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Lipocine Inc. (LPCN-NASDAQ)

Now We Have PDUFA Date; Target To $7

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 (5/14/19)	$1.93
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	**$1.04**
One-Year Return (%)	**52.0**
Beta	**-0.01**
Average Daily Volume (sh)	**349,573**
Shares Outstanding (mil)	**24.6**
Market Capitalization ($mil)	**$47.5**
Short Interest Ratio (days)	**2.24**
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 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)
2018	$0.4 A	$0.0 A	$0.0 A	$0.0 A	$0.4 A
2019	$0.0 A	$0.0 E	$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	-$0.29 E	-$0.33 E	-$0.32 E	-$1.08 E
2020					$2.04 E
2021					$2.74 E

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WHAT'S NEW

First Quarter 2019 Operational and Financial Results

On May 8, 2019 Lipocine (NASDAQ: LPCN) filed its 1Q:19 10-Q and posted its earnings release for the three month period ending March 31, 2019. The company reported zero revenues and net loss per share of ($0.14) compared to prior year revenues of $0.4 million and ($0.13) per share. The most important highlights for 1Q:19 and include the grant of priority motion to Lipocine in the Clarus case, favorable results for and clinical advancement of LPCN 1144 in the Liver Fat Study, participation in several NASH conferences and completion of several requirements for Tlando resubmission. After the end of the quarter, Lipocine announced the PDUFA date for Tlando as November 9th, 2019. We have increased our optimism on the likelihood of approval for Tlando given the favorable outcomes for other TRT approvals and the successful assignment of a PDUFA date, and we raise our target price accordingly.

Lipocine reported no revenues in the quarter. Research and development expenses totaled $1.9 million, increasing 42% due to greater contract research organization costs related to the Tlando ABPM study partially offset by reduced outside service costs, reductions in contract manufacturing costs and lower personnel costs. General and administrative expenses were $1.2 million in the January to March period, contracting 30% from 1Q:18 levels. These changes were due to a reduction in the commercial sales and marketing team, lower stock compensation and bonus as well as decreased professional fees. A rise in administrative costs related to overhead offset aforementioned G&A declines. Net loss for the quarter was ($3.2) million, or ($0.14) per share.

Cash and marketable securities balance was $22.5 million as of March 31, 2019 which includes $5 million of restricted cash. Cash burn for the first quarter was approximately ($3.0) million and net cash from financing was $5.2 million representing a $0.8 million loan repayment from Silicon Valley Bank[1] and $6.1 million in proceeds raised on the issuance of equity through the at-the-market (ATM) facility with Cantor Fitzgerald. Cash burn in 1Q:19 was ($3.0) million compared to ($3.7) million in the prior year.

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 recent 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 is 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 read similar to the Jatenzo's; 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.

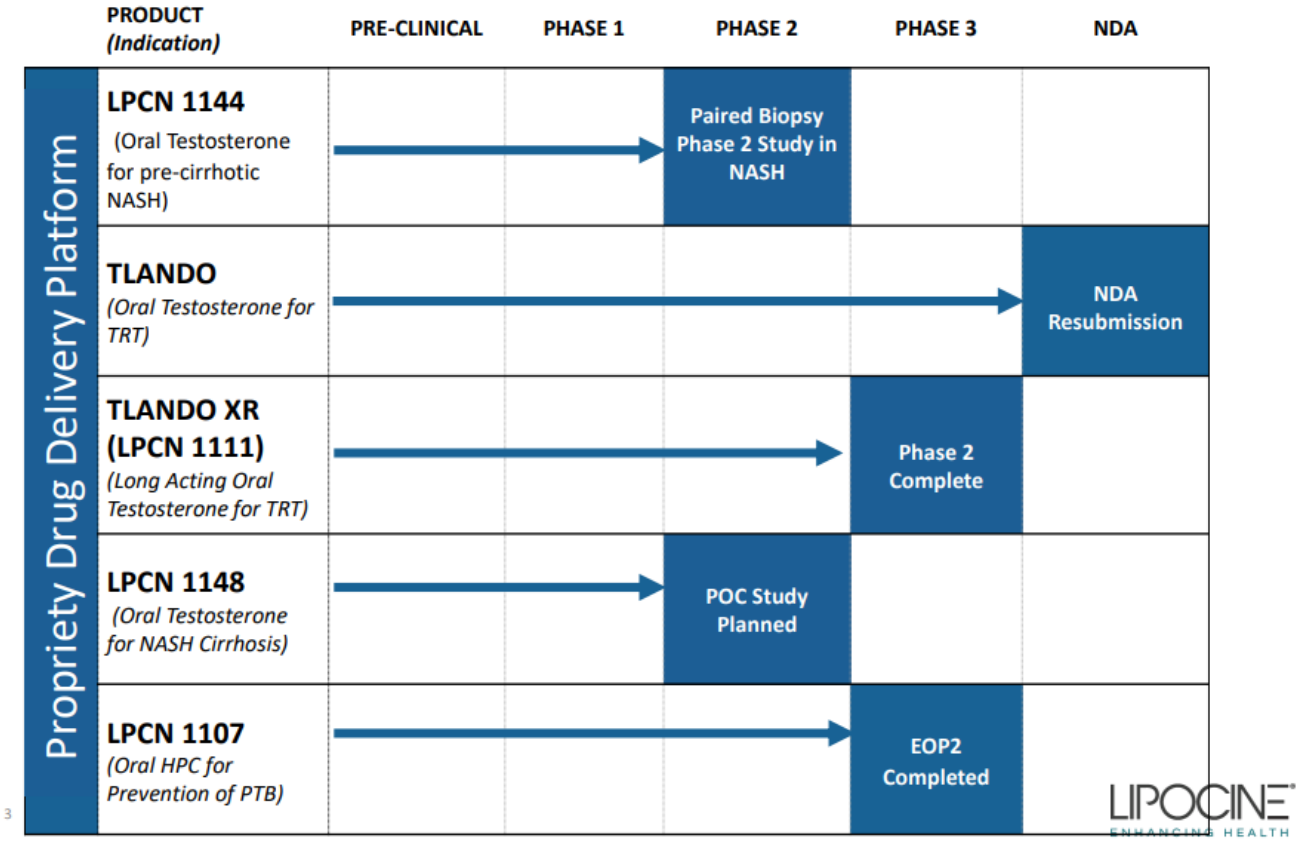
Lipocine has launched its Phase II clinical study for LPCN 1144 and anticipates enrolling its first patient in 3Q:19. The study is anticipated to last for 18 months and cost approximately $8 million.

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 wants 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.

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.

Exhibit I – Lipocine Pipeline



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
- 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. We increase our probability estimate for Tlando approval to 45% which increases our target price to $7.00 per share. We also adjust for an increased share balances, current cash and debt levels. 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 increases to $7.00 per share.

PROJECTED FINANCIALS

Lipocine Inc. - Income Statement

Lipocine Incorporated	2018 A	Q1 A	Q2 E	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**
R&D	$6.5	$1.9	$5.0	$6.0	$6.0	$18.9	$23.0	$23.0
G&A	$5.3	$1.2	$2.0	$2.0	$2.0	$7.2	$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)	($7.0)	($8.0)	($8.0)	($26.1)	$49.6	$79.7
Operating Margin	-					-	-	-
Total Other Income	($0.3)	($0.1)	($0.1)	($0.1)	($0.1)	($0.5)	($0.5)	($0.9)
Pre-Tax Income	$11.7	($3.2)	($7.1)	($8.1)	($8.1)	($26.6)	$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)	($7.1)	($8.1)	($8.1)	($26.6)	$54.3	$76.7
Reported EPS	**($0.55)**	**($0.14)**	**($0.29)**	**($0.33)**	**($0.32)**	**($1.08)**	**$2.04**	**$2.74**
YOY Growth	-					-	-	-
Shares Outstanding	21.4	23.4	24.7	25.0	25.4	24.6	26.6	28.0

Source: Company Filing // Zacks Investment I

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HISTORICAL STOCK PRICE

Lipocine Inc. – Share Price Chart



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