fees and Services” and is incorporated into this item by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this Annual Report on Form 10-K.

1. *Financial Statements.* The financial statements listed on the accompanying Index to Consolidated Financial Statements are filed as part of this report.

2. *Financial statement schedules.* There are no financial statements schedules included because they are either not applicable or the required information is shown in the consolidated financial statements or the notes thereto.

3. *Exhibits*. The following exhibits are filed or incorporated by reference as part of this Form 10-K.

INDEX TO EXHIBITS

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
2.1	Agreement and Plan of Merger and Reorganization, dated July 24, 2013, by and among Marathon Bar Corp., Lipocine Operating Inc., and MBAR Acquisition Corp.	8-K	333-178230	2.1	7/25/2013
3.1	Amended and Restated Certificate of Incorporation	8-K	333-178230	3.2	7/25/2013
3.2	Amended and Restated Bylaws	8-K	333-178230	3.3	7/25/2013
3.3	Certificate of Designation of Series A Junior Participating Preferred Stock.	8-K	001-36357	3.1	12/1/2015
3.4	Certificate of Increase of Series A Junior Participating Preferred Stock	8-K	001-36357	3.1	11/1/2021
4.1	Form of Common Stock certificate	8-K	333-178230	4.1	7/25/2013
4.2	Second Amended and Restated Stockholder Rights Agreement dated as of November 1, 2021 by and between the Company and American Stock Transfer & Trust Company, LLC	8-K	001-36357	4.1	11/1/2021
4.3	Form of Pre-Funded Warrant	8-K	001-36357	4.1	11/14/2019
4.4	Form of Common Warrant	8-K	001-36357	4.2	11/14/2019
4.5	Form of Common Warrant	8-K	001-36357	4.1	2/26/2020
4.6	Description of Registered Securities*				
10.1**	Lipocine Inc. Amended and Restated 2011 Equity Incentive Plan	8-K	333-178230	10.1	7/25/2013
10.2**	Form of Stock Option Agreement and Option Grant Notice under the 2011 Equity Incentive Plan	8-K	333-178230	10.2	7/25/2013
10.3**	Form of Restricted Stock Award Agreement and Notice under the 2011 Equity Incentive Plan	8-K	333-178230	10.3	7/25/2013
10.4**	Form of Restricted Stock Unit Agreement and Notice under the 2011 Equity Incentive Plan	10-K	001-36357	10.4	3/31/2014
10.5**	Amended and Restated Lipocine Inc. 2014 Stock and Incentive Plan	S-8	333-197421	99.1	7/15/2014
10.6	Assignment and Assumption of Lease, dated August 6, 2004, by and between Lipocine Inc. and Genta Salus LLC	8-K	333-178230	10.4	7/25/2013
10.7	Second Lease Extension and Modification Agreement, dated June 21, 2011, by and between Lipocine Inc. and Paradigm Resources, L.C.	8-K	333-178230	10.5	7/25/2013
10.8**	Form of Indemnification Agreement by and between Lipocine Inc. and each of its directors and officers	8-K	333-178230	10.6	7/25/2013
10.9	Registration Rights Agreement, dated May 25, 2004, by and between Lipocine Operating Inc. and Schwarz Pharma Limited (now UCB Manufacturing Ireland Ltd.)	8-K	333-178230	10.8	7/25/2013
10.10	Registration Rights Agreement, dated April 20, 2001, by and among Lipocine Operating Inc., Elan International Services, Ltd., and Elan Pharma International Limited	8-K	333-178230	10.9	7/25/2013
10.11	Form of Securities Purchase Agreement, dated July 26, 2013	8-K	333-178230	10.10	7/31/2013
10.12	Form of Registration Rights Agreement, dated July 26, 2013	8-K	333-178230	10.11	7/31/2013
10.13+	Manufacturing Agreement, dated August 27, 2013, by and between Lipocine Inc. and Encap Drug Delivery.	8-K	333-178230	10.12	9/5/2013
10.14**	Executive Employment Agreement, dated January 7, 2014, by and between Lipocine Inc. and Dr. Mahesh V. Patel	8-K	000-55092	10.1	1/7/2014
10.15**	Amended and Restated Executive Employment Agreement, dated January 7, 2014, by and between Lipocine Inc. and Morgan Brown	8-K	000-550920	10.2	1/7/2014

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.16**	Second Amended and Restated Lipocine Inc. 2014 Stock Incentive Plan	10-Q	001-36357	10.1	8/9/2016
10.17	Commercial Manufacturing Services and Supply Agreement, dated March 3, 2016, by and between Lipocine Inc. and M.W. Encap Ltd.	10-Q	001-36357	10.1	5/9/2016
10.18	Controlled Equity Offering[SM] Sales Agreement, dated March 6, 2017, by and between Lipocine Inc. and Cantor Fitzgerald & Co.	10-K	001-36357	10.22	3/6/2017
10.19**	Second Amended and Restated Executive Employment Agreement, dated March 3, 2017, by and between Lipocine Inc. and Morgan Brown	10-K	001-36357	10.23	3/6/2017
10.20**	Executive Employment Agreement, dated March 3, 2017, by and between Lipocine Inc. and Gregory Bass.	10-K	001-36357	10.24	3/6/2017
10.21**	Vice President Employment Agreement, dated November 5, 2018, by and between Lipocine Inc. and Nachiappan Chidambaram.	10-Q	001-36357	10.1	11/7/18
10.22	Loan and Security Agreement dated January 5, 2018	8-K	001-36357	10.1	1/9/2018
10.23**	Third Amended and Restated Lipocine Inc. 2014 Stock and Incentive Plan	10-Q	001-36357	10.1	8/7/2018
10.24	Securities Purchase Agreement, dated as of November 14, 2019, by and between Lipocine, Inc. and the purchasers identified on the signature pages thereto	8-K	001-36357	10.2	11/14/2019
10.25	Securities Purchase Agreement, dated as of February 25, 2020, by and between Lipocine, Inc. and the purchasers identified on the signature pages thereto	8-K	001-36357	10.2	2/26/2020
10.26	First Amendment to Loan and Security Agreement, dated February 16, 2021, made by and among Lipocine Inc., Lipocine Operating Inc. and Silicon Valley Bank	8-K	001-36357	10.1	2/18/2021
10.27***	License Agreement dated October 14, 2021, by and between Lipocine, Inc. and Antares Pharma, Inc.	10-Q	001-36357	10.1	11/10/2021
10.28***	Amendment No. 1 to Commercial Manufacturing Services and Supply Agreement between Lipocine, Inc. and MW Encap Ltd. Dated October 13, 2021	10-Q	001-36357	10.2	11/10/2021
10.29**	Principal Accounting Officer Employment Agreement, dated March 7, 2022, by and between Lipocine Inc. and Krista Fogarty.	8-K/A	001-36357	10.1	3/7/2022
21.1*	Subsidiaries				
23.1*	Consent of Tanner LLC				
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 Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. 1350.				
32.2*	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. 1350.				

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
101.INS*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL 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	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)				

* Filed herewith

** Management contract or compensation plan or arrangement

\+ Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been submitted separately with the Securities and Exchange Commission.

*** Certain portions of this exhibit have been omitted pursuant to Item 601(b)(10) of Regulation S-K. The Registrant hereby undertakes to furnish to the SEC, upon request, copies of any such instruments.

ITEM 16. FORM 10-K SUMMARY

None

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Lipocine Inc.
(Registrant)

Dated: March 9, 2022

/s/ Mahesh V. Patel
Mahesh V. Patel, President and Chief Executive Officer
(Principal Executive Officer and Principal Financial Officer)

Dated: March 9, 2022

/s/ Krista Fogarty
Krista Fogarty, Corporate Controller
(Principal Accounting Officer)

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 date indicated.

Signature	Title	Date
/s/ Mahesh V. Patel Mahesh V. Patel	President and Chief Executive Officer (Principal Executive Officer and Principal Financial Officer) and Chairman of the Board	March 9, 2022
/s/ Krista Fogarty Krista Fogarty	Corporate Controller (Principal Accounting Officer)	March 9, 2022
/s/ Jeffrey A. Fink Jeffrey A. Fink	Director	March 9, 2022
/s/ John Higuchi John Higuchi	Director	March 9, 2022
/s/ R. Dana Ono R. Dana Ono	Director	March 9, 2022

EXHIBIT 4.6

DESCRIPTION OF THE REGISTRANT'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES
EXCHANGE ACT OF 1934

Lipocine Inc. ("Lipocine," "we," "our," or "us") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended: our common stock.

DESCRIPTION OF CAPITAL STOCK

The following summary of the terms of our capital stock is based upon our Amended and Restated Certificate of Incorporation (the "Certificate of Incorporation") and our Amended and Restated Bylaws (the "Bylaws"). The summary is not complete, and is qualified by reference to our Certificate of Incorporation and our Bylaws, which are filed as exhibits to this Annual Report on Form 10-K and are incorporated by reference herein. We encourage you to read our Certificate of Incorporation, our Bylaws and the applicable provisions of the Delaware General Corporation Law for additional information.

Authorized Shares of Capital Stock

Our authorized capital stock consists of 100,000,000 shares of common stock, $0.0001 par value per share, and 10,000,000 shares of preferred stock, $0.0001 par value per share.

COMMON STOCK

Dividend Rights

Dividends may be declared by the Board of Directors upon the capital stock of the corporation, subject to the provisions of the Certificate of Incorporation and applicable law, if any, at any regular or special meeting. Dividends may be paid in cash, in property, or in shares of the capital stock, subject to the provisions of the Certificate of Incorporation and applicable law.

Voting Rights

Each outstanding share of common stock shall entitle the holder thereof to one vote on each matter properly submitted to the stockholders of the corporation for their vote. Corporate actions can generally be taken by a majority of our board and/or stockholders holding a majority of our outstanding shares, except that amendments to our Bylaws and amendments to certain articles of our Certificate of Incorporation require the vote of at least 66 and 2/3% of the voting power of all of the then-outstanding shares of the capital stock of the Company entitled to vote generally in the election of directors, voting together as a single class. Additionally, our stockholders do not have cumulative voting rights in the election of directors. Accordingly, holders of a plurality of the votes cast at a meeting of stockholders will be able to elect all of the directors then standing for election.

Right to Receive Liquidation Distributions

In the event of our liquidation, dissolution or winding up, holders of our common stock are entitled to receive, ratably, the net assets available to stockholders after payment of all creditors.

Rights and Preferences

Holders of our common stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of our outstanding preferred stock and shares of any series of our preferred stock that we may designate in the future.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC. The transfer agent and registrar's address is 6201 15th Avenue, Brooklyn, NY 11219. Our shares of common stock are issued in uncertificated form only, subject to limited circumstances.

Market Listing

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

Certain Anti-Takeover Effects

Certain provisions of Delaware law, our Certificate of Incorporation and our Bylaws may have the effect of delaying, deferring or discouraging another person from acquiring control of our company. These provisions, which are summarized below, may have the effect of discouraging takeover bids. They are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

Delaware Law

We are governed by the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes mergers, asset sales or other transactions resulting in a financial benefit to the stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years of the date on which it is sought to be determined whether such person is an "interested stockholder," did own, 15% or more of the corporation's outstanding voting stock. These provisions may have the effect of delaying, deferring or preventing a change in our control.

Certificate of Incorporation and Bylaw Provisions

Our Certificate of Incorporation and our Bylaws include a number of provisions that could deter hostile takeovers or delay or prevent changes in control of our management team, including the following:

- *Board of directors vacancies*. Our Certificate of Incorporation and Bylaws authorize only our board of directors to fill vacant directorships, including newly created seats. In addition, the number of directors constituting our board of directors is permitted to be set only by a resolution adopted by our board of directors. These provisions prevent a stockholder from increasing the size of our board of directors and then gaining control of our board of directors by filling the resulting vacancies with its own nominees. This makes it more difficult to change the composition of our board of directors but promotes continuity of management.

● *Stockholder action; special meeting of stockholders*. Our Certificate of Incorporation provides that our stockholders may not take action by written consent, but may only take action at annual or special meetings of our stockholders. As a result, a holder controlling a majority of our capital stock may not be able to amend our Bylaws or remove directors without holding a meeting of our stockholders called in accordance with our Bylaws. Our Bylaws further provide that special meetings of our stockholders may be called only by our board of directors, the Chairperson of our Board of Directors, our Chief Executive Officer, or a majority of the Board of Directors, thus prohibiting a stockholder from calling a special meeting. These provisions might delay the ability of our stockholders to force consideration of a proposal or for stockholders controlling a majority of our capital stock to take any action, including the removal of directors.

● *Advance notice requirements for stockholder proposals and director nominations*. Our Bylaws provide advance notice procedures for stockholders seeking to bring business before our annual meeting of stockholders or to nominate candidates for election as directors at our annual meeting of stockholders. Our Bylaws also specify certain requirements regarding the form and content of a stockholder's notice. These provisions might preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders if the proper procedures are not followed. We expect that these provisions may also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company.

● *No cumulative voting*. The Delaware General Corporation Law provides that stockholders are not entitled to the right to cumulate votes in the election of directors unless a corporation's certificate of incorporation provides otherwise. Our Certificate of Incorporation does not provide for cumulative voting.

● *Issuance of undesignated preferred stock*. Our Board of Directors will have the authority, without further action by the stockholders, to issue up to 10,000,000 shares of undesignated preferred stock with rights and preferences, including voting rights, designated from time to time by our Board of Directors. The existence of authorized but unissued shares of preferred stock would enable our board of directors to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or other means.

EXHIBIT 21.1

SUBSIDIARIES

Lipocine Operating Inc.

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors
Lipocine Inc.:

We consent to the incorporation by reference in the registration statements (Nos. 333-250072, 333-190897, 333-240197, 333-226664, 333-214492, 333-197421 and 333-191695) on Forms S-3 and S-8 of Lipocine Inc. of our report dated March 9, 2022 with respect to the consolidated balance sheets of Lipocine Inc. as of December 31, 2021 and 2020, and the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for the years then ended, and the related notes (collectively, the "consolidated financial statements"), which report appears in the December 31, 2021 annual report on Form 10-K of Lipocine Inc.

/s/ Tanner LLC

Salt Lake City, Utah
March 9, 2022

EXHIBIT 31.1

CERTIFICATIONS

I, Mahesh V. Patel, certify that:

1. I have reviewed this annual report on Form 10-K of Lipocine Inc.;

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

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

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

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

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

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

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

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

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

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

Dated: March 9, 2022

/s/ Mahesh V. Patel

Mahesh V. Patel, President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATIONS

I, Mahesh V. Patel, certify that:

1. I have reviewed this annual report on Form 10-K of Lipocine Inc.;

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

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

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

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

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

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

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

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

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

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

Dated: March 9, 2022

/s/ Mahesh V. Patel

Mahesh V. Patel
(Principal Financial Officer)

EXHIBIT 32.1

CERTIFICATION

In connection with the Annual Report on Form 10-K of Lipocine Inc. (the "Corporation") for the year ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Mahesh V. Patel, President and Chief Executive Officer of the Corporation, hereby certifies, pursuant to Rule 13a-14(b) or Rule 15d-14(b) and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Corporation.

Dated: March 9, 2022

/s/ Mahesh V. Patel

Mahesh V. Patel, President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 32.2

CERTIFICATION

In connection with the Annual Report on Form 10-K of Lipocine Inc. (the "Corporation") for the year ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Mahesh V. Patel, Principal Financial Officer of the Corporation, hereby certifies, pursuant to Rule 13a-14(b) or Rule 15d-14(b) and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Corporation.

Dated: March 9, 2022

/s/ Mahesh V. Patel

Mahesh V. Patel
(Principal Financial Officer)