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John D. Vandermosten, CFA
312-265-9588 / jvandermosten@zacks.com

scr.zacks.com **10 S. Riverside Plaza, Chicago, IL 60606**

Lipocine Inc. (LPCN-NASDAQ)

NASH Trial Launched

Based on our DCF model and a 20% discount rate, LPCN is valued at approximately $7.00 per share. We apply a 45% 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 (8/7/19)	$1.90
Valuation	**$7.00**

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, Tlando, was resubmitted in an NDA in May 2019 and has an assigned PDUFA date of November 9, 2019. We expect a 2020 launch of Tlando and apply a 45% 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. LPCN 1144 is being developed for pre-cirrhotic NASH and is expected to enroll first patients in 3Q:19 for a Ph 2 study.

SUMMARY DATA

52-Week High	**$2.64**
52-Week Low	**$1.04**
One-Year Return (%)	**34.8**
Beta	**0.40**
Average Daily Volume (sh)	**98,134**
Shares Outstanding (mil)	**24.8**
Market Capitalization ($mil)	**$47.1**
Short Interest Ratio (days)	**0.52**
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	$0.0 E	$0.0 E	$0.0 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	-$0.33 E	-$0.32 E	-$0.93 E
2020					$2.04 E
2021					$2.74 E

WHAT'S NEW

Second Quarter 2019 Operational and Financial Results

On August 7, 2019 Lipocine (NASDAQ: LPCN) filed its 2Q:19 10-Q and posted its earnings release for the three month period ending June 30, 2019. The company reported zero revenues and net loss per share of ($0.14) compared to prior year revenues of zero and loss of ($0.15) per share. The most important highlights for the quarter include the announcement of a target action date by the FDA for Tlando, the pursuit of an injunction against Jatenzo and the addition of Lipocine shares to the Russell Microcap Index. Following the end of the quarter, the company announced FDA clearance for testing LPCN 1144 in both hypogonadal and eugonadal NASH patients.

Lipocine reported no revenues in the quarter and net loss of ($3.4) million or ($0.14) per share. Research and development expenses totaled $2.0 million, increasing 32% due to the start of the Liver Fat intervention with oral Testosterone (LiFT) study and costs related to submitting the new drug application (NDA) for Tlando to the FDA. General and administrative costs declined by 18% to $1.4 million on lower personnel costs, a decrease in severance, bonus and stock compensation and other expenses partially offset by an increase in professional fees, corporate insurance and marketing expenses.

Net loss for the quarter was ($3.4) million which compares to ($3.3) million in 2Q:18. This represents ($0.14) on a per share basis on an average balance of 24.6 million shares.

Cash and marketable securities balance was $19.5 million as of June 30, 2019 which includes $5 million of restricted[1] cash. Cash burn for the second quarter was approximately ($2.6) million and net cash used in financing was ($0.6) million representing loan repayment to Silicon Valley Bank. Cash burn of ($2.6) in 2Q:19 million compared to ($2.7) million in the prior year period.

Tlando

On May 14, Lipocine issued a press release announcing the Prescription Drug User Fee Act (PDUFA) goal date of November 9, 2019 for Tlando testosterone replacement therapy. As expected, this is a six month review and includes results from the Ambulatory Blood Pressure Monitoring (ABPM) clinical study and the phlebotomy study that were requested by the Advisory Committee meeting in January 2018. In a previous note, we discussed the results of the APBM study. With approvals for Clarus' Jatenzo and Antares Pharma's (ATRS) Xyosted TRT, we think the FDA has become more open to approvals in this area.

We expect Lipocine to engage with the FDA in the September or October timeframe later this year to refine the label. We anticipate that the label will contain similar black box warnings to other testosterone therapies; however, since there is no titration adjustment, Tlando's label will exclude this complication.

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 undertaken late last year and full enrollment of 36 subjects was achieved in November.

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.

[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.

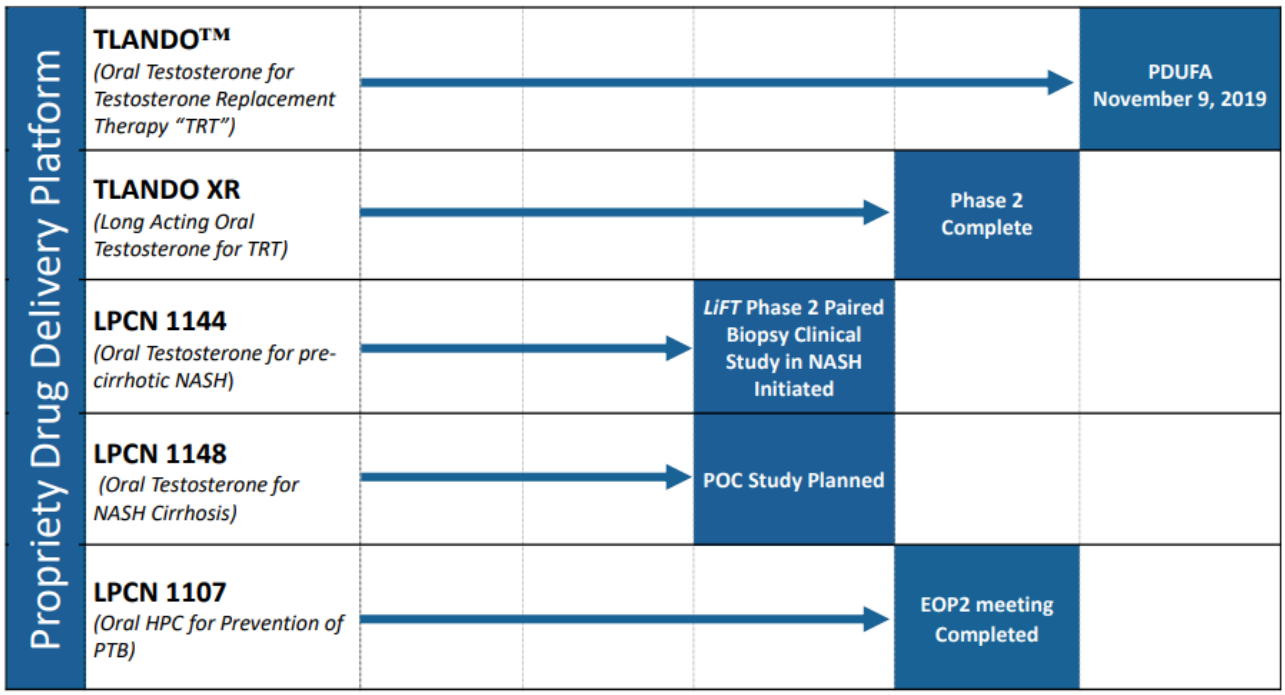
Lipocine has launched its Phase II clinical study for LPCN 1144 and anticipates enrolling its first patient in 3Q:19. In a July 23rd release, Lipocine announced that the FDA would allow the Phase II LiFT trial to enroll eugonadal patients in addition to the NASH patients that were initially targeted. 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.

The trial will be designated LiFT, an acronym of Liver Fat intervention with oral Testosterone and is a paired biopsy Phase II study in NASH subjects. The study design will employ a three-arm, double-blind, placebo controlled construct and enroll approximately 75 biopsy confirmed male NASH subjects with a NAS[2] score of greater or equal to four. The primary endpoint for the study is 12-week MRI-PDFF liver fat reduction. The first patient is expected to be enrolled in 3Q:19. Lipocine is currently screening patients and will use 15 primary sites and 3 backup sites for the study.

LPCN 1148

Lipocine is also 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 a variety of increased risks makes this a potentially worthwhile pursuit. Lipocine plans to initiate a proof of concept trial in the near term to evaluate the potential of this candidate. If the work is successful, efforts to organize an investigational new drug (IND) application could begin before year end.

Exhibit I – Lipocine Pipeline



Clarus Patent Dispute

Lipocine has also seen continued success in its patent dispute against Clarus regarding patent number 8,828,428. The United States Patent and Trademark Office (USPTO) granted Lipocine's Priority Motion in the case and entered an adverse judgment against Clarus. This cancels Clarus' claims to the '428 patent. On February 19th, 2019 Clarus filed an appeal of the ruling, as expected. This initial action is inexpensive and quickly completed. However, if Clarus plans to continue the fight against Lipocine, they must subsequently file a brief, which will require greater expense and effort. This will require Lipocine to file a rebuttal brief, then the appeal will be heard at the federal circuit level, rather than by the USPTO. Based on our understanding, it is rare for a federal court to overturn a USPTO ruling. We are hopeful that Clarus will accept the USPTO ruling and avoid filing the brief, thereby reducing additional costs for both parties and clearing the way for TLANDO to be commercialized following approval.

[2] NAS: NAFLD (Non-alcoholic fatty liver disease) Activity Score. Discussion of the metric can be found here.

In a separate action, Lipocine filed suit against Clarus following the approval of Jatenzo in late March. We discuss the details of Jatenzo and the patent battle in our article Turning the Tables published April 18, 2019.

Milestones

- Tlando ambulatory blood pressure results – 1Q:19
- $6 MM ATM Capital Raise – 1Q:19
- Resubmission of Tlando NDA – May 2019
- Launch of Phase II LPCN 1144 Study – 2Q:19
- Addition to Russell Microcap Index – June 2019
- Enroll First Patient in Phase II LPCN 1144 Study – 3Q:19
- Labeling Discussion for Tlando – Fall 2019
- Tlando PDUFA – November 9, 2019
- Launch Tlando – 2020
- Complete Phase II LPCN 1144 – Year end 2020

Summary

LPCN has successfully resubmitted its NDA for Tlando and has been assigned a PDUFA date. We are increasingly optimistic that the FDA will grant approval for the candidate given the successful outcomes for other TRT and the superior data for blood pressure as compared to Jatenzo and Xyosted. Based on our estimates, first sales of Tlando should commence in early 2020. Lipocine will then be able to shift its development efforts towards other candidates in the pipeline. We are optimistic regarding the opportunity for LPCN 1144 given the large end market, promising preliminary data and well known safety profile for TU. First enrollees are expected in 3Q:19 and we will add a valuation component for LPCN 1144 at that time.

Our target price is derived using a 20% discount rate and probability of eventual sales for LPCN 1021, LPCN 1111 and LPCN 1107 of 45%, 15% and 10% respectively. Based on our estimates of sales, expenses, risk, and updates provided in company documents, our target price is maintained at $7.00 per share.

PROJECTED FINANCIALS

Lipocine Inc. - Income Statement

Lipocine Incorporated	2018 A	Q1 A	Q2 A	Q3 E	Q4 E	2019 E	2020 E	2021 E
Total Revenues ($MM)	**$0.4**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$157.4**	**$217.7**
CoGS	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$55.1	$76.2
Gross Income	$0	$0	$0	$0	$0	$0	$102	$142
Product Gross Margin							*65.0%*	*65.0%*
R&D	$6.5	$1.9	$2.0	$6.0	$6.0	$15.9	$23.0	$23.0
G&A	$5.3	$1.2	$1.4	$2.0	$2.0	$6.6	$28.6	$37.7
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)	($8.0)	($8.0)	($22.5)	$49.6	$79.7
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)	($8.1)	($8.1)	($22.9)	$49.1	$78.9
Taxes & Other	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$5.2	$2.2
Tax Rate	*0%*	*$0.0*	*0%*	*0%*	*0%*	*0%*	*-11%*	*3%*
Net Income	($11.7)	($3.2)	($3.4)	($8.1)	($8.1)	($22.9)	$54.3	$76.7
Reported EPS	**($0.55)**	**($0.14)**	**($0.14)**	**($0.33)**	**($0.32)**	**($0.93)**	**$2.04**	**$2.74**
YOY Growth	-					-	-	-
Shares Outstanding	21.4	23.4	24.6	25.0	25.4	24.6	26.6	28.0

Source: Company Filing // Zacks Investment I

HISTORICAL STOCK PRICE

Lipocine Inc. – Share Price Chart

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