Zacks Small-Cap Research

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Lipocine, Inc. (LPCN - NASDAQ)

LPCN: Phase 3 "SOAR" Completed And Still On Track To File The NDA In The 2nd Half Of 2015…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	09/24/2014
Current Price (05/08/15)	$6.94
Target Price	**$13.50**

UPDATE

Lipocine's lead candidate, LPCN 1021, completed its Phase 3 clinical trial in April 2015 with positive top-line efficacy results reported back in September 2014. Top-line results from the 52-week safety portion of the trial are expected by mid-2015.

In December 2014, the FDA confirmed that the LPCN 1021 development plan and Phase 3 design were sufficient for NDA filing. As per management, the March 2015 pre-NDA meeting with the FDA was quite productive, and we still expect the NDA filing to occur during the second half of 2015.

We believe Lipocine has a strong cash position thanks to completing a public offering of over 5.3 million shares at $6.50 per share in April 2015. Even with the FDA imposing limitations and labeling changes on testosterone replacement therapies in March 2015, we continue to believe the stock represents an attractive long-term investment.

SUMMARY DATA

52-Week High	**$9.88**
52-Week Low	**$3.95**
One-Year Return (%)	**-3.00**
Beta	**3.81**
Average Daily Volume (sh)	**212,451**
Shares Outstanding (mil)	**18**
Market Capitalization ($mil)	**$119**
Short Interest Ratio (days)	**0.60**
Institutional Ownership (%)	**28**
Insider Ownership (%)	**14**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2015 Estimate	**N/A**
P/E using 2016 Estimate	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2015	$0.0 A	$0.0 E	$0.0 E	$0.0 E	$0.0 E
2016					$0.0 E

Earnings per Share

(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$0.41 A	-$0.55 A	-$0.32 A	-$0.32 A	-$1.60 A
2015	-$0.23 A	-$0.23 E	-$0.36 E	-$0.39 E	-$1.25 E
2016					-$1.28 E

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WHAT'S NEW

Financial Review

On May 7, 2015, Lipocine (LPCN) reported financial results for the first quarter ending March 31, 2015. The company did not report any revenues in the quarter. Net loss was $3.0 million, or $0.23 per share, for the first quarter of 2015, compared with a net loss of $5.3 million, or $0.41 per share, for the first quarter of 2014. The loss was less than our forecast as we had anticipated greater R&D and G&A expenditures related to lead candidate, LPCN 1021, for the first quarter 2015.

Research and development expenses were $1.9 million for the first quarter of 2015, compared with $3.4 million for the first quarter of 2014. This was significantly below our projections of $3.5 million for the quarter largely due to reduced internal personnel costs and decreased external service provider costs related to clinical research and contract manufacturing. For the first quarter of 2015, general and administrative expenses were $1.1 million, compared to $1.9 million for the same period in 2014. This decrease was primarily due to reduced legal and accounting fees as well as increased vesting and extension of exercise dates from retiring directors during 2014, partially offset by a slight increase in additional personnel related costs.

On April 29, 2015, Lipocine completed an underwritten public offering of 5.3 million shares of its common stock at $6.50 per share. Lipocine walked away with net proceeds of approximately $32.5 million after fees.

Operating burn for the first quarter of 2015 was $2.9 million. As of March 31, 2015, Lipocine had cash and cash equivalents of $24.8 million. This does not include the net proceeds of $32.5 million from the public offering mentioned above as this occurred subsequent to the quarter end. If we include the $32.5 million net from the public offering, we forecast that Lipocine has roughly $57 million in cash and cash equivalents at the current moment. We are projecting that Lipocine will exit the second quarter of 2015 with approximately $53 million in cash after operating burn for the second quarter is factored in. We believe that the company will spend at least another $7 million in additional LPCN 10210 related R&D expenditures in the upcoming months.

We believe the current cash balance is sufficient to fund operations for the next two years. Assuming that LPCN 1021 is approved in 2016, we believe operating expenses will rise in anticipation of the company hiring an adequate sized specialist sales force to promote the drug, in addition to expenses related to maintaining, expanding and protecting its IP portfolio, and other activities to prepare for the commercialization launch.

FDA Imposes Limitations & Labeling Changes on Testosterone Products

On March 3, 2015, the FDA issued a safety announcement forcing limits on testosterone drugs and requiring labeling changes to warn of potential cardiovascular risks including heart attack and stroke. In the announcement, the FDA clarified that prescription testosterone products are only approved for replacement therapy in men who have "Low T" due to certain medical conditions (such as disorders of the brain, testicles, or pituitary gland that cause hypogonadism that are confirmed by laboratory tests) and that the products are not approved for the treatment of "Low T" due to aging alone. However, the language did not suggest contraindicating for age-related hypogonadism.

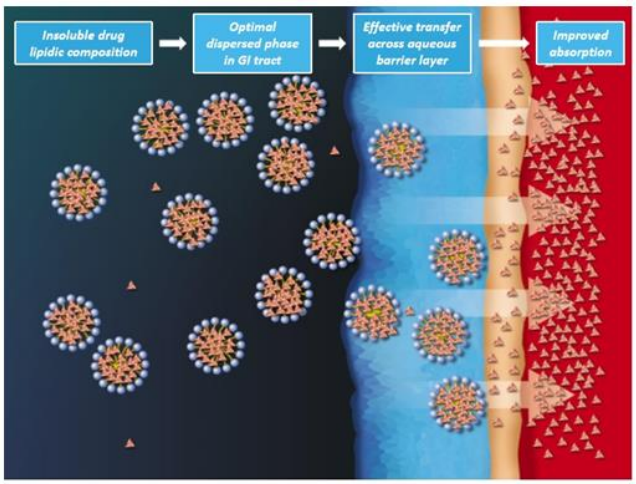
Based on input from an independent advisory committee and published studies, which included aging men treated with testosterone, the FDA deduced that there may be a potential myocardial infarction, stroke and/or death risk from testosterone usage in some individuals. Manufacturers of all approved prescription testosterone products are required to change product labeling to clarify the approved uses of the drug and to add information outlining the possible increased risk of heart attack and stroke in patients taking testosterone. The FDA is also requiring approved testosterone product manufacturers to conduct "a well-designed clinical trial" to address the potential increased risk of heart attack and/or stroke in users of these products.

The FDA encouraged manufacturers to work together or individually on a clinical trial. Lipocine will not be participating in the industry-sponsored trial, as that is only a requirement for approved NDA holders, but will have to perform a separate trial if the drug receives NDA approval.

Prescriptions for "Low T" have dramatically increased over the last ten years, with the number of men being prescribed testosterone having jumped more than 75%, to 2.3 million, between 2009 and 2013, no doubt thanks to the introduction of new formulations and direct-to-consumer advertising campaigns about “Low T”. According to the FDA, about 70% of these patients were between the ages of 40 and 64. The majority of TRT use is in medically required patients. However, it is clear that testosterone is being used to relieve symptoms in men with “Low T” for no apparent reason other than aging. The new FDA rules will restrict testosterone manufacturers from marketing and promoting products for age-related low testosterone.

An Update On LPCN 1021

As a reminder to investors, Lipocine, Inc. is a specialty pharma company that has an oral drug delivery technology, Lip’ral™, for products that affect men’s and women’s health. The Lip’ral™ promicellar technology is a patented platform based on lipid compositions which form an optimal dispersed phase in the gastrointestinal environment for improved absorption of insoluble drugs (*below*). The company is currently developing three product candidates in conjunction with this system (LPCN 1021, LPCN 1111, and LPCN 1107) that are designed to enhance the pharmacokinetic parameters of the drugs, facilitate lower dosing requirements, reduce side effects, and limit gastrointestinal interactions that would otherwise decrease the effectiveness of the compounds.



Dispersion & Absorption in the Gastrointestinal Tract via Lip'ral

Source: Lipocine, Inc.

Lipocine’s lead asset, LPCN 1021, is a testosterone replacement therapy (TRT) designed for oral twice-a-day dosing. The product recently wrapped-up the extension study of a pivotal Phase 3 clinical trial run under protocols in-line with FDA guidelines for approval of TRTs. On April 30, 2015, Lipocine announced completion of the last patient visit in the safety assessment portion of its SOAR (Study of Oral Androgen Replacement) Phase 3 clinical study. As a reminder, Lipocine announced positive top-line efficacy results from the study back in September 2014. SOAR evaluated the safety and efficacy of oral LPCN 1021 in hypogonadal men with low testosterone and showed positive results with respect to the trial's primary efficacy endpoint with no serious drug related or cardiovascular adverse events to date. Top-line results from the 52-week safety assessment portion of the SOAR trial are expected by mid-2015. We look forward to seeing these results.

In December 2014, Lipocine announced that the FDA confirmed that its ongoing SOAR design was acceptable for filing the new drug application (NDA) for the class testosterone replacement therapy (“TRT”) label. At that time, the FDA did not require any additional clinical studies for the NDA filing but did mention that supplementary data may be necessary if any safety concerns are uncovered during the SOAR Phase 3 analysis of results. At the time of this announcement, the FDA acknowledged that internal discussions were still ongoing regarding the FDA Advisory Committee held on September 17, 2014.

On March 24, 2015, Lipocine announced results from the March 19th pre-NDA meeting with the FDA. The purpose of the meeting was to discuss and evaluate the proposed LPCN 1021 NDA package, and to receive guidance on the 505(b)(2) filing and path to approval. As per the FDA’s preliminary response, management does not expect to conduct any additional clinical studies other than the on-going labeling “food effect” study which has always been a requirement for the expected submission of the NDA. The labeling "food effect" study is an open-label, randomized, four period, four treatment, crossover, single dose trial evaluating bioavailability and pharmacokinetics of LPCN

1021 as a function of food fat content in hypogonadal males. The study is currently being conducted at a single site and will enroll 16 hypogonadal males between the ages of 18 and 80. Management plans to submit preliminary results from this study to the FDA in the second quarter of 2015 for review and comment prior to submitting the NDA.

We were expecting these results as the SOAR efficacy data from September 2014 were in-line with FDA approval requirements. We see this confirmation as great news for Lipocine since it is not required to conduct a heart attack and stroke risk study or any additional safety studies prior to filing the NDA for LPCN 1021. It is important to mention that LPCN 1021 will have to adhere to all of the new regulations set forth by the FDA that we outlined above if approved. For instance, cautionary language will be required on the label for possible cardiovascular and stroke related risk with TRT, and the lack of benefit and safety of TRT in age-related hypogonadism.

Additionally, Lipocine will have to conduct a well-designed trial to address the potential increased risk of heart attack and/or stroke in users of the product, but that will occur down the road. We also believe that Lipocine anticipates a safety update in June 2015 with regards to how the product fares against the control, AndroGel®. We are happy to report that Lipocine has been keeping up with the timeline, and we still expect the NDA for LPCN 1021 to be filed with the FDA in the second half of 2015.

…LPCN 1021 Competitive Landscape…

Lipocine has completed the Study of Oral Androgen Replacement (SOAR) Phase 3 clinical trial. As we wait for the 52-week safety data to become available in mid-2105, it is helpful to examine where LPCN 1021 may fit into the competitive landscape in comparison to other oral hypogonadism treatments.

- Clarus Therapeutics is developing **Rextoro®**, an oral formulation of testosterone undecanoate (TU). Rextoro® is formulated to aid absorption of TU via the intestinal lymphatic pathway. Lipocine's LPCN 1021 is TU formulated with the proprietary Lip'ral™ technology to aid in absorption, since TU has poor bioavailability.

- Repros Therapeutics is developing enclomiphene citrate (formerly known as Androxal®), an orally active, single isomer of clomiphene citrate that has been shown to be effective in treating secondary hypogonadism in overweight men wanting to restore normal testicular function. It works by inhibiting the effects of estrogen on the pituitary gland thus stimulating the release of hormones that induce testosterone production. Unlike testosterone administration, it does not adversely affect the testes or fertility.

…Negative Sentiment Towards Rextoro® Continues…

As a reminder to investors, Clarus Therapeutics filed a new drug application (NDA) for Rextoro® on January 3, 2014. On September 18, 2014 there was a Joint Meeting of the Bone, Reproductive and Urologic Drugs Advisory Committee (BRUDAC) and the Drug Safety and Risk Management Advisory Committee (DSRM) to discuss the NDA for Rextoro® (see FDA Briefing Documents). The outcome of the FDA AdCom meeting was decidedly negative for Clarus, with the committee not ready to recommend approval of Rextoro® at the current time. Twelve of 21 committee members voted that there was insufficient evidence to conclude that TU was an effective TRT. Eighteen of 21 members voted that that the overall risk/benefit profile did not support approval of TU for TRT. Those members who voted against supporting approval did so based on the pivotal trial being small, food effects associated with Rextoro® dosing, a high number of dropouts in the pivotal study, missed secondary endpoints, and a lack of robust efficacy. The FDA originally assigned a PDUFA goal date of November 3, 2014; however, there has not been any recent announcement of approval or an update, and since Clarus is a private company we are not anticipating release of the complete response letter or a public comment ahead of the next steps.

We believe the negative view of Rextoro® was not due to the fact it was an oral formulation of TU but rather due to the data itself. We see Clarus issues as specific to Clarus, and do not believe they negatively impact Lipocine whatsoever. In fact, the data generated in Lipocine's SOAR trial compares quite favorably to the data obtained through the two Phase 3 trials of Rextoro®, and while there are some concerns associated with the LPCN 1021 data, we believe the efficacy data is likely to be viewed much more favorably by the FDA than that presented by Clarus in September 2014.

Top-line results from SOAR are presented below. For comparison, we include the Rextoro® Phase 3 studies so investors can compare the data side-by-side. The data clearly show that LPCN 1021 offers superior C_{AVE} and C_{MAX} to Clarus Rextoro®. Secondary safety endpoints also point to LPCN 1021 providing lower risk with respect to the percent of patients above FDA guided C_{MAX} levels. In addition, LPCN 1021 reached the primary endpoints while

Rextoro® did not after statistical analysis using imputed data. We note that the LPCN 1021 data is from 154 patients whereas the Rextoro Phase 3B study is from only 117 patients.

Primary Endpoints	FDA Targets for Approval	LPCN 1021 Phase 3	Rextoro Phase 3A	Rextoro Phase 3B*
Cave 300-1140 ng/dl	**≥ 75%**	88%	84%	75%
Lower bound 95% CI	**≥ 65%**	82%	77%	66%
Secondary Endpoints				
Cmax < 1500 ng/dl	**≥ 85%**	83%	59%	81%
Cmax 1800-2500 ng/dl	**≤ 5%**	4.6%	13%	6%
Cmax > 2500 ng/dl	**0%**	2%	14%	3%

*considered pivotal trial

Primary Endpoints	FDA Targets for Approval	LPCN 1021 LOCF Analysis	Rextoro 3B LOCF Analysis	Rextoro 3B WCS Analysis
Cave 300-1140 ng/dl	**≥ 75%**	80% ✓	71% ✗	60% ✗
Lower bound 95% CI	**≥ 65%**	74% ✓	62% ✗	52% ✗

Sources: Lipocine, Inc.; Clarus Therapeutics

As the committee stated during the review of Rextoro®: "…it would be of great value to (hypogonadal) patients to have an oral treatment option…" We happen to agree with that opinion. However, as a result of the committee voting 18-3 against supporting approval of Rextoro®, it seems highly unlikely that Clarus will gain approval without conducting additional clinical trials. With Lipocine set to file an NDA in the second half of 2015, and our belief that Clarus will be required to perform additional clinical trials, we believe that LPCN 1021 is much further ahead of Rextoro® in becoming the first oral TRT on the market.

It was reported on April 15, 2015 that Clarus withdrew its plan for an $86 million initial public offering that was set to happen in mid-April with Citi and Credit Suisse being the joint bookrunners on the deal. As an aside, Clarus previously withdrew an IPO filing back in July 2011. In our opinion, this strengthens the position for LPCN 1021 becoming the first oral TRT to hit the market. We don't know how Clarus will get funding for Rextoro®, and at this point, we don't know if this drug will ever make it to the market. This recent news further solidifies our belief that that the oral TRT market is Lipocine's to own with major competitor Clarus Therapeutics and Rextoro® facing many issues.

…Repros files NDA for enclomiphene citrate…

Repros Therapeutics' enclomiphene citrate agent is not a traditional TRT, in that rather than administering testosterone to the body, it is a compound that stimulates the body to make more testosterone. It is being targeted specifically for the treatment of secondary hypogonadism, while LPCN 1021, if approved, will be labeled for the treatment of primary hypogonadism (and possibly secondary hypogonadism as well). However, there is some overlap between the two conditions, in that doctors have prescribed the use of TRT for the treatment of low testosterone due to aging or other medical conditions (obesity, diabetes, etc.). Thus, enclomiphene citrate (formerly known as Androxal®) and LPCN 1021 could theoretically be utilized to treat some of the same patients.

Repros has reported results from two Phase 3 studies of Androxal®, with results showing that treatment with Androxal® does not affect sperm production, while treatment with a topical TRT decreases sperm concentration. In addition, Androxal® was shown to increase the average testosterone values for the treated group; however, data was not shown on the percentage of patients that fell within the FDA targets, thus it is not possible to perform a head to head comparison with LPCN 1021. Androxal® data is also from only 40 patients vs. 154 for LPCN 1021.

The company had scheduled a Type B Pre-NDA meeting with the FDA in September 2014. In December 2014, that meeting was changed to a Type C meeting and it was announced that no additional clinical trials would be necessary. The NDA was subsequently filed on February 2, 2015. On April 1, 2015, Repros announced that the NDA for its enclomiphene citrate product had been accepted by the FDA. It was then announced that the FDA assigned a Prescription Drug User Fee Act (PDUFA) goal date of November 30, 2015, for substantive review of the NDA. The FDA is also currently planning to hold an advisory committee meeting on the NDA during the review.

On April 6, 2015, it was announced that the European Medicines Agency (EMA) informed Repros that its enclomiphene citrate capsules were eligible for submission for a centralized marketing authorization application (MAA) as a New Active Substance. We are not sure if this will be ultimately approved, but if the MAA is successful, centralized marketing authorization would be valid in all European Union member states, as well as in the European

Economic Area, a total of 31 countries. It is our understanding, that if enclomiphene citrate is granted New Active Substance status, this will allow an application to be made for a supplementary protection certificate which, if approved, could extend the exclusivity period of the drug.

We believe that all of this means that Repros is ahead of Lipocine by approximately six months; however, we will be unable to gauge how the agencies will view the enclomiphene citrate agent and how likely it is to be approved without a full examination of the data. We will just have to wait and see what happens on this front.

Updates on LPCN 1111 & LPCN 1107

…Positive Top-line Results in Phase 2a Study of LPCN 1111…

On October 13, 2014, Lipocine announced positive top-line results in a Phase 2a study of LPCN 1111, a next-generation oral TRT that has the potential for once daily dosing. This study was an open-label, dose-escalating single and multiple dose study. Subjects received a single dose of 330 mg, 550 mg, or 770 mg of LPCN 1111 followed by once daily dosing of 550 mg for 28 days in 10 subjects and once daily administration of 770 mg for 28 days in eight subjects.

Results showed that a single daily oral dose of LPCN 1111, a novel prodrug of testosterone for oral delivery through the proprietary Lip'ral technology, provided testosterone levels in the eugonadal range, with good dose response and no subjects exceeding peak serum testosterone concentrations of 1500 ng/dl. In addition, LPCN 1111 was well tolerated with no significant adverse events reported. The following table gives a summary of the C_{AVG} and C_{MAX} data.

Measure	550mg QD	770mg QD	*Typical FDA targets for approval of TRT*
% 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, Inc.

As shown in the table, the 770 mg dose QD (once daily) resulted in 88% of subjects within the normal range, which is above the FDA target of 75% of subjects. The fact that testosterone levels could be achieved in the normal range with no subjects developing abnormally high testosterone levels is quite encouraging as a once daily dosing TRT would be clearly differentiated in the marketplace. Secondary safety data on C_{MAX} also looks outstanding. Based on these results, a Phase 2b trial is currently expected to begin in the fourth quarter of 2015 or the first quarter of 2016. We still believe that Lipocine needs some clarification from the FDA on the language of the TRT class label with the goal of determining optimal once daily dosing of LPCN 1111. This is expected to occur at some point in the third quarter of 2015. As per management guidance, LPCN 111 is about 24 months behind LPCN 1021. We have seen very little, if any, investor chatter about LPCN 1111. In our view, based on Phase 2a data, this drug looks like a potential game-changer for TRT.

…Positive Top-line Results in Phase 1b Study of LPCN 1107 In Pregnant Women…

On January 12, 2015, Lipocine announced positive top-line results in a Phase 1b proof of concept study of LPCN 1107, an oral formulation of hydroxyprogesterone caproate (HPC) for the prevention of preterm birth (PTB) in pregnant women. HPC is an injectable drug approved for women who have had a previous PTB. The study was designed to determine the safety, tolerability, bioavailability and PKs of LPCN 1107 as compared to an intramuscular HPC. The Phase 1a data of healthy, non-pregnant women has been presented at the Society for Maternal-Fetal Medicine 35th Annual Meeting.

Preterm birth (less than 37 weeks) is the leading cause of perinatal mortality and morbidity, accounting for as many as 75% of perinatal deaths and complicates 12.5% of all deliveries in the U.S. (Ananth *et. al*, 2006). According to a report for the Institute of Medicine of the National Academics, it is estimated that PTB costs the U.S. more than $26 billion annually, and the first-year medical costs for PTB infants are 10 times higher than for full term infants. We view this as close to a $1 billion market opportunity.

The Phase 1b study was an open-label, three period, three treatment serial dosing study. Eight healthy pregnant women at 16 to 18 weeks gestation received three treatments in sequence. In period 1, patients received two doses of 400 mg oral LPCN 1107, administered 12 hours apart. In period 2, subjects received two doses of 800 mg oral LPCN 1107, administered 12 hours apart. Finally, in period 3, patients received a single dose of 250 mg HPC via intramuscular (IM) injection (marketed product Makena®). Periodic blood sampling was collected over 24 hours following oral administration of the drug and over 28 days after the HPC IM dose.

Results from this study showed the first demonstration of HPC absorption following oral administration in healthy pregnant women. C_{MAX} and AUC for the oral administrations with LPCN 1107 are shown below (*below left*). LPCN 1107 dosing once adjusted to fall between 400 and 800 mg twice a day is expected to be comparable to the marketed 250 mg weekly IM product (*below right*).

Single Dose Pharmacokinetic Parameters

Dosing Regimen (BID) (N=7*)	C_{max} (ng/ml) [range]	AUC_{0-24} (ng.h/ml) [range]
400mg	21.3	156
	[11.5 - 36.2]	[81 - 234]
800 mg	63.2	577
	[37.8 - 144]	[323 - 1365]

* one subject data analysis pending

Simulated Steady State Pharmacokinetic Parameters

Products / Dosing Regimen (N=7*)	$C_{ss,max}$ (ng/ml) [range]	AUC_{SS} (ng.h/ml)# [range]
LPCN 1107 / 400mg BID	21.6	1074
	[12.1 - 36.2]	[573-1601]
LPCN 1107 / 800mg BID	71.1	4058
	[43.8 - 144.1]	[2180-7701]
Intramuscular injection / 250mg weekly	13.0	1817
	[6.5 - 29.4]	[805 - 3904]

* one subject data analysis pending

Source: Lipocine, Inc.

The relative bioavailability of oral to IM administration was similar between pregnant and non-pregnant women (from the Phase 1a study in healthy, non-pregnant women) and can be seen below. Management believes that increasing the dose to the 550-600 mg range BID (from 400 mg BID) will allow for the proper efficacy.

Study population (N)	AUC_{SS} (ng.h/ml)#		Relative bioavailability [oral / IM]
	LPCN 1107/ 400 mg BID Oral	Intramuscular Injection / 250 mg weekly	
Pregnant women (7*)	1074	1817	59 %
Non-pregnant women (10)	1348	2468	55 %

LPCN 1107 Phase 1 Study Results: Bioavailability in Pregnant and Non-Pregnant Women

Source: Lipocine, Inc.

* one subject data analysis pending
# AUCss calculated for post steady state 1 week duration

In this Phase 1b study, LPCN 1107 was well-tolerated with no serious adverse events observed. Management is currently seeking some development guidance from the FDA and has requested a meeting. We believe that there are currently multiple potential development plans for LPCN 1107, but we are unsure of which one, if any, will be acceptable to the FDA. Lipocine will have more clarity regarding the development plan for LPCN 1107 at some point in the second quarter of 2015, and we look forward to receiving this guidance.

…LPCN 1077 Competitive Landscape…

It is important to examine where LPCN 1107 may fit into the competitive landscape in comparison to the other treatment option currently available for prevention of preterm birth (PTB).

- AMAG Pharmaceuticals, Inc. recently acquired Lumara Health in November 2014 for $675 million in upfront payments with the potential of up to $350 million in contingent payments as certain sales milestones are achieved. Lumara Health is the exclusive marketer of **Makena®** (hydroxyprogesterone caproate injection), the only FDA approved product indicated to decrease the rate of PTB in women who are pregnant with one baby and who have delivered one preterm baby spontaneously in the past. Makena® is a weekly intramuscular injection (via 21 gauge needle) administered every seven days beginning between 16 and 20 weeks of gestation to alternating gluteus muscles. It significantly lowered the rate of preterm birth compared to those not

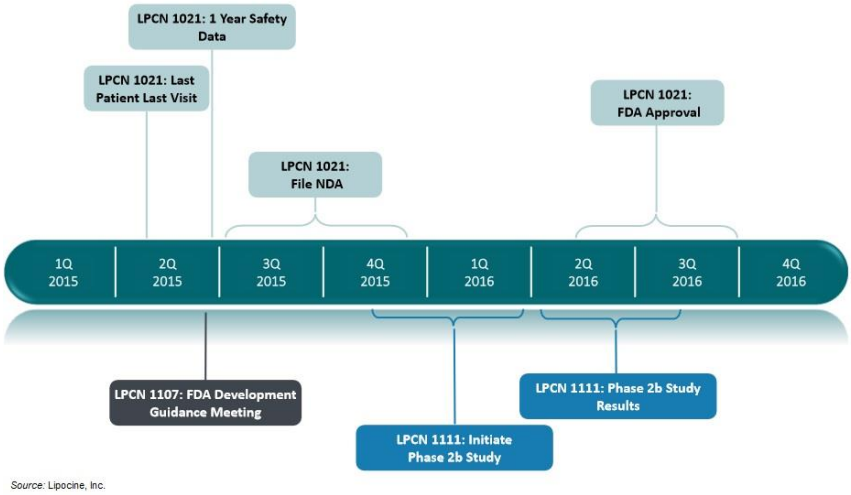
on Makena®. According to Lipocine, the 2014 net sales of Makena® were close to $165.0 million, with 2015 net sales projected to be anywhere between $245 and $270 million and Makena® has orphan drug exclusivity until 2018.

…LPCN 1107: A Future Game Changer In The PTB Space?…

Lipocine believes LPCN 1107 surpasses Makena® in several areas. First of all, LPCN 1107 is an oral formulation with the same API as Makena®, but does not require invasive, weekly injections, and therefore there is no potential for injection site reactions, excessive pain or infections from the weekly injections. This could eliminate anywhere from 18 to 22 injections. Furthermore, this would virtually eliminate the need for weekly doctor/nurse visits with an oral formulation as compared to an IM dose as well as the risk for pulmonary embolism. The most common side effects reported (vs. the control group) were injection site reactions and included pain (35%), swelling (17%) and other side effects such as urticaria (12%). Of those on Makena®, 35% of patients suffer from injection site pain, 17% from swelling and other possible serious side effects.

Management believes that 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. We think LPCN 1107 has potential as an oral version of an already approved IM version, but it is still in the early stages of the process. We will have to wait and see how the LPCN 1107 story plays out but we look forward to learning more about the development plan for the drug in the second quarter of 2015.

Conclusion and Recommendation



Source: Lipocine, Inc.

With seemingly nothing but excellent news for Lipocine over the past several months – completion of SOAR with positive Phase 3 data for LPCN 1021, a productive pre-NDA meeting with the FDA regarding LPCN 1021, a negative review of an oral TRT competitor followed by a withdrawal of a $86 million planned IPO, very positive Phase 2a data for LPCN 1111, and Phase 1b data for LPCN 1107 – it is still quite surprising to us that the stock price is still down over 40% from its September 2014 highs. Clearly, the stock was being weighed down by the negative sentiment expressed in regards to the TRT market following the September 17th meeting regarding the appropriate indicated population for TRT as well as the potential for adverse CV outcomes associated with the use of TRT.

The current market cap is approximately $135 million on a fully diluted basis, and with the company currently holding roughly $57 million in cash that represents an enterprise value of less than $76 million. We still view this as bafflingly low for a company with positive Phase 3 data for a compound that will enter a market in excess of $1 billion.

Although we project that the current cash level should be enough to fund the LPCN 1021 NDA filing in the second half of 2015 as well as advancements of LPCN 111 and 1107 operations for the next 24 months, assuming that LPCN 1021 is approved, we believe that the company needs to start thinking about the costs associated with hiring an adequate sized specialist sales force in addition to expenses related to maintaining, expanding and protecting its IP portfolio as well as preparing the product for commercialization and launch.

However, even with these uncertainties, we feel that investors are overreacting to the recent FDA TRT regulations and that the “sky is not falling”. While there might be slightly more uncertainty regarding the future of the TRT market this has been partially offset by the increased probability of approval for LPCN 1021 following the release of the positive Phase 3 data and the positive outcome from the pre-NDA meeting.

Although it took awhile to receive FDA communication on the TRT label guidelines, it is nice to finally receive some clarity on the situation. The limitations and labeling changes were expected based on the September 17th FDA Advisory Committee meeting, and it has been a relief to many investors that the FDA did not suggest a black box warning related to cardiovascular and stroke risks nor did the FDA contraindicate TRT products for age-related hypogonadism. We see this as a good outcome for sponsors of TRT products.

Lipocine management remains optimistic about progress with LPCN 1021 and continues to believe that it could be the first orally available TRT product, and we would have to agree. At this point, Lipocine is not sure what the FDA requirement will be for a cardiovascular study in the post-approval stage, but we do have clarity from the pre-NDA meeting and it is reassuring to note that no further clinical studies will be required prior to NDA filing.

Although Lipocine is currently focused on LPCN 1021 (as well as LPCN 1111 and LPCN 1107), the company is confident in its potent Lip’ral technology platform that improves oral absorption of extremely water insoluble molecules and believes this platform can be extended to other drugs in the future. At the 27th Roth Conference, management noted that if the NDA is approved, the current plan is to seek a licensing partner for the primary care portion of the market as primary care practitioners currently write 70% of testosterone prescriptions. Lipocine does not have current plans to build out a primary care sales force, but hasn’t ruled out the possibility of building a specialist sales force of approximately 40 to 45 reps that should get 80-85% of the urology and endocrinology prescriber base. It sounds like commercialization talks for LPCN 1021 are underway at Lipocine and we will get more definition in the near future.

We are maintaining our $13.50 price target and a ‘Buy’ rating, and feel that Lipocine represents a very attractive investment opportunity at the current price.

PROJECTED FINANCIALS

Lipocine, Inc.
Income Statement

Lipocine Incorporated	2014 A	Q1 A	Q2 E	Q3 E	Q4 E	2015 E	2016 E
LPCN 1021	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-
LPCN 1111	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth							
LPCN 1107	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth							
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
CoGS	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-					-	-
R&D	$15.5	$1.9	$3.1	$5.2	$6.0	$16.2	$18.0
SG&A	$5.0	$1.1	$1.1	$1.5	$1.6	$5.3	$7.5
Other expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.1	$0.1
Operating Income	($20.5)	($3.0)	($4.2)	($6.7)	($7.6)	($21.6)	($25.6)
Operating Margin	-					-	-
Total Other Income	$0.1	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($20.4)	($3.0)	($4.2)	($6.7)	($7.6)	($21.6)	($25.6)
Taxes & Other	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($20.4)	($3.0)	($4.2)	($6.7)	($7.6)	($21.6)	($25.6)
Reported EPS	**($1.60)**	**($0.23)**	**($0.23)**	**($0.36)**	**($0.39)**	**($1.25)**	**($1.28)**
YOY Growth	-						-
Shares Outstanding	12.8	12.8	18.2	18.8	19.4	17.3	20.0

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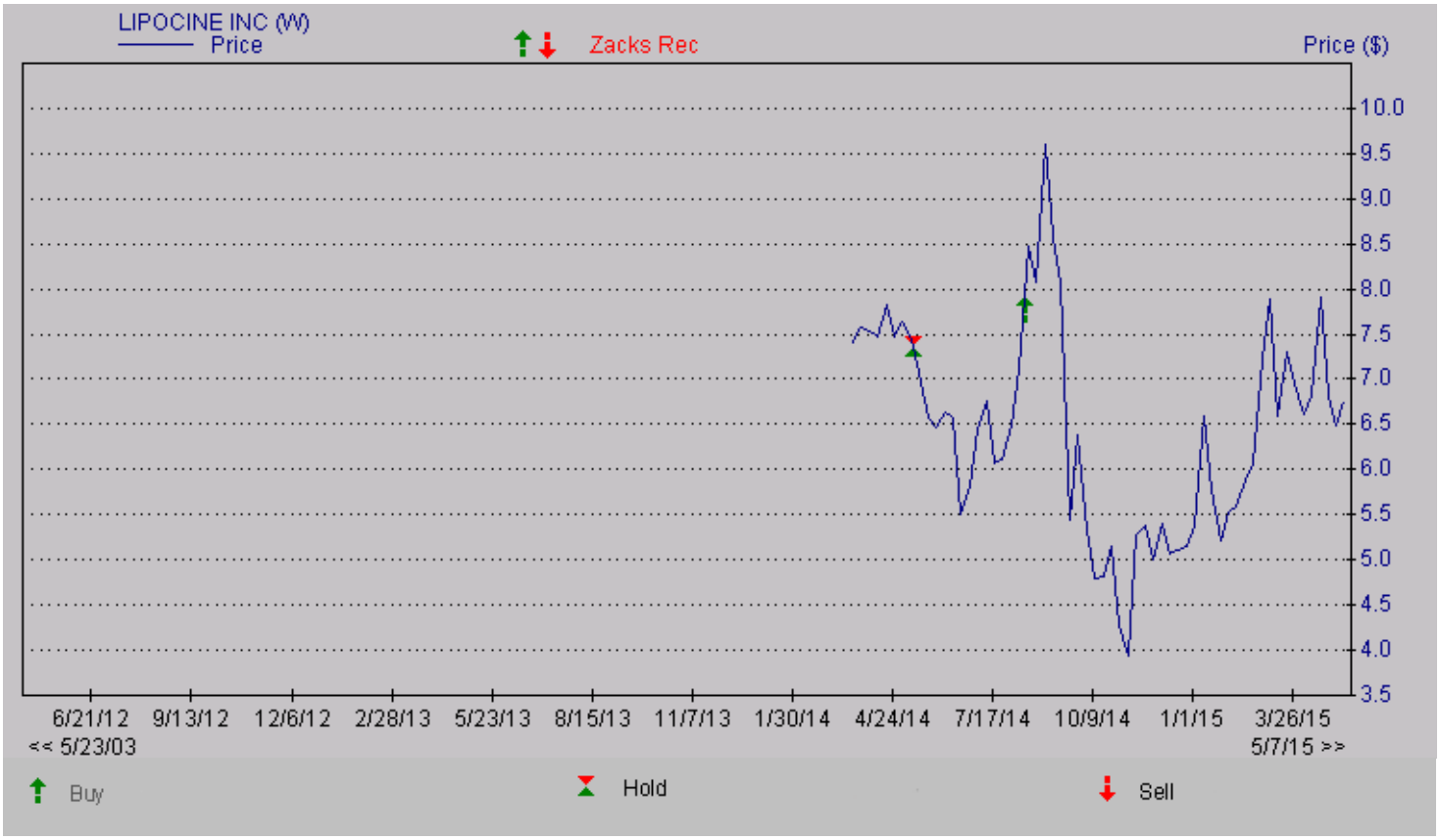

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