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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)

Knocked Down But Not Knocked Out

Based on our DCF model and a 20% discount rate, LPCN is valued at approximately $1.50 per share. We calculate a valuation solely for Phase II asset LPCN 1144 and apply a 15% probability of success. No valuation is attached to Tlando or other development assets.

Current Price (11/14/19)	$0.40
Valuation	**$1.50**

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 five 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 candidates targets NASH.

The lead product, Tlando, resubmitted an NDA in May 2019 and received a CRL on November 8, 2019. We expect Lipocine will hold a meeting in January 2020 with the FDA and announce its intentions afterwards. LPCN's other TRT product, LPCN 1111 and LPCN 1107 for pre-term birth are both on indefinite hold pending additional funding or partner interest. LPCN 1144 is being developed for pre-cirrhotic NASH and has enrolled first patients for a Ph 2 study. LPCN 1148 will target submitting an IND prior to year-end 2019 and will pursue an indication in NASH cirrhosis.

SUMMARY DATA

52-Week High	**$3.45**
52-Week Low	**$0.38**
One-Year Return (%)	**-72.8**
Beta	**0.57**
Average Daily Volume (sh)	**334,889**
Shares Outstanding (mil)	**35.9**
Market Capitalization ($mil)	**$14.4**
Short Interest Ratio (days)	**1.41**
Institutional Ownership (%)	**8.8**
Insider Ownership (%)	**5.2**
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 2019 Estimate	**N/A**
P/E using 2020 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)
2018	$0.4 A	$0.0 A	$0.0 A	$0.0 A	$0.4 A
2019	$0.0 A	$0.0 A	$0.2 A	$0.0 E	$0.2 E
2020					$157.4 E
2021					$217.0 E

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	-$0.13 A	-$0.15 A	-$0.12 A	-$0.15 A	-$0.55 A
2019	-$0.14 A	-$0.14 A	-$0.12 A	-$0.10 E	-$0.50 E
2020					-$0.28 E
2021					-$0.20 E

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WHAT'S NEW

Third Quarter 2019 Operational and Financial Results

On November 12, 2019 Lipocine (NASDAQ: LPCN) filed its 3Q:19 10-Q and posted its earnings release for the three month period ending September 30, 2019. The company reported $165,000 in revenues and a net loss per share of ($0.12) compared to prior year revenues of zero and loss of ($0.12) per share. Activities and results during the quarter were overshadowed by the delivery of a Complete Response Letter (CRL) for Tlando on November 8th. Lipocine is currently seeking a post action meeting with the FDA and will base its future plan on the outcome. The company also continues to develop LPCN 1144, which is currently being evaluated in the Phase II Liver Fat Intervention with oral Testosterone (LiFT) study. The scientific team has also made presentations for LPCN 1144 at The Liver Meeting and for Tlando and at Annual Fall Meeting of the Sexual Medicine Society of North America. Other highlights include the determination of a trial date for the Clarus lawsuit in August 2020 and the issuance of stock and warrants post the earnings release.

Lipocine reported $165,000 in revenues in the July to September period from Spriaso related to the cough and cold field. Operational expenses of $3.1 million were up 33% and net loss totaled ($3.1) million or ($0.12) per share. Research and development expenses reached $1.7 million, rising 20% reflecting the continuation and expansion of the LiFT study partially offset by lower expenditures for Tlando and LPCN 1111. General and administrative costs rose 53% to $1.4 million on higher legal fees related to the Clarus litigation and inflation of corporate insurance.

Net loss for the quarter was ($3.1) million which compares to ($2.5) million in 3Q:18. This represents ($0.12) on a per share basis on an average balance of 24.9 million shares.

Cash and marketable securities balance was $16.5 million as of September 30, 2019 which includes $5 million of restricted[1] cash. Current and non-current debt totals $7.9 million. Cash burn for the third quarter was approximately ($2.8) million and net cash used in financing was ($0.2) million representing loan repayments to Silicon Valley Bank.

Following the submission of the 3Q:19 10-Q, Lipocine announced a public offering and pricing of common stock and warrants. The effort is expected to raise $6.0 million gross proceeds that will be used to support current operations. Roth Capital Partners acted as agent.

Tlando

On May 14, Lipocine issued a press release announcing Tlando's target action date of November 9, 2019 for Tlando testosterone replacement therapy. On November 11, Lipocine announced that the FDA had delivered a CRL. The CRL identified one deficiency stating that the trial did not meet one of the three secondary endpoints for maximal testosterone concentrations (Cmax). No deficiencies related to chemistry, manufacturing and controls were noted. FDA guidelines call for 85% of subjects to achieve a Cmax below 1500 ng/dL and no more than 5% of subjects presenting a Cmax between 1800 ng/dL and 2500 ng/dL and 0% above 2500 ng/dL. In the most recent dosing validation (DV) study, 85% of subjects were below 1500 ng/dL and 7% were between 1800 ng/dL and 2500 ng/dL. Although there were small variations from the FDA guidelines in the original SOAR study for subjects above 2500 ng/dL, the FDA did not identify this as a deficiency during the original New Drug Application (NDA) submission.

At this point it is too early to anticipate the future path for Tlando or the timeline for resubmission if Lipocine chooses to pursue this route. The company is scheduling a post action meeting with the FDA and we anticipate management will evaluate its options following this interaction. Even for minor discrepancies, in our experience, there is a lengthy timeline to prepare documents to address the FDA's concerns and then receive a response. It is likely that Lipocine will pursue a formal dispute resolution process with the FDA and make the case that Cmax characteristics for Tlando are consistent with another recently approved oral product.[2] We note that Clarus' Jatenzo was approved despite exceeding the 0% maximum requirement for patients with a Cmax of over 2500 ng/dL and only 83% below 1500 ng/dL compared to the threshold of a minimum of 85% below 1500 ng/dL.

[1] Tlando was not approved by the FDA by May 31, 2018, and therefore Lipocine is 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] Clarus' Jatenzo was approved March 27, 2019. https://www.fda.gov/news-events/press-announcements/fda-approves-new-oral-testosterone-capsule-treatment-men-certain-forms-hypogonadism

Exhibit I – Comparison of Registrational Study Outcomes for Oral Testosterone[3]

FDA Cmax Threshold	Study Outcome	
	Jatenzo	Tlando DV
Min 85% < 1500 ng/dL	83%	85%
</= 5% 1800-2500 ng/dL	3%	7%
0% > 2500 ng/dL	3%	~1%*

*1 subject of 94 was >2500 ng/dL and a major protocol violator

Due to the uncertainty related to the CRL we suspend our value associated with Tlando until further clarity is provided.

LPCN 1144

Lipocine announced in August 2018 the pursuit of a new indication in nonalcoholic steatohepatitis (NASH). We discuss the indication and Lipocine's efforts in an earlier piece that can be accessed here. Further work was pursued late last year and full enrollment of 36 subjects was achieved in November 2018.

In January, Lipocine announced meaningful liver fat reduction in patients participating in its Liver Fat Study and informed investors that they had filed an investigational new drug (IND) application to begin a Phase II study for NASH. Since LPCN 1144 is the same molecule as TLANDO, for which there have been numerous safety studies completed, LPCN performed a proof of concept (POC) clinical study under the original IND to assess liver fat changes. This 36-person study was conducted in hypogonadal men at risk of developing non-alcoholic steatohepatitis (NASH) and results were measured using the magnetic resonance imaging proton density fat fraction (MRI-PDFF) technique. Topline results were announced in mid-March demonstrating a 4.0% to 8.2% percentage point reduction in liver fat depending on baseline liver fat category. We discussed the results in further detail in our March 14th NASH Topline article.

Lipocine has now launched its Phase II clinical study for LPCN 1144 and dosed its first patient in September. Prior to the start of the trial, Lipocine announced that the FDA would allow the Phase II LiFT trial to enroll eugonadal patients in addition to the NASH patients that were initially targeted. This expansion was based on research that we discussed in a July 29th note. The study is anticipated to last for 18 months and cost approximately $8 million.

LiFT, an acronym of Liver Fat intervention with oral Testosterone, is a paired biopsy Phase II study in NASH subjects. The study design will employ a three-arm, double-blind, placebo controlled structure and enroll approximately 75 biopsy confirmed male NASH subjects with a NAS[4] score of greater or equal to four. The primary endpoint for the study is 12-week MRI-PDFF liver fat reduction and the first patient was enrolled in 3Q:19. As for the anticipated timeline, Lipocine expects top line liver fat reduction data in mid-2020 as measured by MRI-PDFF at 12 weeks. Biopsy data at 36 weeks is expected to be available by the end of 2020 or early 2021.

LPCN 1144 Poster Presentation

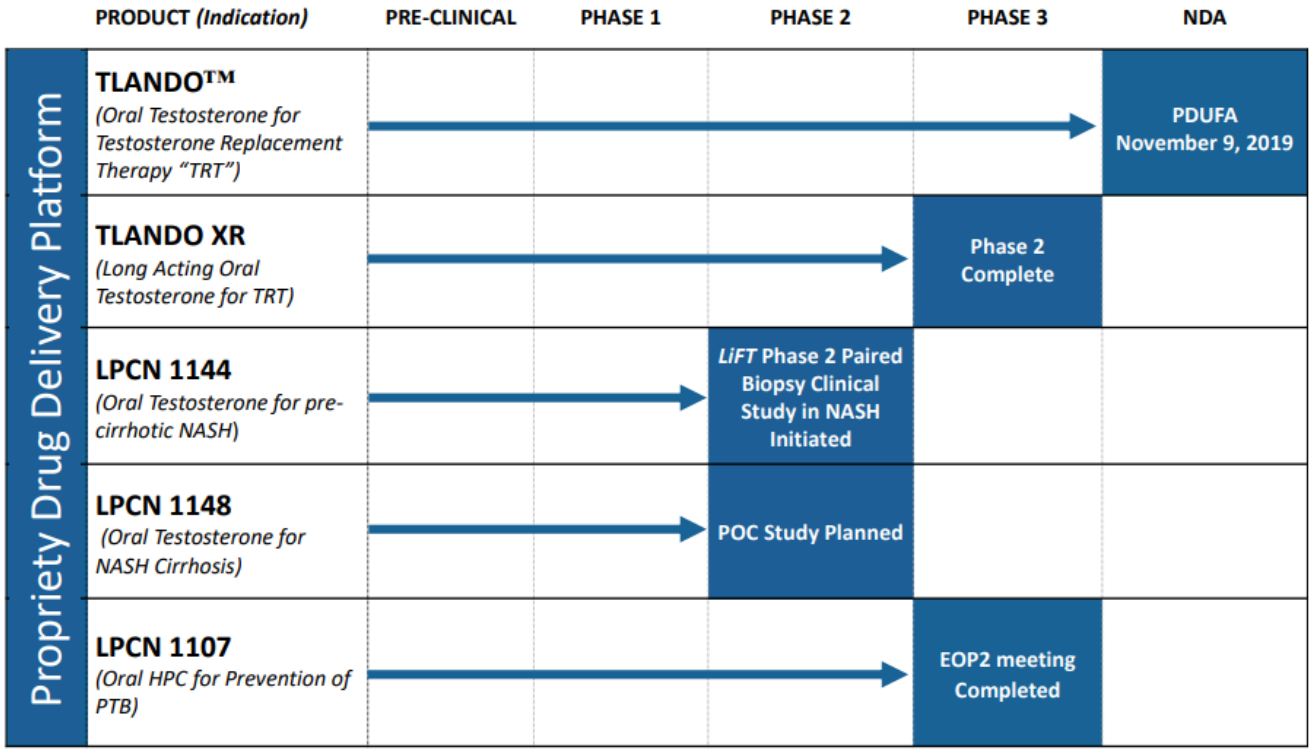
Lipocine presented a poster at the Liver Meeting 2019 entitled "LPCN 1144 Resolves Non-alcoholic Fatty Liver Disease" on November 11th. The poster highlights the correlation between lower free testosterone for NASH as compared to NAFLD patients. Levels of free testosterone decrease significantly with increased incidence of lobular inflammation, hepatocyte ballooning, NAFLD activity score and fibrosis. The poster drew upon information from the recent liver fat study and the SOAR trial demonstrating higher NAFLD prevalence in hypogonadal males and NAFLD and liver fat reduction in subjects following treatment with testosterone. Conclusions from the review associate male hypogonadism with NAFLD and identify resolution of NAFLD in affected patients with administration of LPCN 1144.

[3] FDA Label for Clarus' Jatenzo and Lipocine 3Q:19 10-Q filing.
[4] NAS: NAFLD (Non-alcoholic fatty liver disease) Activity Score. Discussion of the metric can be found here.

LPCN 1148

Lipocine is preparing to develop its testosterone molecule to treat NASH cirrhosis patients. While this is a smaller population than that for pre-cirrhotic NASH, there are no other FDA approved products available. The positive relationship between testosterone and sarcopenia and the increased risks of advancing NASH cirrhosis makes this a worthwhile pursuit. Lipocine plans to initiate a funding dependent proof of concept trial to evaluate the potential of this candidate. Management expects to submit an Investigational New Drug (IND) application for LPCN 1148 prior to year-end 2019.

Exhibit II – Lipocine Pipeline *Prior to Tlando CRL*[5]



Milestones

- Launch of Phase II LPCN 1144 Study – 2Q:19
- Addition to Russell Microcap Index – June 2019
- Enroll/Dose First Patient in Phase II LPCN 1144 Study – 3Q:19
- Tlando CRL – November 9, 2019
- File Investigational New Drug (IND) application for LPCN 1148 – December 2019
- Tlando FDA post action meeting – 2020
- Potentially pursue dispute resolution for Tlando - 1H:20
- Primary endpoint results for LiFT – Mid-2020
- Complete Phase II LPCN 1144 – Year end 2020

[5] Source: Lipocine Corporate Presentation September 2019.

Summary

The receipt of another CRL is a setback for Lipocine, which has thoroughly addressed every discrepancy the FDA has identified. While there is a chance the company can successfully dispute the decision regarding Tlando, we are removing cash flows associated with the candidate and will update our model as new information becomes available. The CRL is not a fatal blow as LPCN 1144 is currently in Phase II trials pursuing an indication with a large unmet need. The unexpected rejection now shifts Lipocine's focus toward NASH indications. The Phase II LiFT trial was launched in the third quarter and we assume that this candidate will pass through Phase II and Phase III studies prior to NDA submission in 2023 and approval in 2024. We attach a 15% probability of approval to the program. Lipocine is also developing LPCN 1148 for cirrhosis patients. While we do not see this entering the clinic until sufficient capital can be raise, we do think it will advance if Phase II data for LPCN 1144 are positive.

We modify our target price to reflect the removal of Tlando, LPCN 1111 and LPCN 1107. Lipocine has insufficient capital to pursue more than one program at this time. We add a valuation component for LPCN 1144 and also adjust shares outstanding to reflect the recent capital raise and assume that another capital raise will take place next year to continue the development of LPCN 1144, assuming clinical trial data is favorable. Our target price moves from $7.00 to $1.50 based on the adjustments.

PROJECTED FINANCIALS

Lipocine Inc. - Income Statement

Lipocine Incorporated	2018 A	Q1 A	Q2 A	Q3 A	Q4 E	2019 E	2020 E	2021 E
Total Revenues ($MM)	**$0.4**	**$0.0**	**$0.0**	**$0.2**	**$0.0**	**$0.2**	**$0.0**	**$0.0**
R&D	$6.5	$1.9	$2.0	$1.7	$1.5	$7.1	$8.2	$9.4
G&A	$5.3	$1.2	$1.4	$1.4	$1.5	$5.5	$5.6	$5.8
Other expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$1.1	$1.1
Operating Income	($11.3)	($3.1)	($3.4)	($3.0)	($3.0)	($12.5)	($14.9)	($16.3)
Operating Margin	-					-	-	-
Total Other Income	($0.3)	($0.1)	($0.1)	($0.1)	($0.1)	($0.4)	($0.5)	($0.9)
Pre-Tax Income	$11.7	($3.2)	($3.4)	($3.1)	($3.1)	($12.8)	($15.4)	($17.2)
Taxes & Other	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0%*	*$0.0*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($11.7)	($3.2)	($3.4)	($3.1)	($3.1)	($12.8)	($15.4)	($17.2)
Reported EPS	**($0.55)**	**($0.14)**	**($0.14)**	**($0.12)**	**($0.10)**	**($0.50)**	**($0.28)**	**($0.20)**
YOY Growth	-					-	-	-
Shares Outstanding	21.4	23.4	24.6	24.9	30.0	25.7	54.6	88.0

Source: Company Filing // Zacks Investment I

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HISTORICAL STOCK PRICE

Lipocine Inc. – Share Price Chart



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