Zacks Small-Cap Research

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Lipocine Inc. (LPCN-NASDAQ)

Early Start to Tlando Validation Trial

Based on our DCF model and a 20% discount rate, LPCN is valued at approximately $9.00 per share. We apply a 50% probability of eventual sales of LPCN 1021 (TLANDO), a 15% probability to LPCN 1111 and a 10% probability to LPCN 1107.

Current Price (12/28/16)	$3.92
Valuation	**$9.00**

OUTLOOK

Lipocine uses its proprietary Lip'ral technology to improve bioavailability and convenience of previously approved compounds using the 505(b)(2) regulatory pathway. Lip'ral's favorable pharmokinetic profile facilitates lower dosing, reduces side effects and eliminates gastrointestinal interactions that limit absorption. Currently, the company has three drugs in development that employ this technology. Two are for the treatment of male hypogonadism and the third for the prevention of pre-term birth.

The lead product, LPCN 1021 (Tlando), received a CRL on June 28, 2016 due to concerns regarding the titration approach used in the trial compared to what is recommended on the label. We anticipate a 1Q:18 launch as a result. LPCN's other TRT product, LPCN 1111, which provides a once daily regimen, is 2 years behind 1021 and is expected to eventually replace the twice daily product. LPCN 1107 for pre-term birth has received an orphan designation and has completed Phase 2 trials.

The Post Action meeting with the FDA provides additional clarity on the anticipated timeline and we maintain our price target to $9.00.

SUMMARY DATA

52-Week High	**$13.02**
52-Week Low	**$2.51**
One-Year Return (%)	**-68.3**
Beta	**1.45**
Average Daily Volume (sh)	**501,577**
Shares Outstanding (mil)	**18.3**
Market Capitalization ($mil)	**$71.6**
Short Interest Ratio (days)	**10.3**
Institutional Ownership (%)	**49.2**
Insider Ownership (%)	**15.9**
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 2016 Estimate	**N/A**
P/E using 2017 Estimate	**N/A**
Zacks Rank	**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)
2015	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2016	$0.0 A	$0.0 A	$0.0 A	$0.0 E	$0.0 E
2017					$0.0 E
2018					$58.3 E

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$0.23 A	-$0.26 A	-$0.35 A	-$0.25 A	-$1.11 A
2016	-$0.38 A	-$0.32 A	-$0.18 A	-$0.22 E	-$1.10 E
2017					-$1.77 E
2018					$0.69 E

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WHAT'S NEW

Update on Validation Trial for Tlando

On December 5th Lipocine Inc. (NASDAQ: LPCN) announced that it will begin its dosing validation study for LPCN 1021 (Tlando) immediately to address the items raised in the CRL in June of this year. The company received feedback from the FDA regarding desired size and duration of the study and felt this information was sufficient to commence with the trial. Completion is targeted within the next 60 to 90 days. LPCN did not develop a full agreement with the FDA as management felt it would take longer than the anticipated duration of the trial to obtain it. As of late December, Lipocine has started screening patients for the validation effort and we expect the first enrollees to begin the test therapy before the end of 2016 and full enrollment to be complete in a couple months. Topline results are anticipated by 2Q:17 targeting the same endpoints as used in the Phase 3 trial.

The dosing validation trial is an open-label, fixed dose, single treatment arm of Tlando which expects to enroll 100 subjects. The dosing period is 24 days and the primary endpoint is the percentage of subjects with an average 24-hour serum testosterone concentration average ("Cavg") within the normal range.[1] Secondary endpoints will examine maximum serum testosterone concentrations ("Cmax").[2]

The FDA will analyze the new data from the validation trial along with the resubmission and we anticipate that this will be followed by a 6-month review by the FDA and a 4Q:17 answer from the agency. If Tlando is approved, first sales are expected by early 2018.

Completion of FDA Post Action Meeting

On October 17, 2016, the company announced that it had held a Post Action meeting in the first half of October with the FDA following the receipt of a Complete Response Letter (CRL) on June 28 of this year. The meeting was held in order to clarify the deficiencies noted in the CRL and assist Lipocine in determining what is necessary to obtain approval of LPCN 1021 (Tlando).

The CRL had identified deficiencies in the dosing algorithm when comparing the protocol used in the trial with the data provided on the drug label. As a result, the FDA required an additional trial to validate the proposed label. In response, Lipocine submitted a new dosing validation clinical study protocol to the FDA.

Tlando Background

On August 28, 2015, Lipocine Inc. submitted a 505(b)(2) New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for Lipocine's lead asset LPCN 1021. LPCN 1021 is a testosterone replacement therapy (TRT) designed for oral twice daily dosing in adult hypogonadal males with low testosterone. The FDA accepted the NDA on October 29, 2015, and subsequently on November 12, 2015, Lipocine announced that the FDA assigned a Prescription Drug User Fee Act (PDUFA) goal date of June 28, 2016 for completion of the review of the NDA. The FDA issued a CRL in June 2016, and met with Lipocine in October 2016 for a Post Action meeting that provided additional clarity on trial design and future steps required for resubmission to the FDA.

The CRL highlighted deficiencies related to dosing as provided in the label. The Phase 3 trial protocol had adjusted dosing based on 15 blood draws taken over a 24 hour period; however, the proposed label only relied on only one blood draw to determine the proper titration. The FDA felt that this inconsistency would lead to dosing errors and as a result will require evidence to support a single point window after administration of Tlando where the patient is evaluated and up-titrated or down-titrated to achieve the optimal dose. Prior to the letter, management felt that the trial design was sufficient as it was based on the Phase 3 trial for Axiron, an Eli Lilly topical testosterone product which was approved in 2010.

We continue to believe the oral formulation of LPCN 1021, if approved, may improve patient compliance as it appears to be a generally safe, effective, and a more convenient TRT option as compared to topical and injectable

[1] As outlined in the SOAR trial discussion, the FDA's guidelines for C_{avg} is serum testosterone in the range of 300 to 1140 ng/dL. Source: http://files.shareholder.com/downloads/AMDA-2BVSIV/3534535703x0x783208/F8BADB0C-F8F1-48BA-96CE-A92F2352A81A/SOAR_Topline_Results.pdf

[2] The FDA threshold for C_{max} serum total testosterone is less than 5% between 1800 and 2500 ng/dL and no serum total testosterone concentrations above 2500 ng/dL.

TRT products that are currently on the market. LPCN 1021 will have to adhere to all of the new regulations set forth by the FDA 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, if LPCN 1021 is approved, there may be post-approval obligations regarding a heart attack and stroke risk study. Lipocine may be have to contribute to an on-going industry-led heart attack and stroke risk study, or it may need to conduct a separate long-term study.

Conclusion

We expect a 4Q:17 FDA announcement date for Tlando with a subsequent launch of the product in early 2018. We believe that the FDA's emphasis on dosing protocols rather than on a fundamental flaw with the Lip'ral technology support eventual approval. We will adjust our model accordingly as additional details become available.

Lipocine has reduced its workforce and other related expenditures in the third quarter and we reduce general and administrative cost in the fourth quarter to reflect these reductions Our price target is $9, based on a 20% discount rate, and probability of eventual sales for LPCN 1021, LPCN 1111 and LPCN 1107 of 50%, 15% and 10% respectively. We maintain a positive view on Lipocine shares as an investment in the specialty pharmaceutical sector based on the company's promising pipeline and Lip'ral technology.

While the FDA's issuance of a complete response letter will delay the launch of Tlando and potentially increase trial costs by several million dollars, we believe that Lipocine will obtain approval for the compound. Based on our estimates of sales, expenses, risk, and updates provided in company documents, our target price remains constant at $9.00 per share.

PROJECTED FINANCIALS

Lipocine Inc. - Income Statement

Lipocine Incorporated	2015 A	Q1 A	Q2 A	Q3 A	Q4 E	2016 E	2017 E	2018 E
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0.0**	**$58.3**
CoGS	$0	$0	$0	$0	$0	$0	$0	$20
Product Gross Margin								*65.0%*
R&D	$12.6	$2.7	$2.6	$1.5	$2.6	$9.3	$22.0	$22.0
SG&A	$5.8	$4.4	$3.2	$1.4	$1.6	$10.6	$15.0	$19.0
Other expenses	$0.0	$0.0	$0.0	$0.4	$0.0	$0.4	$0.1	$0.1
Operating Income	($18.4)	($7.1)	($5.8)	($3.3)	($4.2)	($20.4)	($37.1)	($3.2)
Operating Margin	-					-	-	-
Total Other Income	$0.2	$0.1	$0.1	$0.1	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($18.2)	($7.0)	($5.8)	($3.2)	($4.2)	($20.4)	($37.1)	($3.1)
Taxes & Other	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$18.3
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*581%*
Net Income	($18.2)	($7.0)	($5.8)	($3.2)	($4.2)	($20.4)	($37.1)	$15.1
Reported EPS	**($1.11)**	**($0.38)**	**($0.32)**	**($0.18)**	**($0.22)**	**($1.10)**	**($1.77)**	**$0.69**
YOY Growth						-	-	-
Shares Outstanding	16.5	18.3	18.3	18.3	19.2	18.5	21.0	22.0

Source: Company Filing // Zacks Investment Research, Inc. Estimates

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