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)

LPCN 1021 Topline: NDA Resubmission in 3Q:17

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 (6/20/17)	$4.24
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 June 2016 due to concerns regarding the titration approach used in the trial compared to what is recommended on the label. We anticipate a 2H: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.

SUMMARY DATA

52-Week High	**$7.78**
52-Week Low	**$2.51**
One-Year Return (%)	**-37.7**
Beta	**1.95**
Average Daily Volume (sh)	**164,206**
Shares Outstanding (mil)	**19.3**
Market Capitalization ($mil)	**$81.7**
Short Interest Ratio (days)	**18.0**
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)
2016	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2017	$0.0 A	$0.0 E	$0.0 E	$0.0 E	$0.0 E
2018					$38.9 E
2019					$136.2 E

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	-$0.38 A	-$0.32 A	-$0.18 A	-$0.16 A	-$1.04 A
2017	-$0.26 A	-$0.33 E	-$0.28 E	-$0.30 E	-$1.17 E
2018					$0.25 E
2019					$2.12 E

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WHAT'S NEW

Topline Data Published for DV and DV Studies

Lipocine issued a press release on June 19 along with a conference call highlighting the details of their Dosing Validation (DV) and the Dosing Flexibility (DF) studies which evaluated the efficacy and tolerability of LPCN 1021. The primary endpoint for the trial, C_{avg}, was met with 81% of the DV trial subjects falling into the normal range. This compares to the DF study, which had 70% of subjects within this range. The greater percentage of patients that fell into the normal range for the DV study supports the twice per day dosing regimen for LPCN 1021.

Adverse events were similar in frequency to the SOAR trial and were mild or moderate in intensity, with no hepatic, cardiac or other severe events.

Secondary endpoints examined C_{max} for both the DV and DF studies using limits determined by the FDA for transdermal testosterone. For the Validation study, 85% of subjects achieved a C_{max} below 1,500 ng/dL and 7% were between 1,800 and 2,500 ng/dL. Only one patient exceeded the 2,500 ng/dL limit but was erroneously enrolled in the trial due to the excluding factor of gastric surgery.

The main objective of these two small studies was to validate the twice daily regimen and the titration schedule. With the favorable results within the FDA's normal range, we believe that Lipocine will be able to obtain approval for a fixed dose with no titration. They will propose a 225 mg, twice daily dosing, matching the algorithm reviewed in the SOAR trial.

During the conference call, management provided anticipated timing based on the completion of the DV and DF trials. The new drug application is targeted for submission during the third quarter of 2017 and approximately one month after receipt, we anticipate the FDA will assign a PDUFA date. As we have discussed, since new data is being considered, the FDA will likely require six months to review the study data, suggesting a response by the first quarter of 2018. Assuming a favorable response from the regulatory agency, we anticipate that Lipocine will be able to achieve first sales within 90 days.

Cash levels of $26.8 million are sufficient to steer LPCN 1021 through the resubmission process, but will not support commercialization activities or trials for other programs in the pipeline. Positive news from the FDA will provide the necessary catalyst to attract capital for continued development. The favorable topline data from the DV study and increased clarity on the timeline support our current estimates and target price.

Highlighted Events Year to Date

- Dosing flexibility study initiated in early January following prior month's launch of dosing validation study.
- On March 6, the company entered into a Controlled Equity Offering agreement with Cantor Fitzgerald where up to $20 million in stock may be sold under an at-the-market offering.
- During the first quarter, 667 thousand shares were sold under the offering agreement raising net proceeds of $2.7 million.
- On February 15, Lipocine announced the promotion of Gregory Bass to Chief Commercial Officer.
- On April 24th Lipocine announced it had completed enrollment of the LPCN 1021 fixed dose trials.
- Announcement of topline results from DV and DF study on June 19, 2017

Upcoming Milestones

- Resubmission of LPCN 1021 NDA anticipated in 3Q:17
- Announcement of PDUFA date in late 3Q:17 or early 4Q:17
- Response from FDA regarding approval of LPCN 1021 in 1Q:17
- First sales of LPCN 1021 anticipated before 3Q:18

Summary

As per guidance, LPCN provided a June report of topline results for the DV and DF studies. We expect the next several weeks will be spent conducting additional analysis and preparing the NDA for resubmission. Since the FDA will be reviewing new data, there will likely be a six month review by the FDA and a PDUFA date near the middle part of the first quarter of 2018. This will be followed by a buildup of the required sales force and finding an appropriate partner for the primary care segment over the next 90 days. Based on this timeline, first sales are anticipated to take place prior to 3Q:18.

We believe that the FDA's emphasis on dosing protocols rather than on a fundamental flaw with the Lip'ral technology support eventual approval. With data supportive of the b.i.d. design without the need for titration, we anticipate FDA approval of LPCN 1021. Our target price is derived using a 20% discount rate, and probability of eventual sales for LPCN 1021, LPCN 1111 and LPCN 1107 of 50%, 15% and 10% respectively. Based on our estimates of sales, expenses, risk, and updates provided in company documents, our target price remains $9.00 per share.

PROJECTED FINANCIALS

Lipocine Inc. - Income Statement

Lipocine Incorporated	2016 A	Q1 A	Q2 E	Q3 E	Q4 E	2017 E	2018 E	2019 E
LPCN1021	**$0**	**$0**	**$0**	**$0**	**$0**	**$0.0**	**$38.9**	**$136.2**
YOY Growth	-	-	-	-	-	-	-	-
LPCN1111	**$0**	**$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**	**$38.9**	**$136.2**
CoGS	$0	$0	$0	$0	$0	$0	$14	$48
Product Gross Margin							*65.0%*	*65.0%*
R&D	$8.1	$3.1	$4.5	$4.2	$4.0	$15.8	$22.0	$22.0
SG&A	$10.4	$1.8	$1.8	$1.8	$2.5	$7.9	$19.0	$25.4
Other expenses	$0.7	$0.0	$0.0	$0.0	$0.0	$0.1	$0.1	$0.1
Operating Income	($19.2)	($4.9)	($6.3)	($6.0)	($6.5)	($23.81)	($15.8)	$41.0
Operating Margin	-					-	-	-
Total Other Income	$0.2	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($19.0)	($4.9)	($6.3)	($6.0)	($6.5)	($23.8)	($15.8)	$41.0
Taxes & Other	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$21.4	$7.2
Tax Rate	*0%*	*$0.0*	*0%*	*0%*	*0%*	*0%*	*136%*	*-18%*
Net Income	($19.0)	($4.9)	($6.3)	($6.0)	($6.5)	($23.8)	$5.7	$48.3
Reported EPS	**($1.04)**	**($0.26)**	**($0.33)**	**($0.28)**	**($0.30)**	**($1.17)**	**$0.25**	**$2.12**
YOY Growth	-					-	-	-
Shares Outstanding	18.3	18.7	19.0	21.8	21.9	20.4	22.3	22.8

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

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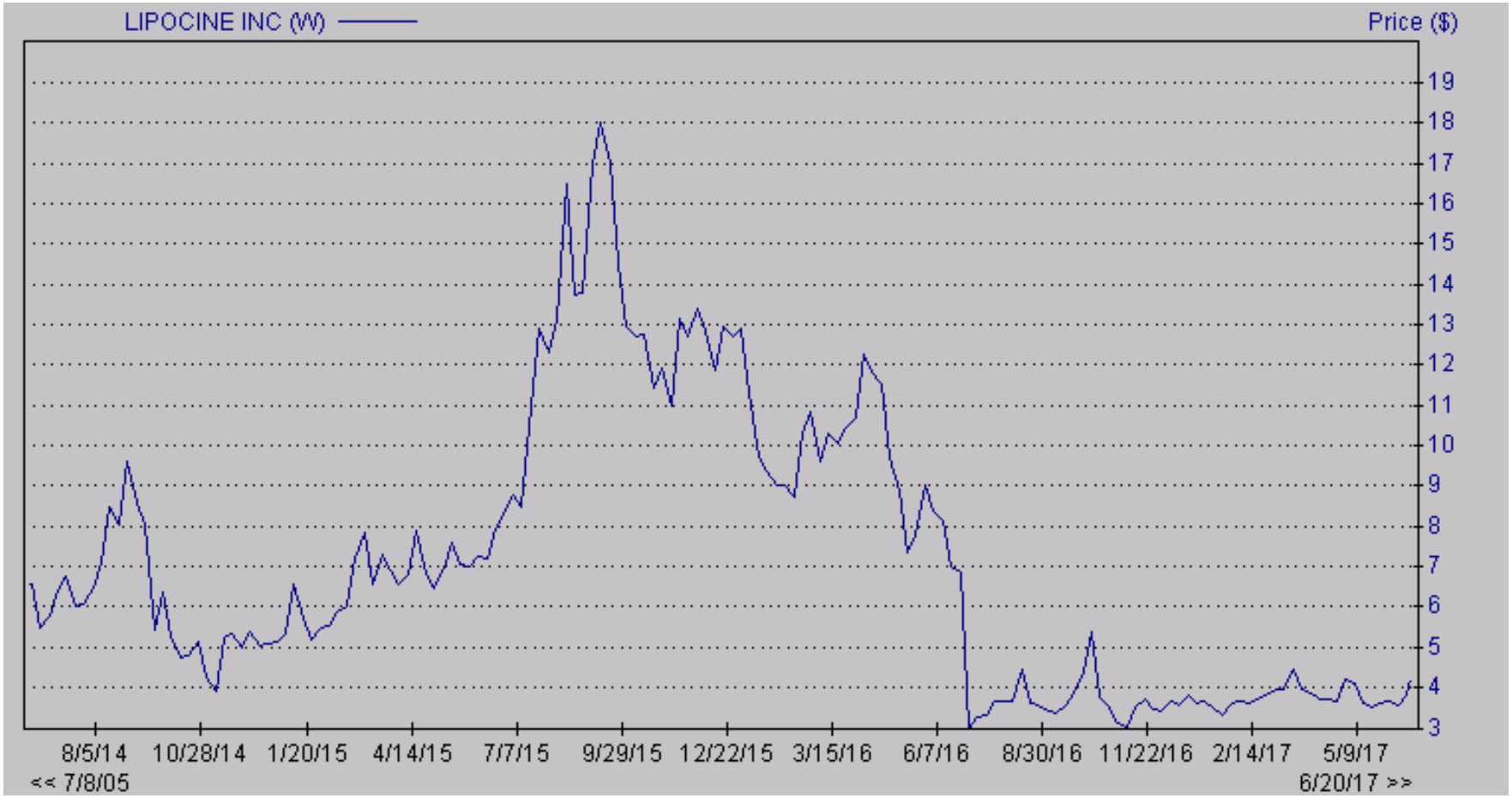
HISTORICAL STOCK PRICE



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