Zacks Small-Cap Research

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Lipocine, Inc. (LPCN - NASDAQ)

LPCN: Positive Phase 3 Results and Enough Cash to Get to the NDA Filing…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	09/24/2014
Current Price (11/11/14)	$4.12
Target Price	**$13.50**

UPDATE

On November 10 2014, Lipocine, Inc. reported financial results for the third quarter of 2014. The company reported no revenues and had a net loss of $4.1 million, or $0.32 per share. The net loss was comprised of $3.2 million in R&D expenses and $0.9 million in G&A expenses.

The company's lead product, LPCN 1021, is in an ongoing Phase 3 clinical trial with the company having reported positive topline results in September 2014. While the stock initially reacted quite favorably to the news, since then it is down almost 45% on fears that the FDA will put restrictions on testosterone replacement therapies. We continue to feel investors are too overwrought from these fears and believe the stock continues to represent an attractive buying opportunity.

SUMMARY DATA

52-Week High	**$9.88**
52-Week Low	**$3.95**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**62,977**
Shares Outstanding (mil)	**13**
Market Capitalization ($mil)	**$53**
Short Interest Ratio (days)	**0.04**
Institutional Ownership (%)	**29**
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 2014 Estimate	**N/A**
P/E using 2015 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)
2013	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2014	$0.0 A	$0.0 A	$0.0 A	$0.0 E	$0.0 E
2015					$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)
2013	-$0.00 A	-$0.00 A	-$0.39 A	-$1.05 A	-$1.44 A
2014	-$0.41 A	-$0.55 A	-$0.32 A	-$0.33 E	-$1.61 E
2015					-$1.89 E
2016					-$1.73 E

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WHAT'S NEW

Financial Results

On November 10, 2014 Lipocine reported financial results for the third quarter of 2014. The company did not report any revenues and had a net loss of $4.1 million, or $0.32 per share. This was compared to a net loss of $3.5 million, or $0.39 per share, for the third quarter of 2013. Research and development expenses totaled $3.2 million for the current quarter, compared to $1.6 million for the corresponding quarter of 2013. The increase was driven primarily by development costs associated with the company's lead product candidates, primarily LPCN 1021. General and administrative expenses totaled $0.9 million in the third quarter of 2014, compared to $1.2 million for the same time period in 2013. The decrease in expenses was primarily the result of higher professional fees associated with preparing to become a publically traded company in 2013.

Lipocine exited the third quarter of 2013 with $31.7 million in cash and cash equivalents. This represents an astonishing 60% of the market value. Operating burn for the current quarter was $2.5 million, thus we project that the current cash level should be enough to fund operations for the next 2+ years. In addition, on October 1, 2014 Lipocine filed a Form S/3 with the U.S. SEC, thereby giving management added financial flexibility for the future.

LPCN 1021 Competitive Landscape

Now that Lipocine has reported positive topline 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.

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.

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, depending on whether Clarus would be required to perform additional clinical trials, this could position LPCN 1021 ahead of Rextoro® in getting the first oral TRT to market.

…Repros plans to file NDA before the end of 2014…

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 that the company would still be filing an NDA before the end of 2014. 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.

Positive Topline Results in Phase 2a Study of LPCN 1111

On October 13, 2014, Lipocine announced positive topline 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 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_{AVE} 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 being planned to start in the first quarter of 2015 such that the company can determine the optimal once daily dosing regimen for use in a Phase 3 trial. 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.

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, and very positive Phase 2a data for LPCN 1111 – it is quite surprising that the stock price is now down over 60% from its September highs. The current market cap is approximately $60 million on a fully diluted basis, and with the company currently holding $31 million in cash that represents an enterprise value of less than $30 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.

Clearly, the stock is 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. Admittedly, there are a number of unanswered questions at this point in regards to how the FDA will ultimately view TRTs and LPCN 1021:

- Will Lipocine have to perform an additional CV safety study?
- Will the data generated in the Phase 3 trial of LPCN 1021 be enough to gain approval?
- Will there be labeling restrictions on TRTs as a group?
- Will there be additional restrictions on oral TRTs?

However, even with these uncertainties, we feel that investors are overreacting to the September 17th meeting 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. 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	2013 A	Q1 A	Q2 A	Q3 A	Q4 E	2014 E	2015 E	2016 E
LPCN 1021	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
YOY Growth		-	-	-	-	-	-	-
LPCN 1111	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
YOY Growth								
LPCN 1107	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
YOY Growth								
Total Revenues	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
CoGS	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Gross Income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Product Gross Margin	-	-	-	-	-	-	-	-
R&D	$5.1	$3.4	$6.0	$3.2	$3.5	$16.1	$25.0	$27.0
SG&A	$3.6	$1.9	$1.0	$0.9	$1.0	$4.8	$9.0	$11.0
Other expenses	$1.9	$0.0	$0.0	$0.0	$0.0	$0.0	$0.1	$0.1
Operating Income	($10.7)	($5.3)	($7.0)	($4.1)	($4.5)	($20.9)	($34.1)	($38.1)
Operating Margin	-	-	-	-	-	-	-	-
Total Other Income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.1	$0.0	$0.0
Pre-Tax Income	($10.6)	($5.3)	($7.0)	($4.1)	($4.5)	($20.8)	($34.1)	($38.1)
Taxes & Other	$0.1	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*99%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($10.6)	($5.3)	($7.0)	($4.1)	($4.5)	($20.8)	($34.1)	($38.1)
Reported EPS	**($1.44)**	**($0.41)**	**($0.55)**	**($0.32)**	**($0.35)**	**($1.63)**	**($2.27)**	**($1.90)**
YOY Growth	-	-				-		-
Shares Outstanding	7.4	12.7	12.8	12.8	13.0	12.8	15.0	20.0

Source: Zacks Investment Research, Inc. *Jason Napodano, CFA*

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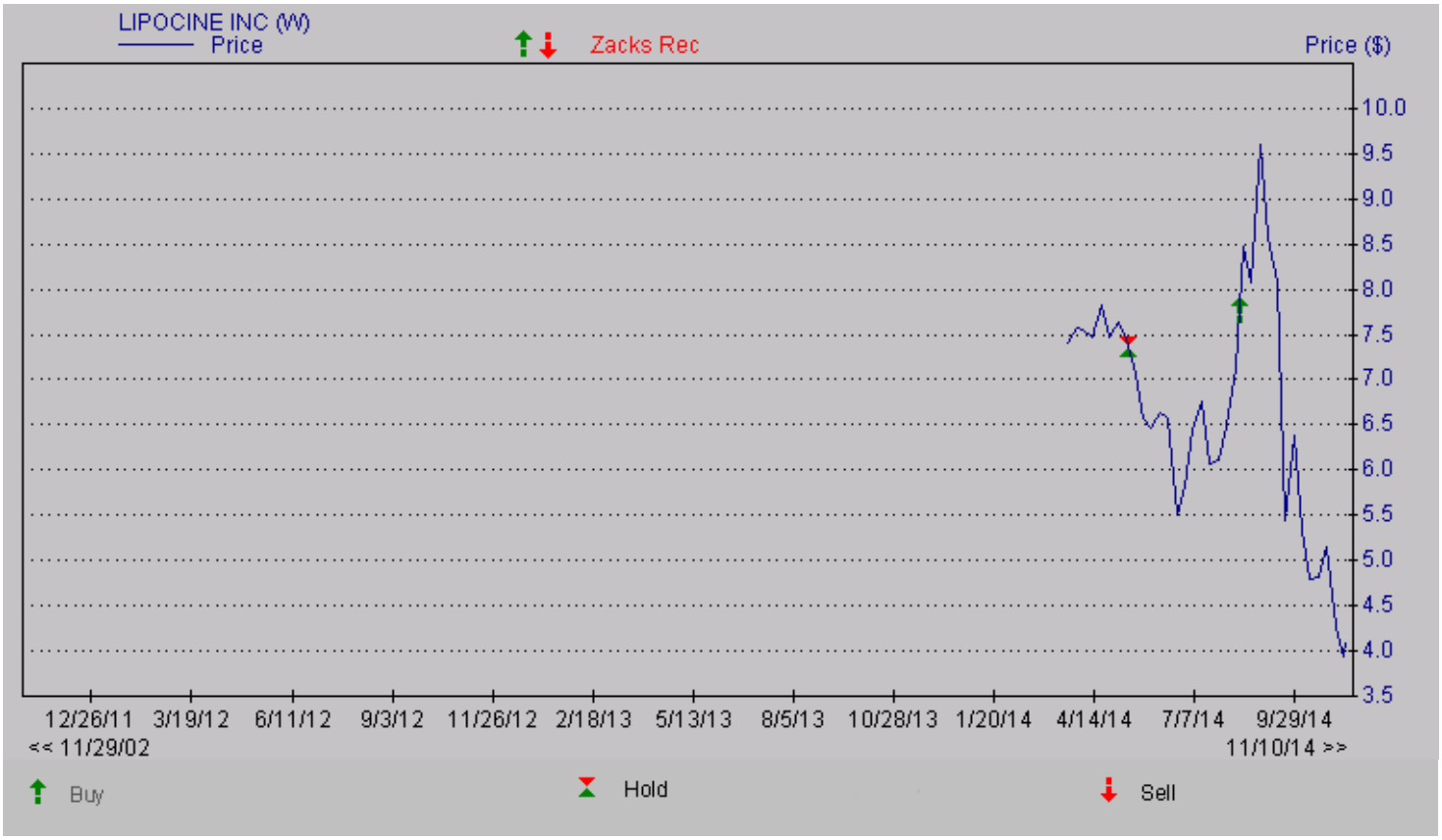

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