Zacks Small-Cap Research

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Lipocine Inc. (LPCN-NASDAQ)

August Resubmission for LPCN 1021: Anticipate 1Q:18 PDUFA Date

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 (8/7/17)	$4.49
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 the proposed label. Since then a DV and DF study were performed supporting the dosing and titration employed in the Ph 3 study. We anticipate an August 2017 resubmission and 2H:18 launch. LPCN's other TRT product, LPCN 1111, which provides a once daily regimen, is currently undergoing toxicology studies in preparation for a Ph 3 study and is expected to eventually replace the twice daily product. LPCN 1107 for pre-term birth has received an orphan designation and is developing a protocol for conducting an eventual Ph 3 trial.

SUMMARY DATA

52-Week High	**$5.90**
52-Week Low	**$3.03**
One-Year Return (%)	**21.7**
Beta	**2.16**
Average Daily Volume (sh)	**448,539**
Shares Outstanding (mil)	**20.7**
Market Capitalization ($mil)	**$92.8**
Short Interest Ratio (days)	**2.34**
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 A	$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	-$0.31 A	-$0.28 E	-$0.30 E	-$1.16 E
2018					$0.25 E
2019					$2.12 E

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WHAT'S NEW

Second Quarter Operational and Financial Results

The highlight of the second quarter was the announcement of topline results from the dosing validation (DV) and dosing flexibility (DF) studies for Lipocine's testosterone therapy, LPCN 1021. The studies supported the Phase 3 design providing LPCN 1021 as a fixed dose with twice daily administration. Results met FDA guidelines for average testosterone levels with 81% of subjects achieving the normal range. Providing LPCN 1021 as a fixed dose with no titration is an important factor for simplicity in administration and monitoring for physicians and their patients. The DV study will be the pivotal study for the resubmission and is expected to be presented to the FDA later this month.

On August 8th Lipocine Inc. (NASDAQ: LPCN) filed its first quarter 2017 10-Q in conjunction with a press release highlighting recent achievements. The company reported 2Q:17 net loss of ($6.1) million which equates to ($0.31) on a per share basis. This compares to our estimates of ($6.3) million and ($0.33) per share. Actual R&D expenditures for the dosing validation (DV) and dosing flexibility (DF) study were lower than our estimates, but did rise by 60% over the same period in the prior year.

Second quarter 2017 R&D expenses were $4.1 million, increasing from the $2.6 million spent in 2Q:16. Higher CRO expenses related to LPCN 1021, as well as the cost of the DV and DF studies were partially offset by lower manufacturing costs. Further offsets were seen in lower year over year expenses attributable to LPCN 1111. G&A expenses of $2.0 million declined 37% compared to the same quarter a year ago on lower business development, market research and pre-commercialization activities related to LPCN 1021 as well as a reduction in workforce which occurred in the third quarter of 2016.

Cash burn for the second quarter was ($4.7) million offset by a net increase in cash from financing of $5.7 million due to the equity issuance under the controlled equity offering sales agreement with Cantor Fitzgerald. Cash and equivalents and investment securities totaled $27.8 million up from $26.8 million in 1Q:17 and $26.8 million at the end of 2016.

Topline Data Published for DV and DV Studies

Lipocine issued a press release on June 19 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.[1] 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[2] 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. The company will propose a 225 mg, twice daily dosing schedule, 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

[1] The FDA guidelines for primary efficacy success is that at least 75% of the subjects on active treatment achieve a testosterone Cavg within the normal range; and the lower bound of the 95% CI must be greater than or equal to 65%.
[2] The FDA guidelines for secondary efficacy success is that at least 85% of the subjects achieve Cmax less than 1500 ng/dL; no greater than 5% of the Subjects have Cmax between 1800 ng/dl and 2500 ng/dL; and zero percent of the subjects have Cmax greater than 2500 ng/dL.

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 ~$28 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. We do note that the ATM agreement with Cantor Fitzgerald may provide additional financing as we progress through the development and regulatory process. Positive news from the FDA will provide the necessary catalyst to continue to attract capital for continued development. The favorable topline data from the DV study and increased timeline clarity, particularly the August resubmission date for LPCN 1021, support our current estimates and target price.

Highlighted Events Year to Date

- Entry 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 1H:17, 1.99 million shares were sold under the offering agreement raising net proceeds of $8.4 million.
- On April 24th Lipocine announced it had completed enrollment of the LPCN 1021 fixed dose trials.
- Topline results from DV and DF study were announced on June 19, 2017
- Lipocine submitted its SPA for LPCN 1107 (Pre-term birth) to the FDA in June 2017.

Competition Update

On June 26, 2017, Clarus Therapeutics, Inc. announced that it had completed its Phase 3 clinical trial for Jatenzo, a twice-daily oral softgel capsule of testosterone undecanoate, and submitted an NDA to the FDA. However, no PDUFA date has been announced as of yet. If Jatenzo is approved by the FDA before LPCN 1021, Clarus may launch Jatenzo before LPCN 1021, providing a commercial advantage to this competitor.

On July 6, 2017, the Australian Acrux confirmed that a generic version of Axiron Topical Solution, 30 mg/1.5 mL (Testosterone Topical Solution, 30 mg/1.5 mL) has been launched in the United States by Perrigo. Acrux also confirmed the availability of an authorized generic version of Axiron in the United States, through an agreement between Eli Lilly and another generics company. We do not see this as materially impacting the competitive environment as there are a number of topical competitors in the market and LPCN 1021 as an oral solution is not competing directly with other methods of administration.

Update on LPCN 1107 (Pre-term Birth)

Lipocine submitted its special protocol assessment (SPA) to the FDA for LPCN 1107 in June and expects a response from the agency before the end of the third quarter. Due to the small patient population size, the FDA has granted orphan status to LPCN 1107, which provides several benefits that will lower trial costs and duration.

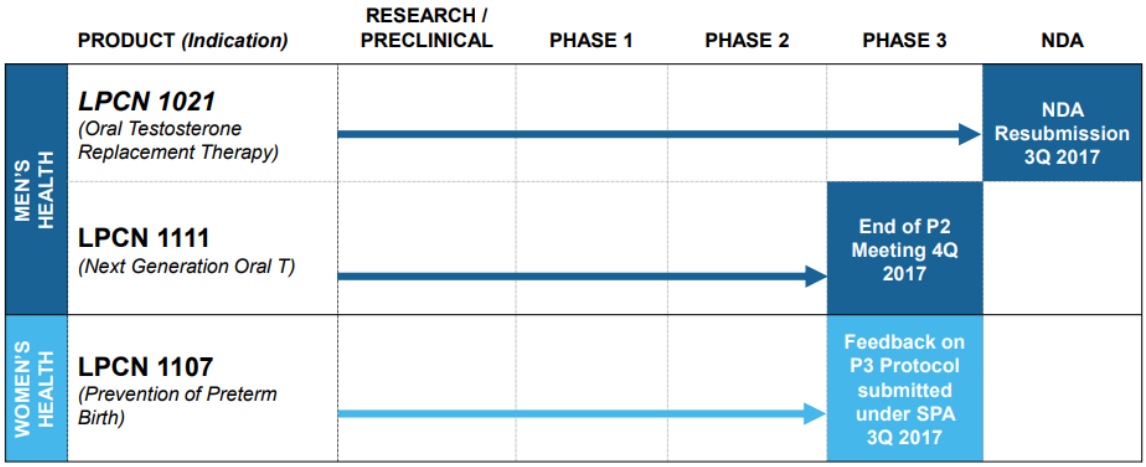
During the end of Phase 2 meeting, the FDA agreed to a randomized, open-label, two-arm clinical study to include LPCN 1107 and intramuscular comparator with treatment for up to 23 weeks. The agency also had a favorable view on the proposed 800 mg, twice per day dosing for the trial. The FDA and Lipocine agreed on a surrogate endpoint of a rate of delivery less than 37 weeks rather than clinical outcomes for the infant and a non-inferiority study margin of 7%, with interim analyses. Based on the proposed endpoints and 90% powering, a full study may require as many as 1,100 subjects per treatment arm, however, the ability to conduct interim analyses may enable the study to enroll fewer subjects. A food effect trial will also be required.

Lipocine expects to interact with the FDA over the next several months determining the best trial design that meets the agency's needs and we expect the design of the Phase 3 trial to develop by the end of the year. Manufacturing (CMC) scale up work, agreement on the protocol with the FDA and additional funding are required before the Phase 3 for LPCN 1107 can begin.

Update on LPCN 1111 (Once-daily Oral Testosterone)

LPCN 1111 is currently undergoing a preclinical toxicity study, following a Phase 2a and 2b study that were completed in 2016. An end of Phase 2 meeting with the FDA is expected in 4Q:17, following the toxicity study and next steps, including additional testing or the initiation of a Phase 3 trial will be determined in conjunction with the FDA

Exhibit I – Lipocine Pipeline



Summary of Milestones

- Resubmission of LPCN 1021 NDA anticipated in August 2017
- Announcement of PDUFA date for LPCN 1021 in late 3Q:17 or early 4Q:17
- Response from FDA regarding approval of LPCN 1021 in 1Q:18
- First sales of LPCN 1021 anticipated before 3Q:18
- LPCN 1111 preclinical toxicology study completion 3Q:17
- LPCN 1111 end of Phase 2 meeting with FDA 4Q:17
- FDA feedback on Phase 3 protocol for LPCN 1107 3Q:17
- CMC process characterization and scale up completed 4Q:17

Summary

LPCN completed its DV and DF studies for LPCN 1021 and now anticipates resubmitting its NDA later this month. We expect a favorable outcome from the FDA as questions regarding dosing and titration have been answered and results from the DV and DF studies confirm the initial proposed label dosing with no titration. We expect the FDA will provide a response with a PDUFA date in 1Q:18. Following the anticipated approval, Lipocine will develop the required sales force and find an appropriate partner to commercialize the primary care segment over the following 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 of LPCN 1021, our main value driver. Progress continues to be made on the other candidates in the pipeline including advancement of the design along with the FDA for LPCN 1107's Phase 3 study. 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 A	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	$4.1	$4.2	$4.0	$15.4	$22.0	$22.0
G&A	$10.4	$1.8	$2.0	$1.8	$2.5	$8.2	$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)	($6.1)	($6.0)	($6.5)	($23.6)	($15.8)	$41.0
Operating Margin	-					-	-	-
Total Other Income	$0.2	$0.0	$0.1	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($19.0)	($4.9)	($6.1)	($6.0)	($6.5)	($23.6)	($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)	($6.1)	($6.0)	($6.5)	($23.6)	$5.7	$48.3
Reported EPS	**($1.04)**	**($0.26)**	**($0.31)**	**($0.28)**	**($0.30)**	**($1.16)**	**$0.25**	**$2.12**
YOY Growth	-					-	-	-
Shares Outstanding	18.3	18.7	19.4	21.8	21.9	20.4	22.3	22.8

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

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