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Lipocine Inc. (LPCN-NASDAQ)

Tlando Studies Complete by 1Q:19 & New Indication in NASH

Based on our DCF model and a 20% discount rate, LPCN is valued at approximately $6.00 per share. We apply a 25% probability of eventual sales of Tlando, a 15% probability to LPCN 1111 and a 10% probability to LPCN 1107. No valuation is provided yet for LPCN 1144.

Current Price (8/10/18)	$1.53
Valuation	**$6.00**

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 pharmocokinetic profile facilitates lower dosing, reduces side effects and eliminates gastrointestinal interactions that limit absorption. Currently, the company has four drugs in development that employ this technology. Two are for the treatment of male hypogonadism, the third for the prevention of pre-term birth and the most recent candidate is for NASH.

The lead product, LPCN 1021 (Tlando), received a second CRL in May 2018 and Lipocine is working to address the deficiencies. We expect a 1H:19 resubmission and FDA response by 2H:19 followed by a 2H:19 launch of Tlando. We apply a 25% probability of FDA approval and eventual sales. LPCN's other TRT product, LPCN 1111, which requires a once daily regimen, is undergoing an end-of-Phase 2 meeting 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	**$4.57**
52-Week Low	**$1.03**
One-Year Return (%)	**-64.6**
Beta	**-0.37**
Average Daily Volume (sh)	**105,532**
Shares Outstanding (mil)	**21.3**
Market Capitalization ($mil)	**$32.5**
Short Interest Ratio (days)	**19.6**
Institutional Ownership (%)	**9.8**
Insider Ownership (%)	**5.8**
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 2017 Estimate	**N/A**
P/E using 2018 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 $US)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2018	$0.4 A	$0.0 A	$0.0 E	$0.0 E	$0.4 E
2019					$54.5 E
2020					$186.0 E

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-$0.26 A	-$0.31 A	-$0.22 A	-$0.25 A	-$1.05 A
2018	-$0.13 A	-$0.15 A	-$0.22 E	-$0.27 E	-$0.78 E
2019					$0.24 E
2020					$2.90 E

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WHAT'S NEW

2Q:18 Operational and Financial Results

Lipocine (NASDAQ: LPCN) filed its 2Q:18 10-Q and posted its earnings release on August 7, 2018 reporting net loss per share of ($0.15). These results were better than our forecast due to lower G&A. Highlights for the quarter and to date include the FDA's issuance of a CRL for Tlando, the commencement of dosing for the ABPM clinical study and the completion of a post action meeting with the FDA regarding resubmission.

No revenues were recorded in the quarter, as expected. Total expenses in the second quarter were $3.2 million, down 48% over the prior year, due to lower costs across the board, related predominantly to deceleration in Tlando development. Research and development costs were $1.5 million in 2Q:18 down from $4.1 million in the same quarter in the prior year. $2.2 million of the decline was due to lower expenses for Tlando slightly offset by increases in personnel costs and other R&D. General and administrative expenses fell 17% to $1.7 million due to fewer legal, intellectual property and commercial activity-related professional fees and decreased personnel costs. Office and overhead expenses were also down as a result of the lease expiration for the company's New Jersey facility.

Cash balance was $25.1 million as of June 30, 2018, up from year end levels of $21.5 million aided by the Silicon Valley Bank loan of $10 million.[1] Cash burn for the quarter was ($2.7) million compared to ($4.7) million in 2Q:17.

New Development Product

Lipocine announced in their August 2018 corporate presentation the pursuit of a new indication in nonalcoholic steatohepatitis (NASH). Currently the drug is in preclinical development and the company expects to conduct and complete an *in-vivo* model proof-of-concept (POC) study in biopsy-confirmed NASH patients in 4Q:18. There are no treatments for NASH and in more advanced stages of the disease, liver transplantation is required. NASH is a more advanced state of fatty liver disease and can progress to a cirrhotic liver and eventually hepatocellular carcinoma or liver cancer. 20 to 30% of the US population suffers from fatty liver (non-alcoholic fatty liver disease – NAFLD) and 15 to 20% of this population progresses to NASH, which is a substantially large population that lacks a cure. In men, testosterone deficiency has been associated with an increased accumulation of visceral adipose tissue and insulin resistance, which are factors contributing to NAFLD and NASH.[2] The relationship with testosterone deficiency has also likely attracted Lipocine's attention to this indication and the company will develop an oral androgen therapy for NASH. We will discuss this opportunity further in a later special report.

May 8 Complete Response Letter

Lipocine received a complete response letter (CRL) from the FDA on May 8, 2017 which identified four deficiencies related to the New Drug Application submitted for Tlando, an oral testosterone product for testosterone replacement therapy. The deficiencies mirrored the concerns highlighted by the January AdCom meeting and include:

- Determining the extent, if any, of *ex vivo* conversion of testosterone undecanoate ("TU") to testosterone ("T") in serum blood collection tubes to confirm the reliability of T data;
- Obtaining definitive evidence pre-approval via an ambulatory blood pressure monitoring (ABPM) study as to whether TLANDO causes a clinically meaningful increase in blood pressure in hypogonadal men;
- Verifying the reliability of Cmax data and providing justification for non-applicability of the agreed-upon and prespecified Cmax secondary endpoints for TLANDO; and,
- Determining the appropriate stopping criteria that can reproducibly and accurately identify those patients who should discontinue use of TLANDO.

Lipocine was already aware of the deficiencies identified in the CRL following the meeting with the January Advisory Committee and was waiting for official confirmation from the agency. Prior to the CRL, the company had initiated work on the ABPM and serum measurement reliability studies and incorporated the details from the FDA response in the design of the study. The company held a post action meeting with the FDA in July to further refine the study

[1] If Tlando is not approved by the FDA on or prior to May 31, 2018, Lipocine will be required to maintain $5.0 million of cash collateral at Silicon Valley Bank (the lender) until such time as it is approved by the FDA.
[2] Modi, Avni; et al. Relevance of low testosterone to non-alcoholic fatty liver disease. Cardiovasc Endocrinol. 2015 Sep 1; 4(3): 83–89.

construction for Tlando. The FDA provided feedback on potential resolution of the identified deficiencies, including clinical design elements and work on the studies is underway. The ABPM effort should take approximately four months and should generate results in 1Q:19. Additionally, a definitive phlebotomy study is expected to yield results before the end of the year. After results are available, we anticipate a Class 2 resubmission to the FDA which requires a six month review cycle. If the agency's concerns are addressed, this sets the stage for a 1H:19 resubmission and a 2H:19 FDA response.

We maintain our probability of FDA approval and ultimate sales for Tlando at 25% and our revenue estimates reflect a 2H:19 launch of Tlando in the US market.

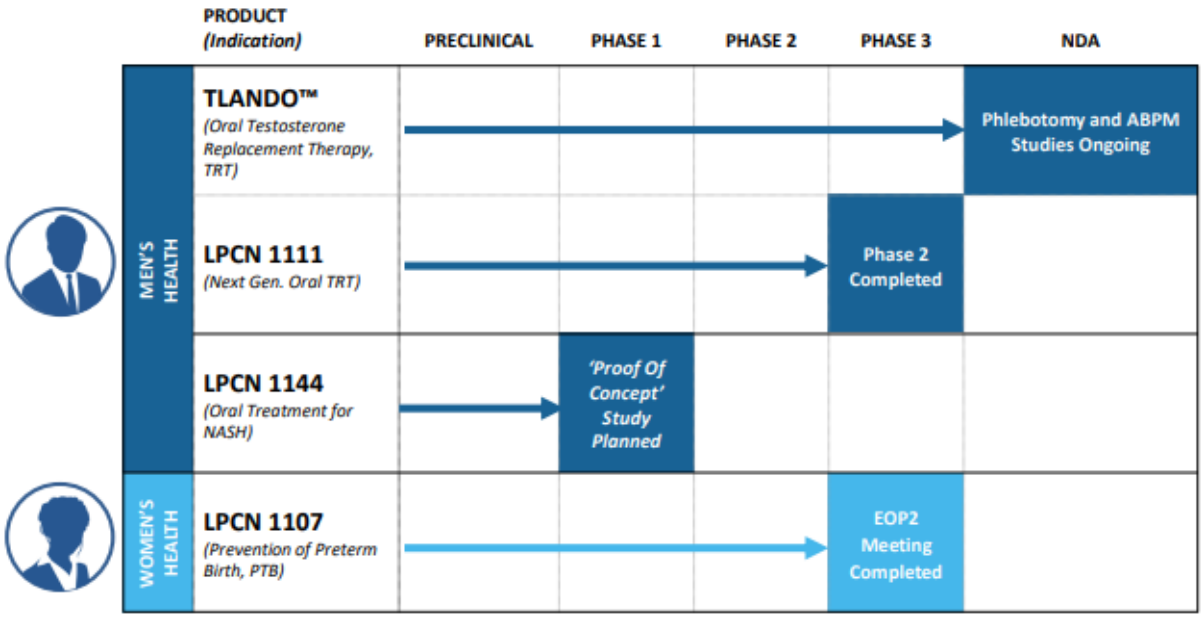
Litigation

A lawsuit was filed against Lipocine in July 2016 related to the FDA's issuance of a CRL in the prior month. In February 2018, Lipocine entered into a memorandum of understanding (MOU) regarding a settlement which is expected to be approved by the court. The MOU has identified a settlement of $4.3 million and the court approved this amount in a July 2nd final order. Lipocine's insurance paid $3.6 million into the settlement combined with the company's retention amount of $0.7 million. These two amounts were paid into escrow to address the litigation settlement.

Milestones

- AdCom delivers a 6:13 vote against the benefit/risk profile for Tlando – January 2018
- Entry into a $10 million loan agreement with Silicon Valley Bank – January 2018
- Settlement of Securities Class Action Lawsuit – February 2018
- CRL Issued for Tlando – May 8, 2018
- Type A/Post Action Meeting – July 19, 2018
- Tlando phlebotomy study results available – 4Q:18
- Tlando ambulatory blood pressure study – 1Q:19
- Resubmission of Tlando NDA – 1H:19
- Anticipated FDA Response for Tlando NDA – 2H:19
- Launch Tlando – 2H:19
- Develop preclinical LPCN 1144 – 2018 / 2019

Exhibit I – Lipocine Pipeline



Valuation

While the negative outcome from the CRL regarding Tlando reduced our valuation, we anticipate that Lipocine will continue to pursue the approval of Tlando by addressing the advisory committee's concerns relating to blood pressure and quality of samples. Based on the timeline provided by the company for the ABPM and phlebotomy study, we have assumed that first sales will commence in 2H:19. Current cash levels are sufficient to reach the end of 2Q:19; however, it is likely that there will be a capital raise prior to launch, assuming a favorable outcome from the FDA, as funds will be required to build the salesforce. Our probability of approval and ultimate sales remain at 25% generating a target price of $6.00 per share.

Summary

LPCN has taken the initiative to address the discrepancies raised in the CRL and we anticipate that all the necessary information for resubmission will be available by the first quarter of 2019. We forecast a 25% probability that Lipocine will obtain FDA approval and commercialize Tlando. Following approval, Lipocine will develop a sales force and acquire an appropriate partner to commercialize the primary care segment which should happen a few months after approval. Based on this timeline, first sales should commence in 2H:19. Lipocine will then be able to shift its development efforts towards LPCN 1111 and 1107.

Our target price is derived using a 20% discount rate and probability of eventual sales for LPCN 1021, LPCN 1111 and LPCN 1107 of 25%, 15% and 10% respectively. Based on our estimates of sales, expenses, risk, and updates provided in company documents, our target price remains at $6.00 per share.

PROJECTED FINANCIALS

Lipocine Inc. - Income Statement

Lipocine Incorporated	2017 A	Q1 A	Q2 A	Q3 E	Q4 E	2018 E	2019 E	2020 E
Total Revenues	**$0.0**	**$0.4**	**$0.0**	**$0.0**	**$0.0**	**$0.4**	**$54.5**	**$186.0**
CoGS	$0.0	$0.0	$0.0	$0.0	$0.0	$0.1	$5.4	$65.1
Product Gross Margin							*90.0%*	*65.0%*
R&D	$11.0	$1.4	$1.5	$1.7	$1.7	$6.3	$22.0	$23.0
G&A	$10.2	$1.7	$1.7	$3.0	$4.0	$10.4	$21.3	$32.9
Other expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$1.1
Operating Income	($21.2)	($2.6)	($3.2)	($4.7)	($5.7)	($16.4)	$5.7	$63.9
Operating Margin	-					-	-	-
Total Other Income	$0.2	($0.1)	($0.1)	($0.1)	($0.1)	($0.4)	($0.5)	($0.5)
Pre-Tax Income	($21.0)	($2.7)	($3.3)	($4.8)	($5.8)	($16.8)	$5.2	$63.4
Taxes & Other	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$1.6
Tax Rate	*0%*	*$0.0*	*0%*	*0%*	*0%*	*0%*	*0%*	*-3%*
Net Income	($21.0)	($2.7)	($3.3)	($4.8)	($5.8)	($16.8)	$5.2	$65.1
Reported EPS	**($1.05)**	**($0.13)**	**($0.15)**	**($0.22)**	**($0.27)**	**($0.78)**	**$0.24**	**$2.90**
YOY Growth	-					-	-	-
Shares Outstanding	20.1	21.3	21.3	21.5	21.6	21.4	21.9	22.4

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

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