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Biotechnology
Company Update
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BUY

Matthew L. Kaplan; mkaplan@ladenburg.com
212.891.5247

LIPOCINE INC.

Positive Pre-NDA Meeting with FDA; Submission Timeline On-Track, BUY $24 PT

LPCN (NASDAQ)

Company & Market Data	
Closing Price (as of 03/24/2015):	$7.29
Rating:	BUY
Price Target:	$24.00
52 Week Range:	$3.70 - $10.35
Shares Outstanding (MM):	13
Market Capitalization (MM):	$94
Cash (MM):	$27.7
Fiscal Year End:	Dec

*Cash (MM): as of December 31, 2014

Estimates			
EPS	**2014A**	**2015E**	**2016E**
1Q	$(0.41)	$(0.25)	$(0.23)
2Q	$(0.55)	$(0.26)	$(0.24)
3Q	$(0.32)	$(0.28)	$(0.25)
4Q	$(0.32)	$(0.41)	$(0.08)
Full Year	$(1.60)	$(1.20)	$(0.80)
Revenue (MM)	$0.0	$0.0	$3.8

Chart Data: Bloomberg

Highlights

Following a positive pre-NDA meeting with FDA, LPCN reiterated 2H15 timeline to submit NDA for LPCN 1021. Based on the FDA's preliminary response from the pre-NDA meeting, LPCN does not expect to conduct any additional clinical studies other than the on-going labeling "food effect" study. The labeling "food effect" study is an open-label, randomized, crossover study evaluating bioavailability and pharmacokinetics of a single dose LPCN 1021 in 16 hypogonadal men as a function of four different fat content meals: fasting, low fat meal (~15% fat), standard meal (~20-35% fat) and high fat meal (~50% fat). LPCN expects to submit preliminary results from the ongoing “food effect” study to the FDA for review in 2Q15. In addition, LPCN has already completed a “food effect” study in 10 post-menopause women (who have negligible background testosterone level) and found that a meal fat content of ~15% - 19% provided sufficient absorption of LPCN 1021 without further enhance of absorption at higher fat content. These data suggested that LPCN 1021 could be sufficiently and reproducibly dosed at a broad range of meal fat contents of 15% or higher (ranging from low fat, standard or high fat meals) without specific restrictions. We look forward to data from the ongoing “food effect” study in hypogonadal men to confirm the prior results. LPCN also expects the one-year safety data from the pivotal Phase 3 SOAR study by mid-2015 and plans to submit NDA for LPCN 1021 in 2H15. Importantly, the FDA again indicated a cardiovascular risk study is not necessary for approval. If LPCN 1021 is approved, FDA suggested, at the appropriate time, LPCN could discuss the possibility of joining other sponsors of approved testosterone replacement therapy (TRT) for potential consortium study on cardiovascular risk of TRT. However, FDA has provided very little specifics regarding such a study.

FDA issued relatively benign label changes for approved testosterone products in early March 2015. The label changes for testosterone products instituted by the FDA include: 1) requiring manufacturers to change the labeling to clarify the approved uses of TRT; 2) add information to the labeling about a possible increased risk of heart attacks and strokes in patients taking testosterone; 3) ensure the correct diagnosis of hypogonadism which requires “laboratory evidence of low T levels measured on at least two separate mornings”; 4) the safety and efficacy of testosterone replacement therapy for age-related hypogonadism has not been established; and 5) the FDA is requiring manufacturers of approved testosterone products to conduct a well-designed clinical trial to more clearly address if there is an increased CV risk associated with these products.

We view the FDA’s definition of hypogonadism in new T label as still representing a broad label defining the use of TRT. Further, there are no specific contra-indications included in the new label for any specific patient type and no Black Box warning for CV risk. FDA also does not appear to be requiring clinical outcome studies for approval and is not requiring a CV risk assessment trial prior to approval. Overall, we believe there are no surprises in this announcement and the required label changes appear to be relatively benign. Consequently, we do not believe the Agency’s changes to the testosterone label will have a significant impact on the market size.

We reiterate our BUY rating and $24 price target.

Following a positive pre-NDA meeting with FDA, LPCN reiterated 2H15 timeline to submit NDA for LPCN 1021. Based on the FDA's preliminary response from the pre-NDA meeting, LPCN does not expect to conduct any additional clinical studies other than the on-going labeling "food effect" study. The labeling "food effect" study is an open-label, randomized, crossover study evaluating bioavailability and pharmacokinetics of a single dose LPCN 1021 in 16 hypogonadal men as a function of four different fat content meals: fasting, low fat meal (~15% fat), standard meal (~20-35% fat) and high fat meal (~50% fat). LPCN expects to submit preliminary results from the ongoing “food effect” study to the FDA for review in 2Q15. In addition, LPCN has already completed a “food effect” study in 10 post-menopause women (who have negligible background testosterone level) and found that a meal fat content of ~15% - 19% provided sufficient absorption of LPCN 1021, while a food fat content of above 19% did not further increase the absorption of LPCN 1021. These data suggested that LPCN 1021 could be sufficiently and reproducibly dosed at a broad range of meal fat contents at 15% or higher (ranging from low fat, standard or high fat meals) without specific restrictions. We look forward to data from the ongoing “food effect” study in hypogonadal men to confirm the prior results. LPCN also expects the one-year safety data from the pivotal Phase 3 SOAR study by mid-2015 and plans to submit NDA for LPCN 1021 in 2H15. Importantly, the FDA again indicated a cardiovascular risk study is not necessary for approval. If LPCN 1021 is approved, FDA suggested, at the appropriate time, LPCN could discuss the possibility of joining other sponsors of approved testosterone replacement therapy (TRT) for potential consortium study on cardiovascular risk of TRT. However, FDA has provided very little specifics regarding such a study.

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Specifically, the FDA noted TRT indication as: “FDA has approved testosterone products to replace testosterone in men who have low testosterone levels associated with certain medical conditions. Examples of these conditions include: Failure of the testicles to produce testosterone because of genetic problems or because of damage from chemotherapy; or Problems with the pituitary gland or part of the brain called the hypothalamus that control the production of testosterone by the testicles.”

We believe the FDA changes to the Testosterone Product Label are relatively benign: Importantly, we view the FDA’s definition of hypogonadism in new T label (detailed above) as still representing a broad label defining the use of TRT. Further, although the new label includes a more prominent warning of a possible increased risk of heart attack and strokes (CV risk was previously in the label) and language associated with the lack of safety and efficacy evidence of TRT in age related hypogonadism, there are no specific contra-indications included in the new label for any specific patient type and no Black Box warning for CV risk. In fact, in its communication the FDA specifically notes based on its review of five observational studies and two meta-analyses examining CV risk associated with TRT that the CV risk data are inconclusive and weak and therefore the FDA is requiring sponsors to complete a post approval CV risk study. The agency is encouraging current manufacturers to work together on a clinical trial to

examine if an increased risk exists associated with TRT. Further, based on this communication, the FDA does not appear to be requiring clinical outcome studies for approval and is not requiring a CV risk assessment trial prior to approval. Overall, we believe there are no surprises in this announcement and the required label changes appear to be relatively benign. Consequently, as the label changes are not overly restrictive and do not limit use to only primary hypogonadism, we do not believe the Agency's changes to the testosterone label will have a significant impact on the market size. We believe this FDA communication eliminates the uncertainty regarding how extensive the label changes and use restrictions would be and the corresponding overhang on LPCN and other companies involved in the space.

FDA Confirmed SOAR Study Acceptable for NDA Filing. In December 2014 and again in March 2015, Lipocine announced that FDA confirmed the design of the ongoing pivotal Phase 3 SOAR study of LPCN 1021 in hypogonadal men with low testosterone (T) is currently acceptable for NDA filing. The FDA reiterated the current standard TRT approval criteria (Table 1) will be applied for LPCN 1021, although acknowledged that it is still internally discussing the advice and recommendations from the FDA Advisory Committee held on September 17, 2014. FDA also did not specify if a label change will be applied to restrict TRT from using in "age-related low T". Importantly, FDA did not identify any additional clinical studies, neither outcome studies nor safety studies, for NDA filing of LPCN 1021. FDA did state that should any safety signal become apparent during analysis of SOAR study results or during the course of their review, it is possible that additional data may be required. Based on the FDA response, Lipocine does not anticipate the need to conduct additional studies above those previously agreed to with the FDA for NDA filing. We expect LPCN to have a pre-NDA meeting with the FDA in late March/early April 2015 which will allow the Company to again clarify if their proposed NDA package is sufficient. We look forward to the outcome of this meeting as it represents another opportunity to clarify and eliminate any perceived regulatory uncertainty.

The 13-week top-line SOAR study data have showed an approval clinical profile of LPCN 1021 under current TRT approval criteria. Among the Efficacy Population Set (EPS) (n=152), 88.2% of subjects achieved serum testosterone Cavg within the normal range (300-1140 ng/dL) with a lower bound of the 95% CI of 81.9%. Among the Safety Set (n=210) for sensitivity analysis, 80.0% of subjects had Cavg within the normal range with lower bound 95% CI of 73.8%. The secondary endpoints were generally consistent with FDA guidelines. 82.9% of EPS subjects showed T Cmax below 1500 ng/dL, which is slightly lower than FDA's 85% threshold. Three patients showed T Cmax over 2500 ng/dL, but all being transient, isolated and sporadic without reporting any AEs. Additionally, LPCN 1021 showed 4.6% of patients had Cmax between 1800 and 2500ng/dL, which met the FDA's criteria of <5%. Safety data were consistent with other TRT products. Safety assessment is continuing for the 52-week period, but 13-week safety data are consistent with other TRT products and comparable to the safety profile seen in Rextoro's pivotal study. We believe these data showed that LPCN 1021 has an efficacy profile as good or better than Androgel and Axiron and clearly superior to Clarus' oral testosterone Rextoro (Table 1). Given these positive SOAR top-line data and the Advisory Committee's consensus on strong need of oral testosterone, we believe LPCN 1021 will have a reasonable high probability of attaining FDA approval. Lipocine plans to submit LPCN 1021 NDA in 2H15 after completing the 52-week safety assessment, a food-effect study and CMC work.

Overview of SOAR Phase 3 study of LPCN 1021. In the randomized, open-label and active-controlled Phase 3 study, 315 subjects were enrolled in total with 210 randomized to LPCN 1021 and 105 to the active control Androgel, for 52 weeks of treatment. The active control is included for safety assessment. LPCN 1021 subjects were started at 225 mg Testosterone Undecanoate ("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 24 hour serum testosterone measured during weeks 3 and 7.

Primary statistical analysis was conducted on Efficacy Population Set (EPS) of 152 subjects, defined as subjects with at least one PK profile (full PK data include three PK profiles on week 3, 7 and 13) and no significant protocol violations. For subjects with less than three full PK profiles among EPS, missing PK data were imputed by last observation carried forward (LOCF). Sensitivity analysis was also performed on the ITT population (N=210) who had at least one dose of LPCN 1021 defined as Safety Set (SS). Among SS, patients with 1-2 PK profiles, LOCF was used to impute missing PK data, and patients without any PK profiles (patients who received a dose of LPCN 1021 but discontinued before the week 3 PK analysis) were considered treatment failures (worst scenario).

The primary endpoint was robustly achieved (Table 1). Among the EPS (N=152), 88.2% subjects achieved serum testosterone Cavg within the normal range (300-1140 ng/dL) with a coefficient of variance of 37% and a lower bound 95% CI of 81.9% (Table 1). Among the SS, 80.0% subjects achieved serum testosterone Cavg within the normal range (300-1140 ng/dL) with lower bound 95% CI of 73.8% (Table 1).

Table 1: Top-line SOAR Phase 3 Efficacy Data: LPCN 1021 Versus Other TRT

Endpoints	FDA Requirement	LPCN 1021 SOAR Results		Rextoro 12011 Study Results		Androgel 1.6%	Axiron
Primary Endpoints		Efficacy Population[1] (N=152)	Safety Set[2] (N=210)	Efficacy Population[3] (N=116)	Sensitivity Set[4] (N=133)	Efficacy sample[5] (N=179)	Completer Set[6] (N=138)
T $C_{ave\ (0\text{-}24hrs)}$ 300-1140ng/dl	≥75% of patients	88.2%	80.0%	75.0%	70.8%	81.6%	84.1%
Lower Bound 95% CI	≥65%	81.9%	73.8%	66.1%	62.7%	75.1%	78.0%
Secondary Endpoints							
T C_{max} ≤1500ng/dl	≥85% of patients	82.9%	NA	82.0%	NA	88.8%	94.8%
T C_{max} 1800-2500ng/dl	≤5% of patients	4.6%	NA	6.0%	NA	5.5%	3.0%
T C_{max} >2500ng/dl	0% of patients	2%[#]	NA	3.0%	NA	1.0%	0.7%

[1]: patients with > 1 PK profile (full PK data include 3 PK profiles) and no significant protocol deviation. LOCF(last observation carried forward) was used to impute data for patients with 1-2 PK profiles; [2]: all patients with at least one dose of LPCN 1021. For patients with 1-2 PK profiles, LOCF used; patients without PK profile were considered treatment failure. [3]: all patients with PK data at Day 114. [4]: Efficacy population plus 17 patients with PK data dat Day 30 and/or 72. LOCF was used to impute missing PK data on Day 114. [5]: all subjects with efficacy data for Day 112. No LOCF computation; [6]: all subjects with efficacy data for Day 120. No LOCF computation.

Source: Lipocine SOAR study top-line results conference call, Clarus presentations, FDA labels of Androgel and Axiron.

The secondary endpoints were generally consistent with FDA guidelines (Table 1). 82.9% of EPS subjects showed T Cmax below 1500 ng/dL, which is slightly lower than FDA's 85% threshold. 3 patients showed T Cmax over 2500 ng/dL, but all being transient, isolated and sporadic without reporting any AEs. Additionally, LPCN 1021 showed 4.6% of patients had Cmax between 1800 and 2500ng/dL, which met the FDA's criteria of <5%.

Titration profile (Table 2). 51% subjects ended up on starting dose 225 mg B.I.D with no titration, 34% subjects titrated down to 150 mg B.I.D while 15% subjects titrated up to 300 mg B.I.D.

Table 2: Titration Profile of LPCN 1021 in Phase 3 SOAR Study

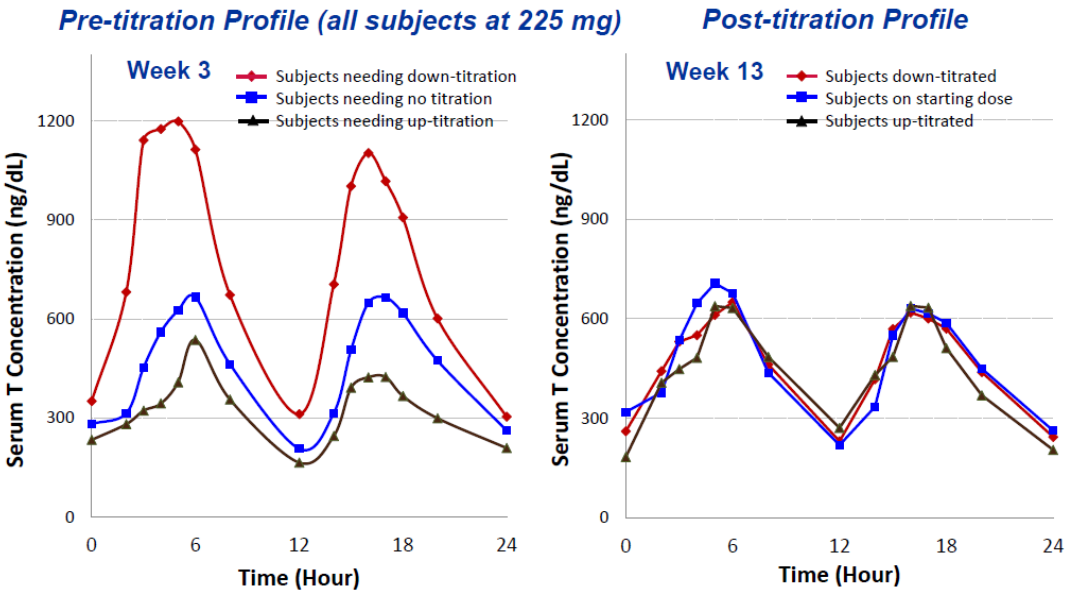
Titration distribution among Efficacy Population Set (N=152) *		
Number of titrations to final dose		
No titration	One titration	Two titration
51%	35%	15%
Titration Direction		
Titrate Up	Titrate Down	
15%	34%	

*Titration Scheme: starting dose at 225 mg TU BID, if needed, titrate up to 300 mg BID or down to 150 mg BID based on 24 hour serum testosterone measured during weeks 3 and 7.

Source: Lipocine SOAR study top-line results conference call.

The data indicate the titration protocol was successful in getting patient T levels to converge at an appropriate serum concentration largely following no dosing change just one dosing modification as 85% of the patients required zero or one dose modification. See chart below for details.

Chart 1: Converging Titration Regimen



Source: Lipocine SOAR study 8K 3/9/15

Safety data consistent with other TRT products. Safety assessment is continuing for the 52-week period, but 13-week safety data are consistent with other TRT products and comparable to the safety profile seen in Rextoro's pivotal study (Table 3).

Table 3. SOAR Phase 3 Preliminary Safety Results: LPCN 1021 Versus Rextoro

	LPCN 1021		Rextoro
	N (%) of 210 subjects	Note	% of 144 subjects
SAE	7 (3%)	None considered drug related	2 (1.4%)
≥ 1 AE	97 (46%)	all mild or moderate; ~1/3 are drug related	70 (48.6%)
AE-related discontinuation	2 (1%)	1 due to increased in PSA 1 due to increase in hematocrit	3 (2.1%)

Source: Lipocine SOAR study top-line results conference call.

Positive top-line LPCN 1111, a once daily oral testosterone, Phase 2a study results reported. The Phase 2a study was an open-label, dose-escalating single and multiple dose study to determine the feasibility of once daily dosing of LPCN 1111 in hypogonadal males. 12 men with serum total testosterone (T) < 300 ng/dL based on two blood draws on two separate days were enrolled. Subjects first received doses of LPCN 1111 as a single dose of 330 mg, 550 mg and 770 mg, then 10 of the subjects were dosed once daily at 550 mg of LPCN 1111 for 28 days. After a washout period, 8 out of the 10 subjects were then dosed once daily with LPCN 1111 at 770 mg for 28 days. 24 hour serum testosterone PK profiles were measured on days 14, 21 and 28. At the 770mg QD dose, 88% of the subjects showed 24 hour average serum T (Cavg) within the normal range (Lipocine didn't disclose the mean+/-SD of Cavg and whether Cavg of the rest 12% of subjects were below 300 ng/dL or above 1100 ng/dL). Meanwhile, no subjects exceeded peak serum T concentration ("Cmax") of 1500 ng/dL at any time during the 28 day dosing periods. In addition, steady state was achieved by day 14 with consistent inter-day performance observed on day 14, 21 and 28. We are impressed with the top-line PK data and believe PK profile such as this could enable LPCN 1111 to nicely meet the current FDA's efficacy criteria for TRT approval (Table 4). Also, LPCN 1111 was well tolerated with no serious adverse events. Although the sample size was small (8 subjects), we are encouraged that the Phase 2a results confirmed the positive results from the Phase 1 study of LPCN 1111 and demonstrated LPCN 1111 clear potential as an once daily oral testosterone, which will offer greater convenience for patients than current TRT on market and should enhance compliance. It is also very encouraging that QD dose of LPCN 1111 achieved a flatter PK steady state without exceeding 1500 ng/dL at any time during the 28 day dosing period, which should reduce inter-day peaks and troughs of current TRT products and offer a more even coverage throughout the day within the normal T range. Based on these positive results, Lipocine plans to begin a multi-dose Phase 2b study in 1Q 2015 to determine the optimal once daily dosing regimen of LPCN 1111.

Table 4: LPCN 1111 Phase 2a Top-line Results

Measure	550mg QD	770mg QD	Typical FDA Approval Target
% subjects with C_{avg} within normal range	67%	88%	≥ 75%
% of subjects with C_{max} ≤1500ng/dL	100%	100%	≥ 85%
% of subjects with C_{max} between 1800ng/dL and 2500mg/dl	0%	0%	≤ 5%
% of subjects with C_{max} > 2500ng/dL	0%	0%	0%

Source: Lipocine press release-10/13/2014

Positive top-line results from two Phase 1 PK studies of LPCN 1107. LPCN 1107 is an oral formulation of hydroxyprogesterone caproate (HPC) being developed for the treatment of preterm birth. The first study was designed to examine the PK and bioavailability of LPCN 1107 versus the standard HPC weekly 250mg intramuscular (IM)

injection. The study was open-label, cross-over trial in 10 healthy non-pregnant women each receiving a single dose of 400mg LPCN 1107 (QD), two doses of 400mg LPCN 1107 12 hours apart (BID), followed by a single IM injection of 250mg HPC, with a one-week washout period between each dosing regimen. The PK data show LPCN 1107 resulted in significant absorption of HPC with a dose response observed between the LPCN 1107 QD and BID dosing with respect to C_{max} and AUC. See Table below for details. The oral bioavailability vs. the IM injection was 55% in this study in healthy non-pregnant women. Additionally, week-5 steady state PK data were simulated showing oral LPCN 1107 could generate HPC exposure levels comparable to IM injection. Importantly, LPCN 1107 was well tolerated in the study (progestogenic menstrual effects were observed with IM HPC and LPCN 1107).

Table 5: Phase 1a (Non-Pregnant) PK Parameters (Geometric Mean and Ranges)

LPCN 1107 Dose (mg)	HPC C_{max} (ng/ml) Mean (Range)	HPC AUC_{0-t} (ng.h/ml) Mean (Range)
400 BID	23.1 (8.5 - 72.1)	173 (82 - 443)
400 QD	13.5 (4.9 - 54.4)	69 (33 - 207)

Source: Lipocine Press Release 5/15/14

Table 6: Phase 1a (Non-Pregnant) Steady State PK (Geometric Mean and Ranges)

HPC Dosing Regimen	HPC $C_{ss\ max}$ (ng/ml) Mean (Range)	HPC AUC_{ss-1} (ng.h/ml) Mean (Range)
LPCN 1107 400mg BID	23.9 (89.6 - 70.0)	1348 (673 - 3381)
Intramuscular injection: 250mg	17.8 (14.0 - 27.0)	2468 (1840 - 3180)

Source: Lipocine Press Release 5/15/14

Lipocine also completed a Phase 1b PK and bioavailability study comparing LPCN 1107 with IM HPC in pregnant women. The first study was designed to examine the PK, bioavailability and tolerability of LPCN 1107 versus the standard HPC weekly 250mg intramuscular (IM) injection. The study was open-label, three-period, cross-over trial in 8 healthy pregnant women each receiving two doses of 400mg LPCN 1107 12 hours apart (BID), two doses of 800mg LPCN 1107 12 hours apart (BID)followed by a single IM injection of 250mg HPC (Makena), with a one-week washout period between each dosing regimen. The PK data show LPCN 1107 resulted in significant absorption of HPC with a dose response observed between the LPCN 1107 400mg BID and 800mg BID dosing with respect to C_{max} and AUC. The oral bioavailability vs. the IM injection observed in this study in healthy pregnant women was 59%. Additionally, week-5 steady state PK data were simulated showing oral LPCN 1107 could generate HPC exposure levels comparable to IM injection. Importantly, LPCN 1107 was well tolerated in the study (progestogenic menstrual effects were observed with IM HPC and LPCN 1107). We expect Lipocine to meet with the FDA during late 2Q15 or early 3Q15 to discuss the path forward for the product. We are encouraged by the PK profile demonstrated to date in both health non-

pregnant women and pregnant women and believe based on the results that LPCN 1107 con provide serum exposures comparable to IM injection of HPC. We believe if successful, LPCN 1107 would be the first oral treatment for the prevention of preterm birth.

Table 7: Phase 1b (Pregnant) PK Parameters (Geometric Mean and Ranges)

LPCN 1107 Dose (N=7)	HPC C_{max} (ng/ml) Mean (Range)	HPC AUC_{0-t} (ng.h/ml) Mean (Range)
400mg BID	21.3 (11.5 - 36.2)	156 (81 - 234)
800mg BID	63.2 (37.8 - 144)	577 (323 - 1365)

Source: Lipocine Press Release 1/12/15

Table 8: Phase 1b (Pregnant) Steady State PK (Geometric Mean and Ranges)

HPC Dosing Regimen (N=7)	HPC $C_{ss\ max}$ (ng/ml) Mean (Range)	HPC AUC_{ss-1} (ng.h/ml) Mean (Range)
LPCN 1107 400mg BID	21.6 (12.1 - 36.2)	1074 (82 - 229)
LPCN 1107 800mg BID	71.1 (43.8 - 144.1)	4058 (311 - 1100)
IM injection: 250mg weekly	13.0 (6.5 - 29.4)	1817 (805 - 3904)

Source: Lipocine Press Release 1/12/15

Of note, approximately 180,000 pregnancies each year in the U.S. are at risk for preterm birth based on a prior history of preterm birth. Further, roughly 12% of pregnancies in the U.S. end in preterm births (babies born with a gestational age of less than 37 completed weeks). We believe, the ability of a therapy to prevent preterm births could convey a significant pharmacoeconomic advantage, as the costs associated with preterm births are substantial. Specifically, preterm babies have substantially more health-related issues and require extended hospital stays, along with greater medical and pharmaceutical interventions than babies carried to term. Currently, women with a history of preterm birth are treated with progesterone (17 alpha-hydroxyprogesterone caproate) injections once per week. The progesterone injections are generally initiated between weeks 16 and 20 of pregnancy and continued until week 37. Progesterone injections are currently available from compounding pharmacies and as an FDA approved formulation called Makena. We believe, if clinical development is successful, LPCN 1107 would represent an attractive alternative to the currently available progesterone injections. With only a very conservative estimate for the penetration (5% to 7% of the pregnancies with a history of preterm births) of the market, and a price of $4,000 for the course of therapy, we estimate LPCN 1107 could generate revenues in the $38 million to $100 million range. Importantly, we believe our estimates are conservative and there could be substantial upside to our projections if LPCN 1107 is successful in the clinic.

Lipocine's proprietary drug delivery platform has potential for further application. Lipocine's drug delivery technology has the potential to be applied to additional proprietary programs. Lipocine utilizes it novel proprietary drug delivery technology Lip'ralTM to

create oral formulations of compounds with poor solubility such as testosterone. Lip'ral promicellar technology (lipid based formulation) enhances the absorption of hydrophobic (poorly soluble) compounds from the gastrointestinal tract and improves bioavailability. Lip'ral has potential utility beyond the Company's current product pipeline (LPCN 1021, LPCN 1111 and LPCN 1107) with applicability to transform other poorly soluble hydrophobic drugs into compounds with an attractive oral bioavailability profile. While focusing on the clinical development of its current portfolio, we expect Lipocine to continue to pursue further applications of its technology which could enhance its pipeline through the application of the Lip'ral technology to additional product opportunities.

Valuation. We believe LPCN's current value is primarily driven by its lead product LPCN 1021. Our $24 price target is supported by a DCF, EPS multiple, and a sum-of-the-parts analysis. The DCF analysis applies a 30% to 35% discount rate, and a 7x to 8x multiple of the 2022 EBITDA of $184 million as the terminal value. The sum-of-the-parts (SOP) analysis employs the revenue generated from LPCN 1021 and LPCN 1111 in the male hypogonadal market and LPCN 1107 in the preterm birth market in higher risk pregnancies in women with a prior history, as well as the current cash position. The SOP analysis utilizes a 22% discount rate for LPCN 1021 and LPCN 1111 royalties, and LPCN 1107 revenues from the U.S. Ex-U.S. revenues for all three products are not included in our revenue assumptions and are left as upside potential. The EPS multiple analysis uses the 2022 fully diluted EPS estimate of $5.72, and utilizes a 15x to 25x multiple and a 25% discount rate. The fully diluted share count used in the EPS multiple analysis takes into consideration considerable future potential dilution. Specifically, our forecasts show the fully diluted shares to be about 20.6 million in 2022, which is more than a 50% increase (Lipocine currently has approximately 12.8 million shares).

Table 9: Target Price Based on DCF Analysis

2022	Discount rates	Value Per Diluted Share					
EBITDA multiples		7	8	9	10	11	12
	15.0%	$77.32	$87.02	$96.71	$106.40	$116.10	$125.79
	20.0%	$56.38	$63.64	$70.89	$78.15	$85.40	$92.66
	25.0%	$41.09	$46.58	$52.08	$57.57	$63.07	$68.56
	30.0%	$29.76	$33.96	$38.17	$42.38	$46.58	$50.79
	35.0%	$21.24	$24.49	$27.75	$31.00	$34.26	$37.51

Source: Ladenburg Thalmann & Co. Estimates

Table 10: Target Price Based on EPS Multiple Analysis (fully diluted)

2022	Discount rates	Target price based on EPS multiple analysis (fully diluted)					
EPS multiples		15	20	25	30	35	40
	10%	$44.88	$59.84	$74.80	$89.75	$104.71	$119.67
	15%	$33.16	$44.21	$55.26	$66.32	$77.37	$88.42
	20%	$24.82	$33.09	$41.36	$49.63	$57.91	$66.18
	25%	$18.80	$25.06	$31.33	$37.59	$43.86	$50.12
	30%	$14.39	$19.19	$23.98	$28.78	$33.58	$38.38
	35%	$11.13	$14.84	$18.55	$22.26	$25.97	$29.68
	40%	$8.69	$11.59	$14.48	$17.38	$20.27	$23.17

Source: Ladenburg Thalmann & Co. Estimates

Table 13: Target Price Based on Sum-of-Part Analysis

Per share value of assets	
LPCN 1021	18.66
LPCN 1111	1.64
LPCN 1107	2.50
Net Cash Value	1.08
Target Price	$ 23.88

Source: Ladenburg Thalmann & Co. Estimates

COMPANY SPECIFIC RISKS

In addition to normal economic and market risk factors that impact most all equities, Lipocine is uniquely subject to risks typical for small- to mid- cap biotech companies: The products the Company is developing may not work, may prove to be unsafe, may never win approval and may never generate meaningful revenues. Changing medical practices, a changing reimbursement environment and/or products introduced by others could shrink the market for the Company's products. The Company may not be able to enforce its own patents or may find itself infringing on patents held by others.

Risks include but are not limited to:

If Lipocine does not receive regulatory approvals to market LPCN 1021, LPCN 1111 or LPCN 1107 in a timely manner, or at all, and their business will be materially harmed and their stock price may be adversely affected.

Even if Lipocine obtains regulatory approval to market LPCN 1021, LPCN 1111 or LPCN 1107, if it and/or LPCN 1021, LPCN 1111 or LPCN 1107 fails to achieve market acceptance, Lipocine may never record meaningful revenues.

If Lipocine's competitors develop and market products that are less expensive, more effective or safer than LPCN 1021, LPCN 1111 or LPCN 1107, or LPCN 1021, LPCN 1111 or LPCN 1107 does not achieve market acceptance versus existing treatments, Lipocine commercial opportunities may be reduced or eliminated.

Lipocine relies on third parties to manufacture and analytically test LPCN 1021, LPCN 1111 or LPCN 1107. If these third parties do not successfully manufacture and test LPCN 1021, LPCN 1111 or LPCN 1107 their business will be harmed.

The status of reimbursement from third-party payors for newly approved health care drugs is uncertain and failure to obtain adequate reimbursement could limit their ability to generate revenue.

Health care reform measures could adversely affect their business.

The intellectual property that Lipocine owns or has licensed relating to their drug candidates, LPCN 1021, LPCN 1111 or LPCN 1107, is limited, which could adversely affect their ability to compete in the market and adversely affect the value of LPCN 1021, LPCN 1111 and LPCN 1107.

Future sales or other issuances of Lipocine common stock could depress the market for their stock.

GENERAL RISKS

In addition, equity markets in general, and the market for biotechnology and life sciences companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies traded in those markets. These broad market and industry factors may materially affect the market price of our common stock, regardless of the company's development and operating performance. Factors influencing a company's stock price include:

Developments concerning a company's drug candidate(s), including the safety and efficacy results from clinical trials and regulatory filings and approvals;

Announcements of technological innovations by them or their competitors including new products;

Developments relating to their intellectual property and those of their competitors, including but not limited to, the commercialization of generic products;

Expectations regarding their financial condition including actual or anticipated operating results;

Expiration or termination of licenses, research contracts or other collaboration agreements.

Table 11: LPCN Model

Lipocine Income Statement (December Fiscal Year; All amounts in '000s except per share items)

	2012A	2013A	1Q14A	2Q14A	3Q14A	4Q14A	2014E	1Q15E	2Q15E	3Q15E	4Q15E	2015E	2016E
Sales/Royalties:													
LPCN 1021 Royalties, 1111 & 1107 Revs	-	-	-	-	-	-	-	-	-	-	-	-	3,779
Product Revenues	-	-					-					-	-
Other	7,710	-					-					-	-
Total product revenue and royalties	**7,710**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**3,779**
COGS	-	-	-	-	-	-	-	-	-	-	-	-	-
R&D	2,281	5,123	3,369	5,974	3,247	2,890	15,479	3,035	3,186	3,346	5,513	15,079	13,720
SG&A	1,551	3,636	1,924	1,036	872	1,170	5,001	1,053	1,106	1,161	1,219	4,539	6,758
Amortization of Product Rights	-	-	-	-	-	-	-	-	-	-	-	-	-
Other charges	-	1,925					-					-	-
Total operating expenses	**3,832**	**10,684**	**5,293**	**7,010**	**4,118**	**4,060**	**20,481**	**4,088**	**4,292**	**4,507**	**6,732**	**19,619**	**20,478**
Operating income (EBIT)	**3,877**	**(10,684)**	**(5,293)**	**(7,010)**	**(4,118)**	**(4,060)**	**(20,481)**	**(4,088)**	**(4,292)**	**(4,507)**	**(6,732)**	**(19,619)**	**(16,699)**
Other expenses													
Interest (expense) income, net	-	-	-	-	-	-	-	35	30	30	30	125	125
Other income (expense), net	10	38	25	38	24	21	108	-	-	-	-	-	-
Total other income (expense), net	10	38	25	38	24	21	108	35	30	30	30	125	125
Pretax Income	**3,888**	**(10,646)**	**(5,267)**	**(6,972)**	**(4,094)**	**(4,040)**	**(20,372)**	**(4,053)**	**(4,262)**	**(4,477)**	**(6,702)**	**(19,494)**	**(16,574)**
Benefit or (Provision for) income taxes	(1)	55	-	-	-	(0)	(0)	-	-	-	-	-	-
Net income	**3,887**	**(10,591)**	**(5,267)**	**(6,972)**	**(4,094)**	**(4,040)**	**(20,373)**	**(4,053)**	**(4,262)**	**(4,477)**	**(6,702)**	**(19,494)**	**(16,574)**
EPS basic	$ 0.26	$ (1.44)	$ (0.41)	$ (0.55)	$ (0.32)	$ (0.32)	$ (1.60)	$ (0.25)	$ (0.26)	$ (0.28)	$ (0.41)	$ (1.20)	$ (0.80)
EPS diluted, GAAP	$ 0.26	$ (1.44)	$ (0.41)	$ (0.55)	$ (0.32)	$ (0.32)	$ (1.60)	$ (0.25)	$ (0.26)	$ (0.28)	$ (0.41)	$ (1.20)	$ (0.80)
Basic shares outstanding	14,989	7,363	12,728	12,770	12,775	12,790	12,766	15,988	16,131	16,277	16,423	16,205	20,717
Diluted shares outstanding	14,989	7,363	12,728	12,770	12,775	12,790	12,766	15,988	16,131	16,277	16,423	16,205	20,717

Source: Company documents and Ladenburg Thalmann & Co. estimates

APPENDIX A: IMPORTANT RESEARCH DISCLOSURES

ANALYST CERTIFICATION

I, Matthew L. Kaplan, attest that the views expressed in this research report accurately reflect my personal views about the subject security and issuer. Furthermore, no part of my compensation was, is, or will be directly or indirectly related to the specific recommendation or views expressed in this research report, provided, however, that:

The research analyst primarily responsible for the preparation of this research report has or will receive compensation based upon various factors, including the volume of trading at the firm in the subject security, as well as the firm's total revenues, a portion of which is generated by investment banking activities.

Additional information regarding the contents of this publication will be furnished upon request. Please contact Ladenburg Thalmann, Compliance Department, 570 Lexington Avenue, 11th floor, New York, New York 10022 (or call 212-409-2000) for any information regarding current disclosures, and where applicable, relevant price charts, in regard to companies that are the subject of this research report.

COMPANY BACKGROUND

Lipocine Inc. is a specialty pharmaceutical company focused on developing their drug delivery technologies to create novel oral formulations for compounds with suboptimal bioavailability. Lipocine's lead program, LPCN 1021, is a Phase 3 ready oral testosterone with BID dosing. The Company also has two earlier stage programs: LPCN 1111 which is their next generation oral testosterone and LPCN 1107 which is an oral product for the prevention of pre-term birth. Lipocine's operations are headquartered in Salt Lake City, Utah.

VALUATION METHODOLOGY

Our $24 price target is supported by a DCF, EPS multiple, and a sum-of-the-parts analysis. The DCF analysis applies a 30% to 35% discount rate, and a 7x to 8x multiple of the 2022 EBITDA of $184 million as the terminal value. The sum-of-the-parts (SOP) analysis employs the revenue generated from LPCN 1021 and LPCN 1111 in the male hypogonadal market and LPCN 1107 in the preterm birth market in higher risk pregnancies in women with a prior history, as well as the current cash position. The SOP analysis utilizes a 22% discount rate for LPCN 1021 and LPCN 1111 royalties, and LPCN 1107 revenues from the U.S. Ex-U.S. revenues for all three products are not included in our revenue assumptions and are left as upside potential. The EPS multiple analysis uses the 2022 fully diluted EPS estimate of $5.72, and utilizes a 15x to 25x multiple and a 25% discount rate. The fully diluted share count used in the EPS multiple analysis takes into consideration considerable future potential dilution. Specifically, our forecasts show the fully diluted shares to be about 20.6 million in 2022, which is more than a 50% increase (Lipocine currently has approximately 12.8 million shares).

RISKS

In addition to normal economic and market risk factors that impact most all equities, LPCN is uniquely subject to risks typical for small- to mid- cap biotech companies: The products the Company is developing may not work, may prove to be unsafe, may never win approval and may never generate meaningful revenues. Changing medical practices, a changing reimbursement environment and/or products introduced by others could shrink the market for the Company's products. The Company may not be able to enforce its own patents or may find itself infringing on patents held by others. Additionally, in the future the Company may no longer meet the requirements for continued listing on the NASDAQ Capital Market.

The Company has a limited operating history and has incurred substantial operating losses since inception. This trend may continue and the Company may never become profitable. The Company has not yet commercialized any of its drug candidates and cannot be sure if it will ever be able to do so. If it is unable to successfully complete clinical trial programs, or if such clinical trials take longer to complete than expected, its ability to execute on its current business strategy will be adversely affected. Pre-clinical testing and clinical development are long, expensive and uncertain processes. If drug candidates do not receive the necessary regulatory approvals, the Company will be unable to commercialize its drug candidates. All of its proprietary technologies are licensed to the Company by third parties. Termination of these license agreements would prevent the Company from developing drug candidates. LPCN relies on third parties to manufacture and analytically test its products. If these third parties do not successfully manufacture and test the products, the Company's business will be harmed. Reliance on third parties, such as clinical research organizations, or CROs, may result in delays in completing, or a failure to complete, clinical trials if such CROs fail to perform under the Company's agreements with them.

For a full review of LPCN specific risk factors investors should refer to the Company's most recent forms 10K and 10Q on file with the SEC.

STOCK RATING DEFINITIONS

Buy: The stock's return is expected to exceed 12.5% over the next twelve months.

Neutral: The stock's return is expected to be plus or minus 12.5% over the next twelve months.

Sell: The stock's return is expected to be negative 12.5% or more over the next twelve months.

Investment Ratings are determined by the ranges described above at the time of initiation of coverage, a change in risk, or a change in target price. At other times, the expected returns may fall outside of these ranges because of price movement and/or volatility. Such interim deviations from specified ranges will be permitted but will become subject to review.

RATINGS DISPERSION AND BANKING RELATIONSHIPS AS OF (March 25, 2015)

Rating	%	IB %
BUY	74.8	57.9
NEUTRAL	25.2	38.3
SELL	0.0	0.0

COMPANIES UNDER MATTHEW'S COVERAGE

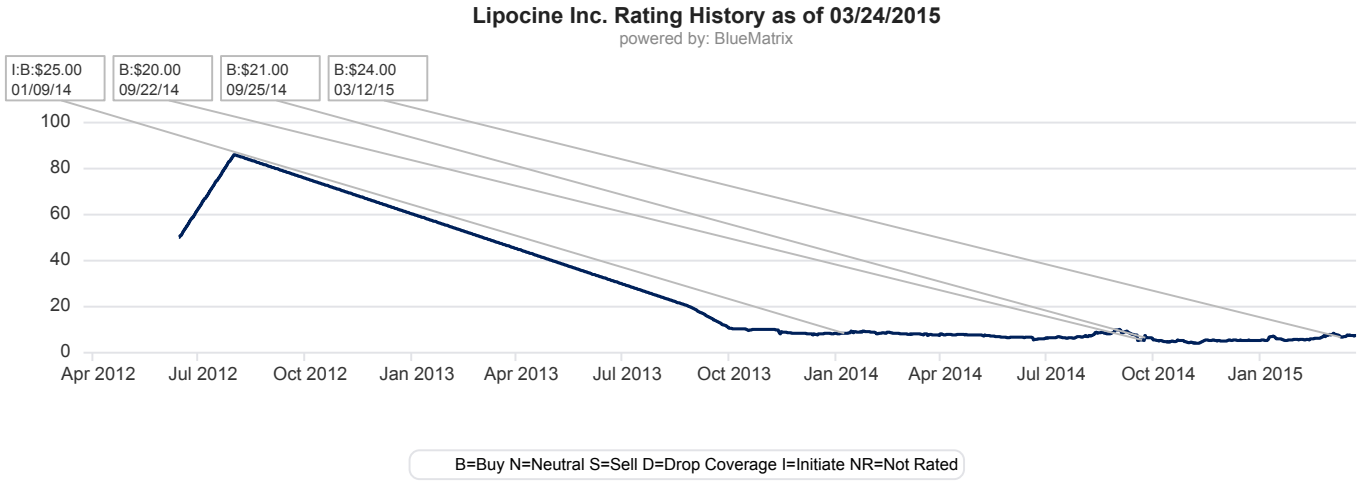
Aradigm Corporation (ARDM)
BioDelivery Sciences International (BDSI)
DARA Biosciences, Inc. (DARA)
Keryx Biopharmaceuticals (KERX)
MediciNova (MNOV)
Repros Therapeutics (RPRX)
TG Therapeutics, Inc. (TGTX)
Xoma Corporation (XOMA)
Antares Pharma, Inc. (ATRS)
Biodel Inc. (BIOD)
Flamel Technologies (FLML)
Lipocine Inc. (LPCN)
pSivida Corp. (PSDV)
Stemline Therapeutics, Inc. (STML)
United Therapeutics (UTHR)
Zosano Pharma, Inc. (ZSAN)

COMPANY SPECIFIC DISCLOSURES

Ladenburg Thalmann & Co. Inc. makes a market in Lipocine Inc..

Ladenburg Thalmann & Co. Inc. intends to seek compensation for investment banking and/or advisory services from Lipocine Inc. within the next 3 months.

INVESTMENT RATING AND PRICE TARGET HISTORY



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Additional Information Available Upon Request

LADENBURG THALMANN
ESTABLISHED 1876

EQUITY RESEARCH

ENERGY, POWER & INFRASTRUCTURE

Power & Electric Utilities

Brian J. Russo, CFA	(646) 432-6312	brusso@ladenburg.com
Vinod Srinivasaraghavan	(212) 409-2085	vsrin@ladenburg.com

Energy Exploration & Production, Master Limited Partnerships, Upstream

Noel A. Parks	(212) 409-2023	nparks@ladenburg.com
Michael Schmitz, CFA	(212) 409-2028	mschmitz@ladenburg.com

Master Limited Partnerships, Midstream & Closed-End Energy MLP & REIT Funds

Eduardo Seda	(212) 409-2034	eseda@ladenburg.com
Hilary Cauley	(212) 409-2072	hcauley@ladenburg.com

Master Limited Partnerships, Downstream & Others

Richard A. Verdi	(212) 409-2060	rverdi@ladenburg.com

Water & Sustainable Infrastructure

Richard A. Verdi	(212) 409-2060	rverdi@ladenburg.com

HEALTHCARE

Biotechnology

Matthew L. Kaplan	(212) 891-5247	mkaplan@ladenburg.com

Biotechnology (BioPharmaceuticals)

Robert (Bert) C. Hazlett, III	(212) 409-2062	rhazlett@ladenburg.com

Biotechnology (Personalized Medicine)

Kevin DeGeeter	(212) 409-2027	kdegeeter@ladenburg.com
James Colby	(212) 409-2058	jcolby@ladenburg.com

Healthcare Equipment & Medical Technologies

Jeffrey S. Cohen	(305) 572-4110	jcohen@ladenburg.com

FINANCIAL INSTITUTIONS

Financial Services – Business Development Cos. & Specialty Finance

Mickey M. Schleien, CFA	(305) 572-4131	mschleien@ladenburg.com

Financial Services – Equity REITs

Daniel P. Donlan	(212) 409-2056	ddonlan@ladenburg.com
John J. Massocca	(212) 409-2543	jmassocca@ladenburg.com

Financial Services – Mortgage REITs

David Walrod, CFA	(212) 409-2031	dwalrod@ladenburg.com

TECHNOLOGY

Internet & Software Services

Jon R. Hickman	(510) 918-4045	jhickman@ladenburg.com

Hardware

Daniel L. Amir	(415) 726-5900	damir@ladenburg.com

Software and Services

Glenn G. Mattson	(212) 409-2073	gmattson@ladenburg.com

TECHNICAL ANALYSIS

Adolfo R. Rueda, CMT	(212) 409-2039	arueda@ladenburg.com

ADDITIONAL CONTACTS

Kenneth Brush, Head of Trading	(212) 409-2011	kbrush@ladenburg.com
Eric Novotny	(212) 409-2011	enovotny@ladenburg.com