Zacks Small-Cap Research

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May 11, 2017
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Lipocine Inc. (LPCN-NASDAQ)

LPCN 1021 Readout in June; 1Q:17 R&D Costs Lower

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 (5/10/17)	$4.02
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.

We maintain our price target of $9.00.

SUMMARY DATA

52-Week High	**$9.59**
52-Week Low	**$2.51**
One-Year Return (%)	**-52.5**
Beta	**1.89**
Average Daily Volume (sh)	**141,404**
Shares Outstanding (mil)	**19.3**
Market Capitalization ($mil)	**$77.5**
Short Interest Ratio (days)	**9.48**
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

1Q:17 Operational and Financial Results

On May 9th Lipocine Inc. (NASDAQ: LPCN) filed its first quarter 2017 10-Q in conjunction with a press release highlighting recent achievements. The company reported 1Q:17 net loss of ($4.9) million which equates to ($0.26) on a per share basis. This compares to our estimates of ($8.9) million and ($0.48) per share. Actual R&D expenditures for the dosing validation (DV) and dosing flexibility (DF) study were lower than our estimates, contributing to the difference between our estimates and actuals.

First quarter 2017 R&D expenses were $3.1 million, increasing 15% from the $2.7 million spent in 1Q:16. Higher CRO expenses related to LPCN 1021, as well as DV and DF studies were partially offset by lower manufacturing costs for the product. Further offsets were seen in LPCN 1111 and LPCN 1107 CRO costs, as both declined year over year. G&A expenses of $1.8 million declined 58% 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.

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. Mr. Bass joined the company in 2006 and will now lead the commercialization of Lipocine's product candidates, chiefly the TRT program.
- On April 24th Lipocine announced it had completed enrollment of the LPCN 1021 fixed dose trials.

Upcoming Milestones

- Topline results from DV and DF studies for LPCN 1021 expected in June 2017
- Resubmission of LPCN 1021 NDA anticipated in 3Q:17
- Submission of LPCN 1107 Phase III protocol anticipated in 2Q:17

LPCN 1021 (Tlando) Update

Lipocine is completing its Dosing Validation (DV) and Dosing Flexibility (DF) studies which are expected to provide top-line results next month. The DV trial is an open-label, fixed dose, single treatment arm of Tlando enrolling 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 DF study was announced in a January 5th release. It will contrast with the DV study in that it will provide a daily dose of 450 mg, divided into three equal parts. Trial design will match that of the DV trial and will include the same primary and secondary endpoints.

The purpose for initiating the second validation trial was for both commercial and regulatory reasons. From a commercial perspective, the additional trial data may provide sufficient evidence for either twice daily or three times

[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.

daily dosing, allowing for additional flexibility in the label when it is determined. From a regulatory perspective, the data will provide additional information in the resubmission to achieve greater compliance with the Cmax constraints.

LPCN 1111 – Once Per Day TRT

LPCN 1111 completed its Phase 2b study in 3Q:16 and the next step is to conduct preclinical toxicology in canine models. These should be completed by mid-year preparing for the anticipated end-of-Phase 2 meeting with the FDA in 2H:17. Our estimates call for FDA approval in 2019 and first sales in 2020 with the product absorbing sales from LPCN 1021, due to its improved dosing schedule. We anticipate a Phase 3 trial launching in 2018.

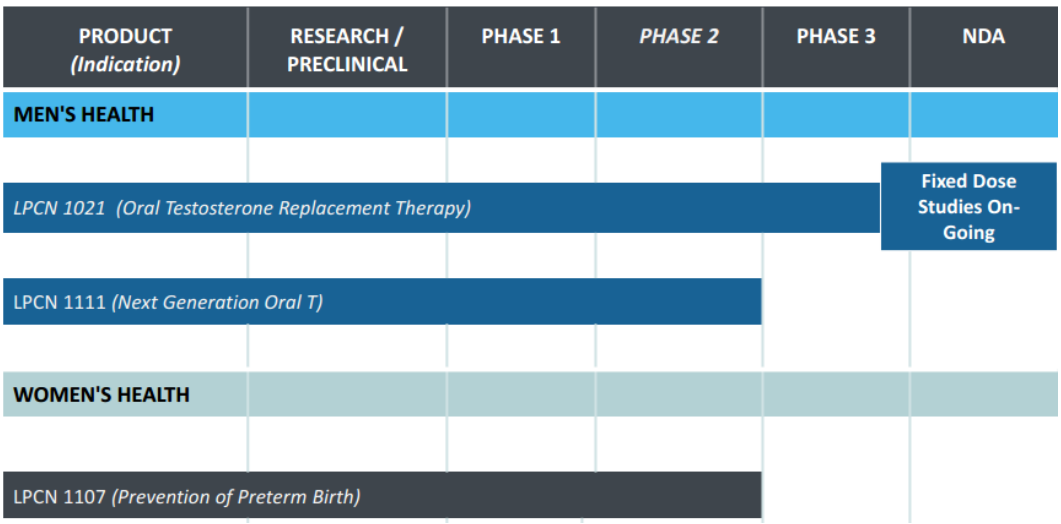
LPCN 1107 – Pre-Term Birth

LPCN 1107, or oral hydroxyprogesterone caproate, has completed its Phase 1a and 1b studies and held its end-of-Phase 2 meeting with the FDA. Since LPCN 1107 is an already known molecular entity, Phase 2 studies are not needed and the next step is to submit a Phase 3 protocol to the FDA via a special protocol assessment (SPA) in the second quarter of 2017. In the end-of-Phase 2 meeting, the FDA agreed to a randomized, open label, two arm clinical study to include a LPCN 1107 arm and a comparator intramuscular arm with treatment up to 23 weeks.

Manufacturing scale-up work for LPCN 1107 is currently underway and must be complete before the start of the Phase 3 clinical study. Additionally, a food effect study will also need to take place either before or during the study. **The FDA has granted orphan drug designation to LPCN 1107** based on a major contribution to patient care, which will provide several benefits that should accelerate approval and provide additional exclusivity for the product.

We note that competitor AMAG Pharmaceuticals (AMAG) that is currently selling an intramuscular (IM) branded version of hydroxyprogesterone caproate named Makena will lose its exclusivity in February 2018. AMAG had hoped to extend this franchise with a less painful subcutaneous (SC) version of the drug and obtain extended exclusivity based on reduced pain. However, AMAG's comparative pain study showed no advantage in the SC arm, eliminating the justification to obtain a favored position on formularies. This does, however, leave Lipocine in a stronger position having not only a superior oral delivery mechanism of the drug (if shown effective and approved), but also little competition from a next generation Makena product.

Pipeline Summary



Summary

We expect a 2Q:17 topline announcement for the DV and DF trials, followed by 3Q:17 analysis, preparation and resubmission. Since the FDA will be reviewing new data, we continue to assume a six month review by the FDA. Based on this timeline, the agency could determine approval by 2Q:18 supporting an ultimate launch by 2H: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. We estimate first sales of LPCN 1107 in 2H:18. We publish our 2019 estimates for the first time, which reflect continue revenue growth for LPCN 1021 and earnings of $2.12 per share.

Lipocine anticipates higher R&D expenses in 2017 compared to 2016. We forecast approximately $3 million apiece for each of the DV and DF trials on top of baseline R&D in the first half of this year. Second half will face resubmission, data management, data collection, advisory committee preparation and other costs related to grooming LPCN 1021 for approval. G&A expenses should fall in 2017 as much of the commercialization preparation that took place in 2016 was reversed following the CRL. We expect some expenditures on CMC, specifically in manufacturing to ensure sufficient product is available for trials and eventual launch. We do not anticipate any expenditures on Phase 3 trials for LPCN 1111 or 1107 in 2017. While the FDA's issuance of a complete response letter has delayed the launch of Tlando and increased trial costs by several million dollars, we believe that Lipocine will obtain approval for the compound. 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 constant at $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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