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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)

Tlando Readouts Coming Soon; NDA to Follow

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 (11/8/18)	$1.63
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 targets 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	**$4.01**
52-Week Low	**$1.03**
One-Year Return (%)	**-54.0**
Beta	**-0.16**
Average Daily Volume (sh)	**89,896**
Shares Outstanding (mil)	**21.5**
Market Capitalization ($mil)	**$35.0**
Short Interest Ratio (days)	**14.5**
Institutional Ownership (%)	**13.5**
Insider Ownership (%)	**11.2**
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 2018 Estimate	**N/A**
P/E using 2019 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 A	$0.0 E	$0.4 E
2019					$0.0 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	-$0.12 A	-$0.15 E	-$0.56 E
2019					-$1.38 E
2020					$2.90 E

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WHAT'S NEW

3Q:18 Operational and Financial Results

Lipocine (NASDAQ: LPCN) filed its 3Q:18 10-Q and posted its earnings release on November 7, 2018 reporting net loss per share of ($0.12). These results were better than our forecast due to lower R&D and G&A. Highlights for the quarter and to date include the continuation of a phlebotomy study to measure Tlando results reliability, completion of enrollment of the ABPM study for Tlando and preclinical and proof of concept work for LPCN 1144 in NASH/NAFLD.

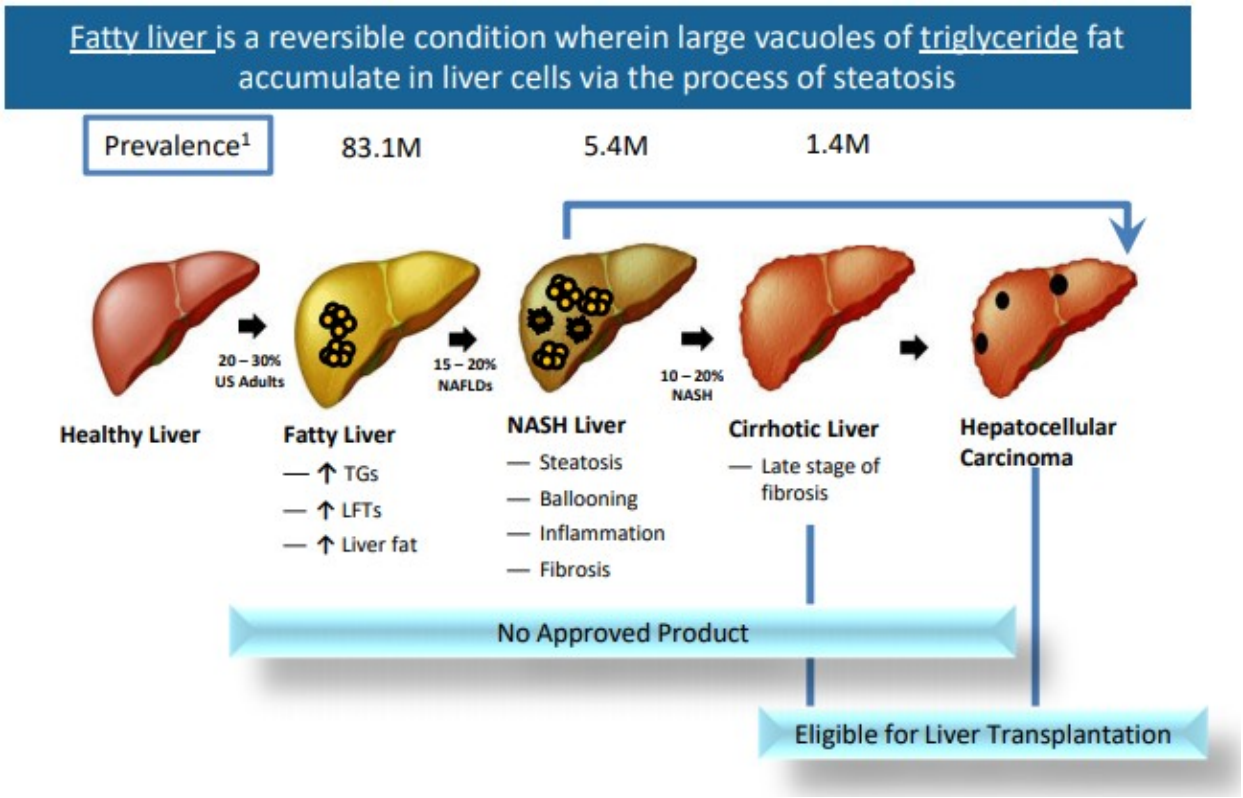
No revenues were recorded in the quarter and total expenses in the third quarter were $2.4 million, down by half compared to the prior year, due to lower personnel costs and lower contract manufacturing costs for Tlando and LPCN 1107. Research and development costs were $1.4 million in 3Q:18 down from $2.0 million in the same quarter in the prior year. $0.3 million of the decline was due to lower expenses for LPCN 1107, with Tlando and LPCN 1111 each lower by $0.1 million. General and administrative expenses fell 66% to $0.9 million due to fewer legal, intellectual property and commercial activity-related professional fees and decreased personnel costs.

Cash balance was $21.9 million as of September 30, 2018, falling $3.2 million sequentially. During the first quarter, Lipocine borrowed $10 million in the Silicon Valley Bank loan.[1] Cash burn for the quarter was ($3.4) million compared to ($4.6) million in 3Q:17.

LPCN 1144

Lipocine announced in their August 2018 corporate presentation the pursuit of a new indication in nonalcoholic steatohepatitis (NASH). Currently the drug is in early stage 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. We discuss the indication and Lipocine's efforts in depth here.

Exhibit I – Non-Alcoholic Fatty Liver Disease (NAFLD)



[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.

Tlando

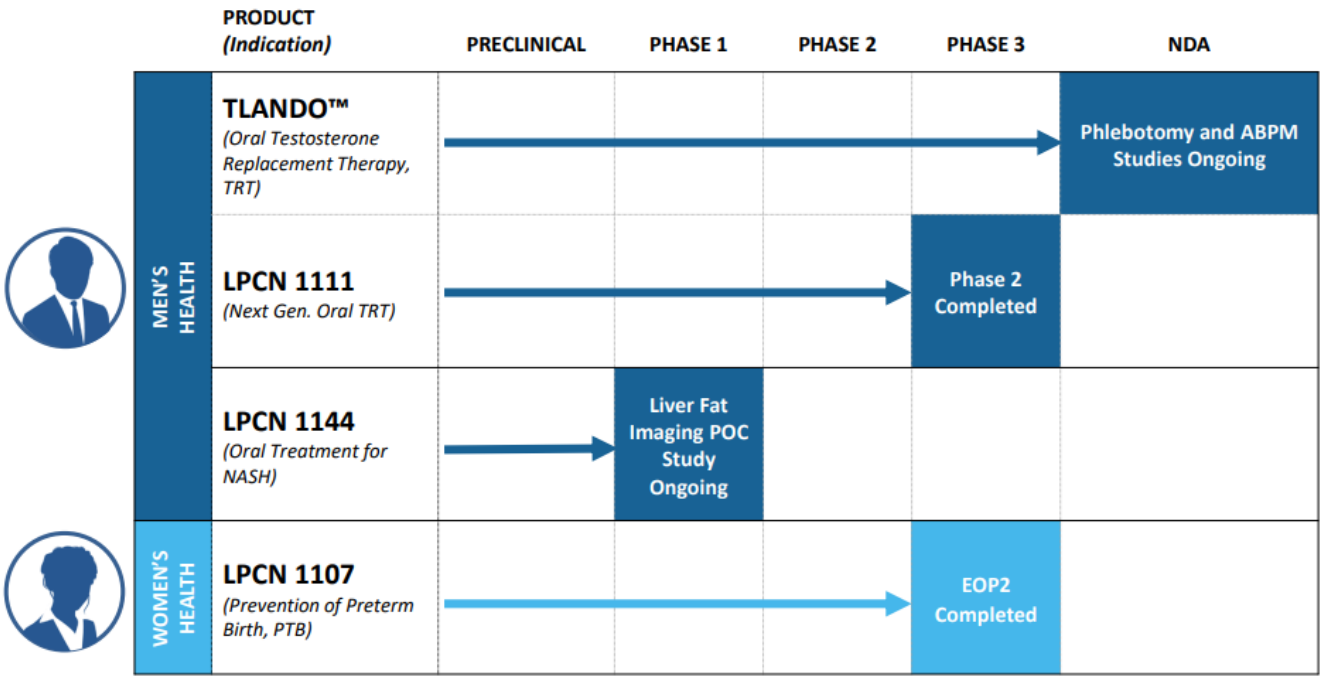
Lipocine is currently conducting an ambulatory blood pressure (ABPM) study and a definitive phlebotomy study on Tlando to satisfy the FDAs concerns regarding blood pressure risks and reliability of sample quality. The ABPM study has been fully enrolled and is expected to provide results in 1Q:19. The phlebotomy study is expected to provide results in 4Q:18. We anticipate that, with favorable data from the two studies, that Lipocine will be able to resubmit a new drug application (NDA) in 1H:19. 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 2H:19 FDA response and subsequent commercialization if approval is granted.

We maintain our probability of FDA approval and ultimate sales for Tlando at 25% and our revenue estimates reflect a 2020 launch of Tlando in the US market.

Milestones

- Executed $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
- Anticipated Tlando phlebotomy study results – 4Q:18
- Anticipated Tlando ambulatory blood pressure results – 1Q:19
- Resubmission of Tlando NDA – 1H:19
- Complete in-vivo model POC study in biopsy-confirmed NASH – 1Q:19
- POC clinical study results in imaging-confirmed NAFLD/NASH patients – 1Q:19
- Anticipated FDA Response for Tlando NDA – 2H:19
- Launch Tlando – 2020
- Develop preclinical LPCN 1144 – 2018 / 2019

Exhibit II – Lipocine Pipeline



Summary

LPCN has taken the initiative to address the discrepancies raised in the CRL and by the Advisory Committee and we anticipate that all the necessary information for resubmission will be available by the first quarter of 2019. After review, we forecast a 25% probability that Lipocine will obtain FDA approval and commercialize Tlando. Based on our estimates, first sales should commence in early 2020. Lipocine will then be able to shift its development efforts towards other candidates in the pipeline.

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 A	Q4 E	2018 E	2019 E	2020 E
Total Revenues	**$0.0**	**$0.4**	**$0.0**	**$0.0**	**$0.0**	**$0.4**	**$0.0**	**$186.0**
CoGS	$0.0	$0.0	$0.0	$0.0	$0.0	$0.1	$0.0	$65.1
Product Gross Margin								*65.0%*
R&D	$11.0	$1.4	$1.5	$1.4	$1.7	$6.0	$22.0	$23.0
G&A	$10.2	$1.7	$1.7	$0.9	$1.5	$5.8	$7.6	$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)	($2.4)	($3.2)	($11.5)	($29.6)	$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)	($2.5)	($3.3)	($11.9)	($30.1)	$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)	($2.5)	($3.3)	($11.9)	($30.1)	$65.1
Reported EPS	**($1.05)**	**($0.13)**	**($0.15)**	**($0.12)**	**($0.15)**	**($0.56)**	**($1.38)**	**$2.90**
YOY Growth	-					-	-	-
Shares Outstanding	20.1	21.3	21.3	21.3	21.6	21.4	21.9	22.4

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

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