Zacks Small-Cap Research

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Lipocine, Inc. (LPCN - NASDAQ)

LPCN: "SOAR" Phase 3 Nears Completion With Enough Cash 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 (03/16/15)	$6.70
Target Price	**$13.50**

UPDATE

On March 11 2015, Lipocine, Inc. reported financial results for the fourth quarter and full year ended December 31, 2014. The company reported no revenues and had a net loss of $20.4 million, or $1.60 per share for the year. The net loss was comprised of $15.5 million in R&D expenses and $5.0 million in G&A expenses for 2014.

The lead candidate, LPCN 1021, is in an ongoing Phase 3 clinical trial with positive top-line efficacy results already reported in September 2014. In December 2014, the FDA confirmed that the LPCN 1021 development plan and Phase 3 design were sufficient for NDA filing, which we expect to occur during the second half of 2015. Even with the FDA imposing limitations and labeling changes on testosterone replacement therapies earlier in the month, we still believe the stock continues to represent an attractive long-term investment.

SUMMARY DATA

52-Week High	**$9.88**
52-Week Low	**$3.95**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**98,274**
Shares Outstanding (mil)	**13**
Market Capitalization ($mil)	**$85**
Short Interest Ratio (days)	**2.06**
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 E	$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	-$0.35 A	-$0.42 A	-$0.47 A	-$0.49 E	-$1.73 E
2016					-$1.38 E

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WHAT'S NEW

Financial Review

On March 11, 2015, Lipocine reported financial results for the fourth quarter and full year ended December 31, 2014. The company did not report any revenues and had a net loss of $20.4 million, or $1.60 per share. This was compared to a net loss of $10.6 million, or $1.44 per share, for the full year of 2013.

Total operating expenses for 2014 totaled $20.5 million, compared to $10.7 million for 2013. Research and development expenses totaled $15.5 million for the full year 2014, compared to $5.1 million for the full year 2013. The increase was driven primarily due to external service provider costs associated with the company's three product candidates, namely LPCN 1021, somewhat counterbalanced by a decrease in drug purchase costs and manufacturing expenses. General and administrative expenses totaled $5.0 million in 2014, compared to $3.6 million for the same time period in 2013. According to management, "The increase was primarily due to increased compensation expense, including increases in equity compensation due primarily to accelerated vesting and/or extension of exercise dates for retiring directors and a terminated officer; as well as increased compensation expense for new administrative personnel and severance payments to a terminated officer."

Lipocine exited 2014 with $27.7 million in cash and cash equivalents, compared with $45.3 million as of December 31, 2013. Operating burn for the fourth quarter was $3.7 million. 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 12+ months. However, we note that on October 1, 2014 Lipocine filed a Form S/3 with the U.S. SEC, thereby giving management added financial flexibility to raise additional cash for the future

What Has Been Going On With The FDA?

…FDA Confirms LPCN 1021 Development Plan For NDA Filing…

On December 15, 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. As a reminder, SOAR is evaluating the safety and efficacy of oral LPCN 1021 in hypogonadal men with low testosterone ("Low T"). 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. Management does not envision the need to conduct further studies for the NDA filing and is confident that SOAR efficacy results are in-line with approval requirements. Dr. Mahesh Patel, Chairman, President and CEO, stated, "We continue to believe that LPCN 1021 represents a 'best-in-class' TRT option with the potential to both improve patient compliance and overcome inadvertent testosterone transference risk." 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.

…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 brain 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.

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 Lipocine, Inc. & Lead Asset LPCN 1021

As a reminder to investors, Lipocine, Inc. is a specialty pharmaceutical company that has an oral drug delivery technology, Lip’ral™, for products that affect men’s and women’s health. The company is currently developing three product candidates (LPCN 1021, LPCN 1111, 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.

Lipocine’s lead asset, LPCN 1021, is a testosterone replacement therapy (TRT) designed for oral twice-a-day dosing. The product is currently wrapping-up the extension study of a pivotal Phase 3 clinical trial run under protocols in-line with FDA guidelines for approval of TRTs. As of March 11, 2015, the ongoing SOAR (Study of Oral Androgen Replacement) Phase 3 clinical study is nearing completion, with the last patient last visit scheduled for the final week in April 2015. As a reminder, the trial demonstrated positive top-line results with a year-long safety assessment producing no usual or serious adverse events to date. The pre-NDA meeting is scheduled for March 19, 2015 to evaluate if the LPCN 1021 package is ready for submission. Lipocine anticipates a safety update in June 2015 with regards to how the product fares against the control, AndroGel®. A few months after the safety update, Lipocine plans to file the NDA. Keeping up with this timeline, we expect the NDA to be filed in the second half of 2015.

…LPCN 1021 Competitive Landscape…

Now that Lipocine has reported positive top-line data from the Study of Oral Androgen Replacement (SOAR) Phase 3 clinical trial, 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 **Androxal®**, an orally active, single isomer of clomiphene citrate that has been shown to be effective in treating secondary hypogonadism. 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® During FDA AdCom Meeting…

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 Rextoro® FDA Briefing Documents). The outcome of the 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. 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 note believe that LPCN 1021 is ahead of Rextoro® in becoming the first oral TRT on the market.

…Repros files NDA for Androxal® …

Repros Therapeutics' Androxal® 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. 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, 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. A month later that meeting was changed to a Type C meeting. After the meeting took place Repros announced that no additional clinical trials would be necessary and the NDA was subsequently filed on February 2, 2015. This means that Repros is ahead of Lipocine by approximately six months; however, we will be unable to gauge how the agency views Androxal® and how likely it is to be approved without a full examination of the data. Given the lack of disclosure, we suspect Androxal® is heading for a complete response letter.

Update 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 planned to start once there is 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. The study was designed to determine the safety, tolerability, bioavailability and PKs of LPCN 1107 as compared to an intramuscular HPC and data has been presented at the Society for Maternal-Fetal Medicine 35th Annual Meeting. As a reminder, PTB is the leading cause of perinatal mortality and morbidity, accounting for as many as 75% of perinatal deaths. HPC is an injectable drug approved for women who have had a previous PTB.

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 [11.5 - 36.2]	156 [81 - 234]
800 mg	63.2 [37.8 - 144]	577 [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 [12.1 - 36.2]	1074 [573-1601]
LPCN 1107 / 800mg BID	71.1 [43.8 - 144.1]	4058 [2180-7701]
Intramuscular injection / 250mg weekly	13.0 [6.5 - 29.4]	1817 [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.

Bioavailability in pregnant and non-pregnant women

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

* one subject data analysis pending

Source: Lipocine, Inc.

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 with a meeting planned for the near future. Lipocine will have more clarity for next steps in the process at some point in the second or third quarter of 2015.

…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 contigent 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. 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.

Conclusion and Recommendation

With seemingly nothing but good news for Lipocine over the past few months – positive Phase 3 data for LPCN 1021, a negative review of an oral TRT competitor, very positive Phase 2a data for LPCN 1111 and Phase 1b data for LPCN 1107 – it is quite surprising 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 $95 million on a fully diluted basis, and with the company currently holding $28 million in cash that represents an enterprise value of less than $70 million. This is bafflingly low for a company with positive Phase 3 data for a compound that will enter a market in excess of $1 billion.

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.

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. At this point, Lipocine is not sure what the FDA requirement will be for a cardiovascular study in the post-approval stage, but hopes to receive further clarity at the pre-NDA meeting scheduled for March 19, 2015. 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.

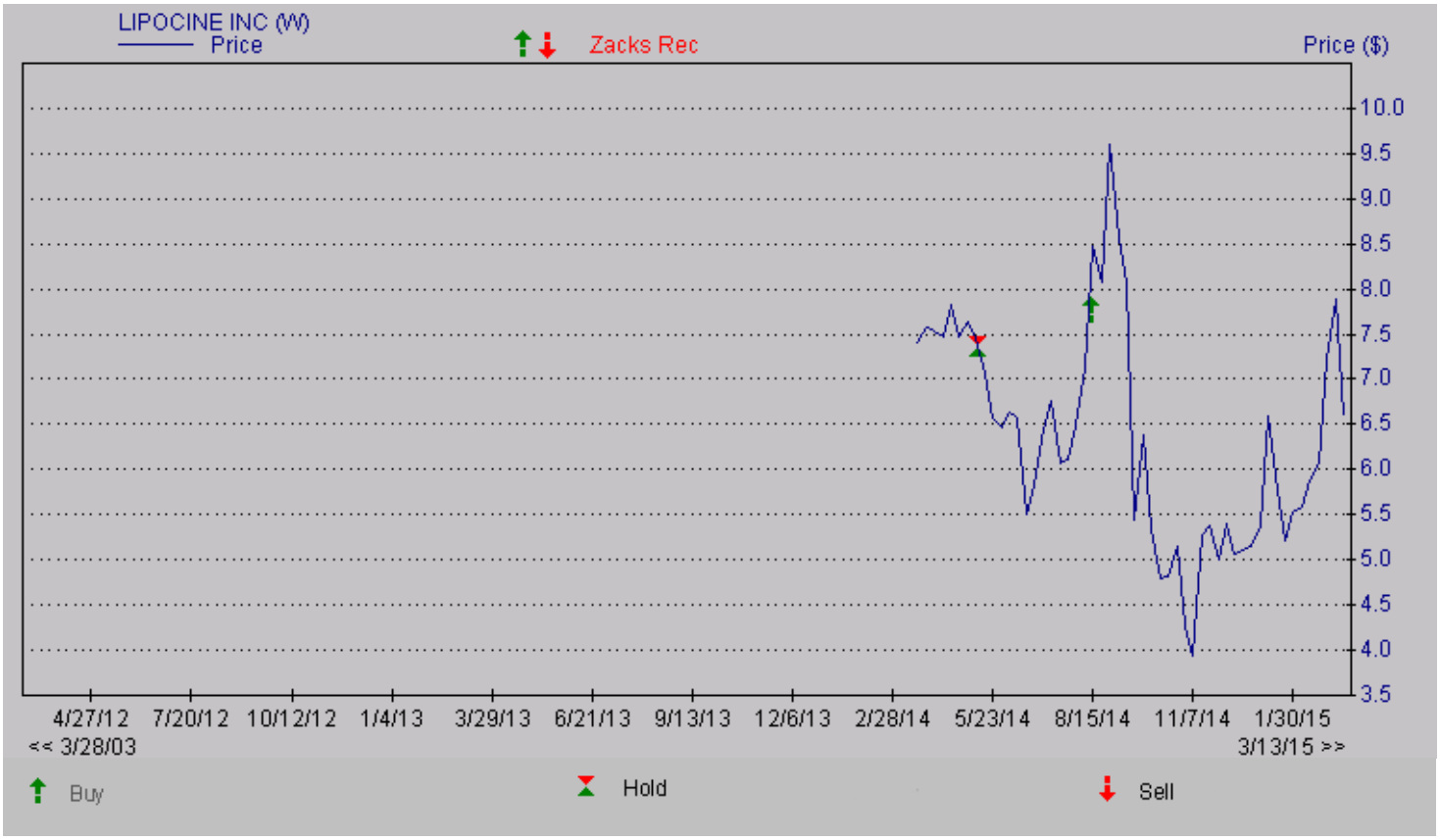
PROJECTED FINANCIALS

Lipocine, Inc.
Income Statement

Lipocine Incorporated	2014 A	Q1 E	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	$3.5	$4.5	$5.5	$6.0	$19.5	$20.0
SG&A	$5.0	$1.4	$1.6	$1.6	$1.8	$6.4	$7.5
Other expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.1	$0.1
Operating Income	($20.5)	($4.9)	($6.1)	($7.1)	($7.8)	($26.0)	($27.6)
Operating Margin	-					-	-
Total Other Income	$0.1	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($20.4)	($4.9)	($6.1)	($7.1)	($7.8)	($26.0)	($27.6)
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)	($4.9)	($6.1)	($7.1)	($7.8)	($26.0)	($27.6)
Reported EPS	**($1.60)**	**($0.35)**	**($0.42)**	**($0.47)**	**($0.49)**	**($1.73)**	**($1.38)**
YOY Growth	-						-
Shares Outstanding	12.8	14.1	14.7	15.3	15.9	15.0	20.0

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Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters.
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