SOLOMON ABADY, Individually and On Behalf of All Others Similarly Situated, 
Plaintiff, 

v. 

LIPOCINE INC., MAHESH V. PATEL, and MORGAN R. BROWN, 
Defendants. 

CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS 

JURY TRIAL DEMANDED 

Civil No. 2:19-cv-00906-PMW 
Honorable Paul M. Warner 
United States Magistrate Judge
Plaintiff Solomon Abady (“Plaintiff”), individually and on behalf of all other persons similarly situated, by Plaintiff’s undersigned attorneys, for Plaintiff’s complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff’s own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff’s attorneys, which included, among other things, a review of the Defendants’ public documents, conference calls and announcements made by Defendants, United States (“U.S.”) Securities and Exchange Commission (“SEC”) filings, wire and press releases published by and regarding Lipocine Inc. (“Lipocine” or the “Company”), analysts’ reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

**NATURE OF THE ACTION**

1. This is a federal securities class action on behalf of a class consisting of all persons other than Defendants who purchased or otherwise acquired Lipocine securities between March 27, 2019, and November 8, 2019, both dates inclusive (the “Class Period”), seeking to recover damages caused by Defendants’ violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”) and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. Headquartered in Salt Lake City, Utah, Lipocine is a specialty pharmaceutical company that focuses on the development of pharmaceutical products in the area of men’s and women’s health. The Company’s primary development programs are based on oral delivery solutions for poorly bioavailable drugs. The Company has a portfolio of product candidates purportedly designed to produce pharmacokinetic characteristics and facilitate lower dosing
requirements, bypass first-pass metabolism in certain cases, reduce side effects, and eliminate gastrointestinal interactions that limit bioavailability.

3. Lipocine’s lead product candidate is TLANDO (LPCN 1021), an oral testosterone replacement therapy. The Company has previously submitted New Drug Applications (“NDA”) for TLANDO twice and, both times, received Complete Response Letters (“CRL”) from the U.S. Food and Drug Administration (“FDA”) rejecting the NDAs. The Company received the first CRL in June 2016 and the second in May 2018.

4. On March 27, 2019, during pre-market hours, Lipocine issued a press release announcing new topline results from a study evaluating TLANDO’s effects on blood pressure (one issue cited by the FDA in a prior CRL rejecting TLANDO’s NDA), as well as the Company’s intention to refile the NDA for TLANDO in the second quarter of 2019 (the “March 2019 Press Release”).

5. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company’s business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the results from Lipocine’s clinical studies of TLANDO were insufficient to demonstrate the drug’s efficacy; (ii) accordingly, Lipocine’s third NDA for TLANDO was highly likely to be found deficient by the FDA; and (iii) as a result, the Company’s public statements were materially false and misleading at all relevant times.

6. On November 11, 2019, Lipocine issued a press release announcing receipt of a CRL from the FDA regarding its NDA for TLANDO (the “November 2019 Press Release”). In that press release, Lipocine advised investors that the FDA had again rejected the NDA for
TLANDO—this time because an efficacy trial had not met three of its secondary endpoints.

Specifically, the November 2019 Press Release stated, in relevant part:

Lipocine . . . announced today that it has received a [CRL] from the [FDA] regarding its [NDA] for TLANDO™, the Company’s oral testosterone product candidate for testosterone replacement therapy (“TRT”) in adult males for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism. A CRL is a communication from the FDA that informs companies that an application cannot be approved in its present form.

The CRL identified one deficiency stating the efficacy trial did not meet the three secondary endpoints for maximal testosterone concentrations (“Cmax”). The CRL does not identify any specific issues relating to the chemistry, manufacturing and controls (“CMC”) of TLANDO.

“We are disappointed by the FDA’s decision and intend to request a meeting with the FDA as soon as possible to discuss a potential path forward for the approval of TLANDO,” said Dr. Mahesh Patel, Chairman, President and Chief Executive Officer of Lipocine.

(Emphasis added.)

7. On this news, Lipocine’s stock price fell $1.93 per share, or 70.7%, to close at $0.80 per share on November 11, 2019.

8. As a result of Defendants’ wrongful acts and omissions, and the precipitous decline in the market value of the Company’s securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

9. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act.
11. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Lipocine is headquartered in this Judicial District, Defendants conduct business in this Judicial District, and a significant portion of Defendants’ activities took place within this Judicial District.

12. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

13. Plaintiff, as set forth in the attached Certification, acquired Lipocine securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

14. Defendant Lipocine is a Delaware corporation with its principal executive offices located at 675 Arapeen Drive, Suite 202, Salt Lake City, Utah 84108. The Company’s securities trade in an efficient market on the NASDAQ Stock Market (“NASDAQ”) under the ticker symbol “LPCN.”

15. Defendant Mahesh V. Patel (“Patel”) has served as Lipocine’s President and Chief Executive Officer at all relevant times.

16. Defendant Morgan R. Brown (“Brown”) has served as Lipocine’s Executive Vice President and Chief Financial Officer at all relevant times.

17. Defendants Patel and Brown are sometimes referred to herein collectively as the “Individual Defendants.”
18. The Individual Defendants possessed the power and authority to control the contents of Lipocine’s SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of Lipocine’s SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with Lipocine, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

**SUBSTANTIVE ALLEGATIONS**

**Background**

19. Headquartered in Salt Lake City, Utah, Lipocine is a specialty pharmaceutical company that focuses on the development of pharmaceutical products in the area of men’s and women’s health. The Company’s primary development programs are based on oral delivery solutions for poorly bioavailable drugs. The Company has a portfolio of product candidates purportedly designed to produce pharmacokinetic characteristics and facilitate lower dosing requirements, bypass first-pass metabolism in certain cases, reduce side effects, and eliminate gastrointestinal interactions that limit bioavailability.

20. Lipocine’s lead product candidate is TLANDO (LPCN 1021), an oral testosterone replacement therapy. The Company has previously submitted NDAs for TLANDO twice and, both times, received CRLs from the FDA rejecting the NDAs. The Company received the first CRL in June 2016 and the second in May 2018.
21. On March 27, 2019, during pre-market hours, Lipocine issued a press release announcing new topline results from a study evaluating TLANDO’s effects on blood pressure (one issue cited by the FDA in a prior CRL rejecting TLANDO’s NDA), as well as the Company’s intention to refile the NDA for TLANDO in the second quarter of 2019.

**Materially False and Misleading Statements Issued During the Class Period**

22. The Class Period begins on March 27, 2019, when Lipocine issued the March 2019 Press Release, touting “findings from the Ambulatory Blood Pressure Monitoring clinical study (NCT03868059)” (“ABPM Study”) “designed to study TLANDO’s effects on blood pressure,” the objective of which “was to characterize blood pressure effects of TLANDO for appropriate [FDA] regulatory action, including Risk Evaluation and Mitigation Strategy (‘REMS’) beyond labeling.” Defendant Patel, as quoted in the March 2019 Press Release, touted TLANDO’s performance in the ABPM Study, stating that Defendants were “pleased with the TLANDO pressor results which [Defendants] believe are in line with a recently approved testosterone replacement therapy.”

23. Also as quoted in the March 2019 Press Release, Defendant Patel announced that Defendants “look forward to resubmitting [the TLANDO] NDA in the second quarter of 2019” and touted that Defendants “remain committed on bringing [their] patient-friendly oral testosterone product candidate to patients in a timely manner.” These statements indicated to investors that Defendants had finally amended the deficiencies from their previously-failed NDA submissions for TLANDO, were confident in resubmitting the NDA for TLANDO to the FDA, and still held high prospects for the commercialization of TLANDO.

24. On May 8, 2019, Lipocine issued a press release announcing the Company’s financial and operating results for its first fiscal quarter of 2019, which was also appended as an
exhibit to a Current Report on Form 8-K filed with the SEC on the same day, and signed by Defendant Patel (the “1Q19 Press Release”). That press release highlighted the “[a]nnounced findings from the [ABPM Study] designed to study TLANDO’s effects on blood pressure,” noting again that “[t]he results appear in line with recently approved testosterone replacement therapy.”

25. The 1Q19 Press Release also quoted Defendant Patel, who proclaimed “important milestones in Lipocine’s most advanced clinical programs during the first quarter of 2019, and in recent weeks,” and assured investors that “[w]ith the successful completion of the ABPM study for TLANDO, [Defendants] look forward to resubmitting [the] NDA for TLANDO in May 2019.”

26. That same day, Lipocine filed a Quarterly Report on Form 10-Q with the SEC, reporting the Company’s financial and operating results for the quarter ended March 31, 2019 (the “1Q19 10-Q”). The 1Q19 10-Q provided a summarized overview the FDA’s previous CRLs issued in response to the NDA for TLANDO, noted the deficiencies addressed in those CRLs, the Company’s subsequent meetings with the FDA to understand how to remediate those deficiencies, and assured investors that, now that the Company had completed studies addressing these deficiencies, the Company was ready to resubmit its NDA for TLANDO. Specifically, the 1Q19 10-Q stated, in relevant part:

On May 8, 2018 TLANDO received a [CRL] from the [FDA] regarding its [NDA] . . . . The CRL identified four deficiencies which include the following: determining the extent, if any, of any clinically meaningful ex vivo conversion of testosterone undecanoate (“TU”) to testosterone (“T”) in serum blood collection tubes to confirm the reliability of T data; obtaining definitive evidence pre-approval via an [ABPM] study as to whether TLANDO causes a clinically meaningful increase in blood pressure in hypogonadal men which is a surrogate marker of predicting cardiovascular outcomes; verifying the reliability of Cmax data and providing justification for non-applicability of the agreed-upon and prespecified Cmax secondary endpoints for TLANDO; and, determining the appropriate stopping criteria that can reproducibly and accurately identify those patients who should discontinue use of TLANDO. The CRL also identified additional comments that are not considered approvability issues. On July 19, 2018, we completed a Post Action Meeting with the FDA in which the deficiencies raised in the CRL were
discussed and a path forward for NDA resubmission for the potential approval of TLANDO was clarified. We recently completed an ABPM clinical study in which 138 subjects were enrolled with a four-month treatment duration. Additionally, we completed a definitive phlebotomy study in the fourth quarter of 2018 which evaluated the extent of *ex vivo* conversion of TU to T. Previously in June 2016, TLANDO received an initial CRL from the FDA that requested additional information related to the dosing algorithm for the proposed label. We conducted the Dosing Validation (“DV”) study to confirm the efficacy of TLANDO with a fixed dose regimen without need for dose adjustment. TLANDO was well tolerated upon 52-week exposure with no reports of drug related Serious Adverse Events (“SAEs”).

27. In a section dedicated to detailing the CRL that Lipocine received from the FDA in June 2016, and the Company’s remedial steps taken to cure the deficiencies identified therein, the 1Q19 10-Q stated, in relevant part:

On June 28, 2016, we received a CRL from the FDA on our original NDA submission . . . . The CRL identified a deficiency related to the dosing algorithm for the label. Specifically, the proposed titration scheme for clinical practice was significantly different from the titration scheme used in the Phase 3 trial leading to discordance in titration decisions between the Phase 3 trial and real-world clinical practice. In response to the CRL, we met with the FDA in a Post Action meeting and proposed a dosing regimen to the FDA based on analyses of existing data. The FDA noted that while the proposed dosing regimen might be acceptable, validation in a clinical trial would be needed prior to resubmission. The DV study was in response to the FDA’s request. We also initiated the Dosing Flexibility (“DF”) study to assess TLANDO in hypogonadal males on a fixed daily dose of 450 mg divided into three equal doses.

We resubmitted our NDA to the FDA in August 2017 based on the results of the DV study. As described more fully below, the DV study confirmed the efficacy of TLANDO with a fixed dose regimen without need for dose adjustment. TLANDO was well tolerated upon 52-week exposure with no reports of drug related Serious Adverse Events (“SAEs”).

28. In a section dedicated to detailing the CRL that Lipocine received from the FDA in May 2018, the 1Q19 Press Release stated, in relevant part:

On May 8, 2018 TLANDO received a CRL from the FDA regarding our NDA. The CRL identified four deficiencies which include the following: determining the extent, if any, of *ex vivo* conversion of TU to T in serum blood collection tubes to confirm the reliability of T data; obtaining definitive evidence pre-approval via an ABPM study as to whether TLANDO causes a clinically meaningful increase in
blood pressure in hypogonadal men, which is a surrogate marker of predicting cardiovascular outcomes; verifying the reliability of Cmax data and providing justification for non-applicability of the agreed-upon and prespecified Cmax secondary endpoints for TLANDO; and, determining the appropriate stopping criteria that can reproducibly and accurately identify those patients who should discontinue use of TLANDO. The CRL also identified additional comments that are not considered approvability issues.

29. In that same section, and with specific respect to Lipocine’s remedial steps taken to cure the deficiencies identified in the CRL received in May 2018, the 1Q19 10-Q stated, in relevant part:

On July 19, 2018, we completed a Post Action Meeting with the FDA in which the deficiencies raised in the CRL were discussed and a path forward for NDA resubmission for the potential approval of TLANDO was clarified. The FDA provided specific feedback on potential resolution of each deficiency, including clinical design elements where appropriate. We have completed an ABPM clinical study in which we enrolled 138 subjects. The ABPM clinical study was uncontrolled and was conducted to assess TLANDO’s effect on blood pressure and to assist the FDA in determining the appropriate regulatory actions for TLANDO related to blood pressure effects, including Risk Evaluation and Mitigation Strategy (“REMS”) beyond labeling. Results from the ABPM Study are in line with a recently approved testosterone replacement therapy. Subsequent to our Advisory Committee meeting for TLANDO on January 10, 2018, we conducted a pilot phlebotomy study to assess whether ex vivo conversion of TU to T in serum blood collection tubes occurs post collection. As described more fully below, we completed our definitive phlebotomy study in the fourth quarter of 2018 based on FDA study design feedback to exclude any potential clinically meaningful ex vivo TU to T conversion post collection. The definitive phlebotomy study results suggest that there is no significant ex vivo TU to T conversion with testosterone measurements when processed within 30 minutes of sample collection under the tube manufacturer’s recommended conditions and consistent with DV Phase 3 instructions and compared against the FDA’s recommended time zero control (processed immediately) T measurement. Finally, we are performing additional analyses of existing data in order to address the Cmax deficiency and dose stopping criteria deficiency identified by the FDA. Although there is no guarantee that TLANDO will ever be approved by the FDA, we believe the data analyses we are performing together with the results from the definitive phlebotomy study and the ABPM clinical study should address the deficiencies identified by the FDA in its CRL.

(Emphases added.)
30. The 1Q19 10-Q also addressed, at length, the various studies Lipocine conducted with TLANDO to cure the defects identified in the previously received CRLs. However, notwithstanding the Company’s remedial clinical studies, conducted with the benefit of “specific feedback on potential resolution of each deficiency, including clinical design elements where appropriate,” the 1Q19 10-Q contained merely generic, boilerplate representations concerning the possibility that Lipocine could receive another CRL for TLANDO’s NDA. In this regard, the 1Q19 10-Q stated, in relevant part:

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

TLANDO is currently our only product candidate that has completed Phase 3 clinical trials, and our business currently depends primarily on its successful development, regulatory approval and commercialization, if approved. We submitted an NDA to the FDA and have received two CRL’s but have not submitted comparable applications to other regulatory authorities. If the FDA denies or further delays approval of TLANDO, our business would be materially and adversely harmed. If the FDA does approve TLANDO, but we are unsuccessful in commercializing TLANDO, our business will be materially and adversely harmed.

Although we have completed Phase 3 efficacy trials with TLANDO, approval from the FDA is not guaranteed. [ . . . ]

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[ . . . ] The FDA may not accept the resubmitted TLANDO NDA due to a variety of reasons, including not addressing all the previously identified deficiencies or not including all requested clinical data, including clinical study reports.

Even if we resubmit our NDA for TLANDO, we may receive another CRL from the FDA which would result in substantial delays and additional studies and expense before we would be in a position to resubmit an NDA responsive to such additional CRL. Our ability to raise capital may also be impaired. If we proceed with any study, we face the risk that the FDA would not agree with the design or results of the study. In addition, the results from the ABPM clinical study may find that TLANDO’s effects on blood pressure are clinically meaningful and approval of TLANDO may never occur.
The FDA may also ask us to perform additional clinical trials or studies, either pre- or post- approval, or provide additional information in order to secure approval. Any such requirement would increase our costs and delay approval and commercialization of TLANDO and would have a material adverse effect on our business and financial condition.

(Emphasis in original.) Plainly, the foregoing risk warning was a generic “catch-all” provision that was not tailored to Lipocine’s actual known risks with respect to the resubmission of its NDA for TLANDO. Specifically, despite meeting with the FDA at least twice to discuss issues with the NDA for TLANDO, during which the FDA provided directed feedback on how to cure the NDA, the foregoing risk warning completely failed to address an efficacy trial’s failure to meet three secondary endpoints for maximal testosterone concentrations.

31. Appended as exhibits to the 1Q19 10-Q were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 (“SOX”), wherein the Individual Defendants certified that “[t]he [1Q19 10-Q] fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended,” and that “[t]he information contained in the [1Q19 10-Q] fairly presents, in all material respects, the financial condition and results of operations of the Corporation.”

32. On May 14, 2019, Lipocine issued a press release announcing the FDA’s acceptance of the Company’s NDA for TLANDO and the receipt of a Prescription Drug User Fee Act (“PDUFA”) action date of November 9, 2019. That press release touted, in relevant part:

Lipocine . . . today announced that the [FDA] has accepted its [NDA] for TLANDO as testosterone replacement therapy (“TRT”) in adult males for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism. The FDA has assigned November 9, 2019 as the [PDUFA] goal date.

In 2018, approximately 7.2M scripts were written for non-oral TRT. An easy to use non-invasive oral TRT option has benefit over topicals due to no risk of accidental testosterone transference. TLANDO is designed as a fixed dose oral TRT.
Research suggests that a fixed dose TRT regimen may be a preferred regimen by
payers, patients, and prescribers. [. . . ]

The NDA incorporates data compiled by Lipocine in order to address deficiencies
identified by the FDA in a [CRL] to the Company in 2018 and discussed in the Post
Action Meeting with the FDA.

33. On August 7, 2019, Lipocine issued a press release announcing the Company’s
financial and operating results for its second fiscal quarter of 2019, which was also appended as
an exhibit to a Current Report on Form 8-K filed with the SEC on the same day, and signed by
Defendant Patel (the “2Q19 Press Release”). That press release touted that the Company had
“[f]iled a[n] [NDA] for TLANDO™ as testosterone replacement therapy . . . in adult males for
conditions associated with a deficiency of endogenous testosterone, also known as
hypogonadism,” and that “[t]he FDA has assigned November 9, 2019 as the [PDUFA] goal date.”

34. The 2Q19 Press Release also quoted Defendant Patel, who touted “important
milestones achieved for . . . TLANDO” and asserted that “[t]he acceptance of the NDA for
TLANDO for treating hypogonadism in males puts [Defendants] on track for potential approval
of this product in the fourth quarter of 2019” and that “TLANDO is designed as a fixed dose oral
TRT.”

35. That same day, Lipocine filed a Quarterly Report on Form 10-Q with the SEC,
reporting the Company’s financial and operating results for the quarter ended June 30, 2019 (the
“2Q19 10-Q”). The 2Q19 10-Q contained statements identical, or else substantively identical, to
those quoted in ¶¶ 26-30 above.

36. Appended as exhibits to the 2Q19 10-Q were signed SOX certifications, wherein
the Individual Defendants certified that “[t]he [2Q19 10-Q] fully complies with the requirements
of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended,” and that “[t]he
information contained in the [2Q19 10-Q] fairly presents, in all material respects, the financial condition and results of operations of the Corporation.”

37. The statements referenced in ¶¶ 22-36 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company’s business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the results from Lipocine’s clinical studies of TLANDO were insufficient to demonstrate the drug’s efficacy; (ii) accordingly, Lipocine’s third NDA for TLANDO was highly likely to be found deficient by the FDA; and (iii) as a result, the Company’s public statements were materially false and misleading at all relevant times.

The Truth Begins to Emerge

38. On November 11, 2019, Lipocine issued a press release announcing receipt of a CRL from the FDA regarding its NDA for TLANDO. In that press release, Lipocine advised investors that the FDA had again rejected the NDA for TLANDO—this time because an efficacy trial had not met three of its secondary endpoints. Specifically, the November 2019 Press Release stated, in relevant part:

Lipocine . . . announced today that it has received a [CRL] from the [FDA] regarding its [NDA] for TLANDO™, the Company’s oral testosterone product candidate for testosterone replacement therapy (“TRT”) in adult males for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism. A CRL is a communication from the FDA that informs companies that an application cannot be approved in its present form.

The CRL identified one deficiency stating the efficacy trial did not meet the three secondary endpoints for maximal testosterone concentrations (“Cmax”). The CRL does not identify any specific issues relating to the chemistry, manufacturing and controls (“CMC”) of TLANDO.

“We are disappointed by the FDA’s decision and intend to request a meeting with the FDA as soon as possible to discuss a potential path forward for the approval of
TLANDO,” said Dr. Mahesh Patel, Chairman, President and Chief Executive Officer of Lipocine.

(Emphasis added.)

39. On this news, Lipocine’s stock price fell $1.93 per share, or 70.7%, to close at $0.80 per share on November 11, 2019.

40. As a result of Defendants’ wrongful acts and omissions, and the precipitous decline in the market value of the Company’s securities, Plaintiff and other Class members have suffered significant losses and damages.

**PLAINTIFF’S CLASS ACTION ALLEGATIONS**

41. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Lipocine securities during the Class Period (the “Class”); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

42. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Lipocine securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Lipocine or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.
43. Plaintiff’s claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants’ wrongful conduct in violation of federal law that is complained of herein.

44. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

45. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

   • whether the federal securities laws were violated by Defendants’ acts as alleged herein;

   • whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Lipocine;

   • whether the Individual Defendants caused Lipocine to issue false and misleading financial statements during the Class Period;

   • whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

   • whether the prices of Lipocine securities during the Class Period were artificially inflated because of the Defendants’ conduct complained of herein; and

   • whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

46. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.
47. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Lipocine securities are traded in an efficient market;
- the Company’s shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company’s securities; and
- Plaintiff and members of the Class purchased, acquired and/or sold Lipocine securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

48. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

49. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in Affiliated Ute Citizens of the State of Utah v. United States, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

**COUNT I**

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

50. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.
51. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

52. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Lipocine securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Lipocine securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

53. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Lipocine securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Lipocine’s finances and business prospects.

54. By virtue of their positions at Lipocine, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended
thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

55. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants’ knowledge and control. As the senior managers and/or directors of Lipocine, the Individual Defendants had knowledge of the details of Lipocine’s internal affairs.

56. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Lipocine. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Lipocine’s businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Lipocine securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Lipocine’s business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Lipocine securities at artificially inflated prices and relied upon the price of the securities,
the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

57. During the Class Period, Lipocine securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Lipocine securities at prices artificially inflated by Defendants’ wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Lipocine securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Lipocine securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

58. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

59. As a direct and proximate result of Defendants’ wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company’s securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

**COUNT II**

(Violations of Section 20(a) of the Exchange Act Against The Individual Defendants)
60. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

61. During the Class Period, the Individual Defendants participated in the operation and management of Lipocine, and conducted and participated, directly and indirectly, in the conduct of Lipocine’s business affairs. Because of their senior positions, they knew the adverse non-public information about Lipocine’s misstatement of income and expenses and false financial statements.

62. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Lipocine’s financial condition and results of operations, and to correct promptly any public statements issued by Lipocine which had become materially false or misleading.

63. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Lipocine disseminated in the marketplace during the Class Period concerning Lipocine’s results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Lipocine to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were “controlling persons” of Lipocine within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Lipocine securities.

64. Each of the Individual Defendants, therefore, acted as a controlling person of Lipocine. By reason of their senior management positions and/or being directors of Lipocine, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Lipocine to engage in the unlawful acts and conduct complained of herein. Each of the
Individual Defendants exercised control over the general operations of Lipocine and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

65. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Lipocine.

**PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys’ fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

**DEMAND FOR TRIAL BY JURY**

Plaintiff hereby demands a trial by jury.

Dated: November 14, 2019

PETERS | SCOFIELD

/s/ David W. Scofield
David W. Scofield

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