Zacks Small-Cap Research

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Lipocine Inc. (LPCN-NASDAQ)

2016 Results; DV and DF Studies Underway with 2Q:17 Readout Expected

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 (3/7/17)	$3.90
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.

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	**$12.66**
52-Week Low	**$2.51**
One-Year Return (%)	**-60.3**
Beta	**1.89**
Average Daily Volume (sh)	**117,220**
Shares Outstanding (mil)	**18.6**
Market Capitalization ($mil)	**$72.5**
Short Interest Ratio (days)	**16.4**
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 A	$0.0 A
2017					$0.0 E
2018					$38.9 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	-$0.16 A	-$1.04 A
2017					-$1.39 E
2018					$0.26 E

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WHAT'S NEW

2016 Operational and Financial Results

On March 6th Lipocine Inc. (NASDAQ: LPCN) filed its 2016 10-K in conjunction with a press release highlighting 2016 achievements. For the year, Lipocine reported a net loss of $19 million and $1.04 per share which compares to our estimates of $20.4 million and $1.10 per share. Lower R&D and lower SG&A both contributed to the difference. We were under the impression that the trial costs related to the dosing validation (DV) study which began in December would cause a sequential jump in R&D expenses rather than a decline.

2016 R&D expenses were $8.1 million, declining from the $12.6 million spent in 2015. Decreased CRO and consultant costs of $3.8 million and a $2.3 million filing fee in 2015 were the key factors behind the change. G&A expenses of $10.4 million rose substantially in 2016. This consisted of $2.0 million in higher personnel costs, $1.2 million of pre-commercialization costs and a $750,000 increase in legal costs due to the patent dispute with Clarus. Restructuring charges of $0.7 million also contributed to the year of year increase and related to a workforce adjustment and severance expenses.

By product, 2016 R&D costs fell for LPCN 1021 by almost $5 million and for LPCN 1107 by $600,000 compared to the prior year. LPCN 1111 countered the trend and doubled over the period to $1.7 million.

Other Events

- On March 6, 2017, 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.
- On February 15, 2017, 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.

LPCN 1021 (Tlando) Update

Currently, Lipocine is in the process of enrolling in its Dosing Validation (DV) and Dosing Flexibility (DF) studies which are expected to provide top-line results in 2Q:17. The DV 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 DV 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 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 Cavg and 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.

[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.

LPCN 1107 – Pre-Term Birth

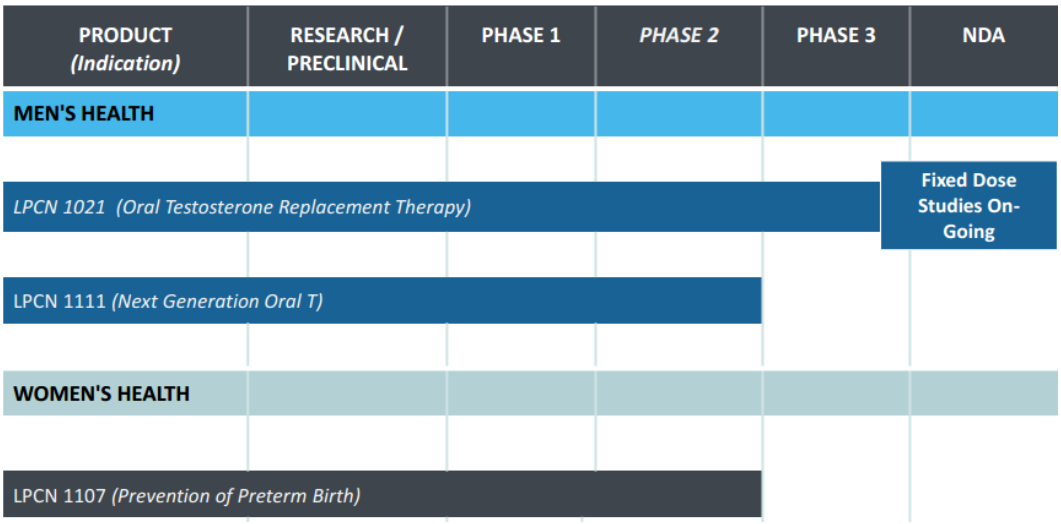
LPCN 1107, or oral hydroxyprogesterone caproate, has completed its Phase 1a and 1b studies and held its end-of-Phase 2 meeting with the FDA. Since LPCN 1107 is an already known molecular entity, Phase 2 studies are not needed and the next step is to submit a Phase 3 protocol to the FDA via a special protocol assessment (SPA) in the first half 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. The FDA also provided feedback on other critical Phase 3 study design considerations including:

- Favorable feedback on the proposed 800 mg BID Phase 3 dose and dosing regimen
- Confirmation of the use of a surrogate primary endpoint focusing on rate of delivery less than 37 weeks gestation rather on clinical infant outcomes
- Acknowledgement that the use of a gestational age endpoint would likely lead to any FDA approval, if granted, being a Subpart H approval (since it is based on a surrogate endpoint) as opposed to a full approval
- Recommended a non-inferiority study margin of 7% with interim analyses.[3]

Manufacturing scale-up work for LPCN 1107 is currently being planned and needs to occur before the start of the Phase 3 clinical study for the drug. 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



[3] Lipocine clarified "A standard statistical design for a non-inferiority study based on the FDA suggested non-inferiority margin of 7% for the primary endpoint may require ~1,100 subjects per treatment arm with a 90% power. However, based on the FDA's feedback of including an interim analysis in the NI design, an adaptive study design is under consideration that may allow for fewer subjects."

Conclusion

We expect a 2Q:17 topline announcement for the DV and DF trials, followed by 3Q:17 analysis, preparation and resubmission. Assuming a six month review by the FDA, the agency could determine approval by 2Q:18 and an ultimate launch in 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 move our estimate of LPCN 1107 sales back three months to 2H:18 to reflect the updated timeline.

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	2015 A	Q1 A	Q2 A	Q3 A	Q4 A	2016 A	2017 E	2018 E
LPCN1021	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0.0**	**$38.9**
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**	**$38.9**
CoGS	$0	$0	$0	$0	$0	$0	$0	$14
Product Gross Margin								*65.0%*
R&D	$12.6	$2.7	$2.6	$1.5	$1.3	$8.1	$20.0	$22.0
SG&A	$5.8	$4.4	$3.2	$1.4	$1.3	$10.4	$8.0	$19.0
Other expenses	$0.0	$0.0	$0.0	$0.4	$0.3	$0.7	$0.1	$0.1
Operating Income	($18.4)	($7.1)	($5.8)	($3.3)	($3.02)	($19.2)	($28.1)	($15.8)
Operating Margin	-					-	-	-
Total Other Income	$0.2	$0.1	$0.1	$0.1	$0.0	$0.2	$0.0	$0.0
Pre-Tax Income	($18.2)	($7.0)	($5.8)	($3.2)	($3.0)	($19.0)	($28.1)	($15.8)
Taxes & Other	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$21.4
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*136%*
Net Income	($18.2)	($7.0)	($5.8)	($3.2)	($3.0)	($19.0)	($28.1)	$5.7
Reported EPS	**($1.11)**	**($0.38)**	**($0.32)**	**($0.18)**	**($0.16)**	**($1.04)**	**($1.39)**	**$0.26**
YOY Growth						-	-	-
Shares Outstanding	16.5	18.3	18.3	18.3	18.3	18.3	20.2	22.0

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

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