

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

FORM 10-K

- ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2019
- or
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 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)

675 Arapeen Drive, Suite 202,
Salt Lake City, Utah
(Address of Principal Executive Offices)

99-0370688
(IRS Employer
Identification No.)

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 Symbols(s)	Name of 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 (Check one):

- 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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

Outstanding Shares

The aggregate market value of the common stock held by non-affiliates of the Registrant was \$43.4 million as of June 30, 2019. 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 12, 2020, the registrant had 47,854,499 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the Registrant's definitive Proxy Statement for its 2019 Annual Meeting of Stockholders are incorporated by reference into Part III of this Form 10-K.

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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.

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 metabolic and endocrine 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 proprietary product candidates designed to produce favorable pharmacokinetic (“PK”) characteristics and facilitate lower dosing requirements, bypass first-pass metabolism in certain cases, reduce side effects, and eliminate gastrointestinal interactions that limit bioavailability.

Our most advanced product candidate, TLANDO™, is an oral testosterone replacement therapy (“TRT”). On November 8, 2019 we received a Complete Response Letter (“CRL”) from the United States Food and Drug Administration (“FDA”) regarding our New Drug Application (“NDA”) filed in May 2019 for TLANDO as a TRT in adult males for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism. A CRL is a communication from the FDA that informs companies that an application cannot be approved in its present form. The CRL identified one deficiency stating the efficacy trial did not meet the three secondary endpoints for maximal testosterone concentrations (“C_{max}”). The CRL did not identify any specific issues relating to chemistry, manufacturing and controls (“CMC”) of TLANDO. We had our Post Action meeting with the FDA in January 2020 and discussed a potential path forward for the approval of TLANDO. Based on the Post Action meeting and written feedback, the FDA indicated our approach to addressing the deficiency through the reanalysis of existing data in accordance with FDA feedback appears to be a reasonable path forward. The FDA requested that the information generated by the reanalysis be submitted as part of an NDA resubmission with a six-month Prescription Drug User Fee Act (“PDUFA”) clock. We resubmitted the NDA on February 28, 2020 and it has been assigned a PDUFA date of August 28, 2020.

Additional pipeline candidates include LPCN 1144, an oral prodrug of bioidentical testosterone comprised of TU for the treatment of pre-cirrhotic non-alcoholic steatohepatitis (“NASH”), TLANDO XR (LPCN 1111), a next generation oral TRT product with the potential for once daily dosing which has completed Phase 2 testing, LPCN 1148, an oral prodrug of bioidentical testosterone for the treatment of NASH cirrhosis, and LPCN 1107, potentially the first oral hydroxyprogesterone caproate product indicated for the prevention of recurrent preterm birth, which has completed an End-of-Phase 2 meeting with the FDA.

LPCN 1144 is currently being tested in the *LiFT* (“Liver Fat intervention with oral Testosterone”) Phase 2 clinical study, a paired-biopsy study in confirmed pre-cirrhotic NASH subjects. Additionally, LPCN 1144 recently completed a Proof-Of-Concept (“POC”) liver imaging clinical study which demonstrated substantial liver fat reductions in hypogonadal males at risk of developing NASH as assessed using magnetic resonance imaging, proton density fat fraction (“MRI-PDFF”) technique.

Industry

Testosterone Background

Testosterone, or T, is the primary circulating sex hormone in males and is critical to the development and maturation of reproductive tissues as well as other secondary male characteristics such as muscle growth and bone density. Synthesized in the gonads of both males (testis) and females (ovaries), testosterone circulates bound to sex hormone binding globulin (“SHBG”, ~60%), loosely bound to albumin, a protein in the blood that binds to testosterone (~40%), or as a free molecule (~1%). Once circulating, testosterone enters cells directly and activates a network of proteins that ultimately result in metabolic conversions, which in turn produce observable effects. The concentration of circulating testosterone can vary drastically over time or between individuals and can be dependent on genetic factors, other medical conditions, lifestyle behaviors, and/or concurrent medication administration. Although large variability exists, the effects of testosterone are also determined by a number of factors including the amount of steroid penetration, sensitivity of enzymes and cellular proteins to the hormone, and the action of genomic receptors at the cellular level. As a result, assessing clinically low, or potentially high, levels of naturally occurring testosterone often requires a number of quantitative tests in conjunction with clinical evaluations.

Hypogonadism Overview

Low serum testosterone causes significant clinical impact and can result in erectile dysfunction, low libido, decreased muscle mass and strength, increased body fat, decreased bone density, decreased vitality and depressed mood. Furthermore, low serum testosterone concentrations have been found to be an independent predictor of a number of cardiovascular risk factors including obesity, abnormal lipid levels, hypertension, type 2 diabetes, and systemic inflammation. Well-designed, prospective clinical trials have determined that low testosterone levels are also independently associated with mortality risk. These findings have generated interest amongst the medical community and general public regarding the importance of maintaining appropriate serum testosterone levels, which has stimulated growth of the testosterone replacement therapy market which peaked in 2013. The testosterone therapy market contracted in 2014 due to a number of factors including the withdrawal of direct to consumer advertising mid-2014 but has seen year-over-year growth since 2014.

Hypogonadism typically refers to a permanent deficiency of sex hormones rather than a temporary deficiency that may be related to acute/chronic illnesses or other medical, personal, or environmental factors. Primary hypogonadism describes disease states that intrinsically affect the gonads. Examples of these include the genetic disorders, Turner syndrome and Klinefelter syndrome. Secondary hypogonadism refers to disease states that affect gonadal-related structures such as the hypothalamus and pituitary gland that directly impact the development of gonads and as such the release of testosterone and other sexual hormones. Kallmann syndrome, in which patients fail to undergo all of the changes associated with puberty, is a type of secondary hypogonadism. Although a number of inherited diseases are known to affect the gonads either directly or indirectly, it is generally believed that the majority of individuals with hypogonadism develop the condition as a result of age-related declines in testosterone or other acquired conditions.

Diagnosis and Treatment of Hypogonadism

Epidemiological studies have determined that total testosterone follows an age-related decline with mean serum concentration at the age of 75 years approximately two thirds that at 25 years. Because naturally occurring testosterone exists at low concentrations, with normal testosterone levels in the range of 300 to 1100 ng/dL automated platform-based assays have been found to lack specificity and are prone to inter-lab variability. The lack of reliable laboratory tests is complicated further by the inter-individual variability seen in an unaffected population. Thus, in order to accurately diagnose hypogonadism in a male, at least two morning serum testosterone levels are performed in conjunction with a clinical assessment of patient symptoms. Patients can only be diagnosed when they present with symptoms that are directly related to low morning serum testosterone level.

Treatment for male hypogonadism (both primary and secondary) is testosterone replacement therapy, or TRT. Some of the reported benefits of TRT include improved libido and sexual function; increased bone density, muscle development, and cognition; as well as a reduction in other risk factors caused by low testosterone.

Testosterone Replacement Market

Due to the wide variability in therapeutic range and other medical conditions that may confound an accurate diagnosis, there is a consensus that male hypogonadism is significantly undertreated. A large study of 1,475 men between the ages of 30 and 79 years old revealed that the prevalence of hypogonadism is about 24%. Based on this prevalence rate and the U.S. Census Bureau's 2017 estimate that there are 90.4 million men between 30 years old and 79 years old, approximately 21.7 million men in the U.S. may have low testosterone. In the study fewer than 4% of patients were receiving treatment for hypogonadism.

Testosterone replacement therapies have been commercially available in the United States for over 70 years and have followed a progression of delivery systems that included subcutaneous, or under-the-skin, injection, intramuscular injection, transdermal patch, and finally topical gels, which initially surfaced in 2000, and creams. In 2018, a weekly subcutaneous-delivery system for testosterone was approved. The difficulty in creating an easy to use/administer and clinically effective testosterone therapy is related to the molecule's complex pharmacokinetics. Pharmacokinetics, or PK, describe how the body affects a specific drug after administration through the mechanism of absorption and distribution, as well as the chemical changes of the substance in the body. For example, oral therapies, which would ideally be the most popular route of delivery, require multiple, high daily doses due to low bioavailability. Bioavailability is the fraction of a drug dose that is actually absorbed into the bloodstream. Additionally, the few oral therapies that have been used in the United States previously quickly went out of favor after significant side effects were revealed, most notably liver toxicity.

Currently, the U.S. TRT market consists of therapies that exist in four forms:

- gel/patch;
- injectable;
- intranasal; and
- buccal tablet, which is a tablet shaped patch applied to the upper gums.

Although transdermal patches were previously the most desirable application type, gel-based TRT has gained increasing popularity due to improved skin tolerability. Despite becoming a popular approach to male hypogonadism treatment, topical gels are not without limitations. Topical gels place women and children at risk of testosterone transference (secondary exposure to gels), which has prompted the FDA to add black box warnings relating to testosterone transference in the label of approved topical products. Despite these limitations, gels have continued to demonstrate significant market penetration.

The male testosterone market was \$1.7 billion in 2018 according to IMS Health data. Additionally, testosterone replacement prescriptions were approximately 7.2 million in 2018 according to IMS Health data. Injectables are the predominant dosage form in this market in terms of annual prescriptions written although topical gels garner the majority of the dollar sales and also have a significant share of total annual prescriptions. The historical growth in the market was driven by increasing recognition by both patients and providers of the prevalence of hypogonadism and its far-reaching medical consequences. Top treatments are marketed by AbbVie Inc. ("AbbVie") and Endo Pharmaceuticals ("Endo").

Product Candidates

Our current portfolio includes our most advanced product candidate, TLANDO, an oral testosterone replacement therapy product candidate, which received a CRL on November 8, 2019. Additionally, we are in the process of establishing our pipeline of other clinical candidates including an oral androgen therapy for the treatment of pre-cirrhotic NASH, LPCN 1144, a next-generation potential once daily oral testosterone replacement therapy, TLANDO XR (LPCN 1111), an androgen therapy for the treatment of NASH cirrhosis, LPCN 1148, and an oral therapy for the prevention of preterm birth, LPCN 1107.

These products are based on our proprietary Lip'ral drug delivery technology platform. Lip'ral technology is a patented technology based on lipidic compositions which form an optimal dispersed phase in the gastrointestinal environment for improved absorption of insoluble drugs. The drug loaded dispersed phase presents the solubilized drug efficiently at the absorption site (gastrointestinal tract membrane) thus improving the absorption process and making the drug less dependent on physiological variables such as dilution, gastro-intestinal pH and food effects for absorption. Lip'ral based formulation enables improved solubilization and higher drug-loading capacity, which can lead to improved bioavailability, reduced dose, faster and more consistent absorption, reduced variability, reduced sensitivity to food effects, improved patient compliance, and targeted lymphatic delivery where appropriate.

TLANDO: An Oral Product Candidate for Testosterone Replacement Therapy

Our most advanced product, TLANDO, is an oral formulation of the chemical, TU, which is an eleven carbon side chain attached to T. TU is an ester prodrug of T. An ester is chemically formed by bonding an acid and an alcohol. Upon the cleavage, or breaking, of the ester bond, T is formed. TU has been approved for use outside the United States for many years for delivery via intra-muscular injection and in oral dosage form and recently TU has received regulatory approval in the United States for delivery via intra-muscular injection. We are using our proprietary technology to facilitate steady gastrointestinal solubilization and absorption of TU. Proof of concept 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 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%.

NDA PDUFA Outcome

On November 8, 2019 we received a CRL from the FDA regarding our NDA filed in May 2019 for TLANDO as a TRT in adult males for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism. The CRL identified one deficiency stating the efficacy trial did not meet the three Cmax secondary endpoints. The CRL does not identify any specific issues relating to CMC of TLANDO. We had a Post Action meeting with the FDA in January 2020 and discussed a potential path forward for the approval of TLANDO. Based on the Post Action meeting and written feedback, the FDA indicated our approach to addressing the deficiency through the reanalysis of existing data in accordance with FDA feedback appears to be a reasonable path forward. The FDA requested that the information generated by the reanalysis be submitted as part of an NDA resubmission with a six-month Prescription Drug User Fee Act ("PDUFA") clock. We resubmitted the NDA on February 28, 2020 and it has been assigned a PDUFA date of August 28, 2020. Previously, we have received two other CRL's from the FDA on TLANDO NDA submissions. The first CRL was received on June 28, 2016 and the second CRL was received on May 8, 2018.

Results from the ABPM Study

The ABPM Study was an open label, single arm study that enrolled 144 male hypogonadal subjects undergoing four months of treatment with TLANDO, 225 mg BID dosing, with 24-hour blood pressure measurements taken at baseline and at the end of the study. There were 138 subjects who received at least one dose of study drug and 126 subjects completed the study. There were 118 subjects enrolled in the ABPM Study with evaluable weighted average 24-hour ABPM data at both baseline and at the end of the study.

Subjects receiving treatment in the ABPM Study had following baseline parameters:

Baseline Parameters	Mean (SD)
Age (years)	53.8 (10.2)
BMI (kg/m ²)	33.1 (5.8)
24h SBP (mm Hg)	127 (16)
24h DBP (mm Hg)	79 (6)

SD = Standard Deviation, BMI = Body Mass Index, SBP = Systolic Blood Pressure, DBP = Diastolic Blood Pressure

Additionally, among the subjects enrolled in the ABPM Study, 48% of the subjects were hypertensive and 24% of subjects were type 2 diabetic.

Top-line results from the ABPM Study are as follows:

Parameter	Mean Change, mm Hg (95% CI)
24-hour SBP	3.82 (1.69, 5.96)
24-hour DBP	1.20 (0.31, 2.08)

CI = Confidence Interval, SBP = Systolic Blood Pressure, DBP = Diastolic Blood Pressure

Of the subjects (n=25) with baseline 24-hour average systolic blood pressure (“SBP”) greater than 140 mm Hg, 32% of the subjects were less than or equal to 140 mm Hg at the end of study. Additionally, of the subjects (n=93) with baseline 24-hour average SBP of less than or equal to 140 mm Hg, 9.7% of the subjects were greater than 140 mm Hg at the end of study.

Results from the Definitive Phlebotomy Study

The definitive phlebotomy study was designed based on the FDA’s protocol recommendations and conducted in response to a deficiency cited in the TLANDO CRL by the FDA to confirm the reliability of TLANDO Phase 3 study results and to assess the impact of any material deviation from instructions on sample collection/processing times by clinical sites.

The definitive phlebotomy study measured testosterone concentrations in blood samples collected in plain serum separation tubes (“SST”) at three-hour and five-hour time points (N=24) post dose and processed within 30 minutes of sample collection under the tube manufacturer’s recommended conditions and consistent with Phase 3 instructions. The definitive phlebotomy study enrolled 12 hypogonadal male subjects and dosed subjects with a single oral 225 mg TU dose of TLANDO. The testosterone measurements in SST were compared against the FDA’s recommended time zero control (processed immediately) measurement of testosterone concentrations in blood samples in plasma tubes with EDTA (“PT”) to assess ex vivo conversion, if any.

The top-line results of the definitive phlebotomy study demonstrated that the overall (N=24) mean percentage difference and the associated percentage standard deviation post dose of testosterone concentrations measured between SST samples and PT samples are -1.0% and 9.2%, respectively.

Results from DV and DF Studies

The DV and DF studies were both an open-label, fixed dose (no titration), single treatment clinical study of oral TRT in hypogonadal males with low testosterone (T) (< 300 ng/dL) that assessed TLANDO in hypogonadal males on a fixed daily dose of 450 mg divided into two equal doses (“BID”) in the DV study and into three equal doses (“TID”) in the DF study. In total, 95 and 100 subjects were enrolled into DV and DF studies, respectively, with 94 and 98 subjects completing the DV and DF studies, respectively.

We believe the results from the DV study confirm the validity of a fixed dose approach without the need for dose titration to orally administering TLANDO although there is no guarantee of FDA approval of TLANDO. The DV study is considered our pivotal efficacy clinical study. TLANDO successfully met the FDA primary efficacy guidelines in the DV study safety statistical analysis set (“SS”) where 80% of the subjects achieved average testosterone levels (“Cavg”) within the normal range with a lower bound confidence interval (“CI”) of 72%. The DF study restored 70% of the subjects’ average testosterone levels within the normal range (Cavg) confirming that twice daily (“BID”) dosing is the appropriate dosing regimen for TLANDO and was the basis for resubmission. The safety set is defined as any subject that was randomized into the study and took at least one dose (N=95 subjects in the DV study and N=100 in the DF study). A baseline carried forward approach was used to account for missing data as a result of subject discontinuation.

The primary efficacy endpoint is the percentage of subjects with Cavg within the normal range, which is defined as 300-1080 ng/dL. The FDA guidelines for primary efficacy success is that at least 75% of the subjects on active treatment achieve a testosterone Cavg within the normal range; and the lower bound of the 95% CI must be greater than or equal to 65%.

The adverse event profile of TLANDO in both the DV and DF studies was consistent with the previously conducted 52-week Phase 3 Study of Androgen Replacement (“SOAR”) clinical trial. All drug related adverse events (“AEs”) were either mild or moderate in intensity and none were severe. To date, the safety database of TLANDO includes ~591 subjects demonstrating a profile consistent with other TRT products.

The secondary endpoints assessed the maximum total testosterone concentration (“Cmax”) post dosing using predetermined limits developed by the FDA for transdermals. The FDA guidelines for secondary efficacy success is that at least 85% of the subjects achieve Cmax less than 1500 ng/dL; no greater than 5% of the subjects have Cmax between 1800 ng/dL and 2500 ng/dL; and zero percent of the subjects have Cmax greater than 2500 ng/dL. Consistent with the definition of Cmax and the pharmacokinetic profile of multiple times a day dosing, two pre-specified analyses were performed, Cmax per dose and Cmax per day.

In the DV study SS Cmax per dose analysis, the percentage of subjects with Cmax less than 1500 ng/dL and between 1800 ng/dL and 2500 ng/dL were 85% and 7%, respectively. Deviations from the predetermined limits in the DV study were observed in the Cmax per day dose analysis for these thresholds as such this efficacy trial did not meet the three Cmax per day secondary endpoints. Only one subject, who was a major protocol violator, exceeded the 2500 ng/dL limit independent of per dose or per day dose analyses.

The DF study SS met all Cmax thresholds in per dose and per day dose analyses.

Prior to conducting the DV study and the DF study, we completed our SOAR pivotal Phase 3 clinical study evaluating efficacy and 52-week safety of TLANDO. The SOAR study is considered our pivotal safety clinical study for the NDA resubmission.

Results from SOAR

SOAR was a randomized, open-label, parallel-group, active-controlled, Phase 3 clinical study of TLANDO in hypogonadal males with low testosterone (< 300 ng/dL). In total, 315 subjects at 40 active sites were assigned, such that 210 were randomized to TLANDO and 105 were randomized to the active control, AndroGel 1.62%®, for 52 weeks of treatment. The active control is included for safety assessment. TLANDO subjects were started at 225 mg TU (equivalent to ~ 142 mg of T) twice daily (“BID”) with a standard meal and then dose titrated, if needed, based on average T levels during the day, Cavg, and peak serum T levels, Cmax, up to 300 mg TU BID or down to 150 mg TU BID based on serum testosterone measured at weeks 3 and 7 based on PK profile with multiple blood samples drawn at each time period. The mean age of the subjects in the trial was ~53 years with ~91% of the patients < 65 years of age. The discontinuation rate for TLANDO was 38% compared to 32% for AndroGel 1.62%.

Primary statistical analysis was conducted using the Efficacy Population Set (“EPS”). The EPS is defined as subjects randomized into the study with at least one PK profile and no significant protocol deviations and includes imputed missing data by last observation carried forward, N=151. Further analysis was performed using the full analysis set (“FAS”) (any subject randomized into the study with at least one post-baseline efficacy variable response, N=193) and the SS (any subject that was randomized into the study and took at least one dose, N=210).

Safety

The safety component of the SOAR trial was completed the last week of April 2015. The safety extension phase was designed to assess safety based on information such as metabolites, biomarkers, laboratory values, serious adverse events SAEs and AEs, with subjects on their stable dose regimen in both the treatment arm and the active control arm. TLANDO treatment was well tolerated in there were no hepatic, cardiac or drug related SAEs.

TLANDO safety highlights include:

- TLANDO was well tolerated during 52 weeks of dosing;
- Overall AE profile for TLANDO was comparable to the active control;
- Cardiac AE profiles were consistent between treatment groups and none of the observed cardiac AEs occurred in greater than 1.0% of the subjects in the TLANDO arm and none were classified as severe; and
- All observed adverse drug reactions (“ADRs”) were classified as mild or moderate in severity and no serious ADRs occurred during the 52-week treatment period.

Food Effect Study

We also completed our labeling “food effect” study in May 2015. Results from the labeling “food effect” study indicate that bioavailability of testosterone from TLANDO is not affected by changes in meal fat content. The results demonstrate comparable testosterone levels between the standard fat meal (similar to the meal instruction provided in the Phase 3 clinical study) and both the low and high fat meals. The labeling “food effect” study was conducted per the FDA requirement and we submitted preliminary results from this study to the FDA in the second quarter of 2015 prior to submitting the NDA.

Other Safety Requirements

Based on our meetings with the FDA, we do not expect to be required to conduct a heart attack and stroke risk study prior to the potential approval of TLANDO. We may, however, be required to conduct a heart attack and stroke risk study on our own or with a consortium of sponsors that have an approved TRT product subsequent to the potential approval of TLANDO.

Recent Competition Update

On March 27, 2019, Clarus Therapeutics, Inc.'s ("Clarus") product JATENZO®, an oral testosterone undecanoate product, was approved by the FDA and also received three years of data exclusivity. It is unclear how Jatenzo's three years of data exclusivity will impact the potential full approvability of TLANDO. The potential exists that, as a result of Clarus' data exclusivity, the approval of TLANDO by the FDA, if ever received, could be delayed until March 27, 2022. On February 10, 2020, Clarus announced that JATENZO® has been launched and is commercially available. Additionally on October 2, 2019, Clarus filed a Citizens Petition with the FDA requesting the FDA establish clear, written guidance regarding the safety and efficacy standards required for oral testosterone drugs. The Citizens Petition also requested that the FDA not approve any oral testosterone drugs until the written guidance is provided by the FDA. We will not know the impact that Clarus' Citizen Petition may have on TLANDO's approval until the FDA addresses the Citizens Petition specifically which may have an adverse effect on TLANDO.

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 pre-cirrhotic NASH. NASH is a more advanced state of non-alcoholic fatty liver disease ("NAFLD") and can progress to a cirrhotic liver and eventually hepatocellular carcinoma or liver cancer. Twenty to thirty percent of the U.S. population is estimated to suffer from NAFLD and fifteen to twenty percent of this group progress to NASH, which is a substantially large population that lacks effective therapy. Currently, there are no FDA approved treatments for NASH. Approximately 50% of NASH patients are in adult males and the number of NASH cases is projected to increase 63% from 16.5 million cases in 2015 to 27.0 million cases in 2030. 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. In men, especially with comorbidities associated with NAFLD/NASH, testosterone deficiency has been associated with an increased accumulation of visceral adipose tissue and insulin resistance, which could be factors contributing to NAFLD/NASH.

History of Liver Disease

The liver is the largest internal organ in the human body and its proper function is indispensable for many critical metabolic functions, including the regulation of lipid and sugar metabolism, the production of important proteins, including those involved in blood clotting, and purification of blood. There are over 100 described diseases of the liver, and because of its many functions, these can be highly debilitating and life-threatening unless effectively treated. Liver diseases can result from injury to the liver caused by a variety of insults, including hepatitis C virus (HCV), hepatitis B virus (HBV), obesity, chronic excessive alcohol use or autoimmune diseases. Regardless of the underlying cause of the disease, there are important similarities in the disease progression including increased inflammatory activity and excessive liver cell apoptosis, which if unresolved leads to fibrosis. Fibrosis, if allowed to progress, will lead to cirrhosis, or excessive scarring of the liver, and eventually reduced liver function. Some patients with liver cirrhosis have a partially functioning liver and may appear asymptomatic for long periods of time, which is referred to as decompensated liver disease. Decompensated liver disease is when the liver is unable to perform its normal functions. Many people with active liver disease remain undiagnosed largely because liver disease patients are often asymptomatic for many years.

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.

Relationship between Hypogonadism and NAFLD

Preclinical and clinical studies in the NAFLD/NASH literature have shown the prevalence of testosterone deficiency across the NAFLD/NASH histological spectrum wherein low testosterone was independently associated with NAFLD/NASH with an inverse relationship between testosterone and NAFLD/NASH symptom severity. A recent National Institute of Diabetes and Digestive and Kidney Diseases (“NIDDK”) report suggests that 75% of biopsy confirmed NASH subjects have less than 372 ng/dL of total testosterone and that the degree of fibrosis severity is inversely related to free testosterone levels; thus, providing a good rationale for testing LPCN 1144 in adult NASH patients regardless of their hypogonadal status. Recently, we received clearance from the FDA to clinically investigate LPCN 1144 in an expanded target population of adult male NASH patients. Specifically, the FDA waived the limitation of only testing LPCN 1144 in NASH subjects with total testosterone levels below 300 ng/dL (threshold for hypogonadism).

Post hoc analyses of our existing clinical trials in subjects with comorbidities typically associated with NASH comorbidities indicate that testosterone therapy significantly and consistently reduced elevated levels of key serum biomarkers (liver function enzymes and serum triglyceride) generally associated with NAFLD/NASH.

Current Status

We have completed a 16-week POC liver imaging clinical study to assess liver fat changes in hypogonadal men at risk of developing NASH using MRI-PDFF technique. Treatment results from the POC liver imaging study demonstrated that 48% of the treated NAFLD subjects, defined as baseline liver fat of at least 5%, had NAFLD resolution, defined as liver fat <5% post treatment. Additionally, 100% of the subjects experiencing NAFLD resolution had at least a 35% relative liver fat reduction from baseline with a relative mean liver fat reduction of 55% in this group. Further results from the POC liver fat clinical study after 16 weeks of treatment are as follows:

Baseline Liver Fat % Category, n	Mean Liver Fat % at Baseline	Relative Reductions at EOS		Responder Rate** at EOS, %
		Mean %	Median %	
At least 10%, n=8	20.5	40	39	75
At least 8%, n=10	18.3	42	42	80
At least 5%, n=21	12.1	33	41	71

**Based on subjects who experienced at least a 30% reduction in liver fat from baseline.

Additionally, we have initiated the *LiFT* (“Liver Fat intervention with oral Testosterone”) Phase 2 clinical study, a paired-biopsy study in confirmed pre-cirrhotic NASH subjects with the first subject being dosed in the third quarter of 2019. The formulations being studied in the Phase 2 clinical trial are differentiated from TLANDO. The *LiFT* Phase 2 clinical study is a prospective, multi-center, randomized, double-blind, placebo-controlled multiple-arm study in biopsy-confirmed hypogonadal or eugonadal male NASH subjects with grade F2/F3 fibrosis and a NAFLD Activity Score (“NAS”) ≥ 4 with a 36-week treatment period. The *LiFT* clinical study is designed to enroll between 60 and 75 biopsy confirmed NASH male subjects, randomized into one of three arms (two test arms and one placebo arm) with a 1:1:1 randomization ratio. We currently expect top-line liver fat reduction data in the second half of 2020, as measured by MRI-PDFF at 12 weeks, followed by 36-week biopsy data which is expected by the first half of 2021.

TLANDO XR (LPCN 1111): A Next-Generation Long-Acting Oral Product Candidate for TRT

TLANDO XR (LPCN 1111) is a next-generation, novel ester prodrug of testosterone which uses the Lip’ral 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 TLANDO XR (LPCN 1111) along with safety and tolerability of TLANDO XR (LPCN 1111) and its metabolites following oral administration of single and multiple doses in hypogonadal men. The Phase 2b clinical trial was a randomized, open label, two-period, multi-dose PK study that enrolled hypogonadal males into five treatment groups. Each of the 12 subjects in a group received treatment for 14 days. Results of the Phase 2b study suggest that the primary objectives were met, including identifying the dose expected to be tested in a Phase 3 study. 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, TLANDO XR (LPCN 1111) was well tolerated with no drug-related severe or serious adverse events reported in the Phase 2b study.

Additionally in October 2014, we completed a Phase 2a proof-of-concept study in hypogonadal men. The Phase 2a open-label, dose-escalating single and multiple dose study enrolled 12 males. Results from the Phase 2a clinical study demonstrated the feasibility of a once daily dosing with TLANDO XR (LPCN 1111) in hypogonadal men and a good dose response. Additionally, the study confirmed that steady state is achieved by day 14 with consistent inter-day performance observed on day 14, 21 and 28. No subjects exceeded C_{max} of 1500 ng/dL at any time during the 28-day dosing period on multi-dose exposure. Overall, TLANDO XR (LPCN 1111) was well tolerated with no serious AE's reported.

We have also completed a preclinical toxicology study with LPCN 1111 in dogs.

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 TLANDO XR (LPCN 1111). Based on the results of the FDA meeting and additional pre-clinical trials conducted after the FDA meeting, we are designing a Phase 3 protocol for TLANDO XR (LPCN 1111) and will solicit FDA feedback once the protocol is complete. Additionally, the FDA previously requested that a food effect study be completed, and that ABPM be included as part of the Phase 3 clinical study. Based on our capital resources and the clinical status of our product candidates, we plan to primarily focus our efforts in 2020 on TLANDO and LPCN 1144. We do not anticipate the initiation of a Phase 3 study with LPCN 1111 to occur in 2020 unless and until additional capital is secured or the product candidate is out-licensed. We are exploring the possibility of licensing LPCN 1111 to a third party, although no licensing agreement has been entered into by the Company.

LPCN 1148: An Oral Prodrug of Bioidentical Testosterone Product Candidate for the Treatment of NASH in Cirrhotic patients

NASH cirrhosis is an end stage NAFLD for which there is no FDA approved drug treatment. During 2015, approximately 1.3 million NASH patients had cirrhosis (fibrosis grade 4). Cirrhosis patients typically experience increased morbidity and mortality and symptoms of hypogonadism such as alteration of hair distribution, anemia, sexual dysfunction, testicular atrophy, muscle wasting, fatigue, osteoporosis, gynecomastia, and other symptoms.

Testosterone levels fall progressively with increasing chronic liver disease severity. Low testosterone levels, reported in up to 90% of male cirrhotic patients, is known to increase adverse outcomes and is a predictor of mortality in these patients with association with increased risk of major infections, death and/ or transplantation rates, increased risk of hepatic decompensation, worsening of sarcopenia, higher Child Pugh score grade and Model for End-stage Liver Disease score as well as severity of portal hypertension and ascites grade.

We are currently formulating plans to conduct a proof-of-concept study in male cirrhotic subjects through consultations with the FDA and key opinion leaders to evaluate the therapeutic potential of LPCN 1148 for the treatment of cirrhotic subjects. We plan to file an Investigational New Drug application ("IND") for LPCN 1148 in March 2020. Based on our capital resources and the clinical status of our product candidates, we plan to primarily focus our efforts in 2020 on TLANDO and LPCN 1144. We do not anticipate the initiation of a Phase 2 study with LPCN 1148 to occur in 2020 unless and until additional capital is secured or the product candidate is out-licensed. We are exploring the possibility of licensing LPCN 1148 to a third party, although no licensing agreement has been entered into by the Company

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 preterm birth (delivery less than 37 weeks) ("PTB") 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.

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 of three dose levels of LPCN 1107 and the injectable intramuscular ("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 (C_{avg0-24}) 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. We have also completed a proof-of-concept Phase 1b clinical study of LPCN 1107 in healthy pregnant women in January 2015 and a proof-of-concept Phase 1a clinical study of LPCN 1107 in healthy non-pregnant women in May 2014. These studies were designed to determine the PK and bioavailability of LPCN 1107 relative to an IM HPC, as well as safety and tolerability.

A traditional pharmacokinetics/pharmacodynamics (“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 Phase 3 development plan for LPCN 1107. During the meetings, the FDA agreed to a randomized, open-label, two-arm clinical study to include a LPCN 1107 arm and a comparator IM arm with treatment up to 23 weeks. The FDA also provided preliminary feedback on other critical Phase 3 study design considerations including: positive feedback on the proposed 800 mg BID Phase 3 dose and dosing regimen; confirmation of the use of a surrogate primary endpoint focusing on rate of delivery less than 37 weeks gestation rather on clinical infant outcomes; acknowledgment that the use of a gestational age endpoint would likely lead to any FDA approval, if granted, being a Subpart H approval; and, recommendation of a non-inferiority (“NI”) study margin of 7% with interim analyses. A standard statistical design for an NI study based on the FDA feedback of 7% for the primary endpoint may require approximately 1,100 subjects per treatment arm with a 90% power. However, based on the FDA’s suggestion of including an interim analysis in the NI design, an adaptive study design is under consideration that may allow for fewer subjects. We submitted the initial LPCN 1107 Phase 3 protocol to the FDA via an SPA in June 2017 and have received multiple rounds of FDA’s feedback. However, agreement with the FDA on the Phase 3 protocol via SPA has not occurred as we are waiting for minutes from the FDA’s Advisory Committee meeting for AMAG Pharmaceuticals’ Makena which was held on October 29, 2019. Final agreement with the FDA on the Phase 3 protocol, if reached, may or may not confirm the FDA’s preliminary feedback on the Phase 3 design. Additionally, a Phase 3 study will not occur until the results from a planned food-effect study with LPCN 1107 are reviewed by the FDA, though manufacturing scale-up work for LPCN 1107 has been completed.

Based on our capital resources and the clinical status of our product candidates, we plan to primarily focus our efforts in 2020 on TLANDO and LPCN 1144. We do not anticipate the initiation of a Phase 3 study with LPCN 1107 to occur in 2020 unless and until additional capital is secured or the product candidate is out-licensed. 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.

Research and Development

We currently have five products in our development pipeline (TLANDO, LPCN 1144, TLANDO XR, LPCN 1148 and LPCN 1107) and we continue to conceptualize and discuss new indications for current products as well as new development opportunities. In 2019 and 2018, we spent \$7.5 million and \$6.5 million, respectively, on research and development.

Competition

Testosterone Market Overview

The gel-based testosterone replacement products that are currently available include AbbVie’s AndroGel® , Eli 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 Auxilium in 2015. Antares Pharma, Inc. markets a sub-cutaneous weekly auto-injector testosterone therapy, Xyosted™. Aytu BioScience Inc. markets an intranasal testosterone therapy, Natesto®, which it licensed from Acerus Pharmaceuticals in 2016. Finally, Clarus markets an oral testosterone replacement therapy, JATENZO®, which received approval in March 2019.

Historically testosterone gels have dominated the testosterone replacement therapy market in terms of sales dollars while intramuscular injections have the highest market share in the testosterone replacement market in terms of annual prescriptions. While gels are a widely-used form of testosterone replacement therapy, 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 ("TE") 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 ("RLD"). Teva's version was found to be bioequivalent 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. Eli 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 Eli Lilly and Company and a leading authorized generics company

Other Therapies in Development

Recently there has been increased interest in developing oral testosterone replacement 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 Pharmaceuticals is developing an oral testosterone undecanoate 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). The product candidate has completed Phase 2 clinical trials in hypogonadal males and an end of Phase 2 meeting has been requested of the FDA. Marinus is also currently conducting Phase 3 studies for TRT in men suffering from hypogonadism.

Mereo BioPharma Group Ltd. is currently developing BGS649, a once weekly aromatase inhibitor, for first-line therapy for the treatment of obese men with hypogonadotropic hypogonadism. BGS649 has completed Phase 2b testing.

TesoRx Pharma LLC is developing an oral bio-identical testosterone, TSX-002, for the treatment of Constitutional Delay of Growth and Puberty. Phase 2 clinical studies have been completed. TesoRx is also developing a potential once-daily oral testosterone undecanoate product candidate, TSX-049, as a testosterone replacement therapy for the treatment of hypogonadism in men.

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 ("UDCA"). There are several product candidates in Phase 3 or earlier clinical or preclinical development for the treatment of NASH, including Genfit SA's PPAR alpha/delta agonist (elafibranor), Gilead Sciences, Inc.'s ASK-1 inhibitor (selonsertib) and Allergan plc's dual CCR2 and CCR5 inhibitor (cenicriviroc), as well as FXR agonists from Novartis AG (tropifexor), Gilead Sciences, Inc. (GS-9674) and Enanta Pharmaceuticals, Inc. (EDP-305).

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. NASH is a complex disease and we believe that it is unlikely that any one therapeutic option will be optimal for every NASH patient.

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 (~180,000 pregnancies annually) is a weekly intramuscular injection of hydroxyprogesterone caproate, marketed by AMAG Pharmaceuticals, Inc. 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 which expired in February 2018. Generic versions of the intramuscular injection of Makena became available during 2018. In order to protect market share, AMAG 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. AMAG Pharmaceuticals 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 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. The advisory committee’s recommendation, while not binding, will be considered by the FDA in making its decision. We are awaiting FDA’s decision regarding Makena before proceeding on further development of LPCN 1107.

AMAG Pharmaceuticals acquired Makena from Lumara Health Inc. in November 2014 for an upfront consideration of \$675.0 million (\$600.0 million in cash and \$75.0 million in AMAG Pharmaceuticals stock) and additional contingent consideration of up to \$350.0 million based on achievement of certain sales milestones.

Manufacturing Agreement

On March 3, 2016, we entered into a Commercial Manufacturing Services and Supply Agreement (the “Manufacturing Agreement”) with M.W. Encap Ltd. (“Encap”), a United Kingdom based contract manufacturer, a division of Capsugel Dosage Form Solutions which is a subsidiary of Lonza. Pursuant to the Manufacturing Agreement, Encap has agreed to manufacture and supply bulk commercial quantities of TLANDO. From the effective date of the Manufacturing Agreement through the fifth anniversary of the date that FDA approval is obtained for the sale and marketing of TLANDO in the United States unless earlier terminated, we have agreed to purchase a minimum of TLANDO on an annual basis from Encap once we receive commercial approval on the basis of a 12-month rolling commercial forecast in which the first 3 months of each rolling forecast are binding on us. Such forecast may be subsequently increased or decreased by us pursuant to the terms of the Manufacturing Agreement.

In general, we may terminate the Manufacturing Agreement without incurring any fees or costs upon 90 days written notice or immediately if Encap is not able to meet our reasonable requirements of TLANDO. We and Encap may each terminate the Manufacturing Agreement upon a material breach of the Manufacturing Agreement by the other party, so long as the other party has not cured such breach within a defined period after written notice of the breach by the non-breaching party or in the event the other party becomes insolvent or goes into bankruptcy, liquidation or receivership. Encap may terminate the Manufacturing Agreement if we have not placed a firm order for TLANDO within a defined period of time from the date of FDA approval of TLANDO. Additionally, Encap may terminate the Manufacturing Agreement without cause upon the provision of written notice within a defined period of time advance written notice.

Additionally, we entered into an Agreement for the Manufacture of Testosterone Undecanoate Liquid Fill Capsules and the Conduct of an ICH Stability Study in Support of Product Registration with Encap pursuant to which Encap manufactured and supplied to us a total of six lots of TLANDO capsules under current good manufacturing practices. These lots were used in Lipocine’s Phase 3 study for TLANDO. Under the agreement, Encap is also conducting an International Conference on Harmonisation stability program on all six capsule lots in support of our resubmitted NDA filing for TLANDO. If Encap is unable to produce sufficient capsules for our future clinical trials or to support demand for TLANDO if it becomes commercially available, our revenue and profitability would be adversely affected.

Intellectual Property

Drug Delivery Technologies for Lipophilic Drug Substances

TLANDO is an oral formulation of the lipophilic prodrug testosterone undecanoate, utilizing our proprietary technology for improved delivery of lipophilic therapeutic agents. 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. As of March 12, 2020, our intellectual property patent portfolio is as follows:

- 11 issued patents in the US related to Oral TU with 2029-2030 expiration dates;
- 4 other US patent applications related to Oral TU;
- 4 US patent applications related to Oral TU with potential expiration dates, if issued, in 2029;
- 6 US patent applications related to Oral TU with potential expiration dates, if issued, in 2030;
- 6 US patent applications related to Oral TU with potential expiration dates, if issued, in 2035-2037;
- 2 issued US patents related to TLANDO XR with expiration dates in 2035;
- 6 US patent applications related to TLANDO XR, with potential expiration dates, if issued, in 2029-2037;
- 6 US patents related to LPCN 1107 with expiration dates in 2031;
- 2 US 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;
- 2 issued patents related to Oral TU in Canada and a patent in New Zealand and Australia that all expire in 2020;
- 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 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 TLANDO XR in the following countries: Europe and Japan, that if issue, will expire in 2037;
- 1 issued patents or applications related to TLANDO XR 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 TLANDO XR 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;
- 2 US Patent applications related to LPCN 1144/1148 and one Patent Cooperation Treaty (“PCT”) application; and
- A US 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. applications (and related foreign patents and applications) that we previously assigned to Spriaso LLC, which could be possibly used with future product candidates.

We currently do not have patent protection for TLANDO in many countries, including 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 TLANDO. Additionally, we have 5 U.S. patents that could be listed in the FDA Orange Book for TLANDO that are expected to expire in 2020, 2029 and 2030. If we 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 5 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 Investigational New Drug application (“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 a New Drug Application (“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 current good manufacturing practice, or 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, pharmacokinetics 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, pharmacokinetics 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, pharmacokinetics, 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, or OBRA, and the Medicare Prescription Drug Improvement and Modernization Act of 2003, or MMA. 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 LLC, 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 will provide facilities and up to 10% of the services of certain employees to Spriaso for a period of up to 18 months which expired January 23, 2015. Effective January 23, 2015, we entered into an amended services agreement with Spriaso in which we agreed to continue providing up to 10% of the services of certain employees to Spriaso at a rate of \$230/hour for a period of six months. The agreement was further amended on July 23, 2015, on January 23, 2016, on July 23, 2016 on January 23, 2017, on July 23, 2017, on January 23, 2018, on July 23, 2018 and again on January 23, 2019 to extend the term of the agreement for an additional six months. The agreement was further amended on July 23, 2019 to extend the term of the agreement for an additional twelve months. The agreement 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, 2019, we had 12 full time employees and we also utilize the services of consultants on a regular basis. Six employees are engaged in drug development activities and six are in general and administration functions. None of our employees are represented by labor unions or covered by collective bargaining agreements.

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.

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 and marketing infrastructure sufficient to commercialize our products. 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.

We depend primarily on the success of our lead product candidate, TLANDO, for which we recently received a Complete Response Letter from the FDA and which may not receive regulatory approval or be successfully commercialized.

TLANDO is currently our only product candidate that has completed Phase 3 clinical trials, and our business currently depends primarily on its successful development, regulatory approval and commercialization, if approved. On November 8, 2019 we received a CRL from the FDA regarding our NDA filed in May 2019 for TLANDO as a TRT in adult males for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism. The CRL identified one deficiency stating the efficacy trial did not meet the three secondary endpoints for maximal testosterone concentrations ("Cmax"). The CRL did not identify any specific issues relating to chemistry, manufacturing and controls ("CMC") of TLANDO. Previously, we have received two other CRL's from the FDA on TLANDO NDA submissions. The first CRL was received on June 28, 2016 and the second CRL was received on May 8, 2018. We have not submitted comparable applications to other regulatory authorities. If the FDA denies or further delays approval of TLANDO, our business would be materially and adversely harmed. If the FDA does approve TLANDO, but we are unsuccessful in commercializing TLANDO, our business will be materially and adversely harmed.

As we have received another CRL from the FDA, approval of TLANDO will be substantially delayed and additional studies and expense may be required before we would be in a position to resubmit an NDA to address the CRL deficiencies. Our ability to raise capital may also be impaired. If we proceed with any study, we face the risk that the FDA would not agree with the design or results of the study.

The FDA may also ask us to perform additional clinical trials or studies, either pre- or post- approval, or provide additional information in order to secure approval. Any such requirement would increase our costs and delay approval and commercialization of TLANDO and would have a material adverse effect on our business and financial condition.

Even if TLANDO is approved, the FDA may limit the indications for which it may be used, include extensive warnings on the product labeling, or require costly ongoing requirements for post-marketing clinical studies including participation in a long-term TRT consortium cardiovascular study and surveillance or other risk management measures to monitor the safety or efficacy of TLANDO. Further, in the event that we seek regulatory approval of TLANDO outside the United States, such markets also 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, 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 the FDA clarifies, modifies or restricts the indicated population for T-replacement in the "class" label, the market for T-replacement products may shrink and our ability to sell and be reimbursed for TLANDO and TLANDO XR (LPCN 1111) could be materially adversely affected and our business could be harmed.

On September 17, 2014, the FDA held a T-class Advisory Committee meeting. 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, 20 of the 21 members of the Advisory Committee voted that the FDA should revise the currently indicated population for T-replacement therapy and recommended changing the label language to restrict the intended uses of the products, particularly in relation to age-related low testosterone. The Committee also supported adding language to the label to guide physicians in better diagnosis of eligible patients for treatment. On March 3, 2015, the FDA issued a safety announcement addressing the Advisory Committee's recommendations.

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.

The actual TRT label revisions have been finalized between the FDA and sponsors with approved T-replacement therapy products. The revised labels are consistent with the FDA's recommendations on March 3, 2015.

Additionally, the FDA stated that they 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. The FDA did not address whether it would require sponsors without an approved T-replacement product to conduct a cardiovascular trial prior to being able to file an NDA. However, on March 19, 2015 we had a pre-NDA meeting with the FDA concerning our pivotal Phase 3 trial for TLANDO. Based on this meeting with the FDA, we do not expect to be required to conduct a heart attack and stroke risk study or any additional safety studies prior to approval of the NDA for TLANDO. More recently the FDA has determined that an ABPM study is required to better assess any blood pressure effects of TLANDO, a surrogate marker of predicting cardiovascular outcome. The ABPM clinical study was completed in the first quarter of 2019. If the FDA changes its position, however, and concludes that a cardiovascular trial is required prior to approving our NDA for TLANDO, such trial would require substantial financial resources, and would delay the regulatory process for TLANDO and our entry into the marketplace, all of which would have a material adverse impact on our business. Further, if TLANDO receives FDA approval, it is unclear what our post-approval obligations may be, if any, in relation to a heart attack and stroke risk study. We may be required to contribute to an on-going industry-led heart attack and stroke risk study or to conduct our own long-term heart attack and stroke risk study, either of which would require substantial financial resources and would have a material adverse impact on our business. If the market for T-replacement products declines, for whatever reason, our business will be materially and adversely harmed.

If T-replacement therapies are found, or are perceived, to create health risks, our ability to sell TLANDO and TLANDO XR (LPCN 1111) could be materially adversely affected and our business could be harmed. Even if our TLANDO and our TLANDO XR (LPCN 1111) are approved, physicians and patients may be deterred from prescribing and using T-replacement therapies, which could depress demand for TLANDO and TLANDO XR (LPCN 1111) and compromise our ability to successfully commercialize TLANDO and TLANDO XR (LPCN 1111).

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 ("DVT") and pulmonary embolism ("PE").

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 Therapeutics 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 they 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 January 9, 2018, a BRUDAC meeting was held for Jatenzo, Clarus Therapeutics' testosterone replacement therapy product candidate. The BRUDAC voted nine in favor and ten against the acceptability of the overall benefit/risk profile to support approval of Jatenzo as a TRT. Jatenzo, a competing oral TU TRT product candidate to TLANDO, has shown a clinically meaningful increase in blood pressure. The FDA may consider this blood pressure increase by a product with the same active ingredient as TLANDO to be an oral TU class effect. Therefore, irrespective of our TLANDO ABPM study findings we may not be successful in overcoming the FDA's belief that the increase in blood pressure is an oral TU class effect rather than a product candidate specific effect. This may result in a TLANDO non-approval, increased label warnings or agreeing to REMS and/or post approval label comprehension study as a condition for approval.

Additionally, the FDA convened a BRUDAC meeting on January 10, 2018 to evaluate the safety and efficacy of TLANDO as a T-replacement product. The BRUDAC voted six in favor and thirteen against the acceptability of the overall benefit/risk profile to support approval of TLANDO as a TRT and ultimately a CRL was received from the FDA citing four deficiencies on May 8, 2018.

Also, on September 29, 2018, Antares Pharma, Inc. announced that it had received approval from the FDA regarding its NDA for XYOSTED™ (testosterone enanthate) injection. However, based on clinical results XYOSTED's label is required to contain a black box warning concerning blood pressure increases. Additionally, the FDA also required the following specific language to be included in XYOSTED's label, "In some patients the increase in blood pressure with XYOSTED may be too small to detect, but can still increase the risk of major adverse cardiovascular events ("MACE")".

Additionally on February 4, 2019, the FDA held a public workshop entitled, "Evaluating the Pressor Effects of Drugs & Ambulatory Blood Pressure Monitoring Studies". The purpose of the workshop was to bring together the stakeholder community, including company sponsors, FDA, and key opinion leaders, to discuss the premarketing assessment of a drug's effect on blood pressure. Topics discussed by the FDA included: study design considerations to definitively assess a drug's effect on blood pressure and appropriate regulatory action; the need to raise physician and patient awareness via labeling or risk mitigation strategies based on blood pressure effects and associated increased cardiovascular risks; the assessment of clinical meaningfulness of blood pressure changes based on findings; appropriately identifying the population at risk; and, a drug's benefit risk analyses.

It is possible that the FDA's evaluation of this topic and further studies on the effects of T-replacement therapies could demonstrate the risk of major adverse cardiovascular events or other health risks or could impose additional requirements that could delay our approval for TLANDO. During our SOAR trial, we collected safety data for TLANDO and a control group, the leading approved T-gel product, but we did not compare safety data from TLANDO to a placebo control group or the control group. If, following its evaluation, the FDA concludes that men using FDA-approved T-replacement therapies face serious cardiovascular risks, it may take actions against T-replacement products generally, which could impact us adversely in a variety of ways, including that the FDA could:

- require additional safety studies before approving TLANDO;
- mandate that certain warnings or precautions be included in our product labeling;
- require that our product carry a "black box warning";
- limit use of TLANDO and TLANDO XR (LPCN 1111) to certain populations, such as men without specified conditions;
- direct us to submit a Risk Evaluation and Mitigation Strategy ("REMS") as part of our NDA to help ensure that the benefits of our product outweigh the potential risks;
- require that we conduct post-marketing studies, potentially including registry, epidemiology or cardiovascular outcomes studies; and
- limit the prospects for regulatory approval and commercial success of our TLANDO and TLANDO XR (LPCN 1111).

Demonstrated T-replacement therapy safety risks, as well as negative publicity about the risks of hormone replacement therapy, including T-replacement, could hurt sales of and impair our ability to successfully commercialize TLANDO and TLANDO XR (LPCN 1111), if approved. If the FDA changes its position from only requiring an ABPM study, however, and concludes that a cardiovascular trial is required prior to approving our NDA for TLANDO, such trial would require substantial financial resources, would delay the regulatory process for TLANDO and our entry into the marketplace, all of which would have a material adverse impact on our business.

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, recent and 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, the Patient Protection and Affordable Care Act (“ACA”), as amended by the Healthcare and Education Affordability Reconciliation Act, 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.

Moreover, President Trump has indicated a desire to repeal ACA. Those efforts have been unsuccessful to date. The implementation of further cost containment measures or the repeal of ACA or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

President Trump has expressed a policy priority to lower the price of prescription drugs. 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.

Furthermore, some Congressional leaders have indicated that further significant changes to Medicare and Medicaid benefits and reimbursement must be made in order to manage the federal budget deficit, particularly in light of the Tax Cuts and Jobs Act of 2017. 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.

We face substantial competition in the TRT market, which may result in others discovering, developing or commercializing products before or more successfully than we do.

We expect to face significant competition for any of our product candidates, if approved. In particular, if approved, TLANDO would compete in the T-replacement therapies market, which is highly competitive and currently dominated by the sale of T-gels in terms of sales dollars and T-injectables in terms of prescriptions. Our success will depend, in large part, on our 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 our business.

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 (marketed by Endo Health Solutions, or Endo), and Fortesta (marketed by Endo);

- T-topical solutions, such as Axiron, a metered dose lotion marketed by Eli Lilly and Co. and related authorized generics;
- 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 Aytu);
- 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 testosterone undecanoate product, was approved by the FDA and also received three years of data exclusivity. It is unclear how Jatenzo's three years of data exclusivity will impact the potential full approvability of TLANDO. The potential exists that, as a result of Clarus' data exclusivity, the approval of TLANDO by the FDA, if ever received, could be delayed until March 27, 2022. On February 10, 2020, Clarus announced that JATENZO® has been launched and is commercially available. Additionally on October 2, 2019, Clarus filed a Citizens Petition with the FDA requesting the FDA establish clear, written guidance regarding the safety and efficacy standards required for oral testosterone drugs. The Citizens Petition also requested that the FDA not approve any oral testosterone drugs until the written guidance is provided by the FDA. We will not know the impact that Clarus' Citizen Petition may have on TLANDO's approval, until the FDA addresses the Citizens Petition specifically which may have an adverse effect on TLANDO.

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 testosterone replacement therapy 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. These competitors have the economic power to acquire and maintain market share, limiting our ability to penetrate the TRT market with our TLANDO product. 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.

The entrance of generic T-gels into the market would likely create downward pricing pressure on all T-replacement therapies and therefore have a negative effect on our business and financial results.

Several companies have filed Abbreviated New Drug Applications, or ANDAs, seeking approval for generic versions of existing T-gels. For example, in April 2012 Perrigo Company filed an ANDA with the FDA seeking approval for a generic version of AndroGel 1.62%. In response to this ANDA, the marketer of AndroGel 1.62% filed patent infringement lawsuits against Perrigo Company to block the approval and marketing of the generic product. In August 2015, the FDA approved the ANDA submitted by Perrigo Company and Perrigo's generic product was also granted 180 days of generic drug exclusivity. The marketer of AndroGel 1.62% may enter into an agreement with Perrigo Company to delay the introduction of a generic AndroGel 1.62%. Additionally, in July 2003, Actavis and Par Pharmaceutical, or Par, filed ANDAs with the FDA seeking approval for generic versions of AndroGel 1%. In response to these ANDAs, the marketer of AndroGel 1% filed patent infringement lawsuits against these two companies to block the approval and marketing of the generic products. In 2006, all the subject companies reached an agreement pursuant to which Actavis agreed not to bring a generic version of AndroGel 1% to the market until August 2015, and Par agreed not to bring a generic version to market until February 2016. The U.S. Federal Trade Commission has questioned the legality of such "pay-to-delay" agreements, and the Supreme Court ruled in June 2013 that such agreements may not be valid. The impact of this ruling on the agreements between the marketer of AndroGel 1% and Actavis and Par, as well as the timing and eventual marketing of generic versions of their respective products, is uncertain at this point.

Additionally, there are several other ANDAs for generic T-gels that have been filed and there is ongoing litigation with each of these ANDAs. Finally, in 2014, two authorized generic T-gels were launched at a lower price than the branded version of the same T-gel. With generic versions of T-gel becoming available in the market, governmental and other pressures to reduce pharmaceutical costs have resulted in physicians writing prescriptions for generic T-gels as opposed to branded T-gels. The entrance of these generic T-gels into the market has caused downward pressure on the pricing of all T-replacement therapies and has materially and adversely affected the level of sales and price at which we could sell TLANDO, and ultimately will materially and adversely impact our revenues and financial results.

The introduction of generic T-gel, may also affect the reimbursement policies of government authorities and third-party payors, such as private health insurers and health maintenance organizations. These organizations determine which medications they will pay for and establish reimbursement levels. Cost containment is a primary concern in the U.S. healthcare industry and elsewhere. Government authorities and these third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for branded medications when there is a generic available. With generic T-gels available in the market, that creates an additional obstacle to the availability of reimbursement for TLANDO. Even if reimbursement is available, the level of such reimbursement could be reduced or limited. Reimbursement may impact the demand for, or the price of, TLANDO. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize TLANDO, and/or our financial results from the sale of related products could be negatively and materially impacted. Rebates and other pricing strategies of generics may erode our revenue and harm our financial performance.

Additionally, TLANDO will not be the only oral testosterone replacement therapy product in the market. If the generic version of a competing oral testosterone replacement therapy product enters the market before TLANDO, then the commercial prospects of TLANDO could be materially and negatively impacted.

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 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.

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 completed a POC liver imaging clinical study. Treatment results from our POC liver imaging clinical study demonstrated that 48% of the treated NAFLD subjects had NAFLD resolution, defined as liver fat <5% post treatment. Additionally, the POC liver imaging clinical study showed a relative mean reduction from baseline of 40% liver fat in subjects with baseline liver fat > 10%. Moreover, there was a 75% responder rate in which subjects experienced at least a 30% relative reduction in liver fat from baseline. Although our POC liver imaging clinical study results were positive, these results from a small single-arm clinical study may not be indicative of ultimate success in a larger Phase 2/3 clinical study, such as the Phases 2 *LiFT* clinical study, with required FDA end-points 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. Accordingly, our results from our POC 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 2 and Phase 3 programs for an NDA filing for LPCN 1144 will be very long and resource intensive.

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 or exceed 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 pharmacokinetics/pharmacodynamics (“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 Phase 3 development plan for LPCN 1107. During the End-of-Phase 2 meeting and subsequent guidance meetings, the FDA agreed to a randomized, open-label, two-arm clinical study to include a LPCN 1107 arm and a comparator IM arm with treatment up to 23 weeks. The FDA also provided feedback on other critical Phase 3 study design considerations including: positive feedback on the proposed 800 mg BID Phase 3 dose and dosing regimen; confirmation of the use of a surrogate primary endpoint focusing on rate of delivery less than 37 weeks gestation rather on clinical infant outcomes; acknowledged that the use of a gestational age endpoint would likely lead to FDA approval, if granted, being a Subpart H approval as opposed to a full approval; and, recommended a non-inferiority study margin of 7% with interim analyses. A standard statistical design for a NI study based on the FDA suggested NI margin of 7% for the primary end point may require ~1,100 subjects per treatment arm with a 90% power. However, based on the FDA’s feedback of including an interim analysis in the NI design, an adaptive study design is under consideration that may allow for fewer subjects. We submitted the initial LPCN 1107 Phase 3 protocol to the FDA via a SPA in June 2017 and have received multiple rounds of FDA feedback. Agreement with the FDA on the Phase 3 protocol via SPA has not occurred and will not occur until results from a planned food-effect study with LPCN 1107 are reviewed by the FDA. Agreement with the FDA on the Phase 3 protocol via SPA has not occurred as we are waiting for minutes from the FDA’s Advisory Committee meeting for AMAG Pharmaceuticals’ Makena which was held on October 29, 2019. Final agreement with the FDA on the Phase 3 protocol, if reached, may or may not confirm the FDA’s preliminary feedback on the Phase 3 design. Additionally, manufacturing scale-up work for LPCN 1107 has been complete. Once the Phase 3 clinical trial is started, the anticipated Phase 3 program for an NDA filing for LPCN 1107 will be very long and expensive.

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

TLANDO XR (LPCN 1111) is in a very early stage of development. We have completed a Phase 2a and Phase 2b study in hypogonadal men. Results from the Phase 2a clinical study demonstrated the feasibility of a once daily dosing with TLANDO XR (LPCN 1111) in hypogonadal men and a good dose response. Results of the Phase 2b study suggest that the primary objectives were met, including identifying the dose expected to be tested in a Phase 3 study. Future studies may not have similar clinical results. Additionally, we have preliminary data demonstrating absorption of TLANDO XR (LPCN 1111) in dogs and in postmenopausal females.

In addition, the active ingredient in TLANDO XR (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 TLANDO XR (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 Current Good Manufacturing Practices (“cGMP”).

Several factors could significantly affect the prospects for TLANDO XR (LPCN 1111), including factors relating to the regulatory approval and clinical development challenges for TLANDO XR (LPCN 1111) discussed above. The anticipated Phase 3 program for an NDA filing for TLANDO XR (LPCN 1111), however, could be very long and expensive.

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 our most advanced product candidate TLANDO as well as four additional earlier stage clinical candidates, LPCN 1144, TLANDO XR (LPCN 1111), LPCN 1148 and LPCN 1107. 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 TLANDO, LPCN 1144, TLANDO XR (LPCN 1111), LPCN 1148 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 TLANDO, LPCN 1144, TLANDO XR (LPCN 1111), LPCN 1148 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 ("CRO") 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, or 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 TLANDO XR (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. 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.

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 a material 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 a material 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;
- the federal Health Insurance Portability and Accountability Act of 1996, or 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 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.

President Trump has expressed a policy priority to lower the price of prescription drugs. 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.

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. Following the receipt of our first CRL for TLANDO, we reduced our workforce by 8 positions, constituting 33% of our workforce. The reduction in workforce involved all functional disciplines. Further, subsequent to our Post Action Meeting with the FDA for TLANDO, we reduced our workforce by two additional positions in October 2016. Following the receipt of our second CRL for TLANDO, we reduced our workforce by 3 positions, constituting 21% of our workforce. Recruiting and retaining qualified scientific personnel, accounting personnel and sales and marketing 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, 2019, we had 12 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, 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.

We may face competition for TLANDO, if approved, 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 (“MMA”) 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 a material 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, hydroxyprogesterone caproate (“HPC”) has not been administered orally in a published clinical trial in any pregnant woman for the prevention of preterm birth. 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 pharmacokinetic 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 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.

Our clinical lots of TLANDO for the Phase 3 trials were manufactured in the United Kingdom, or UK. This entailed obtaining additional permits from regulatory authorities in the United States and UK relating to exportation of our active TU, a controlled substance from the United States and importation of the same into the UK, and exportation of finished product from the UK and importation of the same into the United States. Although we were able to manufacture clinical supplies and import these supplies into the United States, these additional requirements could significantly delay the manufacture of the commercial supplies.

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. Political pressures and adverse publicity could lead to delays in, and increased expenses for, and limit or restrict, the introduction and marketing of TLANDO.

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 law suits 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 the Company, 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.

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.*, 3:16-cv-04009-BRM-LHG, 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. The lawsuits contain substantially identical allegations and alleged 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 lawsuits sought certification as a class action, compensatory damages in an unspecified amount, and unspecified equitable or injunctive relief. On February 15, 2018, the Company and the other defendants entered into a memorandum of understanding to settle the purported securities class action litigation. On March 15, 2018, the Plaintiff filed a motion for preliminary approval of the settlement along with a copy of the parties' stipulation of settlement. On March 21, 2018, the court granted the motion for preliminary approval of the settlement and amended the order on March 28, 2018. On July 2, 2018, the court issued the final order and approved the settlement of \$4.3 million as set forth in the parties' stipulation. The order resolves all of the claims that were or could have been brought in the action being settled. While our insurance carrier covered \$3.6 million of the settlement, 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 February 15, 2019, a purported shareholder filed a shareholder derivative complaint in the Court of Chancery of the State of Delaware, *John Wajda, derivatively on behalf of Lipocine Inc. v. Mahesh Patel, et al.*, against certain of the Company's current and former officers and directors as well as the Company as a nominal defendant. The complaint asserts claims for alleged breaches of fiduciary duty and unjust enrichment arising out of the Company's dissemination of purportedly false and misleading statements relating to the filing of the NDA for TLANDO. The relief sought in the complaint includes unspecified damages, changes to the Company's corporate governance procedures, equitable and/or injunctive relief, restitution, and attorneys' fees. On August 16, 2019, defendants filed a motion to dismiss the complaint. Plaintiff's response to the motion to dismiss was due on October 18, 2019; however rather than file an opposition brief, plaintiffs filed an amended stockholder derivative complaint. Defendants' motion to dismiss the amended complaint was filed on December 12, 2019; plaintiff's response was filed on January 27, 2020 and defendants' reply was filed on February 26, 2020.

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.

We also may be subject to additional types of litigation. On November 2, 2015, Clarus Therapeutics filed a complaint against us in the United States District Court for the District of Delaware alleging that TLANDO will infringe Clarus' 428 patent. The Clarus complaint was dismissed by the District Court in 2016, because at the time there was no actionable infringement on Clarus' 428 patent. Additionally on December 21, 2018, the PTAB granted Lipocine priority motion and entered adverse judgment against Clarus. The PTAB ruling cancels all claims on the Clarus' 428 Patent. However, Clarus appealed the PTAB judgement to the Court of Appeals for the Federal Circuit on February 19, 2019. While the Clarus complaint has been dismissed and all their claims on the Clarus' 428 patent have been cancelled by the PTAB, the possibility remains that the decisions of the PTAB could be reversed upon appeal. Additionally, Clarus could submit its claim again if TLANDO is approved by the FDA and enters the marketplace.

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. The Court held a scheduling conference on August 15, 2019 and a claim construction hearing on February 11, 2020 and scheduled a five-day jury trial beginning on February 8, 2021. On February 11, 2020, we also 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 parties are currently engaged in the fact discovery phase of the lawsuit.

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 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 CROs, medical institutions and collaborators; and also outsource manufacturing to collaborators and/or contract manufacturers. 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 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, and the liver imaging study for LPCN 1144. Additionally, we are utilizing a CRO for the on-going Phase 2 *LiFT* clinical study for LPCN 1144. 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 standards, commonly referred to as Good Clinical Practices, or GCP, 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 rely on a single supplier for our supply of TU, the active pharmaceutical ingredient of TLANDO, and the loss of this supplier could harm our business.

We rely on a single third-party supplier for our supply of TU, the active pharmaceutical ingredient of TLANDO and LPCN 1144. We have a supply agreement in place with this supplier. We have purchased sufficient quantities of TU for early commercial launch supplies should TLANDO get approved by the FDA. We plan on using this same supplier for our commercialization needs if TLANDO is approved. Since there are only a limited number of TU suppliers in the world, if this supplier ceases to provide us with TU, we may be unable to procure TU on commercially favorable terms, may not be able to obtain it in a timely manner, or may not be able to qualify a new supplier timely post FDA approval, if that occurs. Furthermore, the limited number of suppliers of TU may provide such companies with greater opportunity to raise their prices. Any increase in price for TU will likely reduce our gross margins.

We rely on limited suppliers for our supply of inactive ingredients and the loss of these suppliers could harm our business.

We rely on limited qualified third-party raw material suppliers for our supply of inactive ingredients of TLANDO and our other product candidates. We do not have supply agreements in place with these suppliers. We purchased sufficient quantities of these inactives for early commercial launch of TLANDO if it is approved. We plan on using these same suppliers for our commercialization needs if TLANDO is approved. We may be unable to procure inactives on commercially favorable terms, or may not be able to obtain them in a timely manner. Any increase in price for inactives will likely reduce our gross margins.

We depend on M.W. Encap Ltd. for the supply of the TLANDO capsules and the loss of this supplier would significantly harm our business.

We have entered into a Commercial Manufacturing Services and Supply Agreement with M.W. Encap Ltd. (“Encap”), a United Kingdom based contract manufacturer, a division of Capsugel Dosage Form Solutions, which was recently acquired by Lonza Group AG .. Pursuant to the Agreement, Encap has agreed to manufacture and supply bulk commercial quantities of TLANDO. Encap is currently our sole contract manufacturer and is our sole supplier of TLANDO for our clinical trials on a worldwide basis. If Encap is unable to produce sufficient capsules, for whatever reason, to support demand for TLANDO if it becomes commercially available, our revenue and profitability would be materially and adversely harmed. Also, we may not be able to engage an alternative supplier to meet our needs.

Reliance on a third-party manufacturer involves risks, such as capacity and capabilities of the manufacturer to which we would not be subject if we manufactured TLANDO ourselves. We also face risks related to reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control and the possibility of termination or non-renewal of the agreement by the third party, based on its own business priorities, at a time that is costly or damaging to us. The FDA and other regulatory authorities require that TLANDO be manufactured according to cGMP. Any failure by any third-party manufacturers to comply with cGMP could be the basis for action by the FDA to withdraw approvals previously granted to us and for other regulatory action against us.

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 TLANDO, LPCN 1144, TLANDO XR (LPCN 1111), LPCN 1148 or LPCN 1107. 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.

Our financial condition and results of operations for fiscal 2020 may be adversely affected by the recent coronavirus outbreak.

In December 2019, a novel strain of coronavirus was reported to have surfaced in Wuhan, China. At the time of this filing, the outbreak has been most concentrated in China, although cases have been confirmed in other countries. Our operations could be adversely affected to the extent that coronavirus or any other epidemic harms the Chinese or world economy in general. Our operation may experience disruptions, such as temporary closure of our offices and/or suspension of services, which may materially and adversely affect our business, financial condition and results of operations. The duration of the business disruption and related financial impact cannot be reasonably estimated at this time but may materially affect our ability to operate our business and result in additional costs. The extent to which the coronavirus or other health epidemic may impact our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others.

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 control 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:

- our ability to address the deficiencies noted in the latest CRL for TLANDO;
- 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 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 such 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 these 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 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 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. At December 31, 2019, the aggregate fair value of the warrant liability included in the Company's consolidated balance sheet was \$4.6 million. 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 that point in time, we ultimately may incur amounts significantly different than the carrying value.

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. On December 27, 2019, we received a notice from the Listing Qualifications Department of The NASDAQ Stock Market stating that for the last thirty consecutive business days the bid price for our common stock had closed below the minimum \$1.00 per share requirement for continued listing on The NASDAQ Capital Market under NASDAQ Listing Rule 5550(a)(2). In accordance with NASDAQ Listing Rule 5810 (c)(3)(A), we were provided an initial period of 180 calendar days, or until June 24, 2020, to regain compliance. If we do not regain compliance by June 24, 2020, we may be eligible for an additional 180 calendar days to regain compliance.

If we do not regain compliance with Rule 5550(a)(2), the Staff will provide written notification to us that our common stock will be delisted. At that time, we may appeal the Staff's delisting determination to a NASDAQ Hearings Panel, or the Panel. We would remain listed pending the Panel's decision. There can be no assurance that, if we do appeal the delisting determination by the Staff to the Panel, that such appeal would be successful.

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, 2018, 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, 2019, our executive officers and directors beneficially owned approximately 8.4% 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.

Our common stock is thinly traded, may continue to be thinly traded in the future, and our stockholders may be unable to sell at or near asking prices or at all if they need to sell their shares.

Currently, we have a low volume of daily trades in our common stock on NASDAQ. For example, the average daily trading volume in our common stock on NASDAQ during the fourth quarter of 2019 was approximately 707,000 shares per day. Our stockholders may be unable to sell their common stock at or near their asking prices or at all, which may result in substantial losses to our stockholders.

The market for our common stock may be characterized by significant price volatility when compared to seasoned issuers, and we expect that our share price will be more volatile than a seasoned issuer for the indefinite future. As noted above, our common stock may be sporadically and/or thinly traded. As a consequence of this lack of liquidity, the trading of relatively small quantities of shares by our stockholders may disproportionately influence the price of those shares in either direction. The price for our shares could, for example, decline significantly in the event that a large number of shares of our common stock are sold on the market without commensurate demand, as compared to a seasoned issuer that could better absorb those sales without adverse impact on its share price.

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 fails 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 LPCN 1144;
- our ability to respond to the CRLs we have received from the FDA;
- regulatory actions of the FDA, particularly related to TLANDO;
- 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 license agreements, strategic partnerships or collaborations that we may enter into in the future, if any;
- 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, 2021. 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, 2021, 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, 2021, to support our operations, on-going clinical study for LPCN 1144, on-going intellectual property 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 LPCN 1144, TLANDO XR (LPCN 1111), LPCN 1148 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 or intellectual property litigation.

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 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 December 1, 2021. In addition, as TLANDO was not approved by the FDA by May 31, 2018, we are required to maintain \$5.0 million of cash collateral at SVB until such time as TLANDO is approved by the FDA. 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 loans under the Loan Agreement could become immediately due and payable and would 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. 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 collaborations with partners/third parties, if we obtain 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. We have funded our operations to date through sales of our equity securities, debt and payments received under our license and collaboration arrangements from sales of common stock, preferred stock and convertible debt and from license and milestone revenues and research revenue from license and collaboration agreements with corporate partners. We have incurred losses in most years since our inception. As of December 31, 2019, we had an accumulated deficit of \$151.1 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 LPCN 1144, TLANDO XR (LPCN 1111), LPCN 1148 and LPCN 1107, if initiated. In addition, if we eventually obtain marketing approval for TLANDO, we will incur significant sales, marketing and commercialization expenses. As a result, we expect to continue to incur significant operating losses for the foreseeable future as we evaluate our options with TLANDO and further clinical development of LPCN 1144, TLANDO XR (LPCN 1111), LPCN 1148, 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.

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 APIs in our current product candidates TLANDO, LPCN 1144, TLANDO XR (LPCN 1111), LPOCN 1148 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 2020 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 a 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 permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. 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 PTO, or during litigation, under the revised criteria which make it more difficult to obtain or maintain patents.

For example, 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. Clarus has 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 setting a claim construction hearing on February 11, 2020 and a five-day jury trial beginning on August 24, 2020. On February 11, 2020, we also 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 parties are currently engaged in the fact discovery and claim construction phases of the lawsuit.

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 our 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.

In addition, on May 15, 2015 we filed a patent application with the PTO, and requested that an interference be declared between our patent application and the Clarus 428 Patent. Pursuant to Lipocine's request, on December 4, 2015, PTAB declared an interference between the Clarus 428 Patent and Lipocine's application to determine, as between Clarus and Lipocine, who was the first to invent the subject matter of the claimed invention. On December 21, 2018, the PTAB granted a priority motion filed by Lipocine and entered adverse judgment against Clarus. The PTAB ruling cancels all claims on the Clarus 428 Patent. However, Clarus appealed the PTAB judgement to the Court of Appeals for the Federal Circuit on February 19, 2019. While the Clarus complaint has been dismissed and all their claims on the Clarus' 428 patent have been cancelled by the PTAB, the possibility remains that the decisions of the PTAB could be reversed upon appeal. If Clarus were to make a successful appeal, we may be required to cease using the related technology or to attempt to license rights from Clarus; our business could be harmed if Clarus does not offer us a license on commercially reasonable terms, if any license is offered at all.

This interference proceeding and our intellectual property lawsuit against Clarus will consume a portion of our capital resources. Moreover, 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. While the Clarus complaint has been dismissed, the possibility remains that Clarus could submit its claim again if TLANDO is approved by the FDA and enters the marketplace.

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, and if approved by the FDA or other regulatory authorities, our product candidates 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, 2021. 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 May 15, 2015, we filed a patent application with the PTO (14/713,692) and requested that an interference be declared between our patent application and the Clarus 428 Patent. Pursuant to our request, on December 4, 2015, the Patent Trial and Appeal Board (“PTAB”) declared an interference between the Clarus 428 Patent and our application to determine, as between Clarus and us, who was the first to invent the subject matter of the claimed invention. We were declared the Senior Party in the interference. On September 20, 2017 the PTAB issued a Decisions on Motions. The PTAB granted our motion to deny Clarus’ previously accorded priority date for the Clarus 428 Patent and denied Clarus’ motion for an earlier priority date based upon the filing of its provisional applications. Therefore, Clarus has a new priority date of April 16, 2014 for the Clarus 428 patent. The PTAB also granted Clarus’ motion to deny our accorded priority date. Therefore, we have an accorded priority date of May 15, 2015 on its application. As a consequence of this decision, the PTAB has redeclared the interference (No. 106,045) and named Clarus as the senior party and us as the junior party. All other motions were denied. A conference call with the PTAB was held on October 4, 2017 to discuss the next steps, including a priority schedule. After the conference call, the PTAB issued an order setting times in the priority phase. The order indicated that since we are the only party that filed a priority statement, only we shall be permitted to put on a priority case. The priority statement filed by us included a claimed date of invention well prior to Clarus’ accorded benefit date. We filed our motion for priority on January 18, 2018, and thereafter, on March 26, 2018, Clarus filed a notice stating it has not filed, and will not file, a substantive opposition to our priority motion. On December 21, 2018, the PTAB granted Lipocine priority motion and entered adverse judgment against Clarus. The PTAB ruling cancels all claims on the Clarus 428 Patent. On December 21, 2018, the PTAB granted Lipocine’s priority motion and entered adverse judgment against Clarus. The PTAB ruling cancels all claims in the Clarus 428 Patent. On February 19, 2019, Clarus filed an appeal of the PTAB judgement to the Court of Appeals for the Federal Circuit (“CAFC”). Clarus filed its substantive opening brief to the CAFC on May 20, 2019, and Lipocine filed its opposition brief on August 30, 2019. Clarus’ reply brief was filed on October 21, 2019. Oral arguments are scheduled for April 6, 2020.

On February 15, 2019, a purported shareholder filed a shareholder derivative complaint in the Court of Chancery of the State of Delaware, *John Wajda, derivatively on behalf of Lipocine Inc. v. Mahesh Patel, et al.*, against certain of the Company’s current and former officers and directors as well as the Company as a nominal defendant. The complaint asserts claims for alleged breaches of fiduciary duty and unjust enrichment arising out of the Company’s dissemination of purportedly false and misleading statements relating to the filing of the NDA for TLANDO. The relief sought in the complaint includes unspecified damages, changes to the Company’s corporate governance procedures, equitable and/or injunctive relief, restitution, and attorneys’ fees. On August 16, 2019, defendants filed a motion to dismiss the complaint. Plaintiff’s response to the motion to dismiss was due on October 18, 2019; however rather than file an opposition brief, plaintiffs filed an amended stockholder derivative complaint. Defendants’ motion to dismiss the amended complaint was filed on December 12, 2019; plaintiff’s response was filed on January 27, 2020 and defendants’ reply was filed on February 26, 2020. Defendants intend to vigorously defend themselves against these allegations.

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. Clarus has 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 and a claim construction hearing on February 11, 2020 and scheduled a five-day jury trial beginning on February 8, 2021. 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 parties are currently engaged in the fact discovery phase of the lawsuit.

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. The retention amount payable by the Company under our policy is \$1.25 million. The Company intends to vigorously defend against this lawsuit.

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".

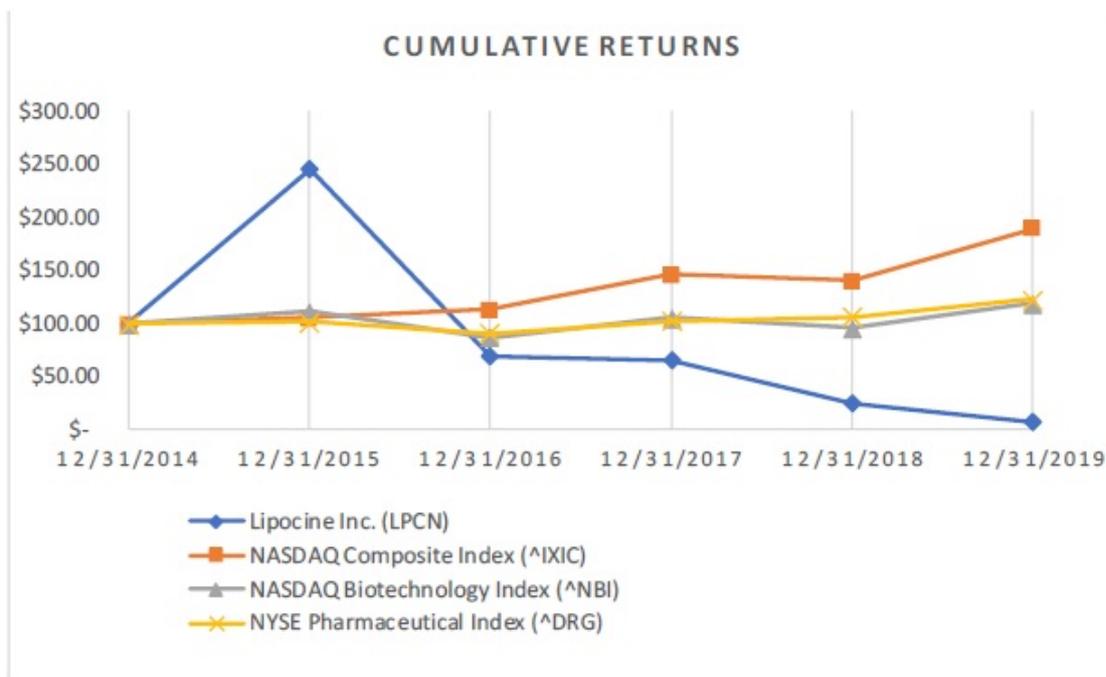
Holdings

As of March 12, 2020, there were approximately 103 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, 2014 through December 31, 2019 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, 2014. The comparisons in the graph are required by the Securities and Exchange Commission and are not intended to forecast or be indicative of possible future performance of our ordinary shares.



Cumulative Returns

	12/31/2014	12/31/2015	12/31/2016	12/31/2017	12/31/2018	12/31/2019
Lipocine Inc. (LPCN)	\$ 100.00	\$ 245.82	\$ 69.96	\$ 65.40	\$ 24.71	\$ 7.32
NASDAQ Composite Index (^IXIC)	100.00	105.73	113.66	145.76	140.10	189.45
NASDAQ Biotechnology Index (^NBI)	100.00	111.42	87.26	105.64	95.79	119.17
NYSE Pharmaceutical Index (^DRG)	100.00	101.62	90.38	102.28	106.76	122.68

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. SELECTED FINANCIAL DATA

The selected statement of operations data for the years ended December 31, 2019 and 2018, and the balance sheet data as of December 31, 2019 and 2018 have been derived from our audited financial statements included elsewhere in this Annual Report on Form 10-K. The selected statement of operations data for the years ended December 31, 2017, 2016 and 2015, and the balance sheet data as of December 31, 2017, 2016 and 2015 have been derived from audited financial statements which are not included in this Annual Report on Form 10-K.

Our historical results are not necessarily indicative of future results. The selected financial data should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and related notes included elsewhere in this Annual Report on Form 10-K.

	As of December 31,				
	2019	2018	2017	2016	2015
Selected Balance Sheet Data					
Cash, cash equivalents, restricted cash and marketable investment securities	\$ 19,068,564	\$ 20,250,576	\$ 21,468,070	\$ 26,840,286	\$ 44,382,827
Total assets	19,658,280	20,851,953	25,325,114	27,342,970	45,377,278
Total liabilities	13,370,484	11,418,280	6,345,126	1,326,169	3,391,861
Accumulated deficit	(151,067,189)	(138,059,845)	(126,399,823)	(105,416,963)	(86,445,455)
Shareholders' equity	6,287,796	9,433,673	18,979,988	26,016,801	41,985,417

	Years Ended December 31,				
	2019	2018	2017	2016	2015
Selected Statement of Operations Data					
Operating loss	\$ (12,900,290)	\$ (11,325,819)	\$ (21,217,976)	\$ (19,186,834)	\$ (18,382,068)
Net loss	(13,007,344)	(11,660,022)	(20,982,860)	(18,971,508)	(18,208,378)
Net loss per share - basic	(0.50)	(0.55)	(1.05)	(1.04)	(1.11)
Net loss per share - diluted	(0.50)	(0.55)	(1.05)	(1.04)	(1.11)

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 metabolic and endocrine 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 proprietary product candidates designed to produce favorable pharmacokinetic ("PK") characteristics and facilitate lower dosing requirements, bypass first-pass metabolism in certain cases, reduce side effects, and eliminate gastrointestinal interactions that limit bioavailability.

Our most advanced product candidate, TLANDO™, is an oral testosterone replacement therapy ("TRT"). On November 8, 2019 we received a Complete Response Letter ("CRL") from the United States Food and Drug Administration ("FDA") regarding our New Drug Application ("NDA") filed in May 2019 for TLANDO as a TRT in adult males for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism. A CRL is a communication from the FDA that informs companies that an application cannot be approved in its present form. The CRL identified one deficiency stating the efficacy trial did not meet the three secondary endpoints for maximal testosterone concentrations ("Cmax"). The CRL did not identify any specific issues relating to chemistry, manufacturing and controls ("CMC") of TLANDO. We had our Post Action meeting with the FDA in January 2020 and discussed a potential path forward for the approval of TLANDO. Based on the Post Action meeting and written feedback, the FDA indicated our approach to addressing the deficiency through the reanalysis of existing data in accordance with FDA feedback appears to be a reasonable path forward. The FDA requested that the information generated by the reanalysis be submitted as part of an NDA resubmission with a six-month Prescription Drug User Fee Act ("PDUFA") clock. We resubmitted the NDA on February 28, 2020 and it has been assigned a PDUFA date of August 28, 2020.

Additional pipeline candidates include LPCN 1144, an oral prodrug of bioidentical testosterone comprised of TU for the treatment of pre-cirrhotic non-alcoholic steatohepatitis (“NASH”), TLANDO XR (LPCN 1111), a next generation oral TRT product with the potential for once daily dosing which has completed Phase 2 testing, LPCN 1148, an oral prodrug of bioidentical testosterone for the treatment of NASH cirrhosis, and LPCN 1107, potentially the first oral hydroxyprogesterone caproate product indicated for the prevention of recurrent preterm birth, which has completed an End-of-Phase 2 meeting with the FDA.

LPCN 1144 is currently being tested in the *LIFT* (“Liver Fat intervention with oral Testosterone”) Phase 2 clinical study, a paired-biopsy study in confirmed pre-cirrhotic NASH subjects. Additionally, LPCN 1144 recently completed a Proof-Of-Concept (“POC”) liver imaging clinical study which demonstrated substantial liver fat reductions in hypogonadal males at risk of developing NASH as assessed using magnetic resonance imaging, proton density fat fraction (“MRI-PDFF”) technique.

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 we do not expect to generate revenue from product sales unless and until we obtain regulatory approval of TLANDO or other products.

We have incurred losses in most years since our inception. As of December 31, 2019, we had an accumulated deficit of \$151.0 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 \$13.0 million for the year ended December 31, 2019, compared to \$11.7 million for the year ended December 31, 2018. 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 associated with our operations.

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

- conduct any other pre or post-approval clinical studies required in support of TLANDO;
- conduct further development of our other product candidates, including 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.

To fund future long-term operations, 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 as outlined in our most recent CRL, 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, 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.

Our Product Candidates

Our current portfolio includes our most advanced product candidate, TLANDO, an oral testosterone replacement therapy product candidate, which received a CRL on November 8, 2019. Additionally, we are in the process of establishing our pipeline of other clinical candidates including an oral androgen therapy for the treatment of pre-cirrhotic NASH, LPCN 1144, a next-generation potential once daily oral testosterone replacement therapy, TLANDO XR (LPCN 1111), an androgen therapy for the treatment of NASH cirrhosis, LPCN 1148, and an oral therapy for the prevention of preterm birth, LPCN 1107.

Our Development Pipeline

TLANDO: An Oral Product Candidate for Testosterone Replacement Therapy

Our most advanced product, TLANDO, is an oral formulation of the chemical, TU, which is an eleven carbon side chain attached to T. TU is an ester prodrug of T. An ester is chemically formed by bonding an acid and an alcohol. Upon the cleavage, or breaking, of the ester bond, T is formed. TU has been approved for use outside the United States for many years for delivery via intra-muscular injection and in oral dosage form and recently TU has received regulatory approval in the United States for delivery via intra-muscular injection. We are using our proprietary technology to facilitate steady gastrointestinal solubilization and absorption of TU. Proof of concept 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 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%.

NDA PDUFA Outcome

On November 8, 2019 we received a CRL from the FDA regarding our NDA filed in May 2019 for TLANDO as a TRT in adult males for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism. The CRL identified one deficiency stating the efficacy trial did not meet the three Cmax secondary endpoints. The CRL does not identify any specific issues relating to CMC of TLANDO. We had a Post Action meeting with the FDA in January 2020 and discussed a potential path forward for the approval of TLANDO. Based on the Post Action meeting and written feedback, the FDA indicated our approach to addressing the deficiency through the reanalysis of existing data in accordance with FDA feedback appears to be a reasonable path forward. The FDA requested that the information generated by the reanalysis be submitted as part of an NDA resubmission with a six-month PDUFA clock. We resubmitted the NDA on February 28, 2020 and it has been assigned a PDUFA date of August 28, 2020. Previously, we have received two other CRL's from the FDA on TLANDO NDA submissions. The first CRL was received on June 28, 2016 and the second CRL was received on May 8, 2018.

Results from the ABPM Study

The ABPM Study was an open label, single arm study that enrolled 144 male hypogonadal subjects undergoing four months of treatment with TLANDO, 225 mg BID dosing, with 24-hour blood pressure measurements taken at baseline and at the end of the study. There were 138 subjects who received at least one dose of study drug and 126 subjects completed the study. There were 118 subjects enrolled in the ABPM Study with evaluable weighted average 24-hour ABPM data at both baseline and at the end of the study.

Subjects receiving treatment in the ABPM Study had following baseline parameters:

Baseline Parameters	Mean (SD)
Age (years)	53.8 (10.2)
BMI (kg/m ²)	33.1(5.8)
24h SBP (mm Hg)	127(16)
24h DBP (mm Hg)	79(6)

SD = Standard Deviation, BMI = Body Mass Index, SBP = Systolic Blood Pressure, DBP = Diastolic Blood Pressure

Additionally, among the subjects enrolled in the ABPM Study, 48% of the subjects were hypertensive and 24% of subjects were type 2 diabetic.

Top-line results from the ABPM Study are as follows:

Parameter	Mean Change, mm Hg (95% CI)
24-hour SBP	3.82 (1.69, 5.96)
24-hour DBP	1.20 (0.31, 2.08)

CI = Confidence Interval, SBP = Systolic Blood Pressure, DBP = Diastolic Blood Pressure

Of the subjects (n=25) with baseline 24-hour average systolic blood pressure (“SBP”) greater than 140 mm Hg, 32% of the subjects were less than or equal to 140 mm Hg at the end of study. Additionally, of the subjects (n=93) with baseline 24-hour average SBP of less than or equal to 140 mm Hg, 9.7% of the subjects were greater than 140 mm Hg at the end of study.

Results from the Definitive Phlebotomy Study

The definitive phlebotomy study was designed based on the FDA’s protocol recommendations and conducted in response to a deficiency cited in the TLANDO CRL by the FDA to confirm the reliability of TLANDO Phase 3 study results and to assess the impact of any material deviation from instructions on sample collection/processing times by clinical sites.

The definitive phlebotomy study measured testosterone concentrations in blood samples collected in plain serum separation tubes (“SST”) at three-hour and five-hour time points (N=24) post dose and processed within 30 minutes of sample collection under the tube manufacturer’s recommended conditions and consistent with Phase 3 instructions. The definitive phlebotomy study enrolled 12 hypogonadal male subjects and dosed subjects with a single oral 225 mg TU dose of TLANDO. The testosterone measurements in SST were compared against the FDA’s recommended time zero control (processed immediately) measurement of testosterone concentrations in blood samples in plasma tubes with EDTA (“PT”) to assess ex vivo conversion, if any.

The top-line results of the definitive phlebotomy study demonstrated that the overall (N=24) mean percentage difference and the associated percentage standard deviation post dose of testosterone concentrations measured between SST samples and PT samples are -1.0% and 9.2%, respectively.

Results from DV and DF Studies

The DV and DF studies were both an open-label, fixed dose (no titration), single treatment clinical study of oral TRT in hypogonadal males with low testosterone (T) (< 300 ng/dL) that assessed TLANDO in hypogonadal males on a fixed daily dose of 450 mg divided into two equal doses (“BID”) in the DV study and into three equal doses (“TID”) in the DF study. In total, 95 and 100 subjects were enrolled into DV and DF studies, respectively, with 94 and 98 subjects completing the DV and DF studies, respectively.

We believe the results from the DV study confirm the validity of a fixed dose approach without the need for dose titration to orally administering TLANDO although there is no guarantee of FDA approval of TLANDO. The DV study is considered our pivotal efficacy clinical study. TLANDO successfully met the FDA primary efficacy guidelines in the DV study safety statistical analysis set (“SS”) where 80% of the subjects achieved average testosterone levels (“Cavg”) within the normal range with a lower bound confidence interval (“CI”) of 72%. The DF study restored 70% of the subjects’ average testosterone levels within the normal range (Cavg) confirming that twice daily (“BID”) dosing is the appropriate dosing regimen for TLANDO and was the basis for resubmission. The safety set is defined as any subject that was randomized into the study and took at least one dose (N=95 subjects in the DV study and N=100 in the DF study). A baseline carried forward approach was used to account for missing data as a result of subject discontinuation.

The primary efficacy endpoint is the percentage of subjects with Cavg within the normal range, which is defined as 300-1080 ng/dL. The FDA guidelines for primary efficacy success is that at least 75% of the subjects on active treatment achieve a testosterone Cavg within the normal range; and the lower bound of the 95% CI must be greater than or equal to 65%.

The adverse event profile of TLANDO in both the DV and DF studies was consistent with the previously conducted 52-week Phase 3 Study of Androgen Replacement (“SOAR”) clinical trial. All drug related adverse events (“AEs”) were either mild or moderate in intensity and none were severe. To date, the safety database of TLANDO includes ~591 subjects demonstrating a profile consistent with other TRT products.

The secondary endpoints assessed the maximum total testosterone concentration (“C_{max}”) post dosing using predetermined limits developed by the FDA for transdermals. The FDA guidelines for secondary efficacy success is that at least 85% of the subjects achieve C_{max} less than 1500 ng/dL; no greater than 5% of the subjects have C_{max} between 1800 ng/dl and 2500 ng/dL; and zero percent of the subjects have C_{max} greater than 2500 ng/dL. Consistent with the definition of C_{max} and the pharmacokinetic profile of multiple times a day dosing, two pre-specified analyses were performed, C_{max} per dose and C_{max} per day.

In the DV study SS C_{max} per dose analysis, the percentage of subjects with C_{max} less than 1500 ng/dL and between 1800 ng/dL and 2500 ng/dL were 85% and 7%, respectively. Deviations from the predetermined limits in the DV study were observed in the C_{max} per day dose analysis for these thresholds as such this efficacy trial did not meet the three C_{max} per day secondary endpoints. Only one subject, who was a major protocol violator, exceeded the 2500 ng/dL limit independent of per dose or per day dose analyses.

The DF study SS met all C_{max} thresholds in per dose and per day dose analyses.

Prior to conducting the DV study and the DF study, we completed our SOAR pivotal Phase 3 clinical study evaluating efficacy and 52-week safety of TLANDO. The SOAR study is considered our pivotal safety clinical study for the NDA resubmission.

Results from SOAR

SOAR was a randomized, open-label, parallel-group, active-controlled, Phase 3 clinical study of TLANDO in hypogonadal males with low testosterone (< 300 ng/dL). In total, 315 subjects at 40 active sites were assigned, such that 210 were randomized to TLANDO and 105 were randomized to the active control, AndroGel 1.62%®, for 52 weeks of treatment. The active control is included for safety assessment. TLANDO subjects were started at 225 mg TU (equivalent to ~ 142 mg of T) twice daily (“BID”) with a standard meal and then dose titrated, if needed, based on average T levels during the day, C_{avg}, and peak serum T levels, C_{max}, up to 300 mg TU BID or down to 150 mg TU BID based on serum testosterone measured at weeks 3 and 7 based on PK profile with multiple blood samples drawn at each time period. The mean age of the subjects in the trial was ~53 years with ~91% of the patients < 65 years of age. The discontinuation rate for TLANDO was 38% compared to 32% for AndroGel 1.62%.

Primary statistical analysis was conducted using the Efficacy Population Set (“EPS”). The EPS is defined as subjects randomized into the study with at least one PK profile and no significant protocol deviations and includes imputed missing data by last observation carried forward, N=151. Further analysis was performed using the full analysis set (“FAS”) (any subject randomized into the study with at least one post-baseline efficacy variable response, N=193) and the SS (any subject that was randomized into the study and took at least one dose, N=210).

Safety

The safety component of the SOAR trial was completed the last week of April 2015. The safety extension phase was designed to assess safety based on information such as metabolites, biomarkers, laboratory values, serious adverse events SAEs and AEs, with subjects on their stable dose regimen in both the treatment arm and the active control arm. TLANDO treatment was well tolerated in there were no hepatic, cardiac or drug related SAEs.

TLANDO safety highlights include:

- TLANDO was well tolerated during 52 weeks of dosing;
- Overall AE profile for TLANDO was comparable to the active control;
- Cardiac AE profiles were consistent between treatment groups and none of the observed cardiac AEs occurred in greater than 1.0% of the subjects in the TLANDO arm and none were classified as severe; and
- All observed adverse drug reactions (“ADRs”) were classified as mild or moderate in severity and no serious ADRs occurred during the 52-week treatment period.

Food Effect Study

We also completed our labeling "food effect" study in May 2015. Results from the labeling "food effect" study indicate that bioavailability of testosterone from TLANDO is not affected by changes in meal fat content. The results demonstrate comparable testosterone levels between the standard fat meal (similar to the meal instruction provided in the Phase 3 clinical study) and both the low and high fat meals. The labeling "food effect" study was conducted per the FDA requirement and we submitted preliminary results from this study to the FDA in the second quarter of 2015 prior to submitting the NDA.

Other Safety Requirements

Based on our meetings with the FDA, we do not expect to be required to conduct a heart attack and stroke risk study prior to the potential approval of TLANDO. We may, however, be required to conduct a heart attack and stroke risk study on our own or with a consortium of sponsors that have an approved TRT product subsequent to the potential approval of TLANDO.

Recent Competition Update

On March 27, 2019, Clarus Therapeutics, Inc.'s ("Clarus") product JATENZO®, an oral testosterone undecanoate product, was approved by the FDA and also received three years of data exclusivity. It is unclear how Jatenzo's three years of data exclusivity will impact the potential full approvability of TLANDO. The potential exists that, as a result of Clarus' data exclusivity, the approval of TLANDO by the FDA, if ever received, could be delayed until March 27, 2022. On February 10, 2020, Clarus announced that JATENZO® has been launched and is commercially available. Additionally on October 2, 2019, Clarus filed a Citizens Petition with the FDA requesting the FDA establish clear, written guidance regarding the safety and efficacy standards required for oral testosterone drugs. The Citizens Petition also requested that the FDA not approve any oral testosterone drugs until the written guidance is provided by the FDA. We will not know the impact that Clarus' Citizen Petition may have on TLANDO's approval, until the FDA addresses the Citizens Petition specifically which may have an adverse effect on TLANDO.

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 pre-cirrhotic NASH. NASH is a more advanced state of non-alcoholic fatty liver disease ("NAFLD") and can progress to a cirrhotic liver and eventually hepatocellular carcinoma or liver cancer. Twenty to thirty percent of the U.S. population is estimated to suffer from NAFLD and fifteen to twenty percent of this group progress to NASH, which is a substantially large population that lacks effective therapy. Currently, there are no FDA approved treatments for NASH. Approximately 50% of NASH patients are in adult males and the number of NASH cases is projected to increase 63% from 16.5 million cases in 2015 to 27.0 million cases in 2030. 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. In men, especially with comorbidities associated with NAFLD/NASH, testosterone deficiency has been associated with an increased accumulation of visceral adipose tissue and insulin resistance, which could be factors contributing to NAFLD/NASH.

History of Liver Disease

The liver is the largest internal organ in the human body and its proper function is indispensable for many critical metabolic functions, including the regulation of lipid and sugar metabolism, the production of important proteins, including those involved in blood clotting, and purification of blood. There are over 100 described diseases of the liver, and because of its many functions, these can be highly debilitating and life-threatening unless effectively treated. Liver diseases can result from injury to the liver caused by a variety of insults, including hepatitis C virus (HCV), hepatitis B virus (HBV), obesity, chronic excessive alcohol use or autoimmune diseases. Regardless of the underlying cause of the disease, there are important similarities in the disease progression including increased inflammatory activity and excessive liver cell apoptosis, which if unresolved leads to fibrosis. Fibrosis, if allowed to progress, will lead to cirrhosis, or excessive scarring of the liver, and eventually reduced liver function. Some patients with liver cirrhosis have a partially functioning liver and may appear asymptomatic for long periods of time, which is referred to as decompensated liver disease. Decompensated liver disease is when the liver is unable to perform its normal functions. Many people with active liver disease remain undiagnosed largely because liver disease patients are often asymptomatic for many years.

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.

Relationship between Hypogonadism and NAFLD

Preclinical and clinical studies in the NAFLD/NASH literature have shown the prevalence of testosterone deficiency across the NAFLD/NASH histological spectrum wherein low testosterone was independently associated with NAFLD/NASH with an inverse relationship between testosterone and NAFLD/NASH symptom severity. A recent National Institute of Diabetes and Digestive and Kidney Diseases (“NIDDK”) report suggests that 75% of biopsy confirmed NASH subjects have less than 372 ng/dL of total testosterone and that the degree of fibrosis severity is inversely related to free testosterone levels; thus, providing a good rationale for testing LPCN 1144 in adult NASH patients regardless of their hypogonadal status. Recently, we received clearance from the FDA to clinically investigate LPCN 1144 in an expanded target population of adult male NASH patients. Specifically, the FDA waived the limitation of only testing LPCN 1144 in NASH subjects with total testosterone levels below 300 ng/dL (threshold for hypogonadism).

Post hoc analyses of our existing clinical trials in subjects with comorbidities typically associated with NASH comorbidities indicate that testosterone therapy significantly and consistently reduced elevated levels of key serum biomarkers (liver function enzymes and serum triglyceride) generally associated with NAFLD/NASH.

Current Status

We have completed a 16-week POC liver imaging clinical study to assess liver fat changes in hypogonadal men at risk of developing NASH using MRI-PDFF technique. Treatment results from the POC liver imaging study demonstrated that 48% of the treated NAFLD subjects, defined as baseline liver fat of at least 5%, had NAFLD resolution, defined as liver fat <5% post treatment. Additionally, 100% of the subjects experiencing NAFLD resolution had at least a 35% relative liver fat reduction from baseline with a relative mean liver fat reduction of 55% in this group. Further results from the POC liver fat clinical study after 16 weeks of treatment are as follows:

Baseline Liver Fat % Category, n	Mean Liver Fat % at Baseline	Relative Reductions at EOS		Responder Rate** at EOS, %
		Mean %	Median %	
At least 10%, n=8	20.5	40	39	75
At least 8%, n=10	18.3	42	42	80
At least 5%, n=21	12.1	33	41	71

**Based on subjects who experienced at least a 30% reduction in liver fat from baseline.

Additionally, we have initiated the *LiFT* (“Liver Fat intervention with oral Testosterone”) Phase 2 clinical study, a paired-biopsy study in confirmed pre-cirrhotic NASH subjects with the first subject being dosed in the third quarter of 2019. The formulations being studied in the Phase 2 clinical trial are differentiated from TLANDO. The *LiFT* Phase 2 clinical study is a prospective, multi-center, randomized, double-blind, placebo-controlled multiple-arm study in biopsy-confirmed hypogonadal or eugonadal male NASH subjects with grade F2/F3 fibrosis and a NAFLD Activity Score (“NAS”) ≥ 4 with a 36-week treatment period. The *LiFT* clinical study is designed to enroll between 60 and 75 biopsy confirmed NASH male subjects, randomized into one of three arms (two test arms and one placebo arm) with a 1:1:1 randomization ratio. We currently expect top-line liver fat reduction data in the second half of 2020, as measured by MRI-PDFF at 12 weeks, followed by 36-week biopsy data which is expected by the first half of 2021.

TLANDO XR (LPCN 1111): A Next-Generation Long-Acting Oral Product Candidate for TRT

TLANDO XR (LPCN 1111) is a next-generation, novel ester prodrug of testosterone which uses the Lip'ral 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 TLANDO XR (LPCN 1111) along with safety and tolerability of TLANDO XR (LPCN 1111) and its metabolites following oral administration of single and multiple doses in hypogonadal men. The Phase 2b clinical trial was a randomized, open label, two-period, multi-dose PK study that enrolled hypogonadal males into five treatment groups. Each of the 12 subjects in a group received treatment for 14 days. Results of the Phase 2b study suggest that the primary objectives were met, including identifying the dose expected to be tested in a Phase 3 study. 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, TLANDO XR (LPCN 1111) was well tolerated with no drug-related severe or serious adverse events reported in the Phase 2b study.

Additionally in October 2014, we completed a Phase 2a proof-of-concept study in hypogonadal men. The Phase 2a open-label, dose-escalating single and multiple dose study enrolled 12 males. Results from the Phase 2a clinical study demonstrated the feasibility of a once daily dosing with TLANDO XR (LPCN 1111) in hypogonadal men and a good dose response. Additionally, the study confirmed that steady state is achieved by day 14 with consistent inter-day performance observed on day 14, 21 and 28. No subjects exceeded C_{max} of 1500 ng/dL at any time during the 28-day dosing period on multi-dose exposure. Overall, TLANDO XR (LPCN 1111) was well tolerated with no serious AE's reported.

We have also completed a preclinical toxicology study with LPCN 1111 in dogs.

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 TLANDO XR (LPCN 1111). Based on the results of the FDA meeting and additional pre-clinical trials conducted after the FDA meeting, we are designing a Phase 3 protocol for TLANDO XR (LPCN 1111) and will solicit FDA feedback once the protocol is complete. Additionally, the FDA previously requested that a food effect study be completed, and that ABPM be included as part of the Phase 3 clinical study. Based on our capital resources and the clinical status of our product candidates, we plan to primarily focus our efforts in 2020 on TLANDO and LPCN 1144. We do not anticipate the initiation of a Phase 3 study with LPCN 1111 to occur in 2020 unless and until additional capital is secured or the product candidate is out-licensed. We are exploring the possibility of licensing LPCN 1111 to a third party, although no licensing agreement has been entered into by the Company

LPCN 1148: An Oral Prodrug of Bioidentical Testosterone Product Candidate for the Treatment of NASH in Cirrhotic patients

NASH cirrhosis is an end stage NAFLD for which there is no FDA approved drug treatment. During 2015, approximately 1.3 million NASH patients had cirrhosis (fibrosis grade 4). Cirrhosis patients typically experience increased morbidity and mortality and symptoms of hypogonadism such as alteration of hair distribution, anemia, sexual dysfunction, testicular atrophy, muscle wasting, fatigue, osteoporosis, gynecomastia, and other symptoms.

Testosterone levels fall progressively with increasing chronic liver disease severity. Low testosterone levels, reported in up to 90% of male cirrhotic patients, is known to increase adverse outcomes and is a predictor of mortality in these patients with association with increased risk of major infections, death and/ or transplantation rates, increased risk of for hepatic decompensation, worsening of sarcopenia, higher Child Pugh score grade and Model for End-stage Liver Disease score as well as severity of portal hypertension and ascites grade.

We are currently formulating plans to conduct a proof-of-concept study in male cirrhotic subjects through consultations with the FDA and key opinion leaders to evaluate the therapeutic potential of LPCN 1148 for the treatment of cirrhotic subjects. We plan to file an Investigational New Drug application ("IND") for LPCN 1148 in March 2020. Based on our capital resources and the clinical status of our product candidates, we plan to primarily focus our efforts in 2020 on TLANDO and LPCN 1144. We do not anticipate the initiation of a Phase 2 study with LPCN 1148 to occur in 2020 unless and until additional capital is secured or the product candidate is out-licensed. We are exploring the possibility of licensing LPCN 1148 to a third party, although no licensing agreement has been entered into by the Company

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 preterm birth (delivery less than 37 weeks) (“PTB”) 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.

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 of three dose levels of LPCN 1107 and the injectable intramuscular (“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. We have also completed a proof-of-concept Phase 1b clinical study of LPCN 1107 in healthy pregnant women in January 2015 and a proof-of-concept Phase 1a clinical study of LPCN 1107 in healthy non-pregnant women in May 2014. These studies were designed to determine the PK and bioavailability of LPCN 1107 relative to an IM HPC, as well as safety and tolerability.

A traditional pharmacokinetics/pharmacodynamics (“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 Phase 3 development plan for LPCN 1107. During the meetings, the FDA agreed to a randomized, open-label, two-arm clinical study to include a LPCN 1107 arm and a comparator IM arm with treatment up to 23 weeks. The FDA also provided preliminary feedback on other critical Phase 3 study design considerations including: positive feedback on the proposed 800 mg BID Phase 3 dose and dosing regimen; confirmation of the use of a surrogate primary endpoint focusing on rate of delivery less than 37 weeks gestation rather on clinical infant outcomes; acknowledgment that the use of a gestational age endpoint would likely lead to any FDA approval, if granted, being a Subpart H approval; and, recommendation of a non-inferiority (“NI”) study margin of 7% with interim analyses. A standard statistical design for an NI study based on the FDA feedback of 7% for the primary endpoint may require approximately 1,100 subjects per treatment arm with a 90% power. However, based on the FDA’s suggestion of including an interim analysis in the NI design, an adaptive study design is under consideration that may allow for fewer subjects. We submitted the initial LPCN 1107 Phase 3 protocol to the FDA via an SPA in June 2017 and have received multiple rounds of FDA’s feedback. However, agreement with the FDA on the Phase 3 protocol via SPA has not occurred as we are waiting for minutes from the FDA’s Advisory Committee meeting for AMAG Pharmaceuticals’ Makena which was held on October 29, 2019. Final agreement with the FDA on the Phase 3 protocol, if reached, may or may not confirm the FDA’s preliminary feedback on the Phase 3 design. Additionally, a Phase 3 study will not occur until the results from a planned food-effect study with LPCN 1107 are reviewed by the FDA, though manufacturing scale-up work for LPCN 1107 has been completed.

Based on our capital resources and the clinical status of our product candidates, we plan to primarily focus our efforts in 2020 on TLANDO and LPCN 1144. We do not anticipate the initiation of a Phase 3 study with LPCN 1107 to occur in 2020 unless and until additional capital is secured or the product candidate is out-licensed. 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 Lipicine 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.

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, milestone payments and research support from our licensees. Since our inception through December 31, 2019, we have generated \$28.1 million in revenue under our various license and collaboration arrangements and from government grants. We may never generate revenues from TLANDO or any of our other 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 \$111.1 million in research and development expenses through December 31, 2019.

As a result of the CRL we received from the FDA on TLANDO's NDA, we are uncertain as to whether we will incur additional research and developments costs for TLANDO. On February 16, 2020, we met with the FDA in a Post Action Meeting to review our CRL, and based on these discussions, we do not expect to conduct any additional clinical trials with TLANDO for TRT. However, 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 other product candidates, including the ongoing *LiFT* Phase 2 clinical study with LPCN 1144.

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 for testosterone replacement therapies.

We have also incurred significant manufacturing costs to prepare launch supplies for TLANDO. However, future 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 TLANDO;
- our dependence on third-party manufacturers for the production of satisfactory finished product for registration and launch should regulatory approval be obtained;
- the potential for future license or co-promote arrangements for TLANDO, 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 the development of TLANDO and our other 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 1144, TLANDO XR (LPCN 1111), LPCN 1148, LPCN 1107 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 LPCN 1144, TLANDO XR (LPCN 1111), LPCN 1148, 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,	
	2019	2018
External service provider costs:		
TLANDO	\$ 2,417,152	\$ 3,506,704
LPCN 1111	146,622	124,796
LPCN 1107	42,918	297,763
LPCN 1144	2,611,993	131,982
Total external service provider costs	5,218,685	4,061,245
Internal personnel costs	1,669,969	1,817,124
Other research and development costs	579,556	586,339
Total research and development	\$ 7,468,210	\$ 6,464,708

We expect research and development expenses to increase in the future as we conduct future clinical studies, including the *LiFT* Phase 2 clinical study with LPCN 1144 and as we manufacture commercial supplies of TLANDO pre-approval, and when and if we conduct Phase 2 clinical studies with LPCN 1148 and Phase 3 clinical studies with TLANDO XR (LPCN 1111) and LPCN 1107. 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.

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, marketing, sales 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 our on-going patent interference and patent infringement lawsuits against Clarus.

We expect that general and administrative expenses will increase in the future as we incur additional legal fees in the on-going court cases with Clarus. Additional areas that may see increases as we mature as a public company include 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 reduce general and administrative expenses in order to extend our ability to continue as a going concern.

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.

Results of Operations

Comparison of the Years Ended December 31, 2019 and 2018

The following table summarizes our results of operations for the years ended December 31, 2019 and 2018:

	Years Ended December 31,		Variance
	2019	2018	
Revenue	\$ 164,990	\$ 428,031	\$ (263,041)
Research and development expenses	7,468,210	6,464,708	1,003,502
General and administrative expenses	5,597,070	5,289,142	307,928
Other expense, net	343,254	333,503	9,751
Unrealized gain on warrant liability	236,400	-	236,400
Income tax expense	200	700	(500)

Revenue

We recognized license revenue of \$165,000 during the year ended December 31, 2019, compared to license revenue of \$428,000 during the year ended December 31, 2018. License revenue in both 2019 and 2018 relates to royalty payments received from Spriaso LLC (“Spriaso”) under a licensing agreement in the cough and cold field.

Research and Development Expenses

The increase in research and development expenses during the year ended December 31, 2019 was primarily due to increased contract research organization and outside consulting and manufacturing costs for the LPCN 1144 *LiFT* Phase 2 clinical study in NASH subjects of \$2.5 million and a \$22,000 increase in costs for TLANDO XR (LPCN 1111). These increases were offset by a \$1.1 million decrease in costs incurred in conjunction with TLANDO with the completion of the ABPM study and the filing of the NDA in the first half of 2019, a \$255,000 decrease in contract manufacturing costs for LPCN 1107, and a \$147,000 decrease in personnel expense.

General and Administrative Expenses

The increase in general and administrative expenses during the year ended December 31, 2019 was primarily due to a \$1.4 million increase in legal costs associated with the lawsuit filed against Clarus for patent infringement in 2019, in addition to a \$192,000 increase in corporate insurance, offset by a \$1.2 million decrease in personnel costs, which includes a decrease of \$588,000 in salaries and related benefits mainly from the elimination of our commercial sales and marketing team in 2018, a decrease in severance compensation of \$213,000, a decrease in stock compensation expense of \$254,000, and a \$153,000 decrease in bonus expense. Additionally, we also had a \$37,000 loss on disposition of property in 2018 that did not occur in 2019.

Other Expense, Net

The increase in other expense, net, during the year ended December 31, 2019 was due to a \$36,000 decrease in interest income earned during the year ended 2019 due to lower average balances of cash, cash equivalents and marketable securities, which was offset by a \$27,000 decrease in interest expense on our Loan and Security Agreement with SVB, as a result of lower principal balances in 2019 compared to 2018.

Unrealized Gain on Warrant Liability

We recorded a \$236,000 non-cash gain on the change in fair value of warrant liability during the year ended December 31, 2019 related to warrants issued in the November 2019 Offering. We did not record a similar change during the year ended December 31, 2018 as there were no similar warrants outstanding in 2018. The gain in 2019 was attributable to a decrease in the stock price of our common stock and a decrease in the remaining term of the warrants from the November 2019 Offering to December 31, 2019. 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, and the risk-free interest rate.

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 evaluate our options related to TLANDO and as we advance clinical development of LPCN 1144, TLANDO XR (LPCN 1111), LPCN 1148, LPCN 1107 and any other product candidate, including continued research efforts.

As of December 31, 2019, we had \$14.1 million of unrestricted cash, cash equivalents and marketable investment securities compared to \$15.3 million at December 31, 2018. Additionally, as of December 31, 2019 and December 31, 2018 we had \$5.0 million of restricted cash, which is required to be maintained as cash collateral under the SVB Loan and Security Agreement until TLANDO is approved by the FDA.

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 \$375,000. 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 November 18, 2019, we 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 common stock and a common 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 common stock and one common 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, 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 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. The loan matures on December 1, 2021. We were only required to make monthly interest payments until December 31, 2018, and are now required to also make equal monthly payments of principal and interest for the remainder of the term. 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), subject to a prepayment charge if the loan has been outstanding for less than two years, which prepayment charge is determined based on the date the loan is prepaid. 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 are required to maintain \$5.0 million of cash collateral at SVB until such time as TLANDO is approved by the FDA. 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 its 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 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 \$25.0 million 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, 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 the Company’s Registration Statement on Form S-3 (File No. 333-220942) (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. On November 7, 2019, the Company filed a prospectus supplement in which the Company disclosed that the Company was no longer subject to the limitations of General Instruction I.B.6. of Form S-3. However, as of the filing of this Annual Report on Form 10-K, the Company is now subject to the limitations of General Instruction I.B.6. of Form S-3, and in accordance with the terms of the Sales Agreement, the amount of shares of our common stock available for sale under the New Form S-3 is now limited to one-third of the aggregate market value of our common equity held by non-affiliates of the Company over any rolling 12-month period.

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

As of December 31, 2019, we have sold 6,635,535 shares of our common stock resulting in net proceeds of approximately \$19.3 million under the Sales Agreement which is net of \$716,000 in expenses consisting of commissions paid to Cantor in connection with these sales and other offering and accounting costs.

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, 2021. 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, 2021, 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, 2021, to support our operations, on-going clinical study for LPCN 1144, ongoing intellectual property litigation with Clarus and compliance with regulatory requirements. If the Company is unsuccessful in raising additional capital its 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 1144, TLANDO XR (LPCN 1111), LPCN 1148 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 or intellectual property litigation.

We can raise capital pursuant to the Sales Agreement in the ATM Offering when not restricted due to the terms of a previous financing but may choose not to issue common stock if our market price is too low to justify such sales in our discretion. 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. 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 and pre-commercialization 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:

- further clinical development requirements or other requirements of the FDA related to approval of TLANDO;
- 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 1144, TLANDO XR (LPCN 1111), LPCN 1148 and LPCN 1107;
- the scope of clinical and other work required to obtain approval of TLANDO and our other product candidates;

- 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 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 ATM Offering. 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.

Sources and Uses of Cash

The following table provides a summary of our cash flows for the years ended December 31, 2019 and 2018:

	<u>Years ended December 31,</u>	
	<u>2019</u>	<u>2018</u>
Cash used in operating activities	\$ (11,666,217)	\$ (12,078,825)
Cash provided by investing activities	2,998,227	11,293,281
Cash provided by financing activities	10,318,974	10,652,334

Net Cash Used in Operating Activities

During the years ended December 31, 2019 and 2018, net cash used in operating activities was \$11.7 million and \$12.1 million, respectively.

Net cash used in operating activities during the years ended December 31, 2019 and 2018 was primarily attributable to cash outlays to support on-going operations, including research and development expenses and general and administrative expenses. During 2019, we performed activities related to the ABPM study for TLANDO, the submission of the TLANDO NDA, the POC liver imaging study for LPCN 1144 and the *LiFT* Phase 2 paired biopsy clinical study for LPCN 1144. During 2018, we performed activities related to the BRUDAC meeting for TLANDO on January 10, 2018 as well as initiated the ABPM and definitive phlebotomy clinical studies for TLANDO.

Net Cash Provided by Investing Activities

During the years ended December 31, 2019 and 2018, net cash provided by investing activities was \$3.0 million and \$11.3 million, respectively.

Net cash provided by investing activities during 2019 and 2018 was primarily the result of utilizing marketable investment securities, net, of \$3.0 million and \$11.3 million, respectively, to fund current operations. There were no capital expenditures for 2019 or 2018.

Net Cash Provided by Financing Activities

During the years ended December 31, 2019 and 2018, net cash provided by financing activities was \$10.3 million and \$10.7 million, respectively.

Net cash provided by financing activities during 2019 was primarily attributable to the net proceeds from the sale of 12,000,000 shares of common stock and pre-funded warrants in a registered direct offering resulting in net proceeds of \$5.6 million and net proceeds from the sale of 3,650,479 shares of common stock pursuant to the ATM Offering resulting in net proceeds of \$8.0 million, offset by \$3.3 million in debt principal repayments under the SVB Loan and Security Agreement.

Net cash provided by financing activities during 2018 was primarily attributable to \$10.0 million received in proceeds from the SVB Loan and Security Agreement and the net proceeds from the sale of common stock pursuant to the ATM Offering of \$652,000.

Employee stock option exercises provided approximately \$56,000 and zero of cash during 2019 and 2018, respectively. 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, 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 plus one percent per annum, which interest is payable monthly. The loan matures over three years beginning January 1, 2019 and maturing December 1, 2021 and the Company is required to make equal monthly payments of principal and interest for the remaining term of the loan. The Company will also be required to pay an additional final payment equal to \$650,000 (the "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 February 24, 2020, we modified and extended the lease through February 28, 2021.

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. 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 limited revenue in 2019 and 2018 under a licensing agreement with Spriaso LLC.

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, 2019, we do not have any active collaboration agreements except for an agreement to provide joint research and development services through January 23, 2015 which was assigned to Spriaso LLC as described in Note 12 of Lipocine Inc.’s annual financial statements included in this filing.

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, 2019, there was \$507,000 of total unrecognized compensation cost related to unvested share-based compensation arrangements granted under the Company’s stock option plan. Additionally as of December 31, 2019, there was \$958,000 of total unrecognized compensation cost related to unvested restricted stock units that have either time based or performance vesting.

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 \$63,000 increase in interest expense, while a one percent decrease in the prime rate would result in a \$76,000 decrease in interest expense.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTAL DATA

LIPOCINE INC. INDEX TO FINANCIAL STATEMENTS

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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 sheet of Lipocine Inc. and subsidiaries (the Company) as of December 31, 2019 and 2018, 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 financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for years then ended, in conformity with U.S. generally accepted accounting principles.

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 audit. 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 audit 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 audit, 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 audit 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.

/s/ Tanner LLC

We have served as the Company's auditor since 2018
Salt Lake City, Utah
March 12, 2020

LIPOCINE INC. AND SUBSIDIARIES

Consolidated Balance Sheets

December 31, 2019 and 2018

	2019	2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 9,728,523	\$ 8,077,539
Restricted cash	5,000,000	5,000,000
Marketable investment securities	4,340,041	7,173,037
Accrued interest income	16,522	38,514
Prepaid and other current assets	545,887	520,113
	19,630,973	20,809,203
Property and equipment, net of accumulated depreciation of \$1,140,143 and \$1,124,700, respectively	3,554	18,997
Other assets	23,753	23,753
Total assets	\$ 19,658,280	\$ 20,851,953
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,182,241	\$ 671,280
Accrued expenses	449,303	487,135
Debt - current portion	3,333,333	3,333,333
	4,964,877	4,491,748
Debt - non-current portion	3,814,407	6,926,532
Warrant liability	4,591,200	-
Total liabilities	13,370,484	11,418,280
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; 37,655,175 and 21,737,196 issued and 37,649,465 and 21,731,486 outstanding	3,766	2,174
Additional paid-in capital	157,391,969	147,533,019
Treasury stock at cost, 5,710 shares	(40,712)	(40,712)
Accumulated other comprehensive loss	(38)	(963)
Accumulated deficit	(151,067,189)	(138,059,845)
	6,287,796	9,433,673
Total stockholders' equity	6,287,796	9,433,673
Total liabilities and stockholders' equity	\$ 19,658,280	\$ 20,851,953

See accompanying notes to consolidated financial statements

LIPOCINE INC. AND SUBSIDIARIES

Consolidated Statements of Operations and Comprehensive Loss

Years Ended December 31, 2019 and 2018

	<u>2019</u>	<u>2018</u>
Revenues:		
License revenue	\$ 164,990	\$ 428,031
Total revenues	<u>164,990</u>	<u>428,031</u>
Operating expenses:		
Research and development	7,468,210	6,464,708
General and administrative	5,597,070	5,289,142
Total operating expenses	<u>13,065,280</u>	<u>11,753,850</u>
Operating loss	(12,900,290)	(11,325,819)
Other expense, net	(343,254)	(333,503)
Unrealized gain on warrant liability	236,400	-
Loss before income tax expense	<u>(13,007,144)</u>	<u>(11,659,322)</u>
Income tax expense	(200)	(700)
Net loss	<u>\$ (13,007,344)</u>	<u>\$ (11,660,022)</u>
Basic loss per share attributable to common stock	<u>\$ (0.50)</u>	<u>\$ (0.55)</u>
Weighted average common shares outstanding, basic	<u>25,882,273</u>	<u>21,352,339</u>
Diluted loss per share attributable to common stock	<u>\$ (0.50)</u>	<u>\$ (0.55)</u>
Weighted average common shares outstanding, diluted	<u>25,882,273</u>	<u>21,352,339</u>
Comprehensive loss:		
Net loss	\$ (13,007,344)	\$ (11,660,022)
Unrealized net gain on available-for-sale securities	925	3,653
Comprehensive loss	<u>\$ (13,006,419)</u>	<u>\$ (11,656,369)</u>

See accompanying notes to consolidated financial statements

LIPOCINE INC. AND SUBSIDIARIES

Consolidated Statements of Changes in Stockholders' Equity

Years Ended December 31, 2019 and 2018

	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, 2017	21,264,539	\$ 2,127	5,710	\$ (40,712)	\$ 145,423,012	\$ (4,616)	\$ (126,399,823)	18,979,988
Net loss	-	-	-	-	-	-	(11,660,022)	(11,660,022)
Unrealized net gain on marketable investment securities	-	-	-	-	-	3,653	-	3,653
Stock-based compensation	-	-	-	-	1,457,720	-	-	1,457,720
Common stock sold through ATM offering	466,947	47	-	-	652,287	-	-	652,334
Balances at December 31, 2018	21,731,486	\$ 2,174	5,710	\$ (40,712)	\$ 147,533,019	\$ (963)	\$ (138,059,845)	\$ 9,433,673
Net loss	-	-	-	-	-	-	(13,007,344)	(13,007,344)
Unrealized net gain on marketable investment securities	-	-	-	-	-	925	-	925
Common stock sold through equity offering	10,450,000	1,045	-	-	766,897	-	-	767,942
Pre-funded warrant exercises	1,550,000	155	-	-	-	-	-	155
Stock-based compensation	-	-	-	-	1,035,834	-	-	1,035,834
Option exercises	20,000	2	-	-	56,198	-	-	56,200
Vesting of restricted stock units	247,500	25	-	-	(25)	-	-	-
Common stock sold through ATM offering	3,650,479	365	-	-	8,000,046	-	-	8,000,411
Balances at December 31, 2019	<u>37,649,465</u>	<u>\$ 3,766</u>	<u>5,710</u>	<u>\$ (40,712)</u>	<u>\$ 157,391,969</u>	<u>\$ (38)</u>	<u>\$ (151,067,189)</u>	<u>\$ 6,287,796</u>

See accompanying notes to consolidated financial statements

LIPOCINE INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

Years Ending December 31, 2019 and 2018

	2019	2018
Cash flows from operating activities:		
Net loss	\$ (13,007,344)	\$ (11,660,022)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation expense	15,443	18,595
Stock-based compensation expense	1,035,834	1,457,720
Loss on disposition of property and equipment	-	37,478
Non-cash interest expense	221,209	259,865
Non-cash gain on change in fair value of warrant liability	(236,400)	-
Amortization of premium/discount on marketable investment securities	(164,306)	(198,344)
Changes in operating assets and liabilities:		
Accrued interest income	21,992	(15,447)
Litigation insurance recovery	-	3,319,927
Prepaid and other current assets	(25,774)	(111,886)
Accounts payable	510,961	73,210
Litigation settlement payable	-	(4,250,000)
Accrued expenses	(37,832)	(1,009,921)
Cash used in operating activities	(11,666,217)	(12,078,825)
Cash flows from investing activities:		
Refund of rental deposit	-	7,000
Purchases of marketable investment securities	(16,851,568)	(25,552,679)
Maturities of marketable investment securities	19,849,795	36,838,960
Cash provided by investing activities	2,998,227	11,293,281
Cash flows from financing activities:		
Proceeds from debt	-	10,000,000
Debt repayments	(3,333,334)	-
Proceeds from stock option exercises	56,200	-
Proceeds from sale of Class A and Class B units	5,595,542	-
Proceeds from exercise of pre-funded warrants	155	-
Net proceeds from sale of common stock through ATM	8,000,411	652,334
Cash provided by financing activities	10,318,974	10,652,334
Net increase in cash and cash equivalents	1,650,984	9,866,790
Cash, cash equivalents and restricted cash at beginning of period	13,077,539	3,210,749
Cash, cash equivalents and restricted cash at end of period	\$ 14,728,523	\$ 13,077,539
Supplemental disclosure of cash flow information:		
Interest paid	545,536	533,542
Income taxes paid	700	700
Supplemental disclosure of non-cash investing and financing activities:		
Unrealized net gain on marketable investment securities	925	3,653
Accrued final payment charge on debt	221,209	259,865
Allocation of equity offering proceeds to warrant liability	4,827,600	-

See accompanying notes to consolidated financial statements

LIPOCINE INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2019 and 2018

(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; 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 \$9.7 million and \$8.1 million at December 31, 2019 and 2018.

(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 2019 and 2018 and the Company did not record an allowance for doubtful accounts as of December 31, 2019 and 2018 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 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.

LIPOCINE INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2019 and 2018

(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.

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.

LIPOCINE INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2019 and 2018

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

(h) Share-Based Payments

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 \$1.0 million and \$1.5 million for the years ended December 31, 2019 and 2018, allocated as follows:

	Year Ended	
	2019	2018
Research and development	\$ 419,801	\$ 587,437
General and administrative	616,033	870,283
	\$ 1,035,834	\$ 1,457,720

The Company issued 79,000 stock options and 423,000 stock options, respectively, during the years ended December 31, 2019 and 2018, respectively. Additionally, the Company issued 280,120 and 540,000 restricted stock units, respectively, during the years ended December 31, 2019 and 2018, 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: Since the Company did not have sufficient trading history, the volatility factor was based on the average of similar public companies through August 2014. When selecting similar companies, the Company considered the industry, stage of life cycle, size, and financial leverage. Beginning in August 2014, the volatility factor is based on a combination of the Company's trading history since March 2014 and the average of similar public companies. Beginning in July 2017, the volatility factor is based solely on the Company's trading history since March 2014.

LIPOCINE INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2019 and 2018

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

For options granted in 2019 and 2018, the Company calculated the fair value of each option grant on the respective dates of grant using the following weighted average assumptions:

	<u>2019</u>	<u>2018</u>
Expected term	5.67 years	5.78 years
Risk-free interest rate	1.82%	2.80%
Expected dividend yield	—	—
Expected volatility	80.38%	83.56%

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, 2019, there was \$507,000 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 1.49 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, 2019 and 2018 was approximately \$1.25 per share and \$1.01 per share, respectively. Additionally, as of December 31, 2019, there was \$958,000 of total unrecognized compensation cost related to unvested restricted stock units that have either time-based vesting or performance-based vesting.

(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.

LIPOCINE INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2019 and 2018

(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, 2019 and 2018:

	<u>December 31, 2019</u>	<u>Fair value measurements at reporting date using</u>		
		<u>Level 1 inputs</u>	<u>Level 2 inputs</u>	<u>Level 3 inputs</u>
Assets:				
Cash equivalents - money market funds and commercial paper	\$ 8,921,249	\$ 6,575,862	\$ 2,345,387	\$ -
Corporate bonds, notes and commercial paper	4,340,041	-	4,340,041	-
	<u>\$ 13,261,290</u>	<u>\$ 6,575,862</u>	<u>\$ 6,685,428</u>	<u>\$ -</u>
Liabilities:				
Warrant liability	\$ 4,591,200	-	-	\$ 4,591,200
	<u>\$ 17,852,490</u>	<u>\$ 6,575,862</u>	<u>\$ 6,685,428</u>	<u>\$ 4,591,200</u>

LIPOCINE INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2019 and 2018

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

	December 31,	Fair value measurements at reporting date using		
	2018	Level 1 inputs	Level 2 inputs	Level 3 inputs
Assets:				
Cash equivalents - money market funds and corporate bonds	\$ 7,331,005	\$ 4,835,433	\$ 2,495,572	\$ -
Government treasury bills	897,381	897,381	-	-
Corporate bonds, notes and commercial paper	6,275,656	-	6,275,656	-
	<u>\$ 14,504,042</u>	<u>\$ 5,732,814</u>	<u>\$ 8,771,228</u>	<u>\$ -</u>

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, commercial paper 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. Cash equivalents related to 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.

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. The pricing service utilizes broker/dealer quotes, bids and offers, benchmark yields and credit spreads and other observable inputs. Other United States government agency bonds 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, 2019, include (i) volatility of 225.93%, (ii) risk free interest rate of 1.69%, (iii) strike price of \$0.50, (iv) fair value of common stock of \$0.385, and (v) expected life of 4.9 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, 2019 and 2018.

LIPOCINE INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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(2) Summary of Significant Accounting Policies – (continued)

(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.

The following table sets forth the computation of basic and diluted earnings (loss) per share of common stock for the years ended December 31, 2019 and 2018.

	Year Ended December 31,	
	2019	2018
Basic loss per share attributable to common stock:		
Numerator		
Net loss	\$ (13,007,344)	\$ (11,660,022)
Denominator		
Weighted avg. common shares outstanding	25,882,273	21,352,339
Basic loss per share attributable to common stock	\$ (0.50)	\$ (0.55)
Diluted loss per share attributable to common stock:		
Numerator		
Net loss	\$ (13,007,344)	\$ (11,660,022)
Denominator		
Weighted avg. common shares outstanding	25,882,273	21,352,339
Diluted loss per share attributable to common stock	\$ (0.50)	\$ (0.55)

LIPOCINE INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2019 and 2018

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

The computation of diluted earnings per share for the years ended December 31, 2019 and 2018 does not include stock options, warrants or unvested restricted stock units to purchase shares in the computation of diluted earnings per share because these instruments were antidilutive:

	December 31,	
	2019	2018
Stock options	2,310,485	2,424,617
Warrants	12,000,000	-
Unvested restricted stock units	661,307	682,124

(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. Debt securities are carried at fair value with unrealized holding gains and losses, net of the related tax effect, included in accumulated other comprehensive 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, 2019 and 2018 were as follows:

December 31, 2019	Amortized Cost	Gross unrealized holding gains	Gross unrealized holding losses	Aggregate fair value
Corporate bonds, notes and commercial paper	4,340,079	-	(38)	4,340,041
	<u>\$ 4,340,079</u>	<u>\$ -</u>	<u>\$ (38)</u>	<u>\$ 4,340,041</u>

LIPOCINE INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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(3) Marketable Investment Securities - (continued)

December 31, 2018	Amortized Cost	Gross unrealized holding gains	Gross unrealized holding losses	Aggregate fair value
Government treasury bills	\$ 897,481	\$ -	\$ (100)	\$ 897,381
Corporate bonds, notes and commercial paper	6,276,519	-	(879)	6,275,656
	<u>\$ 7,174,000</u>	<u>\$ -</u>	<u>\$ (979)</u>	<u>\$ 7,173,037</u>

Maturities of debt securities classified as available-for-sale securities at December 31, 2019 are as follows:

	Amortized Cost	Aggregate fair value
Due within one year	\$ 4,340,079	\$ 4,340,041
	<u>\$ 4,340,079</u>	<u>\$ 4,340,041</u>

There were no sales of marketable investment securities during the years ended December 31, 2019 and 2018 and therefore no realized gains or losses. Additionally, \$19.8 million and \$36.8 million of marketable investment securities matured during the years ended December 31, 2019 and 2018, respectively. The Company determined there were no other-than-temporary impairments for the years ended December 31, 2019 and 2018.

(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 during the years ended December 31, 2019 and 2018.

(b) 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 \$5.4 million and \$4.1 million under these agreements in 2019 and 2018 and has recorded these expenses in research and development expenses.

LIPOCINE INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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(5) Loan and Security Agreement

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 (6% as of December 31, 2019), which interest is payable monthly. The loan matures on December 1, 2021. The Company was only required to make monthly interest payments until December 31, 2018, following which the Company is required to also make equal monthly payments of principal and interest for the remainder of the term. 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 \$481,000 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), subject to a prepayment charge if the loan has been outstanding for less than two years, which prepayment charge is determined based on the date the loan is prepaid.

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. In addition, as TLANDO was not approved by the United States Food and Drug Administration (“FDA”) prior to May 31, 2018, the Company maintains \$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.

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.

Future maturities principal payments on debt at December 31, 2019, are as follows:

Years Ending December 31,	Amount (in thousands)
2020	3,333
2021	3,334
Thereafter	—
	\$ 6,667

LIPOCINE INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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(5) Loan and Security Agreement – (continued)

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the consolidated balance sheet that sum to the total of the same such amounts shown in the statement of cash flows.

	December 31, 2019
Cash and cash equivalents	\$ 9,728,523
Restricted cash	5,000,000
Cash, cash equivalents, and restricted cash shown in the statement of cash flows	\$ 14,728,523

Amounts included in restricted cash represent those required to be set aside by the Loan and Security Agreement. The restriction will lapse if and when TLANDO is approved by the FDA.

(6) Property and Equipment

Property and equipment consisted of the following:

	December 31, 2019	December 31, 2018
Computer equipment and software	\$ 43,361	\$ 43,361
Lab and office equipment	1,048,932	1,048,932
Furniture and fixtures	51,404	51,404
	1,143,697	1,143,697
Less accumulated depreciation	(1,140,143)	(1,124,700)
	\$ 3,554	\$ 18,997

Depreciation expense for the years ended December 31, 2019 and 2018 was approximately \$15,000 and \$19,000, respectively.

LIPOCINE INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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(7) Income Taxes

(a) Income Tax Expense

Income tax expense consists of:

	December 31,	
	2019	2018
U.S. federal	\$ -	\$ -
State and local	200	700
Deferred	-	-
Total	<u>\$ 200</u>	<u>\$ 700</u>

(b) Tax Rate Reconciliation

Income tax expense was \$200 and \$700, respectively, for the years ended December 31, 2019 and 2018 and differed from the amounts computed by applying the U.S. federal income tax rate of 21% for 2019 and 2018, respectively, to pretax income from continuing operations as a result of the following:

	December 31,	
	2019	2018
Computed "expected" tax expense (benefit)	\$ (2,731,500)	\$ (2,448,457)
Increase (reduction) in income taxes resulting from:		
Change in valuation allowance	3,037,041	2,671,563
State and local income taxes, net of federal income tax benefit	158	553
Stock expense	114,458	136,903
Research and development tax credits	(357,561)	(266,163)
Orphan drug tax credit	(14,357)	(95,822)
Other, net	(48,039)	2,123
	<u>\$ 200</u>	<u>\$ 700</u>

LIPOCINE INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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(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, 2019 and 2018 are presented below.

	December 31,	
	2019	2018
Deferred tax assets:		
Stock-based compensation	\$ 1,637,731	\$ 1,540,215
Net operating loss carryforwards	30,574,751	27,397,503
Employee benefits	48,423	48,294
Research and development tax credits	3,833,189	3,362,473
Orphan drug tax credits	1,162,757	1,144,583
Plant and equipment	1,782	234
Other deductible temporary differences	5,806	378
Total gross deferred tax assets	<u>37,264,439</u>	<u>33,493,680</u>
Less valuation allowance	(37,264,439)	(33,493,680)
Net deferred tax assets	<u>\$ -</u>	<u>\$ -</u>

The valuation allowance for deferred tax assets as of December 31, 2019 and 2018 was \$37.3 million and \$33.5 million, respectively. The net change in the valuation allowance was an increase of \$3.8 million in 2019 and an increase of \$2.7 million in 2018. 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.

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.

LIPOCINE INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2019 and 2018

(7) Income Taxes – (continued)

As of December 31, 2019, we had NOL and research and development credit carryforwards for U.S. federal income tax reporting purposes of approximately \$118.9 million and \$2.7 million, respectively. Approximately \$20.2 million of the NOL will expire between 2023 and 2033 and \$76.4 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 2019 and 2018 NOL of \$22.3 million can be carried forward indefinitely. The research and development credits will begin to expire in 2033 through 2038. We have orphan drug credit carry forwards of approximately \$1.2 million which will expire if unused through 2039.

We also have state NOL and research and development credit carry-forwards of approximately \$112.2 million and \$1.2 million, respectively. Approximately \$572,000 of the Company's state NOL expires in 2020, \$37.0 million expires between 2021 and 2029, and \$74.6 million will expire in 2030 through 2033. The state research and development credits expire in 2023 through 2033.

The Company's federal and state income tax returns for December 31, 2016 through 2019 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, 2019 and 2018 are as follows:

	December 31,	
	2019	2018
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 and on February 24, 2020, the Company extended the lease through February 28, 2021. Additionally, on December 28, 2015, the Company entered into an operating lease for office space in Lawrenceville, New Jersey through January 31, 2018. The Company vacated the Lawrenceville, New Jersey office on January 31, 2018.

LIPOCINE INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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(8) Leases – (continued)

Future minimum lease payments under non-cancelable operating leases as of December 31, 2019 are:

	Operating leases
Year ending December 31:	
2020	55,064
Total minimum lease payments	\$ 55,064

The Company's rent expense was \$329,000 and \$323,000 for the years ended December 31, 2019 and 2018, respectively.

(9) Stockholders' Equity

(a) Issuance of 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 \$375,000. 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 consisted 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 \$0.0001 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.

LIPOCINE INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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(9) Stockholders' Equity – (continued)

In March 2017, the Company entered into a Controlled Equity Offering Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor"), to sell shares of our common stock, with aggregate gross sales proceeds of up to \$20.0 million, from time to time, through an "at the market" ("ATM"), equity offering program, under which Cantor acts as sales agent. The shares of common stock to be sold under the Sales Agreement were originally sold and issued pursuant to the Company's Registration Statement on Form S-3 (File No. 333-199093) (the "Prior Form S-3"), which was previously declared effective by the Securities and Exchange Commission, and the related prospectus and one or more prospectus supplements. On October 13, 2017, the Company filed a Form S-3 (File No. 333-220942) (the "New Form S-3") to replace the Prior Form S-3. The New Form S-3 has been declared effective by the Securities and Exchange Commission, and the Prior Form S-3 has been terminated. The New Form S-3 registered the sale of up to \$150.0 million of any combination of common stock, preferred stock, debt securities, warrants and units pursuant to a shelf registration statement. The New Form S-3 also contains a prospectus pursuant to which we may sell, from time to time, shares of our common stock having an aggregate offering price of up to \$25.0 million through Cantor as our sales agent, pursuant to the Sales Agreement.

As of December 31, 2019, we had sold an aggregate of 6,635,535 shares at a weighted-average sales price of \$3.02 per share under the ATM for aggregate gross proceeds of \$20.0 million and net proceeds of \$19.3 million, after deducting sales agent commission and discounts and our other offering costs. During the year ended December 31, 2019, the Company sold an aggregate of 3,650,479 shares at a weighted-average sales price of \$2.26 per share under the ATM for aggregate gross proceeds of \$8.2 million and \$8.0 million in net proceeds. During the year ended December 31, 2018, the Company sold an aggregate of 466,947 shares at a weighted-average sales price of \$1.45 per share under the ATM for aggregate gross proceeds of \$678,000 and \$652,000 in net proceeds.

(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.

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.

LIPOCINE INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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(9) Stockholders' Equity – (continued)

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, 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. 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 3,221,906 shares are authorized for issuance under the 2014 Plan, with 662,263 shares remaining available for grant as of December 31, 2019.

A summary of stock option activity is as follows:

	<u>Outstanding stock options</u>	
	<u>Number of shares</u>	<u>Weighted average exercise price</u>
Balance at December 31, 2018	2,424,617	\$ 5.00
Options granted	79,000	1.84
Options exercised	(20,000)	2.81
Options forfeited	(21,221)	2.17
Options cancelled	(151,911)	6.93
Balance at December 31, 2019	<u>2,310,485</u>	4.81
Options exercisable at December 31, 2019	1,910,323	5.39

LIPOCINE INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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(9) Stockholders' Equity – (continued)

The following table summarizes information about stock options outstanding and exercisable at December 31, 2019:

Options outstanding				Options exercisable			
Number outstanding	Weighted average remaining contractual life (Years)	Weighted average exercise price	Aggregate intrinsic value	Number exercisable	Weighted average remaining contractual life (Years)	Weighted average exercise price	Aggregate intrinsic value
2,310,485	6.04	\$ 4.81	\$ -	1,910,323	5.47	\$ 5.39	\$ -

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, 2019 and 2018 was \$1,000 and zero. There were 20,000 and zero stock options exercised during the years ended December 31, 2019 and 2018.

(d) Restricted Stock Units

A summary of restricted stock unit activity is as follows:

	Number of unvested restricted stock units
Balance at December 31, 2018	682,124
Granted	280,120
Vested	(247,500)
Cancelled	(53,437)
Balance at December 31, 2019	<u>661,307</u>

(e) 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.

LIPOCINE INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2019 and 2018

(9) Stockholders' Equity – (continued)

As of December 31, 2019, the Company had 12,000,000 warrants outstanding to purchase an equal number of shares of common stock. The fair value of these warrants on November 18, 2019 (closing date of November 2019 Offering) and December 31, 2019 was determined using the Black-Scholes option pricing model with the following Level 3 inputs (as defined in the November 2019 Offering):

	November 18, 2019	December 31, 2019
Expected life in years	5.00	4.88
Risk-free interest rate	1.63%	1.69%
Dividend yield	—	—
Volatility	224.47%	225.93%
Stock price	\$ 0.41	\$ 0.39

During the year ended December 31, 2019, the Company recorded a non-cash gain of \$236,000 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, 2018	\$ -
Initial fair value of common stock warrants issued in November 2019 Offering	4,827,600
Change in fair value of common stock warrants during 2019	(236,400)
Balance at December 31, 2019	<u>\$ 4,591,200</u>

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

	Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding at December 31, 2018	-	\$ -	-	\$ -
Issued	12,000,000	0.50	5.00	-
Exercised	-	-	-	-
Expired	-	-	-	-
Cancelled	-	-	-	-
Forfeited	-	-	-	-
Balance at December 31, 2019	<u>12,000,000</u>	<u>\$ 0.50</u>	<u>4.88</u>	<u>\$ -</u>

LIPOCINE INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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(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 \$63,000 and \$84,000, respectively, to the 401(k) Plan during the years ended December 31, 2019 and 2018.

(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 July 2, 2018 the court signed a final order approving the parties’ agreement to settle the purported securities class action litigation captioned *In re Lipocine Inc. Securities Litigation, 2:17CV00182 DB (D. Utah)* which was originally filed against the Company on July 1, 2016. The final order issued by the court specifically finds that the settlement set forth in the parties’ stipulation is fair, reasonable, adequate, and in the best interests of the Class, and resolves all of the claims that were or could have been brought in the action being settled. The Company maintains insurance for claims of this nature. When the Company signed the memorandum of understanding to settle the purported securities class action litigation, the potential liability became probable and estimable. The Company recorded a litigation settlement liability for \$4.3 million as of December 31, 2017. Additionally, the Company recorded a litigation insurance settlement recovery receivable of \$3.3 million as of December 31, 2017 which represented the estimated insurance claims proceeds from our insurance carrier in excess of the Company’s retention. As of December 31, 2018, the Company and the insurance carrier have remitted the full balance of the litigation settlement and, as such, the litigation settlement liability and litigation insurance receivable have zero balances.

On February 15, 2019, a purported shareholder filed a shareholder derivative complaint in the Court of Chancery of the State of Delaware, *John Wajda, derivatively on behalf of Lipocine Inc. v. Mahesh Patel, et al.*, against certain of the Company’s current and former officers and directors as well as the Company as a nominal defendant. The complaint asserts claims for alleged breaches of fiduciary duty and unjust enrichment arising out of the Company’s dissemination of purportedly false and misleading statements relating to the filing of the New Drug Application (“NDA”) for TLANDO. The relief sought in the complaint includes unspecified damages, changes to the Company’s corporate governance procedures, equitable and/or injunctive relief, restitution, and attorneys’ fees. On August 16, 2019, defendants filed a motion to dismiss the complaint. Plaintiff’s response to the motion to dismiss was due on October 18, 2019; however rather than file an opposition brief, plaintiffs filed an amended stockholder derivative complaint. Defendants’ motion to dismiss the amended complaint was filed on December 12, 2019; plaintiff’s response was filed on January 27, 2020 and defendants’ reply was filed on February 26, 2020. The Company intends to vigorously defend itself and its current and former officers and directors against these allegations and has not recorded a liability related to this derivative complaint as the outcome is not probable nor can an estimate be made of loss, if any.

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. Clarus has 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 and a claim construction hearing on February 11, 2020 and scheduled a five-day jury trial beginning on February 8, 2021. 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. The parties are currently engaged in the fact discovery phase of the lawsuit.

LIPOCINE INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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(11) Commitments and Contingencies – (continued)

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. The Company insurance that covers claims of this nature. The retention amount payable by the Company under our policy is \$1.25 million. The Company intends to vigorously defend itself and its current and former officers and directors against these allegations and has 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.

Beyond *John Wajda, derivatively on behalf of Lipocine Inc. v. Mahesh Patel, et al.* and *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.

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

On July 23, 2013, the Company entered into an assignment/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. Under the service agreement, the Company provided facilities and up to 10 percent of the services of certain employees to Spriaso for a period of 18 months which expired January 23, 2015. Effective January 23, 2015, the Company entered into an amended services agreement with Spriaso in which the Company agreed to continue providing up to 10 percent of the services of certain employees to Spriaso at a rate of \$230/hour for a period of six months. The agreement was further amended on July 23, 2015, on January 23, 2016, on July 23, 2016, on January 23, 2017, on July 23, 2017 on January 23, 2018, July 23, 2018 and again on January 23, 2019 to extend the term of the agreement for an additional six months. The agreement was further amended on July 23, 2019 to extend the term of the agreement for an additional twelve months. The agreement may be extended upon written agreement of Spriaso and the Company. The Company received reimbursements of zero and \$5,000 for the years ended December 31, 2019 and 2018, respectively. Additionally, during the years ended December 31, 2019 and 2018, the Company received \$165,000 and \$428,000, respectively, in royalty payments 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.

LIPOCINE INC. AND SUBSIDIARIES
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(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

Recently Adopted Accounting Pronouncements

Effective January 1, 2019, the Company adopted ASU No. 2016-02, *Leases* (“ASU 2016-02”). ASU 2016-02 requires lessees to record most leases on their balance sheets but recognize expenses on their income statements in a manner similar to current accounting. The adoption of ASU 2016-02 did not have a material impact on the Company’s condensed consolidated financial statements as the Company did not have a lease with a term greater than one year.

Effective January 1, 2019, the Company adopted ASU No. 2018-07, *Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* (“ASU 2018-07”), which aligns accounting for share-based payments issued to nonemployees to that of employees under the existing guidance of Topic 718, with certain exceptions. This update supersedes previous guidance for equity-based payments to nonemployees under Subtopic 505-50, *Equity - Equity-Based Payments to Non-Employees*. The adoption of ASU 2018-07 did not have a material impact on the Company’s 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, or 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 U.S. Securities and Exchange Commission'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, 2019.

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, 2019. In making this assessment, we used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in *Internal Control-Integrated Framework (2013)*. Based on our assessment we believe that, as of December 31, 2019, 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, 2019, 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.

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 2019 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 2019 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 2019 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 2019 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 2019 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
4.1	Form of Common Stock certificate	8-K	333-178230	4.1	7/25/2013
4.2	Amended and Restated Stockholder Rights Agreement dated as of November 5, 2018 by and between the Company and American Stock Transfer & Trust Company, LLC	10-Q	001-36357	4.1	11/7/2018
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 OfferingSM 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
16.1	Letter from KPMG LLP to the Securities and Exchange Commission, dated June 29, 2018	8-K	001-36357	16.1	6/29/2018
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*	XBRL Instance Document				
101.SCH*	XBRL Taxonomy Extension Schema Document				
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB*	XBRL Taxonomy Extension Labels Linkbase Document				
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document				

* 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.

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 13, 2020

/s/ Mahesh V. Patel

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

Dated: March 13, 2020

/s/ Morgan R. Brown

Morgan R. Brown, Executive Vice President
and Chief Financial Officer
(Principal Financial and 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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Mahesh V. Patel</u> Mahesh V. Patel	President and Chief Executive Officer (Principal Executive Officer) and Chairman of the Board	March 13, 2020
<u>/s/ Morgan R. Brown</u> Morgan R. Brown	Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 13, 2020
<u>/s/ Jeffrey A. Fink</u> Jeffrey A. Fink	Director	March 13, 2020
<u>/s/ John Higuchi</u> John Higuchi	Director	March 13, 2020
<u>/s/ Stephen A. Hill</u> Stephen A. Hill	Director	March 13, 2020
<u>/s/ R. Dana Ono</u> R. Dana Ono	Director	March 13, 2020

**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. As of March [], 2020, there were [] shares of common stock outstanding, held of record by [] stockholders. In addition, as of December 31, 2019, there were: (i) [] shares of common stock subject to outstanding options; (ii) [] shares of common stock subject to outstanding restricted stock units; and (iii) [] shares of common stock reserved for future issuance under our Third Amended and Restated 2014 Stock and Incentive Plan. As of March [], 2020, there were no shares of preferred stock outstanding.

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.

SUBSIDIARIES

Lipocine Operating Inc.

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. 333-220942, 333-190897, 333-197421, 333-191695, 333-214492 and 333-226664) on Forms S-3 and S-8 of Lipocine Inc. of our report dated March 12, 2020 with respect to the consolidated balance sheets of Lipocine Inc. as of December 31, 2019 and 2018, 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, 2019 annual report on Form 10-K of Lipocine Inc.

/s/ Tanner LLC

Salt Lake City, Utah
March 12, 2020

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 13, 2020

/s/ Mahesh V. Patel

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

CERTIFICATIONS

I, Morgan R. Brown, 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 13, 2020

/s/ Morgan R. Brown

Morgan R. Brown, Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

CERTIFICATION

In connection with the Annual Report on Form 10-K of Lipocine Inc. (the "Corporation") for the year ended December 31, 2019 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(d) 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 13, 2020

/s/ Mahesh V. Patel

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

CERTIFICATION

In connection with the Annual Report on Form 10-K of Lipocine Inc. (the "Corporation") for the year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Morgan R. Brown, Executive Vice President and Chief Financial Officer of the Corporation, hereby certifies, pursuant to Rule 13a-14(b) or Rule 15d-14(d) 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 13, 2020

/s/ Morgan R. Brown

Morgan R. Brown, Executive Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)
