Zacks Small-Cap Research

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John D. Vandermosten, CFA
312-265-9588 / jvandermosten@zacks.com

10 S. Riverside Plaza, Chicago, IL 60606

Lipocine Inc. (LPCN-NASDAQ)

FDA Post Action Meeting Provides Clarity on Tlando Timeline.

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 (10/17/16)	$3.65
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 1170 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	**$14.80**
52-Week Low	**$2.51**
One-Year Return (%)	**-71.5**
Beta	**1.65**
Average Daily Volume (sh)	**506,130**
Shares Outstanding (mil)	**18.3**
Market Capitalization ($mil)	**$66.6**
Short Interest Ratio (days)	**17.2**
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 E	$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 E	-$1.11 E
2016	-$0.38 A	-$0.32 A	-$0.29 E	-$0.28 E	-$1.27 E
2017					-$1.77 E
2018					$0.69 E

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WHAT'S NEW

Completion of FDA Post Action Meeting

On October 17, 2016, Lipocine Inc. (NASDAQ:LPCN) 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 will require an additional trial that will validate the recommendations in the proposed label. In response, Lipocine has submitted a new dosing validation clinical study protocol to the FDA, and the agency has agreed to review the protocol through a Special Protocol Assessment ("SPA"). The SPA is an advance declaration from the FDA that the trial design is acceptable in terms of clinical endpoints and statistical analyses for eventual submission for approval.

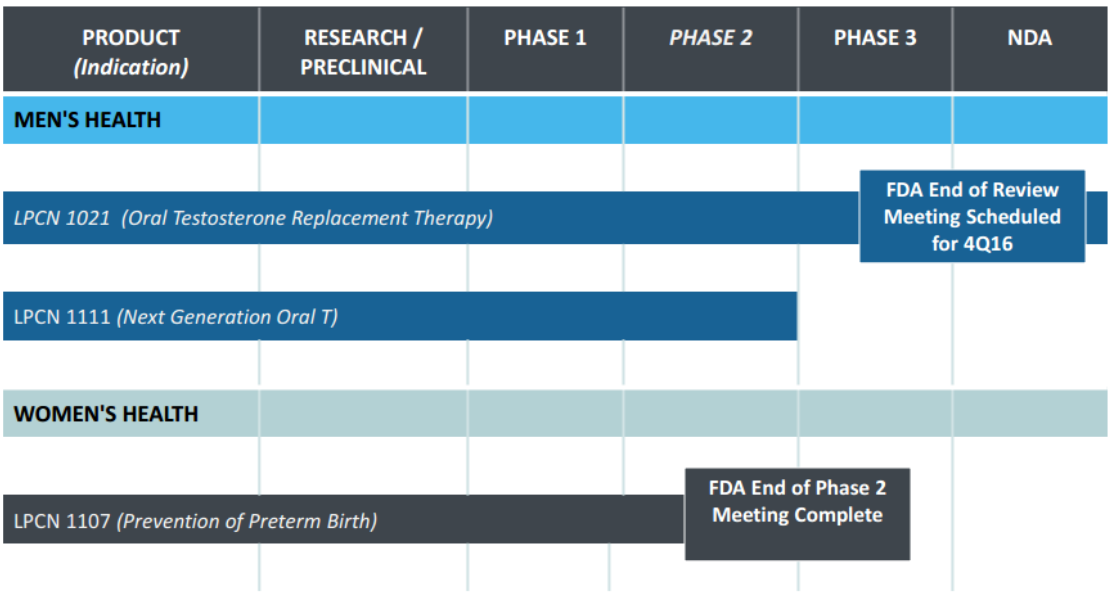
Based on our discussion with management, we anticipate an approval of the SPA by the end of November, in line with the mandated 45-day turnaround for the FDA. Due to December holidays, we anticipate the trial to begin with the new year, and to last for up to three months, ending sometime around the end of the first quarter 2017. We forecast that the trial will require from 25 to 50 enrollees as to satisfy powering requirements and we anticipate additional costs of $1 to $5 million which will be incurred in 1Q:17.

The FDA will require new data from the validation trial which will be included in the resubmission and we anticipate that the new information will advocate for a Class 2 resubmission. A Class 2 resubmission provides a 6-month target for the FDA to provide a response, which should generate a 4Q:17 answer from the agency. If Tlando is approved, first sales may begin late 2017 or early 2018.

LPCN 1111 Phase 2b Topline

Lipocine will have a meeting with the FDA in 4Q:16 to determine the design for the Phase 3 trial for LPCN 1111. When the company developed the Phase 3 trial for LPCN 1111's predecessor, the once per day TRT therapy, the FDA required a 52 week extension study as Tlando was the first oral product in the class. Management believes that a study that requires another extension study would run about $25 million. However, now that the oral administration route is better understood, LPCN 1111 trials may be able to rely on the Tlando research to determine safety. If this is the case, then Lipocine will only need perform the efficacy study and costs will fall dramatically to an estimated $5 million.

Exhibit I – LPCN Pipeline



LPCN 1107 Milestones

The company also has a 4Q:16 milestone for LPCN 1107, which is the oral product for prevention of recurrent pre-term birth. Lipocine met with the FDA at the end of August for the end of Phase 2 meeting and received guidance on the clinical path forward. The next meeting in the current quarter will clarify study design, protocol and the number of subjects.

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 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

The FDA's responses with regard to the Post Action meeting suggest a pathway that will result in a 4Q:17 announcement date for Tlando with a subsequent launch of the product. We believe that the FDA's emphasis on dosing protocols rather than on a fundamental flaw with the Lip'ral technology support eventual approval. While there is still some uncertainty regarding the duration of the trial, there is additional clarity due to the guidance provided at the Post Action meeting and we have taken a conservative approach regarding response times. Based on current information, we estimate that if approved, Tlando will achieve first sales in 2018. We will adjust our model accordingly as additional details become available.

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 E	Q4 E	2016 E	2017 E	2018 E
LPCN1021	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0.0**	**$58.3**
YOY Growth	-	-	-	-	-	-	-	-
LPCN1111	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth								
LPCN1107	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth								
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	$2.6	$2.6	$10.4	$22.0	$22.0
G&A	$5.8	$4.4	$3.2	$2.8	$2.8	$13.2	$15.0	$19.0
Other expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.1	$0.1	$0.1
Operating Income	($18.4)	($7.1)	($5.8)	($5.4)	($5.4)	($23.7)	($37.1)	($3.2)
Operating Margin	-					-	-	-
Total Other Income	$0.2	$0.1	$0.1	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($18.2)	($7.0)	($5.8)	($5.4)	($5.4)	($23.7)	($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)	($5.4)	($5.4)	($23.7)	($37.1)	$15.1
Reported EPS	**($1.11)**	**($0.38)**	**($0.32)**	**($0.29)**	**($0.28)**	**($1.27)**	**($1.77)**	**$0.69**
YOY Growth						-	-	-
Shares Outstanding	16.5	18.3	18.3	19.0	19.2	18.7	21.0	22.0

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

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