LIPOCINE INC.

FORM 10-K
(Annual Report)

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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, 2014

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	**99-0370688**
(State or Other Jurisdiction of Incorporation or Organization)	**(IRS Employer Identification No.)**
675 Arapeen Drive, Suite 202, Salt Lake City, Utah	**84108**
(Address of Principal Executive Offices)	**(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	**Name of Exchange on Which Registered**
Common Stock, par value $0.0001 per share	**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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant 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 and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, a non-accelerated filer, or a smaller reporting company.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☐	Smaller reporting company ☒

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 $70.2 million as of June 30,2014. 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 11, 2015, the registrant had 12,848,466 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the Registrant's definitive Proxy Statement for its 2015 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 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", 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.

PART I

ITEM 1. BUSINESS

Organizational Background

Marathon Bar Corp. ("Marathon Bar") was incorporated on October 13, 2011, in the State of Delaware. On July 24, 2013, Marathon Bar and MBAR Acquisition Corp. ("Merger Sub"), a wholly owned subsidiary of Marathon Bar, and Lipocine Operating Inc. ("Lipocine Operating"), a privately held company incorporated in Delaware, executed an Agreement and Plan of Merger ("Merger Agreement"). Pursuant to the Merger Agreement, Merger Sub merged with and into Lipocine Operating and Lipocine Operating was the surviving entity. Additionally pursuant to the Merger Agreement, Marathon Bar changed its name to Lipocine Inc. The Merger is accounted for as a reverse-merger and recapitalization.

General

We are a specialty pharmaceutical company focused on applying our oral drug delivery technology for the development of pharmaceutical products in the area of men's and women's health. 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 characteristics and facilitate lower dosing requirements, bypass first-pass metabolism, reduce side effects, and eliminate gastrointestinal interactions that limit bioavailability. Our lead product candidate, LPCN 1021, is an oral testosterone replacement therapy, or TRT, designed for convenient twice-a-day dosing and has demonstrated positive top-line efficacy results in Phase 3 testing. Additional pipeline candidates include LPCN 1111, a next generation oral testosterone therapy product targeted for once daily dosing, that is currently in Phase 2 testing, and LPCN 1107, which has the potential to become the first oral hydroxyprogesterone caproate product indicated for the prevention of recurrent preterm birth, and is currently in Phase 1 testing.

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 this 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.

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 Kleinfelter 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 1140ng/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, multiple 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 more than one low morning serum testosterone level.

Treatment for male hypogonadism (both primary and secondary) is testosterone replacement therapy. Some of the reported benefits of testosterone replacement therapy include improved libido, 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, difficulty of diagnosis, and other medical conditions that may confound an accurate diagnosis, there is a consensus that male hypogonadism is significantly undertreated. A large study of 2,162 men over the age of 45 visiting primary care practices in the United States revealed that the prevalence of hypogonadism is about 39%. This correlates to approximately 14 million patients in this age group. 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, intramuscular, transdermal patch, and finally topical gels, which initially surfaced in 2000. In 2014, a long acting intramuscular injection and an intranasal 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 were used in the United States quickly went out of favor after significant side effects were revealed, most notably liver toxicity.

Currently, the U.S. testosterone replacement 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 testosterone replacement therapies have gained increasing popularity due to improved skin tolerability. Despite becoming the most 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 U.S. Food and Drug Administration, or 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 exceeded $2 billion in 2013 according to Global Industry Analyst Inc. Additionally testosterone replacement prescriptions were approximately 6.5 million in 2014 according to IMS Health data. Gels are the predominant dosage form in this market. 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, Eli-Lilly, and Endo.

Product Candidates

Our current portfolio, shown below, includes our lead product candidate LPCN 1021, an oral testosterone replacement therapy, which is currently in a pivotal Phase 3 clinical study. Additionally, we are currently in the process of establishing our pipeline of early clinical treatments including a next generation testosterone replacement therapy, LPCN 1111, and an oral therapy for the prevention of preterm birth, LPCN 1107.

Our Development Pipeline

Product Candidate	Indication	Status	Next Expected Milestone(s)
Men's Health			
LPCN 1021	Testosterone Replacement	Phase 3	Pre-NDA Meeting with FDA (March 19, 2015) Completion of Phase 3 study - Last Patient Last Visit (April 2015) Phase 3 Safety Data (2Q 2015) File NDA (2H 2015)
LPCN 1111	Testosterone Replacement	Phase 2	Commence Phase 2b study subject to FDA clarity on the TRT "class" label and financial resources (3Q 2015)
Women's Health			
LPCN 1107	Prevention of Preterm Birth	Phase 1	Meet with the FDA to determine development path (2Q 2015 - 3Q 2015)

These products are based on our proprietary Lip'ral promicellar drug delivery technology platform. Lip'ral promicellar 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.

LPCN 1021: An Oral Product Candidate for Testosterone Replacement Therapy

Our lead product, LPCN 1021, is an oral formulation of the chemical testosterone undecanoate, or TU, an eleven carbon side chain attached to testosterone. It is an ester prodrug of testosterone, which is an inactive form of testosterone. Upon the cleavage, or breaking, of the ester bond, the pharmacologically active drug, testosterone is formed. An ester is a chemical between an acid and alcohol. 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 TU recently received approval in the United States for delivery via intra-muscular injection. However, the oral dosage form which is approved outside the United States provides sub-therapeutic serum testosterone levels at the approved dose. We are using our Lip'ral technology to facilitate steady gastrointestinal solubilization and absorption of TU for convenient twice daily dosing of TU. Proof of concept was initially established in 2006, and subsequently LPCN 1021 was licensed to Solvay Pharmaceuticals, Inc., or Solvay, which was then acquired by Abbott Products, Inc., or Abbott, in 2009. Following a portfolio review associated with the spin-off of AbbVie by Abbott in 2011, the rights to LPCN 1021 were reacquired by us.

We have received top-line efficacy results from our ongoing Study of Oral Androgen Replacement, or SOAR, pivotal Phase 3 clinical study evaluating efficacy and safety of LPCN 1021. SOAR is a randomized, open-label, parallel-group, active-controlled, Phase 3 clinical study of oral TRT 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 LPCN 1021 and 105 were randomized to the active control, for 52 weeks of treatment. The active control is included for safety assessment. LPCN 1021 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, up to 300 mg TU BID or down to 150 mg TU BID based on serum testosterone measured during weeks 3 and 7. The mean age of the subjects in the trial is ~53 years with ~91% of the patients < 65 years of age. Men enrolled in the SOAR trial > 65 years of age were required to have been diagnosed with hypogonadism prior to 65 years of age.

Top Line Results From SOAR

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=152. 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=192) and the safety set ("SS") (any subject that was randomized into the study and took at least one dose, N=210).

Efficacy . The primary efficacy end point is the percentage of subjects with an average 24 hour serum testosterone concentration ("Cavg") within the normal range, which is defined as 300-1140 ng/dL, after 13 weeks of treatment. 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% confidence interval ("CI") must be greater than 65%.

LPCN 1021 successfully met the FDA primary efficacy guideline. In the EPS analysis, 88% of the subjects on active treatment achieved testosterone Cavg within the normal range with lower bound CI of 82%. Additionally, sensitivity analysis using the FAS and SS reaffirmed the finding that LPCN 1021 successfully met the FDA primary efficacy guideline as 88% and 80%, respectively, of the subjects on active treatment achieved testosterone Cavg within the normal range with lower bound CI of 82% and 74%, respectively.

Other highlights from the efficacy results include:

- Mean Cavg was 447 ng/dL with coefficient of variance of 37%;
- Less than 12% of the subjects were outside the tesosterone Cavg normal range at final dose;
- 85% of subjects arrived at final dose with no more than one titration; and

- 51% of subjects were on the final dose of 225 mg BID which was also the starting dose.

Safety. Although the safety component of the SOAR trial is on-going, LPCN 1021 treatment has been well tolerated to date.

LPCN 1021 safety highlights through week 13 of treatment for the last enrolled patient include:

- 3% of the subjects reported a serious adverse events ("SAE"), with none of the SAE's classified as drug related or cardiac in nature;
- All the drug related adverse events were either mild or moderate in intensity (none were severe); and
- Hematocrit ("Hct") and prostate specific antigen ("PSA") increases were noted and consistent with other TRT products with one subject discontinued for elevated Hct exceeding pre-specified limits and one subject discontinued for elevated PSA exceeding pre-specified limits.

In the EPS analysis, Cmax ≤1500 ng/dL was 83%, Cmax between 1800 and 2500 ng/dL was 4.6% and Cmax > 2500 ng/dL was 2%. Three patients had a Cmax >2500 ng/dL which were transient, isolated and sporadic. Moreover, none of these subjects reported any AE's. Results were generally consistent with those of approved TRT products.

The safety extension phase of the SOAR trial is on-going. The safety extension phase is designed to assess safety information such as metabolites, biomarkers, laboratory values, SAEs and AEs, with subjects on their stable dose regimen in both the treatment arm and the active control arm.

In December 2014 we received confirmation from the FDA that the design of our SOAR trial is currently acceptable for filing an NDA for the class TRT labeling. The FDA reiterated the primary efficacy endpoint required for approval being 75% of subjects with a Cavg for serum testosterone in the normal range with the lower bound of the two-sided 95% confidence interval being >65%. Additionally, the FDA did not identify any additional clinical studies that would be required for NDA filing, but did state that should any safety signal become apparent during analysis of our SOAR trial results or during the course of their review, it is possible that additional data may be required. Based on the response received, we do not anticipate the need to conduct additional studies above those previously agreed to with the FDA for NDA filing. Finally the FDA highlighted the need to ensure our efficacy data was robust to sensitivity analyses with various data sets, including the FAS .

We expect to have a pre-NDA meeting with the FDA on March 19, 2015. Additionally we expect the last patient last visit in the safety extension phase of the SOAR trial to be in April 2015 with top-line safety results in the second quarter of 2015 and an NDA filing to occur during the second half of 2015 assuming successful safety results.

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

LPCN 1111 is a next-generation, novel ester prodrug of testosterone which uses the Lip'ral technology to enhance solubility and improve systemic absorption. A Phase 1 single dose, randomized, open label, crossover study in 8 postmenopausal women has been completed and the pharmacokinetics suggested feasibility of either once-daily dosing or twice daily dosing with relatively high Cavg. This study was conducted ex-U.S. after obtaining the necessary regulatory approvals for conducting the study in the foreign country so no IND application was required in the United States. We have completed a pre-investigational new drug, or pre-IND, meeting with the FDA.

In October 2014, we successfully 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. These subjects had serum total testosterone < 300 ng/dL based on two blood draws on two separate days. Subjects received doses of LPCN 1111 as a single dose of 330 mg, 550 mg, 770 mg, followed by once daily administration of 550 mg for 28 days in 10 subjects, and once daily administration of 770 mg for 28 days in eight subjects. Results from the Phase 2a clinical study demonstrated the feasibility of a once daily dosing with 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 Cmax of 1500 ng/dL at any time during the 28 day dosing period on multi-dose exposure. Overall, LPCN 1111 was well tolerated with no serious adverse events. We expect to initiate a Phase 2b dose finding study in hypogonadal men in the third quarter of 2015 subject to clarity from the FDA on the TRT "class" label and financial resources.

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 prevention of preterm birth in women with a prior history of at least one preterm birth. We successfully completed a proof-of-concept Phase 1b clinical study of LPCN 1107 in healthy pregnant women in January 2015. The study was designed to determine the pharmacokinetics and bioavailability of LPCN 1107 relative to an intramuscular ("IM") HPC, as well as safety and tolerability, in healthy pregnant female volunteers. The Phase 1b open-label study enrolled eight healthy, pregnant women at 16 to 18 weeks gestation. All subjects received three treatments in sequence. In period one, subjects received two doses of 400 mg oral LPCN 1107, administered 12 hours apart. In period two, subjects received two doses of 800 mg oral LPCN 1107, administered 12 hours apart. In period three, subjects were given 250 mg of HPC via intramuscular injection (marketed product Makena®). Blood samples were collected periodically over 24 hours following oral dosing and over 28 days following the IM dose. Results of this study confirmed our pre-clinical data and Phase 1a clinical study data, suggesting meaningful drug levels of HPC can be obtained after oral administration. We also successfully completed a proof-of-concept Phase 1a clinical study of LPCN 1107 in healthy non-pregnant women in May 2014. The study was designed to determine the pharmacokinetics and bioavailability of LPCN 1107 relative to an IM HPC, as well as safety and tolerability, in healthy non-pregnant female volunteers. Results of this study confirmed our pre-clinical data and suggest meaningful drug levels of HPC can be obtained after oral administration. Prior to conducting the Phase 1a and Phase 1b studies, the product completed a 28-day repeat dose toxicity study in dogs. We plan to discuss the development plan with FDA in the second quarter 2015 or third quarter 2015 before deciding next steps in the program. There are multiple potential development plans for LPCN 1107 with no assurances which, if any, will be acceptable to the FDA. Each potential development plan has a different timeline and cost.

Research and Development

We currently have three products in our development pipeline (LPCN 1021, LPCN 1111 and LPCN 1107) and we continue to conceptualize and discuss new indications for current products as well as new development opportunities. In 2014 and 2013, we spent $15.5 million and $5.1 million, respectively, on research and development.

Competition

Testosterone Market Overview

The gel-based testosterone replacement products that are currently available include AndroGel, marketed by AbbVie, Endo ’ s Testim and Fortesta and their respective authorized generics and Eli Lilly ’ s Axiron. Transdermal patches include Actavis’s Androderm. Intramuscular forms of testosterone also exist although commercialized mostly in generic forms and in branded form as Aveed® by Endo International. Additionally, Endo markets the buccal testosterone replacement therapy Striant and the Testopel implantable testosterone pellets, which it acquired from Auxillium in 2015 and a intranasal testosterone therapy Natesto, which it licensed from Trimel in 2014.

Testosterone gels dominate the testosterone replacement therapy market. While gels are the most 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. We believe, a safe and effective oral therapy would increase patient convenience and compliance, while eliminating the testosterone transference risk associated with gels.

The FDA recently 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 and employed 505(b)(2) submissions citing AndroGel as their reference listed drugs ("RLD"). Teva’s version was found to be bioinequivalent to AndroGel®, hence the BX rating. Upsher-Smith Laboratories also received approval for a version of Auxilium’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.

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 replacement therapies.

Clarus Therapeutics, Inc. has completed Phase 3 and subsequently filed an NDA in early 2014 with Rextoro® (formerly CLR-610), a twice-daily oral softgel capsule of TU, as a testosterone replacement therapy for the treatment of hypogonadism in men. On September 18, 2014, Clarus and the FDA had an Advisory Committee meeting to evaluate the safety and efficacy of Rextoro. 18 of the 21 members of the Advisory Committee voted that the overall benefit/risk profile of Rextoro is not acceptable to support approval for T-replacement therapy. The reported PDUFA date for the Rextoro NDA was November of 2014. To our knowledge, an approval of Rextoro has not been reported by the FDA in their list of approval announcements.

Antares Pharma, Inc. is developing a testosterone enanthate auto-injector administered subcutaneously once each week. The product candidate is currently in a double-blind, multiple-dose, Phase 3 study with a reported estimated completion date of November 2015.

SOV Therapeutics, Inc. is developing a twice-daily oral testosterone undecanoate as a testosterone replacement therapy for the treatment of hypogonadism in men and in the treatment of Constitutional Delay of Growth and Puberty in adolescent boys (14-17 years of age).

Repros Therapeutics Inc. filed an NDA in the first quarter of 2015 with Androxal® (enclomiphene citrate), an orally-bioavailable isomer of the selective estrogen receptor modulator clomifene citrate, as a testosterone therapy for the treatment of male secondary hypogonadism.

Novartis is currently developing BGS649, an aromatase inhibitor, as a testosterone therapy for the treatment of obese, hypogonadotropic hypogonadal men.

TesoRx Pharma LLC is developing a twice-daily oral bio-identical testosterone as a testosterone replacement therapy for the treatment of hypoganadism in men. Phase 2 clinical studies have been completed.

Apricus Biosciences, Inc. is developing Fispemifene, a once-daily orally administered selective estrogen receptor modulator for multiple urological conditions, including secondary hypogonadism. A Phase 2b clinical study is expected to commence in the second half of 2015.

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. 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.

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. Net sales of Makena in 2014 were approximately $165.0 million with 2015 projected Makena net sales of between $245.0 and $270.0 million.

We believe LPCN 1107 has the potential to become the first oral HPC product for the prevention of preterm birth in women with a prior history of at least one preterm birth. Potential benefits of our oral product candidate relative to the current injectable product include the following:

- Elimination of pain and site reactions associated with weekly injections;
- Elimination of weekly doctor visits or visits from the nurse; and
- Elimination of interference/disruption of personal, family or professional activities associated with weekly visits.

LPCN 1107 has completed a proof-of-concept PK study in healthy pregnant women as well as a proof-of-concept PK study in healthy non-pregnant women. The studies were designed to determine the pharmacokinetics and bioavailability of LPCN 1107 relative to an IM HPC, as well as safety and tolerability, in healthy pregnant and non-pregnant female volunteers. Results of these studies confirmed our pre-clinical data and suggest meaningful drug levels of HPC can be obtained after oral administration. To the best of our knowledge, there is no report in the literature showing HPC oral bioavailability comparable to intramuscular injection. LPCN 1107 has also completed a 28-day repeated dose toxicity and toxicokinetics study in dogs. We plan to review the development plan with the FDA before deciding next steps in the program.

The oral product may also be eligible for orphan drug designation since it is intended to treat “rare diseases or conditions” and if the oral product is deemed by the FDA to be a major contribution to patient care based on the potential benefits of the oral product over the injectable product outlined above. There is no guarantee that the FDA would deem an oral product to be a major contribution to patient care. For this and other reasons, we may not receive orphan drug designation for LPCN 1107.

Manufacturing Agreement

We have 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 Drug Delivery, or Encap, a United Kingdom based contract manufacturer, a division of Capsugel Dosage Form Solutions, pursuant to which Encap manufactured and supplied to us a total of six lots of LPCN 1021 capsules under current good manufacturing practices. These lots are being used in Lipocine’s Phase 3 study for LPCN 1021. Under the agreement, Encap is also conducting an International Conference on Harmonisation stability program on all six capsule lots in support of our planned NDA filing for LPCN 1021. If Encap is unable to produce sufficient capsules for our future clinical trials or to support demand for LPCN 1021 if it becomes commercially available, our revenue and profitability would be adversely affected.

We may terminate the agreement, subject to payment of cancellation fees. We and Encap may each terminate the agreement upon a material breach of the 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. We also have the right to terminate the agreement for other good cause, including technical, scientific or business reasons, upon a minimum period of written notice to Encap. If Encap achieves certain milestones by the applicable due dates, we will be obligated to purchase a percent of our commercial supply of LPCN 1021 from Encap for a limited time period, subject to our right to buy out such commitment on terms to be negotiated.

Intellectual Property

Drug Delivery Technologies for Lipophilic Drug Substances

LPCN 1021 is an oral formulation of the lipophilic prodrug testosterone undecanoate for convenient twice daily dosing, 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 11, 2015, we own 8 issued U.S. patents, 23 pending U.S. patent applications, 19 issued foreign patents, 29 pending foreign patent applications and two pending PCT applications. Of the above, we have 5 issued U.S. patents, 11 pending U.S. patent applications, 16 issued foreign patents and 8 pending foreign patent applications relating to various aspects of LPCN 1021.

We also license in the fields other than cough and cold, 2 U.S. patents and 2 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.

Our issued U.S. Patent No. 6,267,985 covers pharmaceutical compositions comprising a therapeutic agent being solubilized in a triglyceride, and it is expected to expire in 2019. We have corresponding patents in Australia, Canada, and New Zealand. These corresponding foreign patents are all expected to expire in 2020. Our issued U.S. Patents No. 6,569,463 and 6,923,988, and one further pending U.S. patent application cover various aspects of pharmaceutical compositions comprising a hydrophobic active ingredient admixed with a hydrophilic surfactant and other components (for example, a lipophilic additive), and are expected to expire in 2019 and 2020, respectively, and if the application were to issue, 2019. We have corresponding patents in Australia, Canada and New Zealand, which are expected to expire in 2020.

We also have 2 issued US patents (U.S. Patent No. 8,865,695 and U.S. Patent No. 8,778,922), 2 pending U.S. patent applications, one issued patent in Mexico and 8 corresponding foreign patent applications (one each in Europe, Hong Kong, Australia, Brazil, Canada and India and two in Japan) directed to oral pharmaceutical composition comprising a testosterone ester and a hydrophilic and a lipophilic surfactant and methods of their use. These patents and applications, if they issue, are expected to expire in 2029 in the U.S. and 2030 in foreign jurisdictions. The Australian application has been accepted and is currently being opposed by Clarus, Inc.

We also have 2 pending U.S. patent applications, 3 foreign patents (one each in Australia, Canada and New Zealand) directed to oral dosage forms comprising a drug, a solubilizer, and a release modulator. The pending U.S. patent applications, if they issue, are expected to expire as early as 2023, and the foreign patents are expected to expire in 2026.

We also have 1 pending U.S. patent application directed to pharmaceutical compositions comprising a sex hormone with corresponding foreign patents in Australia, Canada, Japan and New Zealand. This application, if it issues, is expected to expire in 2019, while the foreign patents are expected to expire in 2024.

We also have 4 pending U.S. applications directed to high strength capsule formulations of testosterone undecanoate and methods of their use. These applications, if they issue, are expected to expire in 2030.

We also have 3 pending U.S. patent applications related to solid dosage forms that have testosterone undecanoate. These applications, if they issue, are expected to expire in 2030.

We currently do not have patent protection for LPCN 1021 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 LPCN 1021. Additionally, the 5 U.S. patents that could be listed in the FDA Orange Book for LPCN 1021 are expected to expire in 2019, 2020 and 2029. Upon expiration and if we are actively marketing the LPCN 1021 product, if we have no other issued U.S. patents covering the product, we will lose certain advantages that come with 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 three patents.

Our remaining issued U.S. patents, pending U.S. patent applications, issued foreign patents, and pending foreign patent applications are not currently used in the LPCN 1021 technology, but may be used with alternate versions of, or future product candidates utilizing, our delivery technology for lipophilic drugs (as used for the LPCN 1111, LPCN 1107 product candidates or other product candidates).

LPCN 1107 is covered by US Patent No. 8,951,996 and pending U.S. patent applications with corresponding counterpart applications filed in Australia, Brazil, Canada, China, Europe, India, Israel, Japan, New Zealand, South Africa, and South Korea. The U.S. patent and pending U.S. patent applications, if they issue, are expected to expire as early as 2031, and the foreign patent applications if they issue, are expected to expire in 2032.

LPCN 1111 is covered by US applications with corresponding counterparts filed in Argentina, Paraguay, Taiwan, Uruguay and Venezuela with a PCT application filed as well which can be filed into other foreign jurisdictions at the appropriate time. The U.S. patent application, if it issues, is expected to expire as early as 2029, and the foreign patent applications if they issue, are expected to expire in 2029.

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

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 legislation requires licensing 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 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. 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 current cGMPs;

- Submission to the FDA of an IND, which must become effective before human clinical trials may begin in the United States;

- Performance of adequate and well-controlled human clinical trials according to the FDA's current GCPs, to establish the safety and efficacy of the proposed pharmaceutical product for its intended use;

- Submission to the FDA of an NDA for a new pharmaceutical product;

- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the pharmaceutical product is produced to assess compliance with the FDA's 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 approvals are 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 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, 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.

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, PPACA, substantially changes the way healthcare is financed by both governmental and private insurers. Among other cost containment measures, PPACA 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 co-ordinates 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, William I. Higuchi, and their affiliates. Mahesh V. Patel is our President and Chief Executive Officer and a 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, however the agreement may be extended upon written agreement of Spriaso and us. Additionally Spriaso filed its first NDA in 2014, 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, 2014, we had 13 full time employees and we also utilize the services of consultants on a regular basis. Eight employees are engaged in drug development activities and five are in support and administration. None of our employees are represented by labor unions or covered by collective bargaining agreements.

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 patients 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 biopharmaceutical 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, LPCN 1021, which is still under clinical development and may not receive regulatory approval or be successfully commercialized.

LPCN 1021 is currently our only product candidate that has completed Phase 2 clinical trials, and our business currently depends primarily on its successful development, regulatory approval and commercialization. We are not permitted to market LPCN 1021 in the United States until we receive approval of an NDA from the FDA, or in any foreign countries until we receive the requisite approval from such countries. We have not scaled up the pivotal study formulation to commercial scale, if required. We have not submitted an NDA to the FDA or comparable applications to other regulatory authorities. Before we submit an NDA to the FDA for LPCN 1021 as a TRT we must complete our pivotal Phase 3 trial and an additional pharmacokinetic study for labeling purposes. We have not commenced the additional pharmacokinetic study.

In addition, although we have released top-line results from Phase 3 trial of LPCN 1021, the study is still on-going and safety results at the completion of our pivotal Phase 3 trial may not be consistent with top-line safety results. 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. Our pivotal Phase 3 trial will evaluate the safety and efficacy of LPCN 1021 over a longer period of time in a patient population which will be almost four times larger than our repeat-dose Phase 2 trials. Accordingly, the safety results from Phase 2 trials or early top-line safety results from our pivotal Phase 3 trial for LPCN 1021 may not be predictive of the safety results we may obtain at the completion of our pivotal Phase 3 trial of LPCN 1021. Our pivotal Phase 3 trial may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials, or even terminate further development.

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 LPCN 1021and 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 Committees recommendations. Although actual TRT label revisions will still need to be negotiated between the FDA and sponsors with approved T-replacement therapy products, the FDA did communicate 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;
- limiting use of T-replacement products to patients who have hypogonadism confirmed through blood levels testing;
- adding cautionary language stating that the benefit and safety have not been established for the treatment of low testosterone levels due to aging; and
- adding cautionary language stating the possible increased risk of heart attacks and strokes associated with testosterone uselimiting payer reimbursement to only those patients specifically indicated on the label.

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. If the FDA concludes that a cardiovascular trial is required prior to filing an NDA for LPCN 1021, such trial would require substantial financial resources, would delay the regulatory process for LPCN 1021 and our entry into the marketplace, all of which would have a material impact on our business.

If T-replacement therapies are found, or are perceived, to create health risks, our ability to sell LPCN 1021 and LPCN 1111 could be materially adversely affected and our business could be harmed. Even if our LPCN 1021and our LPCN 1111 are approved, physicians and patients may be deterred from prescribing and using T-replacement therapies, which could depress demand for LPCN 1021and LPCN 1111 and compromise our ability to successfully commercialize LPCN 1021 and LPCN 1111.

Recent 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. Finally 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 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 Rextoro 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 Rextoro data supported approval.

It is possible that the FDA's evaluation of the Advisory Committee recommendations 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 ability to file an NDA for LPCN 1021. During our SOAR trial, we are collecting safety data for LPCN 1021 and a control group, the leading approved T-gel product, but we are not comparing safety data from LPCN 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 LPCN 1021;
- mandate that certain warnings or precautions be included in our product labeling;
- require that our product carry a "black box warning";
- limit use of LPCN 1021and LPCN 1111 to certain populations, such as men under a specified age or 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 LPCN 1021 and 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 LPCN 1021 and LPCN 1111, if approved. In the interim, the FDA's evaluation could also impact the timing with respect to the filing of our NDA.

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

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

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

Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payers can be critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. 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.

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, or PPACA, as amended by the Healthcare and Education Affordability Reconciliation Act, became law in the United States. PPACA substantially changes the way healthcare is financed by both governmental and private insurers and significantly affects the healthcare industry. The provisions of PPACA 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 PPACA 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. 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 PPACA will result in additional downward pressure on the reimbursement we may receive for any approved and covered product, and could seriously harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payers. In the future, the U.S. government may institute further controls and different reimbursement schemes and limits on Medicare and Medicaid spending or reimbursement that may affect the payments we could collect from sales of any products in the United States. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

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, LPCN 1021 would compete in the T-replacement therapies market, which is highly competitive and currently dominated by the sale of T-gels, which is estimated to account for approximately 86% of U.S. sales in the T-replacement therapies market in 2013. 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 LPCN 1021. 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 LPCN 1021, 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 LPCN 1021:

- T-gels, such as AndroGel (marketed by Abbvie) and Perrigo's AB-rated 1% generic of Androgel, Testim (marketed by Endo Health Solutions, or Endo), Fortesta (marketed by Endo); and additionally TEVA has a FDA approval for a T-gel but has not yet launched the product;
- T-topical solutions, such as Axiron, a metered dose lotion marketed by Eli Lilly and Co.;
- T-injectables;
- Branded longer-acting injectable, such as Aveed (marketed by Endo);
- T-nasals, such as Natesto (marketed by Endo);
- methyl-T, such as Methitest (marketed by Impax) and Testred (marketed by Valeant);
- transdermal patches, such a Androderm (marketed by Actavis Pharmaceuticals, Inc.);
- buccal patches, such as Striant (marketed by Endo);
- generic testosterone enanthate intra-muscular injectables;
- authorized generic T-gels; and
- subcutaneous injectable pellets, such as Testopel (marketed by Endo).

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 LPCN 1021 are in varying stages of development, some of which may be approved, marketed and/or commercialized prior to LPCN 1021. 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, LPCN 1021 may not be the first oral testosterone replacement therapy to market, which may significantly affect the market acceptance and commercial success of LPCN 1021.

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

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 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. If a generic version of T-gel were to become available in the market, governmental and other pressures to reduce pharmaceutical costs may result in physicians writing prescriptions for generic T-gels as opposed to branded T-gels. The entrance of any generic T-gel into the market would likely cause downward pressure on the pricing of all T-replacement therapies, and could materially adversely affect the level of sales and price at which we could sell LPCN 1021, and ultimately significantly 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. If generic T-gel is available in the market, that may create an additional obstacle to the availability of reimbursement for LPCN 1021. 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, LPCN 1021. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize LPCN 1021, and/or our financial results from the sale of related products could be negatively and materially impacted.

Additionally, LPCN 1021 may not be the first oral testosterone replacement therapy product to market. In this event, if the generic version of a competing oral testosterone replacement therapy product enters the market before our product, then the commercial prospects of LPCN 1021 could be significantly and negatively impacted.

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 a Phase 1b proof-of-concept clinical study in healthy pregnant women and a Phase 1a proof-of-concept study in health non-pregnant women to date. Although these studies demonstrated oral absorption of LPCN 1107 is possible, we may not be able to match blood levels shown with the intramuscular injection comparator product over a longer duration. Furthermore, our completed Phase 1 clinical study 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 and Phase 1b studies may not be predictive of the results we may obtain from further studies and trials.

We plan to review the development plan with the FDA before deciding next steps in the program. The anticipated Phase 3 program for an NDA filing for LPCN 1107, however, could be very long and expensive.

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

LPCN 1111 is in a very early stage of development. We have preliminary data demonstrating absorption of LPCN 1111 in dogs and in postmenopausal females. Additionally, we recently completed a Phase 2a study in hypogonadal men. Results from the Phase 2a clinical study demonstrated the feasibility of a once daily dosing with LPCN 1111in hypogonadal men and a good dose response. Future studies may not have similar clinical results.

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

We plan to initiate a Phase 2b dose finding study in the third quarter of 2013 subject to clarity from the FDA on the TRT "class" label and financial resources. Several factors could significantly affect the prospects for LPCN 1111, including factors relating to the regulatory approval and clinical development challenges for LPCN 1111 discussed above. Assuming a successful Phase 2b study, the Phase 3 programs for an NDA filing for LPCN 1111 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 lead product candidate LPCN 1021, for which we are currently conducting a pivotal Phase 3 clinical study. We are also developing two additional earlier stage clinical candidates, LPCN 1111 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 LPCN 1021, LPCN 1111 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 LPCN 1021, LPCN 1111, LPCN 1107 and any future product candidates, is subject to extensive regulations by the U.S. Food and Drug Administration, or 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, or CRO, that we retain to conduct 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 New Drug Application, or NDA, 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 Risk Evaluation and Mitigation Strategy, or 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;
- with respect to LPCN 1021 and LPCN 1111, the FDA may not grant a five-year exclusivity to Testosterone prodrug present as the active; and
- with respect to LPCN 1107, the FDA may not grant Orphan Drug Designation for the oral product if they do not deem it to be a major contribution to patient care over intramuscular injection, or for other reasons.

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 protocols and human testing, 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 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. 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. 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. 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 a federal healthcare program 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.

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

We currently have no sales and marketing 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 all of our product candidates. The marketing collaborators we work with may not be adequate, successful or could terminate or materially reduce the effort they direct to our products. The development of a marketing and sales capability will require significant expenditures, management resources and time. The cost of establishing such a sales force may exceed any potential product revenues, or our marketing and sales efforts may be unsuccessful. If we are unable to develop an internal marketing 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 develop and seek regulatory approval for our product candidates and/or effectively market and sell approved products, if any.

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

We are highly dependent on Dr. Mahesh V. Patel and the other principal members of our executive team. Employment with our executives and other employees are "at will", meaning that there is no mandatory fixed term and their employment with us may be terminated by us or by them for any or no reason. The loss of the services of any of our executives or other key employees might impede the achievement of our research, development and commercialization objectives. Recruiting and retaining qualified scientific personnel, 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, 2014, we had only 13 employees, and we currently expect to experience significant growth in the number of employees and the scope of our operations. 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, such as the development of LPCN 1021. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate or increase our 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.

Recent 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 LPCN 1021, 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, or 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, which 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, or 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 hydroxy progesterone caproate, Makena, and (ii) oral delivery of HPC could have a very different pharmokinetic 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. Though state controlled substances laws often mirror federal law, 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 has to be rulemaking or legislative action, which could delay commercialization.

Our clinical lots of LPCN 1021 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. Political pressures and adverse publicity could lead to delays in, and increased expenses for, and limit or restrict, the introduction and marketing of LPCN 1021.

We may have to dedicate resources to the settlement of litigation.

Securities legislation in the United States makes it relatively easy for stockholders to sue. This could lead to frivolous law suits which could 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. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. If we were to be sued, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

If we are required to defend patent infringement actions brought by 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 may be diverted from business operations even if the outcome is in our favor. If we are required to defend our patents or trademarks against infringement by third parties, we may be required to pay substantial litigation costs, managerial attention and financial resources may be diverted from our research and development operations even if the outcome is in our favor.

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 as well as outsourcing 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 have engaged a CRO to conduct our pivotal Phase 3 trial for LPCN 1021. As a result, we have less direct control over the conduct of our pivotal Phase 3 trial, the timing and completion of the trial and the management of data developed through the trial 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, 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 LPCN 1021 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 LPCN 1021 and preclude our ability to commercialize LPCN 1021, thereby limiting or preventing our ability to generate revenue from its sales.

We rely on a single supplier for our supply of TU, the active pharmaceutical ingredient of LPCN 1021, and the loss of either of these supplier could harm our business.

We rely on a single third-party supplier for our supply of TU, the active pharmaceutical ingredient of LPCN 1021. We do not have supply agreements in place with this supplier. We have purchased sufficient quantities of TU for our pivotal Phase 3 trial and we plan on using this same supplier for our commercialization needs if LPCN 1021 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 LPCN 1021. We do not have supply agreements in place with these suppliers. We have purchased sufficient quantities of these inactives for our pivotal Phase 3 trial and we plan on using these same suppliers for our commercialization needs if LPCN 1021 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 Encap Drug Delivery for the supply of the LPCN 1021 capsules, and the termination of our agreement with Encap Drug Delivery would harm our business.

We signed a manufacturing agreement with Encap Drug Delivery, a third-party contract manufacturer, in August 2013. Encap Drug Delivery is our sole supplier of LPCN 1021 capsules for the Phase 3 trial on a worldwide basis. We plan to negotiate a commercial supply agreement for LPCN 1021 with a CMO prior to a NDA filing for LPCN 1021. If Encap Drug Delivery is unable to produce sufficient capsules for our clinical trial or to support demand for LPCN 1021 if it becomes commercially available, our revenue and profitability would be adversely affected.

Reliance on a third-party manufacturer involves risks, such as capacity and capabilities to which we would not be subject if we manufactured LPCN 1021 ourselves, including 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 nonrenewal 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 LPCN 1021 be manufactured according to cGMP. Any failure by our 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.

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 of LPCN 1021, LPCN 1111 or LPCN 1107. We intend to continue to develop our product candidates in the United States without a partner. 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. 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 outside of the United States on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all.

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

Risks Related to Ownership of Our Common Stock

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, beginning with the year ending on December 31, 2013, 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, if and when required, 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. For so long as we remain as an emerging growth company or a smaller reporting company, our accounting firm will not be required to provide an opinion regarding our internal controls over financial reporting.

As a result of the Merger, we will incur additional expenses to comply with the requirements of being a public company in the United States.

As a public company, and particularly after we cease to be an "emerging growth company" or a "smaller reporting company", we will incur significantly more legal, accounting and other expenses than Lipocine Operating incurred 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:

- 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;
- announcements of new products, technologies, commercial relationships, acquisitions or other events by us or our competitors;
- 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; 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 and 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 the shares. We may have little or no ability to impact or alter such decisions.

Anti-takeover provisions in our amended and restated certificate of incorporation and our amended and restated bylaws, as well as provisions of Delaware law, 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.

The existence of the foregoing provisions and anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our company, thereby reducing the likelihood that stockholders could receive a premium for their common stock in an acquisition.

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.

Although the board of directors of Marathon Bar declared a cash dividend to its stockholders of record in connection with the Merger, we do not anticipate paying any further 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 control over our affairs.

As of December 31, 2014, our executive officers and directors beneficially owned approximately 13.74% of our common stock. These stockholders, if they act together, may be able to control 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 our change in control and might affect the market price of our common stock.

There is a limited trading market for our common stock.

There has been a limited public trading market for our common stock. If a larger market for our common stock does not develop or is not sustained, it may be difficult for our stockholders to sell their shares of common stock at an attractive price or at all. In the absence of an active trading market for our common stock, stockholders may not be able to sell their common stock at or above the price at which they acquired the shares or at the time that they would like to sell. We cannot predict the prices at which our common stock will trade. Although our common stock is trading on The NASDAQ Capital Market, we cannot assure you that we will be able to maintain such listing.

Risks Relating to Our Financial Position and Capital Requirements

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

We may 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:

- the duration of regulatory uncertainty relating to the TRT class;
- the scope, size, rate of progress, results and costs of completing our pivotal Phase 3 trial of LPCN 1021;
- the cost, timing and outcomes of our efforts to obtain marketing approval for our product candidates in the United States;
- payments received under any strategic partnerships or collaborations that we may enter into in the future, if any;
- the cost of filing, prosecuting and enforcing patent claims; and
- the costs associated with commercializing our product candidates if we receive marketing approval, including the cost and timing of developing sales and marketing capabilities or entering into strategic collaborations to market and sell our products.

Changing circumstances may cause us to consume capital significantly faster than we currently anticipate. Additional financing may not be available when we need it or may not be available on terms that are favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. If adequate funds are not available to us on a timely basis, or at all, we may be unable to continue the development of our product candidates or to commercialize our product, if approved, unless we find a partner.

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 LPCN 1021 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, LPCN 1021. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- successfully complete our pivotal Phase 3 trial;
- obtain U.S. and foreign marketing approval for LPCN 1021 as a TRT;
- commercialize LPCN 1021 by developing a sales force and/or entering into collaborations with partners/third parties, if we obtain marketing approval for LPCN 1021; and
- achieve market acceptance of LPCN 1021 in the medical community and with third-party payors.

Even if LPCN 1021 is approved for commercial sale, which we do not expect to occur before mid-2016, we expect to incur significant costs as we prepare to commercialize LPCN 1021. Despite receiving marketing approval and expending these costs, LPCN 1021 may not be a commercially successful drug. 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 LPCN 1021. We have funded our operations to date through proceeds 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, 2014, we had an accumulated deficit of $68.2 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. We expect to incur additional and increasing operating losses over the next several years. 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 our pivotal Phase 3 trial of LPCN 1021 and other clinical trials associated with LPCN 1111 and LPCN 1107. In addition, if we obtain marketing approval for LPCN 1021, we may incur significant sales, marketing and outsourced manufacturing expenses. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. 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.

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 one securities and industry analyst 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 the current securities analyst ceases coverage of our company, the trading price for our stock could be negatively impacted. If the analyst who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

We are an emerging growth company and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we continue to be an emerging growth company, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory stockholder vote on executive compensation and any golden parachute payments not previously approved, exemption from the requirement of auditor attestation in the assessment of our internal control over financial reporting and exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board. If we do, the information that we provide stockholders may be different than what is available with respect to other public companies. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We will remain an emerging growth company until the earliest of (1) the end of the fiscal year in which the market value of our common stock that is held by non-affiliates exceeds $700 million as of the end of the second fiscal quarter, (2) the end of the fiscal year in which we have total annual gross revenues of $1 billion or more during such fiscal year, (3) the date on which we issue more than $1 billion in non-convertible debt in a three-year period or (4) the end of the fiscal year following the fifth anniversary of the date of the first sale of our common stock pursuant to an effective registration statement filed under the Securities Act. Decreased disclosures in our SEC filings due to our status as an “emerging growth company” may make it harder for investors to analyze our results of operations and financial prospects.

We are a smaller reporting company and we cannot be certain if the reduced disclosure requirements applicable to smaller reporting companies will make our common stock less attractive to investors.

We are currently a “smaller reporting company”, meaning that we are not an investment company, an asset-backed issuer, or a majority-owned subsidiary of a parent company that is not a smaller reporting company and have a public float of less than $75 million. In the event that we are still considered a “smaller reporting company,” at such time we cease being an “emerging growth company”, we will be required to provide additional disclosure in our SEC filings. However, similar to “emerging growth companies”, “smaller reporting companies” are able to provide simplified executive compensation disclosures in their filings; are exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that independent registered public accounting firms provide an attestation report on the effectiveness of internal control over financial reporting; and have certain other decreased disclosure obligations in their SEC filings, including, among other things, only being required to provide two years of audited financial statements in annual reports. Decreased disclosures in our SEC filings due to our status as a “smaller reporting company” may make it harder for investors to analyze our results of operations and financial prospects.

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 recent changes regarding how patent laws are interpreted, and both the 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 LPCN 1021, 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 inventions, or parts of our inventions, 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 LPCN 1021 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 LPCN 1021.Likewise, our United States patents covering certain technology used in our product candidates, including LPCN 1021, are expected to expire on various dates from November 23, 2019 through January 2029. 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 LPCN 1021. 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 Hatch-Waxman Amendments 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 Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. 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 the court to rule that the patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. In addition, there is a risk that the 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 our owned or licensed patents. In addition, the U.S. Supreme Court has recently changed some tests regarding granting 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 proceeding before the PTO, or during litigation, under the revised criteria which make it more difficult to obtain or maintain patents.

While our in-licensed patents and applications are not currently used in our product candidates, should we develop other product candidates that are covered by this intellectual property, we rely on our licensor to file and prosecute patent applications and maintain patents and otherwise protect certain 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 license 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 LPCN 1021 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 the Company has the obligation to cooperate. In either case of these enforcement actions 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 LPCN 1021 and our other product candidates.

In addition, we may file a request for interference, known as a Suggestion of Interference, on competitor patent applications and issued patents with the U.S. Patent Office if we believe we have priority over competitor patent applications and patents. Interference proceedings may fail and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party; our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Even if successful in such interferences, it may result in substantial costs to us and distraction to our management. Moreover, we may be subject to a third party preissuance submission of prior art to the U.S. Patent and Trademark Office, 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.

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.

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 in February 28, 2018. We believe that our existing facilities are suitable and adequate and that we have sufficient capacity to meet our current anticipated needs.

ITEM 3. LEGAL PROCEEDINGS

Although we may, from time to time, be a party to certain lawsuits in the ordinary course of business, we are not currently involved in any lawsuits that would have a material adverse effect on our results of operations, financial condition, or cash flows.

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

From June 5, 2012 to July 27, 2013, the common stock of Marathon Bar was quoted on the OTC Electronic Bulletin Board, or OTCBB, under the symbol "MBAR". From July 27, 2013 to August 22, 2013, our common stock was quoted on the OTCBB under the symbol "MBARD". Our common stock was quoted on the OTCQB and OTCBB under the symbol "LPCN" from August 22, 2013 and March 20, 2014. Since March 21, 2014, our common stock has been quoted on The NASDAQ Capital Market. There was no bid or ask quoted for the quarter ended March 31, 2013 and June 30, 2013.

The following table sets forth, for the periods indicated, the high and low closing sales prices for our common stock, as reported on the OTCBB/OTCQB and The NASDAQ Capital Market.

	High	Low
2013		
First Quarter	$ N/A	$ N/A
Second Quarter	N/A	N/A
Third Quarter	20.00	6.00
Fourth Quarter	10.00	7.50
2014		
First Quarter	$ 9.28	$ 7.44
Second Quarter	8.00	5.52
Third Quarter	9.88	5.09
Fourth Quarter	5.51	3.95

Holders

As of March 11, 2015, there were approximately 148 holders of record of our common stock. This number does not included an undetermined number of stockholders whose stock is held in "street" or "nominee" name.

Dividends

Although the board of directors of Marathon Bar declared a cash dividend to its stockholders of record in connection with the Merger, we do not anticipate paying any further 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.

Use of Proceeds

On November 25, 2013, the SEC declared effective our Registration Statement on Form S-1 (File No. 333-192069) relating to our public offering. The registration statement related to 1,492,000 shares of our common stock, par value $0.0001 per share. On November 25, 2013, we sold 1,492,000 shares of our common stock at the price of $8.25, for an aggregate sale price of $12.3 million, settling those sales on November 29, 2013. On December 6, 2013, we sold an additional 223,800 shares of our common stock at the price of $8.25, for an aggregate sales price of $1.8 million upon the exercise of the over-allotment. The sole book-running manager for our offering was Ladenburg Thalmann & Co. Inc. and the lead manager was National Securities Corporation. Following the sale of the 1,715,800 shares of our common stock, the offering terminated.

We paid $1.1 million in underwriting discounts and commissions in connection with the offering of the shares sold on our behalf. We also incurred $485,000 of other offering expenses. The net offering proceeds to us, after deducting underwriting discounts and commissions and offering expenses paid by us, was approximately $12.5 million.

None of the underwriting discounts and commissions or offering expenses were paid, directly or indirectly, to any of our directors or officers or their associates or to persons owning 10% or more of our common stock or to any affiliates of ours.

We expect to use the remainder of the net proceeds from this offering to conduct clinical trials for our lead product candidate LPCN 1021 and other product candidates and the balance for working capital and other general corporate purposes.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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.

On July 24, 2013, Marathon Bar Corp. ("Marathon Bar"), a Delaware corporation and MBAR Acquisition Corp. ("Merger Sub"), a wholly owned subsidiary of Marathon Bar, and Lipocine Operating Inc. ("Lipocine Operating"), a privately held company incorporated in Delaware, executed an Agreement and Plan of Merger ("Merger Agreement"). Pursuant to the Merger Agreement, Merger Sub merged with and into Lipocine Operating and Lipocine Operating was the surviving entity. Additionally pursuant to the Merger Agreement, Marathon Bar changed its name to Lipocine Inc. The Merger is accounted for as a reverse-merger and recapitalization. Lipocine Operating is the acquirer for financial reporting purposes and Marathon Bar is the acquired company. Consequently, the assets and liabilities and the operations that are reflected in the historical financial statements prior to the Merger are those of Lipocine Operating and are recorded at the historical cost basis of Lipocine Operating, and the consolidated financial statements after completion of the Merger include the assets, liabilities and operations of Marathon Bar and Lipocine Operating ("Combined Company"), from the closing date of the Merger. Additionally all historical equity accounts of Lipocine Operating, including par value per share, share and per share numbers, have been adjusted to reflect the number of shares received in the Merger.

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 tothose 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 specialty pharmaceutical company focused on applying our oral drug delivery technology for the development of pharmaceutical products in the area of men's and women's health. Our proprietary delivery technology is 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 characteristics and facilitate lower dosing requirements, bypass first-pass metabolism, reduce side effects, and eliminate gastrointestinal interactions that limit bioavailability. Our current portfolio, includes our lead product candidate LPCN 1021, an oral testosterone replacement therapy ("TRT"), which is currently in a pivotal Phase 3 clinical study. Additionally, we are currently in the process of establishing our pipeline of early clinical treatments including a next generation oral TRT, LPCN 1111, and an oral therapy for the prevention of preterm birth, LPCN 1107.

To date, we have funded our operations primarily through the sale of equity securities and convertible debt and through up-front payments, research funding 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 LPCN 1021 or other products.

We have incurred losses in most years since our inception. As of December 31, 2014, we had an accumulated deficit of $68.2 million. Income and losses fluctuate year to year, primarily depending on the timing of recognition of revenues from our license and collaboration agreements. Our net loss was $20.4 million for the year ended December 31, 2014, compared to $10.6 million for the year ended December 31, 2013. 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 increasing operating losses for at least the next several years. In the near term, we anticipate that our expenses will increase as we:

- manufacture registration batches of LPCN 1021;
- complete our pivotal Phase 3 trial and other pharmacokinetic studies of LPCN 1021 and, if these trials are successful, prepare and file our NDA for LPCN 1021;
- conduct further clinical development of our other product candidates, including LPCN 1111 and LPCN 1107;
- continue our research efforts;
- 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, the timing and results of our ongoing development efforts, the potential expansion of our current development programs, potential new 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 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 our license and collaboration agreements and public and private equity securities offerings, there can be no assurance that we will be able to do so in the future.

Our Product Candidates

Our current portfolio of proprietary product candidates consists of our lead product candidate LPCN 1021, an oral TRT, a next generation oral TRT, LPCN 1111, and an oral therapy for the prevention of recurrent preterm birth, LPCN 1107.

LPCN 1021: An Oral Product Candidate for Testosterone Replacement Therapy

Our lead product, LPCN 1021, is an oral formulation of the chemical testosterone undecanoate ("TU"), an eleven carbon side chain attached to testosterone. TU is an ester prodrug of testosterone, which is an inactive form of testosterone. Upon the cleavage, or breaking, of the ester bond, the pharmacologically active drug, testosterone is formed. An ester is a chemical between an acid and alcohol. 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 TU recently received approval in the United States for delivery via intra-muscular injection. However, the oral dosage form which is approved outside the United States provides sub-therapeutic serum testosterone levels at the approved dose. We are using our Lip'ral technology to facilitate steady gastrointestinal solubilization and absorption of TU for convenient twice daily dosing of TU. Proof of concept was initially established in 2006, and subsequently LPCN 1021 was licensed to Solvay Pharmaceuticals, Inc. ("Solvay") which was then acquired by Abbott Products, Inc. ("Abbott") in 2009. Following a portfolio review associated with the spin-off of AbbVie by Abbott in 2011, the rights to LPCN 1021 were reacquired by us. All obligations under the prior license agreement have been completed except that Lipocine will owe Abbott a perpetual 1.5% royalty on net sales should Lipocine decide to use certain Solvay/Abbott formulations or a perpetual 1% royalty on net sales should Lipocine use data generated during the term of the Solvay/Abbott agreement in any regulatory filings for a product. 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%.

We have received top-line efficacy results from our ongoing Study of Oral Androgen Replacement ("SOAR") pivotal Phase 3 clinical study evaluating efficacy and safety of LPCN 1021. SOAR is a randomized, open-label, parallel-group, active-controlled, Phase 3 clinical study of oral TRT 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 LPCN 1021 and 105 were randomized to the active control, for 52 weeks of treatment. The active control is included for safety assessment. LPCN 1021 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, up to 300 mg TU BID or down to 150 mg TU BID based on serum testosterone measured during weeks 3 and 7. The mean age of the subjects in the trial is ~53 yrs with ~91% of the patients < 65 yrs of age.

Top Line Results From SOAR

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=152. 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=192) and the safety set ("SS") (any subject that was randomized into the study and took at least one dose, N=210).

Efficacy

The primary efficacy end point is the percentage of subjects with an average 24 hour serum testosterone concentration ("Cavg") within the normal range, which is defined as 300-1140 ng/dL, after 13 weeks of treatment. 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% confidence interval ("CI") must be greater than 65%.

LPCN 1021 successfully met the FDA primary efficacy guideline. In the EPS analysis, 88% of the subjects on active treatment achieved testosterone Cavg within the normal range with lower bound CI of 82%. Additionally, sensitivity analysis using the FAS and SS reaffirmed the finding that LPCN 1021 successfully met the FDA primary efficacy guideline as 88% and 80%, respectively, of the subjects on active treatment achieved testosterone Cavg within the normal range with lower bound CI of 82% and 74%, respectively.

Other highlights from the efficacy results include:

- Mean Cavg was 447 ng/dL with coefficient of variance of 37%;
- Less than 12% of the subjects were outside the tesosterone Cavg normal range at final dose;
- 85% of subjects arrived at final dose with no more than one titration; and

- 51% of subjects were on final dose of 225 mg BID which was also the starting dose.

Safety

Although the safety component of the SOAR trial is on-going, LPCN 1021 treatment has been well tolerated to date.

LPCN 1021 safety highlights through week 13 of treatment include:

- 3% of the subjects reported a serious adverse events ("SAE"), with none of the SAE's being drug related;
- All the drug related adverse events were either mild or moderate in intensity (none were severe); and
- Hematocrit ("Hct") and prostate specific antigen ("PSA") increases were noted and consistent with other TRT products with one subject discontinued for elevated Hct exceeding pre-specified limits and one subject discontinued for elevated PSA exceeding pre-specified limits.

In the EPS analysis, Cmax ≤1500 ng/dL was 83%, Cmax between 1800 and 2500 ng/dL was 4.6% and Cmax > 2500 ng/dL was 2%. Three patients had a Cmax >2500 ng/dL which were transient, isolated and sporadic. Moreover, none of these subjects reported any AE's. Results were generally consistent with those of approved TRT products.

The safety extension phase of the SOAR trial is on-going. The safety extension phase is designed to assess safety information such as metabolites, biomarkers, laboratory values, SAEs and AEs, with subjects on their stable dose regimen in both the treatment arm and the active control arm.

In December 2014 we received confirmation from the FDA that the design of our SOAR trial is currently acceptable for filing an NDA for the class TRT labeling. The FDA reiterated the primary efficacy endpoint required for approval being 75% of subjects with a Cavg for serum testosterone in the normal range with the lower bound of the two-sided 95% confidence interval being >65%. Additionally, the FDA did not identify any additional clinical studies that would be required for NDA filing, but did state that should any safety signal become apparent during analysis of our SOAR trial results or during the course of their review, it is possible that additional data may be required. Based on the response received, we do not anticipate the need to conduct additional studies above those previously agreed to with the FDA for NDA filing.

We expect to have a pre-NDA meeting with the FDA on March 19, 2015. Additionally we expect the last patient last visit in the safety extension phase of the SOAR trial to be in April 2015 with top-line safety results in the second quarter of 2015 and an NDA filing to occur during the second half of 2015 assuming successful safety results.

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

LPCN 1111 is a next-generation, novel ester prodrug of testosterone which uses the Lip'ral technology to enhance solubility and improve systemic absorption. In October 2014, we successfully 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. These subjects had serum total testosterone < 300 ng/dL based on two blood draws on two separate days. Subjects received doses of LPCN 1111 as a single dose of 330 mg, 550 mg, 770 mg, followed by once daily administration of 550 mg for 28 days in 10 subjects, and once daily administration of 770 mg for 28 days in eight subjects. Results from the Phase 2a clinical study demonstrated the feasibility of a once daily dosing with LPCN 1111in 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 Cmax of 1500 ng/dL at any time during the 28 day dosing period on multi-dose exposure. Overall, LPCN 1111 was well tolerated with no serious adverse events. We expect to initiate a Phase 2b dose finding study in hypogonadal men in the third quarter of 2015 subject to clarity from the FDA on the TRT "class" label and financial resources.

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 prevention of preterm birth in women with a prior history of at least one preterm birth. We successfully 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 pharmacokinetics and bioavailability of LPCN 1107 relative to an intramuscular ("IM") HPC, as well as safety and tolerability. The Phase 1b open-label study enrolled eight healthy, pregnant women at 16 to 18 weeks gestation. All subjects received three treatments in sequence. In period one, subjects received two doses of 400 mg oral LPCN 1107, administered 12 hours apart. In period two, subjects received two doses of 800 mg oral LPCN 1107, administered 12 hours apart. In period three, subjects were given 250 mg of HPC via intramuscular injection (marketed product Makena®). Blood samples were collected periodically over 24 hours following oral dosing and over 28 days following the IM dose. Results of these studies confirmed our pre-clinical data and suggest meaningful drug levels of HPC can be obtained after oral administration in both pregnant and non-pregnant women. Prior to conducting the Phase 1a and Phase 1b studies, the product completed a 28-day repeat dose toxicity study in dogs. We plan to discuss the development plan with the FDA in the second quarter 2015 or third quarter 2015 before deciding next steps in the program. There are multiple potential development plans for LPCN 1107 with no assurances which, if any, will be acceptable to the FDA. Each potential development plan has a different timeline and cost.

Financial Operations Overview

Revenue

To date, we have not generated any revenues from product sales and do not expect to do so for a number of years. Revenues to date have been generated substantially from license fees, milestone payments and research support from our licensees. Since our inception through December 31, 2014, we have generated $27.5 million in revenue under our various license and collaboration arrangements and from government grants. We do not anticipate significant revenue from any license arrangements in the foreseeable future. We may never generate revenues from LPCN 1021 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 $65.5 million in research and development expenses through December 31, 2014.

We expect to incur research and developments costs for LPCN 1021 at the rate of $2 to $3 million per quarter as we complete our pivotal Phase 3 trial, conduct other pharmacokinetic studies, and if appropriate, file an NDA. We believe it will cost approximately $8.0 million to complete this process. However, these expenditures are subject to numerous uncertainties regarding timing and cost to completion.

Completion of our pivotal Phase 3 trial with LPCN1021 may take longer than currently estimated or the FDA may require additional clinical trials or non-clinical studies. 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;
- potential changes by the FDA in clinical trial and NDA filing requirements for testosterone replacement therapies; and
- unanticipated safety issues that may prolong the Phase 3 trial.

We also expect to incur significant manufacturing costs to prepare validation batches of finished product and customary regulatory costs associated with the preparation and filing of our NDA, if and when submitted, which will be significant. However, these expenditures are subject to numerous uncertainties regarding timing and cost to completion, including, among others:

- the costs, timing and outcome of our other pharmacokinetic studies and other development activities of LPCN 1021;
- our dependence on third-party manufacturers for the production of clinical trial materials and satisfactory finished product for registration;
- the costs and timing of regulatory submission for LPCN 1021 and the outcome of regulatory reviews;
- the potential for future license arrangements for LPCN 1021, 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 action taken by the FDA or other regulatory authorities.

A change of outcome for any of these variables with respect to the development of LPCN 1021 could mean a significant change in the costs and timing associated with these efforts.

Summary of Research and Development Expense

Our research and development efforts have primarily been focused on LPCN 1021 through the end of 2013. Beginning in 2014, we have on-going clinical trials with all of our three product candidates. Additionally, we incur significant costs for our other research programs. The following table summarizes our research and development expenses:

	Years Ended December 31,	
	2014	**2013**
External service provider costs:		
LPCN 1021	$ 10,970,372	$ 2,935,989
LPCN 1111	1,280,014	35,249
LPCN 1107	605,823	182
Other product candidates	30,165	2,514
Total external service provider costs	12,886,374	2,973,934
Internal personnel costs	2,148,115	1,704,835
Other research and development costs	444,957	444,095
Total research and development	$ 15,479,446	$ 5,122,864

External service provider costs under a collaborative product development agreement are recorded net of reimbursement. In July 2013, we assigned the collaborative agreement to an affiliated entity as described in Note 11 of the “Notes to Consolidated Financial Statements”. As a result, we were not entitled to reimbursement of any amounts under the agreement during year ended December 31, 2014. A total of $468,000 was reimbursed under the agreement during the year ended December 31, 2013 and recorded net in research and development expense.

Given the early 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 1111, 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 1111, 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.

General and Administrative Expenses

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

They also include expenses for the cost of preparing, filling and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims.

We expect that general and administrative expenses will increase as we mature as a public company. These increases will likely include salaries and related expenses, 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 and other costs. In addition, if our pivotal Phase 3 trial of LPCN 1021 is successful and we then prepare and file our NDA for LPCN 1021, we expect general and administrative expenses to increase as we incur costs of pre-commercialization and, potentially, commercialization activities.

Reverse Merger Costs

Reverse merger costs relate to external expenses associated with our reverse merger with Marathon Bar on July 24, 2013. Reverse merger costs consist primarily of professional fees for accounting, legal, printing and transfer agent services.

Settlement for Termination of Certain Rights in Stock Purchase Agreement

Settlement for termination of certain rights in stock purchase agreement relates to stock issuance expenses associated with terminating certain rights, including anti-dilution provisions, in our stock purchase agreement with an existing shareholder on July 24, 2013.

Other Income, Net

Other income, net consists primarily of interest earned on our cash and cash equivalents.

Results of Operations

Comparison of the Years Ended December 31, 2014 and 2013

The following table summarizes our results of operations for the years ended December 31, 2014 and 2013:

	Years Ended December 31,		
	2014	**2013**	**Variance**
Research and development expenses	$ 15,479,446	$ 5,122,864	10,356,582
General and administrative expenses	5,001,368	3,635,690	1,365,678
Reverse merger costs	-	1,011,630	(1,011,630)
Settlement for termination of certain rights in stock purchase agreement	-	913,446	(913,446)
Other income, net	108,338	38,476	69,862
Income tax benefit (expense)	(200)	55,048	(55,248)

Research and Development Expenses

The increase in research and development expenses in the year ended December 31, 2014 was primarily due to an increase in external service provider costs of $9.9 million and an increase of $443,000 in internal personnel costs. The increase in external service provider costs was primarily due to an increase of $10.9 million in clinical research costs and an increase of $106,000 in consulting expenses for clinical and regulatory advisors, primarily related to our Phase 3 clinical trial for LPCN 1021. The increase in personnel costs included $167,000 in severance payments to a terminated officer. These increases was partially offset by a reduction in manufacturing and drug purchase costs of $1.1 million which were incurred in 2013 and not repeated in 2014.

General and Administrative Expenses

The increase in general and administrative expenses in the year ended December 31, 2014 was primarily due to an increase in equity compensation of $637,000 due primarily to accelerated vesting and/or extension of exercise dates for retiring directors and a terminated officer; increased compensation expense of $312,000 for new administrative personnel including a full year of salary of our chief financial officer; other compensation increases of $135,000, including $92,000 in severance payments to a terminated officer, $24,000 in employer 401(k) plan match which began in April 2014, and $19,000 in salary increases in 2014; increased director and officer liability insurance expense of $99,000 for the first full year as a public company; $67,000 for recruiting expense; and an increase of $69,000 for a higher allocation of overhead expenses based on a higher allocation of direct labor hours for general and administrative personnel relative to research and development personnel.

Reverse Merger Costs

Reverse merger costs incurred during the year ended December 31, 2013 relate to the Merger with Marathon Bar which closed on July 24, 2013, and is comprised of $340,000 for the cost of the Marathon Bar shell, $527,000 in legal services, $98,000 in accounting services, $38,000 in printer fees and $9,000 in other miscellaneous expenses.

Settlement for Termination of Certain Rights in Stock Purchase Agreement

Settlement for termination of certain rights in stock purchase agreement incurred during the year ended December 31, 2013 relates to 152,241 shares of common stock issued to an existing shareholder on July 24, 2013 for the termination of certain rights included in a stock purchase agreement, including an anti-dilution provision.

Other Income, Net

The increase in other income, net, primarily reflects increased interest earned on a larger balance in cash and cash equivalents in 2014 as a result of our offerings of common stock in July 2013 and November 2013.

Income Tax Benefit (Expense)

The increase in income tax expense relates to a reversal of accrued income taxes payable in 2013 due to the reversal of an uncertain tax position which was not repeated in 2014.

Liquidity and Capital Resources

Since our inception, our operations have been primarily financed through sales of our equity and payments received under our license and collaboration arrangements. We have devoted our resources to funding research and development programs, including discovery research, preclinical and clinical development activities. We have incurred operating losses in most years since our inception and we expect to continue to incur operating losses into the foreseeable future as we advance the ongoing development of our lead product candidate LPCN 1021 and further clinical development of LPCN 1111, LPCN 1107 and our other programs and continued research efforts.

As of December 31, 2014 we had $27.7 million of cash and cash equivalents compared to $45.3 million at December 31, 2013. We believe that our existing capital resources, together with interest thereon, will be sufficient to meet our projected operating requirements for the next twelve months. While we believe we have sufficient liquidity and capital resources to fund our projected operating requirements beyond December 31, 2015, we will need to raise additional capital at some point to support our operations, long-term research and development and commercialization of our products. 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. Further, our operating plan may change, and we may need additional funds to meet operational needs and capital requirements for product development and commercialization sooner than planned. We currently have no credit facility or committed sources of capital. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates and the extent to which we may be able to enter into collaborations with third parties to participate in the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our anticipated clinical studies and ongoing development and commercialization efforts. To fund future operations, we will need to raise additional capital and our requirements will depend on many factors, including the following:

- the clarification by the FDA of the regulatory environment for the TRT class;
- the scope, rate of progress, results and cost of our clinical studies, preclinical testing and other related activities;
- the cost of manufacturing clinical supplies, and establishing commercial supplies, of our product candidates and any products that we may develop;
- the number and characteristics of product candidates that we pursue;
- the cost, timing and outcomes of regulatory approvals;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- 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 acceptable terms, or at all. 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 commercialization efforts. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. To the extent that we raise additional capital through marketing and distribution arrangements or 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 to 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 that adversely affect our stockholders' rights. 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 delay research and development programs, liquidate assets, dispose of rights, commercialize or license products or product candidates earlier than planned or on less favorable terms than desired or reduce or cease operations.

	Years Ended December 31,	
	2014	**2013**
Cash used in operating activities	$ (17,304,163)	$ (8,588,456)
Cash used in investing activities	(38,361)	(1,206)
Cash provided by (used in) financing activities	(255,119)	48,476,246

Operating Activities

Cash used in operating activities was $17.3 million for the year ended December 31, 2014, and $8.6 million for the year ended December 31, 2013, an increase of $8.7 million. Included in the increase was a $8.8 million increase in net loss, a $913,000 decrease in non-cash expense for settlement for termination of certain rights in stock purchase agreement and a $1.1 million decrease in accounts payable. The changes were partially offset by a $914,000 increase in stock-based compensation, a $1.2 million increase in prepaid expenses and other assets, a $922,000 increase in accrued expenses and a $55,000 decrease in income taxes payable.

Investing Activities

Investing activities consist primarily of the refund of a rental deposit and purchases of property and equipment. We received $21,000 in a refund of our rental deposit when we extended our property lease in May 2014. Additionally, we acquired $60,000 of property and equipment in the year ended December 31, 2014 compared to $1,000 in the year ended December 31, 2013.

Financing Activities

Financing activities consist primarily of net proceeds from the sale of common stock, the exercise of stock options and the purchase of treasury stock. Cash provided by (used in) financing activities was $(255,000) and $48.5 million, respectively, during the year ended December 31, 2014 and 2013. During year ended December 31, 2014, we paid accrued common stock offering costs of $271,000 related to the sale of common stock in an underwritten transaction in November and December 2013. During the year ended December 31,2014, we also received $16,000 from the exercise of stock options compared to $11,000 from the exercise of stock options during the year ended December 31, 2013. Additionally during the year ended December 31, 2013, we repurchased $53,000 of treasury stock and received $48.5 million from the sale of common stock in an offering to accredited investors in July 2013 and from the sale of common stock in an underwritten transaction in November and December 2013.

Contractual Commitments and Contingencies

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 May 6, 2014, we modified and extended the lease through February 28, 2018. Our remaining commitment through 2018 under this lease is $935,000.

Other Contractual Obligations

We enter into contracts in the normal course of business with clinical research organizations for clinical trials and clinical 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.

JOBS Act Accounting Election

We are an "emerging growth company," as defined in the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards, and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

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 3 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

Revenue is recognized when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed and determinable, and collectability is reasonably assured. We recognize license and other up-front fees as earned. Milestone payments are recognized upon successful completion of a performance milestone event. Contract revenues related to collaborative research and development agreements are recognized on a ratable basis as services are performed. Any amounts received in advance of performance are recorded as deferred revenue until earned.

We may enter into arrangements with collaboration partners that sometimes involve multiple deliverables. These arrangements may contain one or more of the following elements: license and other up-front fees, contract research and development services, milestone payments and royalties. Each deliverable in the arrangement is evaluated to determine whether it meets the criteria to be accounted for as a separate unit of accounting or whether it should be combined with other deliverables. When deliverables are separable, consideration is allocated to the separate units of accounting based upon the relative selling price method, and appropriate revenue recognition principles are applied to each unit. When we determine that the arrangement should be accounted for as a single unit of accounting, revenue is recognized over the period for which performance obligations will be performed.

Up-front, nonrefundable fees and milestone payments we receive under license and collaboration arrangements that include future obligations, in whatever form, are recognized ratably over the expected performance period under each respective arrangement. Under these arrangements, we make our best estimate of the period over which we expect to fulfill our performance obligations, which may include technology transfer assistance, research activities, clinical development activities, and manufacturing activities from development through the commercialization of the product. Given the uncertainties of these extended collaboration arrangements, significant judgment is required to determine the duration of the performance period. For license and collaboration arrangements where no future obligations exist, up-front, nonrefundable fees and milestone payments are recognized when received. Any amounts received in advance of performance are recorded as deferred revenue until recognized.

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, 2014, we do not have any active collaboration agreements except for an agreement to provide joint research and development services which was assigned to Spriaso LLC as described in Note 4 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 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.

During November 2014, we modified 149,498 existing time-vested options of two terminated executives by extending the exercise period to three years from the date of modification under the terms of their respective employment and severance agreements. Compensation expense of $166,000 was recorded as a result of the modification. During January 2014, we modified 366,126 existing time-vested and performance options as well as restricted stock awards of two retiring board of directors by fully vesting all unvested equity awards and extending the exercise period to three years from the date of modification. Compensation expense of $836,000 was recorded as a result of the modification. During January 2013, we modified 907,336 existing time-vested and performance-based stock options by lowering the exercise price to $2.81 on a post merger basis. Additionally, we modified the vesting terms for our unvested performance-based stock options and unvested restricted stock to vest on the earlier of the first dosing in the pivotal clinical study for our lead drug candidate, or 50% in January 2014 and 50% in January 2015. Compensation expense of $422,000 was recorded as a result of modifications. During 2013 we determined that it was probable that the performance milestone related to the unvested stock options and restricted stock would occur. As a result, the remaining compensation expense between the date the milestone became probable and the expected milestone date of February 2014 was recognized

ratably over that period.

In addition, we grant stock options to nonemployee consultants from time to time in exchange for services performed for us. Equity instruments granted to nonemployees are subject to periodic revaluation over their vesting terms.

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, 2014, there was $1.6 million of total unrecognized compensation cost related to unvested share-based compensation arrangements granted under our Incentive Plan.

New Accounting Standards

Refer to Note 12 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

Not Applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTAL DATA

LIPOCINE INC.
INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Lipocine Inc.:

We have audited the accompanying consolidated balance sheets of Lipocine Inc. and subsidiaries as of December 31, 2014 and 2013, and the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2014. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Lipocine Inc. and subsidiaries as of December 31, 2014 and 2013, and the results of their operations and their cash flows for each of the years in the two-year period ended December 31, 2014 in conformity with U.S. generally accepted accounting principles.

/s/ KPMG LLP

Salt Lake City, Utah
March 11, 2015

LIPOCINE INC. AND SUBSIDIARIES

Consolidated Balance Sheets

December 31, 2014 and 2013

	2014	2013
Assets		
Current assets:		
Cash and cash equivalents	$ 27,666,055	$ 45,263,698
Prepaid and other current assets	229,912	770,030
Total current assets	27,895,967	46,033,728
Property and equipment, net accumulated depreciation of $1,034,029 and $1,019,409, respectively	73,782	28,794
Other assets	23,753	45,000
Total assets	$ 27,993,502	$ 46,107,522
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 306,276	$ 1,027,021
Accrued expenses	1,327,256	256,754
Total current liabilities	1,633,532	1,283,775
Total liabilities	1,633,532	1,283,775
Commitments and contingencies (notes 7 and 10)		
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; 12,800,382 and 12,668,393 issued and 12,794,672 and 12,668,393 outstanding	1,280	1,267
Additional paid-in capital	94,636,479	92,686,881
Treasury stock at cost, 5,710 and zero shares	(40,712)	-
Accumulated deficit	(68,237,077)	(47,864,401)
Total stockholders' equity	26,359,970	44,823,747
Total liabilities and stockholders' equity	$ 27,993,502	$ 46,107,522

See accompanying notes to consolidated financial statements

LIPOCINE INC. AND SUBSIDIARIES

Consolidated Statements of Operations and Comprehensive Loss

Years Ending December 31, 2014 and 2013

	2014	2013
Operating expenses:		
Research and development	$ 15,479,446	$ 5,122,864
General and administrative	5,001,368	3,635,690
Reverse merger costs	-	1,011,630
Settlement for termination of certain rights in stock purchase agreement	-	913,446
Total operating expenses	20,480,814	10,683,630
Operating loss	(20,480,814)	(10,683,630)
Other income, net	108,338	38,476
Loss before income tax expense	(20,372,476)	(10,645,154)
Income tax benefit (expense)	(200)	55,048
Net loss	$ (20,372,676)	$ (10,590,106)
Basic loss per share attributable to common stock	$ (1.60)	$ (1.44)
Weighted average common shares outstanding, basic	12,766,295	7,363,076
Diluted loss per share attributable to common stock	$ (1.60)	$ (1.44)
Weighted average common shares outstanding, diluted	12,766,295	7,363,076
Comprehensive loss	$ (20,372,676)	$ (10,590,106)

See accompanying notes to consolidated financial statements

LIPOCINE INC. AND SUBSIDIARIES

Consolidated Statements of Changes in Stockholders' Equity

Years Ending December 31, 2014 and 2013

	Common Stock		Treasury Stock				
	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
Balances at December 31, 2012	4,455,790	$ 446	-	$ -	$ 42,590,042	$ (37,274,295)	$ 5,316,193
Net loss	-	-	-	-	-	(10,590,106)	(10,590,106)
Stock-based compensation	-	-	-	-	979,151	-	979,151
Option exercises	3,761	-	-	-	10,575	-	10,575
Vesting of restricted stock awards	7,763	1	-	-	(1)	-	-
Repurchase and retirement of common stock	(8,626)	(1)	-	-	(53,099)	-	(53,100)
Issuance of common stock in private offering	6,336,664	634	-	-	35,709,011	-	35,709,645
Issuance of common stock in offering	1,715,800	172	-	-	12,537,771	-	12,537,943
Common stock issued in reverse merger	5,000	-	-	-	-	-	-
Issuance of common stock for termination of certain rights in stock purchase agreement	152,241	15	-	-	913,431	-	913,446
Balances at December 31, 2013	12,668,393	$ 1,267	-	$ -	$ 92,686,881	$ (47,864,401)	$ 44,823,747
Net loss	-	-	-	-	-	(20,372,676)	(20,372,676)
Stock-based compensation	-	-	-	-	1,892,835	-	1,892,835
Option exercises	20,205	2	-	-	56,774	-	56,776
Vesting of restricted stock awards	96,784	10	-	-	(10)	-	-
Vesting or restricted stock units	15,000	1	-	-	(1)	-	-
Purchase of treasury stock	(5,710)	-	5,710	(40,712)	-	-	(40,712)
Balances at December 31, 2014	12,794,672	$ 1,280	5,710	$ (40,712)	$ 94,636,479	$ (68,237,077)	$ 26,359,970

See accompanying notes to consolidated financial statements

LIPOCINE INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

Years Ending December 31, 2014 and 2013

	2014	2013
Cash flows from operating activities:		
Net loss	$ (20,372,676)	$ (10,590,106)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	14,620	21,767
Forgiveness of related party receivable	-	3,815
Stock-based compensation expense	1,892,835	979,151
Settlement for termination of certain rights in stock purchase agreement	-	913,446
Changes in operating assets and liabilities:		
Prepaid and other current assets	540,118	(679,096)
Accounts payable	(449,562)	668,811
Accrued expenses	1,070,502	148,804
Income taxes payable	-	(55,048)
Cash used in operating activities	(17,304,163)	(8,588,456)
Cash flows from investing activities:		
Refund of long-term rental deposit	21,247	-
Purchases of property and equipment	(59,608)	(1,206)
Cash used in investing activities	(38,361)	(1,206)
Cash flows from financing activities:		
Proceeds from stock option exercises	16,064	10,575
Net proceeds from common stock offerings	-	48,518,771
Payment of accrued common stock offering costs	(271,183)	-
Purchase of restricted stock from employees	-	(53,100)
Cash provided by financing activities	(255,119)	48,476,246
Net decrease in cash and cash equivalents	(17,597,643)	39,886,584
Cash and cash equivalents at beginning of period	45,263,698	5,377,114
Cash and cash equivalents at end of period	$ 27,666,055	$ 45,263,698
Supplemental disclosure of non-cash financing activities:		
Accrued common stock offering costs	$ -	$ 271,183
Stock received as consideration for stock option exercises and recognized as treasury stock	40,712	-

See accompanying notes to consolidated financial statements

(1) Description of Business

Lipocine Inc. ("Lipocine" or the "Company") 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 and through the sale of equity securities. The Company is incorporated under the laws of the State of Delaware.

(2) Merger Agreement

On July 24, 2013, Marathon Bar Corp. ("Marathon Bar"), a Delaware corporation and MBAR Acquisition Corp. ("Merger Sub"), a wholly owned subsidiary of Marathon Bar, and Lipocine Operating Inc. ("Lipocine Operating"), a privately held company incorporated in Delaware, executed an Agreement and Plan of Merger ("Merger Agreement"). Pursuant to the Merger Agreement, Merger Sub merged with and into Lipocine Operating and Lipocine Operating was the surviving entity. Additionally pursuant to the Merger Agreement, Marathon Bar changed its name to Lipocine Inc.

The Merger is accounted for as a reverse-merger and recapitalization. Lipocine Operating is the acquirer for financial reporting purposes and Marathon Bar is the acquired company. Consequently, the assets and liabilities and the operations that are reflected in the historical financial statements prior to the Merger are those of Lipocine Operating and are recorded at the historical cost basis of Lipocine Operating, and the consolidated financial statements after completion of the Merger include the assets, liabilities and operations of Marathon Bar and Lipocine Operating ("Combined Company"), from the closing date of the Merger. Therefore, the historical equity accounts and awards of Lipocine, including par value per share, share and per share numbers, have been adjusted to reflect the number of shares received in the Merger.

(3) 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 revenue recognition; stock-based compensation; valuation of deferred taxes; 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 equivalents were zero and $1.9 million for December 31, 2014 and 2013.

(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 2014 and 2013 and the Company did not record an allowance for doubtful accounts as of December 31, 2014 and 2013 as there were no accounts receivable outstanding. The Company does not have any off-balance-sheet credit exposure related to its customers.

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

(d) Revenue Recognition

Revenue is recognized when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed or determinable, and collectability is reasonably assured. The Company recognizes up-front license fees as earned. Milestone payments are recognized upon successful completion of a performance milestone event. Contract revenues related to collaborative research and development agreements are recognized on a ratable basis as services are performed. Any amounts received in advance of performance are recorded as deferred revenue until earned.

The Company enters into arrangements with collaboration partners that sometimes involve multiple deliverables. These arrangements may contain one or more of the following elements: license and other up-front fees, contract research and development services, milestone payments and royalties. Each deliverable in the arrangement is evaluated to determine whether it meets the criteria to be accounted for as a separate unit of accounting or whether it should be combined with other deliverables. When deliverables are separable, consideration is allocated to the separate units of accounting based upon the relative selling price method, and appropriate revenue recognition principles are applied to each unit. When the Company determines that the arrangement should be accounted for as a single unit of accounting, revenue is recognized over the period for which performance obligations will be performed.

Up-front, nonrefundable fees and milestone payments received by the Company under license and collaboration arrangements that include future obligations, in whatever form, are recognized ratably over the expected performance period under each respective arrangement. Under these arrangements, the Company makes its best estimate of the period over which it expects to fulfill its performance obligations, which may include technology transfer assistance, research activities, clinical development activities, and manufacturing activities from development through the commercialization of the product. Given the uncertainties of these extended collaboration arrangements, significant judgment is required to determine the duration of the performance period. For license and collaboration arrangements where no future performance obligations exist, up-front, nonrefundable fees and milestone payments are recognized when received. Any amounts received in advance of performance are recorded as deferred revenue until recognized.

The Company may provide research and development services under collaboration arrangements to advance the development of jointly owned products. The Company records the expenses incurred and reimbursed on a net basis.

(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.

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

(g) Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is provided against net deferred tax assets if, based upon the available evidence, it is more likely than not that some or all of the net deferred tax assets will not be realized.
The Company recognizes the effect of income tax positions only if those positions are more likely than not of being sustained. Recognized income tax positions are measured at the largest amount that is greater than 50 percent likely of being realized. Changes in recognition or measurement are reflected in the period in which the change in judgment occurs. The Company records interest and penalties related to unrecognized tax benefits as a component of its income tax expense.

(h) Share-Based Payments

The Company recognizes stock-based compensation expense for grants of stock option awards, restricted stock units and restricted stock under the Company's Incentive Plan to employees 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 grants, 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 will vest, which is based on whether the Company considers the options' performance conditions to be probable of attainment. The Company's estimates of the number of performance-based options that will vest will be revised, if necessary, in subsequent periods. In addition, the Company grants stock options to nonemployee consultants from time to time in exchange for services performed for the Company. Equity instruments granted to nonemployees are subject to periodic revaluation over their vesting terms.

During November 2014, the Company modified 149,498 existing time-vested options of two terminated executives by extending the exercise period to three years from the date of modification under the terms of the executive's respective employment and severance agreements. Compensation expense of $166,000 was recorded as a result of the modification. On January 6, 2014, we modified 366,126 existing time-vested and performance options as well as restricted stock awards of two retiring board of directors by fully vesting all unvested equity awards and extending the exercise period to three years from the date of modification. Compensation expense of $836,000 was recorded as a result of the modification. On January 31, 2013, the Company modified 907,336 existing time-vested and performance stock options by lowering the exercise price to $2.81. Additionally, the Company modified the vesting terms for its unvested performance stock options and unvested restricted stock to vest on the earlier of the first dosing in the pivotal clinical study for its lead drug candidate, or 50% on January 31, 2014 and 50% on January 31, 2015. Compensation expense of $422,000 was recorded as a result of the modifications. In August 2013, the Company determined that it was probable that the performance milestone related to these unvested stock options and restricted stock awards would occur. As a result, the remaining compensation expense between the date the milestone became probable and the expected milestone date of February 2014 was recognized ratably over that period.

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 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 $1.9 million and $979,000 for the years ended December 31, 2014 and 2013, allocated as follows:

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

	Year Ended December 31,	
	2014	2013
Research and development	$ 579,711	$ 303,177
General and administrative	1,313,124	675,974
	$ 1,892,835	$ 979,151

In 2014, the Company issued 337,689 stock options. In 2013, the Company issued 354,027 stock options, 15,000 restricted stock units and 12,000 restricted stock awards.

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 was based on a combination of the Company's trading history since March 2014 and the average of similar public companies.

For options granted in 2014 and 2013, the Company calculated the fair value of each option grant on the respective dates of grant using the following weighted average assumptions:

	2014	2013
Expected term	5.87 years	5.88 years
Risk-free interest rate	1.75%	1.38%
Expected dividend yield	—	—
Expected volatility	76.30%	68.27%

Financial Accounting Standards Board ("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, 2014, there was $1.6 million of total unrecognized compensation cost related to unvested share-based compensation arrangements granted under the Company's stock option plan. That cost is expected to be recognized over a weighted average period of 2.44 years and will be adjusted for subsequent changes in estimated forfeitures. The weighted average fair value of share-based compensation awards granted during the year ended December 31, 2014 was approximately $5.45.

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

(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.

For prepaid and other current assets, related-party receivable, accounts payable, and accrued expenses, the carrying amounts approximate fair value because of the short maturity of these instruments.

At December 31, 2014, the Company did not have any assets and liabilities that were measured at fair value on a recurring basis using quoted prices in active markets for identical instruments (Level 1), significant other observable inputs (Level 2), and significant unobservable inputs (Level 3). 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, 2013:

		Fair value measurements at reporting date using		
	December 31, 2013	Level 1 inputs	Level 2 inputs	Level 3 inputs
Assets:				
Cash equivalents-money market funds	$ 1,933,480	$ 1,933,480	$ -	$ -
	$ 1,933,480	$ 1,933,480	$ -	$ -

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 with original maturities to the Company of three months or less, and are purchased daily at par value with specified yield rates. Due to the high ratings and short-term nature of the funds, the Company considers all cash equivalents as Level 1.

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 for the years ended December 31, 2014 or 2013.

(3) 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. Net income (loss) available to common shareholders for the year ended December 31, 2014 and 2013 was calculated using the two-class method, which is an earnings (loss) allocation method for computing earnings (loss) per share when an entity's capital structure includes common stock and participating securities. The two-class method determines earnings (losses) per share based on dividends declared on common stock and participating securities (i.e., distributed earnings) and participation rights of participating securities in any undistributed earnings (loss). The application of the two-class method was required since the Company's unvested restricted stock contains non-forfeitable rights to dividends or dividend equivalents. However, unvested restricted stock grants are not included in computing basic earnings (loss) per share for periods where the Company has losses as these securities are not contractually obligated to share in losses of the Company.

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 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, 2014 and 2013..

	Year Ended December 31,	
	2014	**2013**
Basic loss per share attributable to common stock:		
Numerator		
Net loss	$ (20,372,676)	$ (10,590,106)
Denominator		
Weighted avg. common shares outstanding	12,766,295	7,363,076
Basic loss per share attributable to common stock	$ (1.60)	$ (1.44)
Diluted loss per share attributable to common stock:		
Numerator		
Net loss	$ (20,372,676)	$ (10,590,106)
Denominator		
Weighted avg. common shares outstanding	12,766,295	7,363,076
Diluted loss per share attributable to common stock	$ (1.60)	$ (1.44)

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

The computation of diluted earnings per share for the years ended December 31, 2014 and 2013 does not include the following unvested restricted stock awards, restricted stock units, stock options and warrants to purchase shares in the computation of diluted earnings per share because these instruments were antidilutive:

	December 31,	
	2014	**2013**
Stock options	1,528,737	1,264,345
Unvested restricted stock	7,000	103,784
Unvested restricted stock units	-	15,000
Warrants	20,467	20,467

(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.

(4) Collaborative 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.). 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 1.5% royalty on net sales should Lipocine decide to use certain Solvay/Abbott formulations or a perpetual 1% royalty on net sales should Lipocine use data generated during the term of the Solvay/Abbott agreement in any regulatory filings for a product. 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, 2014 and 2013.

(4) Collaborative Agreements – (continued)

(b) Nexgen Pharma, Inc.

On May 21, 2011, the Company entered into a collaborative product development agreement with Nexgen Pharma, Inc. (“Nexgen”). Under the agreement, the parties agreed to jointly develop certain products for the treatment of coughs and colds and to share future revenues from those products. Nexgen agreed to reimburse the Company at cost for all future clinical costs incurred in the development of the products. The Company is responsible for certain new drug application (“NDA”) filing costs with the Food and Drug Administration (“FDA”) under terms of this contract and, additionally, will participate on a joint steering committee with Nexgen for the development, regulatory, and manufacturing strategy of product candidates. On July 23, 2013, the Company transferred all rights and obligations under this agreement to Spriaso, LLC ("Spriaso") (see note 11). As a result, the Company was not entitled to reimbursement for any amounts during the year ended December 31, 2014, while Nexgen reimbursed the Company for a total of $468,000 during the year ended December 31, 2013 for related expenses under the agreement, which the Company recorded, net, as research and development expense.

(c) Contract Research and Development

The Company has entered into agreements with various contract organizations that conduct preclinical, clinical, analytical and manufacturing development work on behalf of the Company as well as a number of independent contractors, primarily clinical researchers, who serve as advisors to the Company. The Company incurred expenses of $12.9 million and $3.4 million under these agreements in 2014 and 2013 and has recorded these expenses in research and development expenses.

(5) Property and Equipment

Property and equipment consisted of the following:

	December 31, 2014	December 31, 2013
Lab and office equipment	$ 41,792	$ 36,755
Computer equipment and software	1,014,615	960,044
Furniture and fixtures	51,404	51,404
	1,107,811	1,048,203
Less accumulated depreciation	(1,034,029)	(1,019,409)
	$ 73,782	$ 28,794

Depreciation and amortization expense for the years ended December 31, 2014 and 2013 was $15,000 and $22,000.

(6) Income Taxes

(a) Income Tax Expense

Income tax expense consists of:

	Current	Deferred	Total
Year ended December 31, 2014:			
State and local	$ 200	$ -	$ 200
	$ 200	$ -	$ 200
Year ended December 31, 2013:			
U.S. federal	$ (55,148)	$ -	$ (55,148)
State and local	100	-	100
	$ (55,048)	$ -	$ (55,048)

(b) Tax Rate Reconciliation

Income tax expense (benefit) was $200 and ($55,000) for the years ended December 31, 2014 and 2013 and differed from the amounts computed by applying the U.S. federal income tax rate of 34% to pretax income from continuing operations as a result of the following:

	December 31,	
	2014	2013
Computed "expected" tax benefit	$ (6,926,642)	$ (3,619,353)
Increase (reduction) in income taxes resulting from:		
Change in valuation allowance	7,748,579	(493,355)
Loss of tax attributes due to change in ownership	(127,572)	3,540,653
Transaction fees	-	394,803
Settlement for termination of stock rights	-	310,572
State and local income taxes, net of federal income tax benefit	132	66
Stock expense	45,097	85,270
Research and development tax credits	(743,186)	(227,189)
Other, net	3,792	(46,515)
	$ 200	$ (55,048)

(6) 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, 2014 and 2013 are presented below.

	December 31, 2014	December 31, 2013
Deferred tax assets:		
Stock-based compensation	$ 1,851,668	$ 1,152,904
Net operating loss carryforwards	17,479,654	10,041,416
Employee benefits	41,568	59,505
Research and development tax credits	1,419,165	410,490
Other deductible tempory differences	97,656	-
Total gross deferred tax assets	20,889,711	11,664,315
Less valuation allowance	(20,886,811)	(11,660,247)
Net deferred tax assets	2,900	4,068
Deferred tax liabilities:		
Plant and equipment	(2,900)	(4,068)
Total gross deferred tax liabilities	(2,900)	(4,068)
Net deferred tax liabilities	$ -	$ -

On December 19, 2014, the Tax Increase Prevention Act of 2014, which includes an extension of the research and experimentation tax credit for amounts paid or incurred through December 31, 2014, retroactive to January 1, 2014, with no substantive changes to the credit, was signed into law.

The valuation allowance for deferred tax assets as of December 31, 2014 and 2013 was $20.9 million and $11.7 million. The net change in the valuation allowance was an increase of $9.2 million and $41,000 in 2014 and 2013. 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.

(6) Income Taxes – (continued)

As of December 31, 2014, we had NOL and research and development credit carryforwards for U.S. federal income tax reporting purposes of approximately $44.1 million and $911,000, respectively. Approximately $10.2 million of the NOLs will begin to expire in 2023 with the balance expiring from 2024 through 2034 and the research and development credits will expire in 2034.

We also have state NOL and research and development credit carry-forwards of approximately $50.0 million and $508,000, respectively. Approximately $12.4 million of the Company's state NOLs expire in 2018 with the remaining balance expiring from 2019 through 2029. The state research and development credits expire in 2023 through 2028.

The Company's federal and state income tax returns for December 31, 2011 through 2014 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, 2014 and 2013 are as follows:

	December 31	
	2014	2013
Balance, beginning of year	$ -	$ 28,304
Balance, end of year	$ -	$ -

The unrecognized tax contingency has been reversed in the 2013 tax provision to reflect the Company’s ability to afford itself of tax law which negates the contingency.

(7) Leases

On August 6, 2004, the Company assumed a noncancelable operating lease for office space and laboratory facilities. On May 6, 2014, the Company modified and extended the lease through February 28, 2018.

Future minimum lease payments under the noncancelable operating lease as of December 31, 2014 are:

	Operating leases
Year ending December 31:	
2015	285,756
2016	294,373
2017	303,119
2018	51,903
Total minimum lease payments	$ 935,151

The Company’s rent expense was $327,000 and $356,000 for the years ended December 31, 2014 and 2013.

(8) Stockholders’ Equity

(a) Issuance of Common Stock

On July 24, 2013, the Company issued 152,241 shares of common stock to an existing shareholder for the termination of certain rights, including an anti-dilutive provision, contained in its stock purchase agreement. As a result of the common stock issuance, the Company recorded an operating expense of $913,446 during the year ended December 31, 2013.

(8) Stockholders' Equity – (continued)

On July 30, 2013, the Company sold 6,336,664 shares of common stock to certain accredited investors. Net proceeds to the Company from the sale totaled approximately $35.7 million, after deducting the direct and incremental expenses of the offering and the commissions in connection with the offering paid by the Company of $2.3 million. On November 29, 2013 and December 6, 2013, the Company sold 1,715,800 shares of common stock in an underwritten offering. Net proceeds to the Company from the sale totaled approximately $12.5 million, after deducting the direct and incremental expenses of the offering and the commissions in connection with the offering paid by the Company of $1.6 million.

(b) 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. In January 2011, the board of directors adopted the 2011 Plan that provides for the granting of nonqualified and incentive stock options, restricted stock units and restricted stock. The 2011 Plan assumed all of the obligations, which existed under the previous 2000 Stock Option Plan. Under the 2011 Plan, the Company has granted nonqualified and incentive stock options for the purchase of common stock to directors, employees and nonemployees providing services to the Company. 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 1,271,906 shares are authorized for issuance under the 2014 Plan, with 1,020,076 shares remaining available for grant as of December 31, 2014.

A summary of stock option activity is as follows:

	Outstanding stock options	
	Number of shares	Weighted average exercise price
Balance at December 31, 2013	1,264,345	$ 3.25
Options granted	337,689	8.24
Options exercised	(20,205)	2.81
Options forfeited	(51,980)	7.72
Options cancelled	(1,112)	12.84
Balance at December 31, 2014	1,528,737	4.20
Options exercisable at December 31, 2014	1,143,920	3.14

The following table summarizes information about stock options outstanding and exercisable at December 31, 2014:

Options outstanding				Options exercisable			
Number outstanding	Weighted average remaining contractual life (Years)	Weighted average exercise price	Aggregate intrinsic value	Number exerciseable	Weighted average remaining contractual life (Years)	Weighted average exercise price	Aggregate intrinsic value
1,528,737	7.17	$ 4.20	$ 2,732,092	1,143,920	6.45	$ 3.14	$ 2,607,844

(8) Stockholders' Equity – (continued)

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, 2014 and 2013 was $87,000 and $12,000. There were 20,205 and 3,761 stock options exercised during the years ended December 31, 2014 and 2013.

(c) Restricted Common Stock

In 2010, the Company issued 112,720 shares of restricted common stock to employees. Ten percent of the issued restricted common stock vested on December 31, 2011. The remaining ninety percent of the restricted shares were modified on January 31, 2013 to vest on the earlier of the first dosing in the pivotal clinical study for its lead drug candidate, or 50% on January 31, 2014 and 50% on January 31, 2015. Compensation expense was recorded as a result of the modification (see note 8(b)). The grant date fair value of these shares when issued was $5.75 per share. The Company includes unvested restricted stock in outstanding shares for financial reporting purposes when the awards vest.

On June 28, 2013, the Company accelerated the vesting of 7,763 shares of restricted common stock and repurchased a combined total of 8,626 shares of common stock from six employees at a price of $6.16 per share. The acceleration of the vesting resulted in the recognition of $16,000 in stock-based compensation expense. The repurchased shares were retired during the reverse merger and charged against additional paid-in-capital (see note 2).

On September 16, 2013, the Company issued 12,000 shares of restricted common stock to an employee. These shares vest over time with one-third vesting on the one-year anniversary of award, with the balance vesting monthly on a pro-rata basis over the subsequent two years.

Additionally, restricted shares issued to two members of the board of directors were further modified upon their retirement on January 6, 2014 to fully vest unvested restricted shares. Compensation expense was recorded as a result of the modifications (see note 3(h)). The grant date fair value of these shares when issued was $5.75 per share.

A summary of restricted common stock activity is as follows:

	Number of unvested restricted shares
Balance at December 31, 2013	103,784
Granted	-
Vested	(96,784)
Cancelled	-
Balance at December 31, 2014	7,000

(8) Stockholders' Equity – (continued)

(d) Restricted Stock Units

On December 10, 2013, the Company issued 15,000 shares of restricted stock units to employees. These units cliff vest on December 31, 2014.

A summary of restricted stock unit activity is as follows:

	Restricted Stock Units
Balance at December 31, 2013	15,000
Granted	-
Vested	(15,000)
Cancelled	-
Balance at December 31, 2014	-

(e) Warrants

For charitable purposes, on December 23, 2003, the Company granted warrants to a local university for 20,467 shares of common stock at a price of $12.21 per share with an original expiration date of December 31, 2010. In January 2011, the Company extended the term to December 31, 2015 at the same price.

(9) 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. Prior to April 1, 2014, the 401(k) Plan permitted but did not require additional matching and profit sharing contributions to the 401(k) Plan by the Company on behalf of the participants. The Company contributed $48,000 to the 401(k) Plan during the year ended December 31, 2014 and did not make any contributions to the 401(k) Plan during the year ended December 31, 2013.

(10) Commitments and Contingencies

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.

(11) Agreement with Spriaso, LLC

On July 23, 2013, the Company entered into an assignment/license and a services agreement with Spriaso, LLC (“Spriaso”), a related-party that is majority-owned by two current directors of Lipocine Inc. and two former directors of Lipocine Inc. 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 Nexgen. In exchange, the Company will receive a royalty of 20 percent of the net proceeds received by Spriaso, up to a maximum of $10 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 will provide 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 , however the agreement may be extended upon written agreement of Spriaso and the Company. 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 FASB Accounting Standards Codification ("ASC") Topic 810-10, *Consolidations* , however the Company is not the primary beneficiary and has therefore not consolidated Spriaso.

(12) Recent Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update ("ASU") 2014-09, *Revenue from the Contracts with Customers* . Under the new standard, an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In order to do so, an entity would follow the five-step process for in-scope transactions: 1) identify the contract with a customer, 2) identify the separate performance obligations in the contract, 3) determine the transaction price, 4) allocate the transaction price to the separate performance obligations in the contract, and 5) recognize revenue when (or as) the entity satisfies a performance obligation. For public entities, the provisions of the new standard are effective for annual reporting periods beginning after December 15, 2016 and early adoption is not permitted. An entity can apply the new revenue standard retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying the standard recognized at the date of initial application in retained earnings. The Company is in the process of determining our approach to the adoption of this new revenue recognition standard, as well as the anticipated impact to the Company’s financial position or results of operations.

In August 2014, FASB issued ASU No. 2014-15, *Presentation of Financial Statements – Going Concern* . ASU 2014-15 provides guidance regarding management’s responsibility to evaluate whether there exists substantial doubt about an organization’s ability to continue as a going concern and to provide related footnote disclosures in certain circumstances. The standard is effective for annual reporting periods beginning after December 15, 2016, and interim periods thereafter. The Company does not believe this pronouncement will have a material effect on the Company's financial position or results of operations.

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, 2014.

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, 2014. 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 (1992)* . Based on our assessment we believe that, as of December 31, 2014, our internal control over financial reporting is effective based on those criteria.

Change in Internal Control over Financial Reporting

During the year ended December 31, 2014, 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 2015 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 2015 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 2015 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 2015 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 2015 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

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
4.1	Form of Common Stock certificate	8-K	333-178230	4.1	7/25/2013
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	8-K	000-379633	10.1	5/27/2014
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	Warrant issued to University of Utah, as amended, dated December 23, 2003	8-K	333-178230	10.7	7/25/2013
10.10	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
10.11	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
10.12	Form of Securities Purchase Agreement, dated July 26, 2013	8-K	333-178230	10.10	7/31/2013
10.13	Form of Registration Rights Agreement, dated July 26, 2013	8-K	333-178230	10.11	7/31/2013
10.14+	Manufacturing Agreement, dated August 27, 2013, by and between Lipocine Inc. and Encap Drug Delivery.	8-K	333-178230	10.12	9/5/2013
10.15**	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
10.16**	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
10.17**	Executive Employment Agreement, dated January 7, 2014, by and between Lipocine Inc. and Gerald Simmons	8-K	000-55092	10.3	1/7/2014
10.18**	Executive Employment Agreement, dated January 7, 2014, by and between Lipocine Inc. and Dr. Srinivasan Venkateshwaran	8-K	000-55092	10.4	1/7/2014
21.1 *	Subsidiaries				
31.1 *	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
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. (1)				
32.2 *	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. 1350. (1)				

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
101.INS *	XBRL Instance Document (2)				
101.SCH *	XBRL Taxonomy Extension Schema Document (2)				
101.CAL *	XBRL Taxonomy Extension Calculation Linkbase Document (2)				
101.DEF *	XBRL Taxonomy Extension Definition Linkbase Document (2)				
101.LAB *	XBRL Taxonomy Extension Labels Linkbase Document (2)				
101.PRE *	XBRL Taxonomy Extension Presentation Linkbase Document (2)				

* 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.

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 11, 2015

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

Dated: March 11, 2015

/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.

Signature	Title	Date
/s/ Mahesh V. Patel Mahesh V. Patel	President and Chief Executive Officer (Principal Executive Officer) and Chairman of the Board	March 11, 2015
/s/ Morgan R. Brown Morgan R. Brown	Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 11, 2015
/s/ Jeffrey A. Fink Jeffrey A. Fink	Director	March 11, 2015
/s/ John Higuchi John Higuchi	Director	March 11, 2015
/s/ Stephen A. Hill Stephen A. Hill	Director	March 11, 2015
/s/ R. Dana Ono R. Dana Ono	Director	March 11, 2015

EXHIBIT 21.1

SUBSIDIARIES

Lipocine Operating Inc.

EXHIBIT 31.1

CERTIFICATIONS

I, Mahesh V. Patel, certify that:

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

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

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

4. The registrant's other certifying officer(s) 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 11, 2015

/s/ Mahesh V. Patel

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

EXHIBIT 31.2

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(s) 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 11, 2015

/s/ Morgan R. Brown

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

EXHIBIT 32.1

CERTIFICATION

In connection with the Annual Report on Form 10-K of Lipocine Inc. (the "Corporation") for the year ended December 31, 2014 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 11, 2015

/s/ Mahesh V. Patel

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

EXHIBIT 32.2

CERTIFICATION

In connection with the Annual Report on Form 10-K of Lipocine Inc. (the "Corporation") for the quarter ended December 31, 2014 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 11, 2015

/s/ Morgan R. Brown

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