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Lipocine Inc. (LPCN-NASDAQ)

Target Date: August!

Based on our DCF model and a 20% discount rate, LPCN is valued at approximately $3.00 per share. We add back a valuation for recently resubmitted TLANDO applying a 10% probability of success and continue to include Phase II asset LPCN 1144 applying a 15% probability of success. No valuation is attached to Tlando or other development assets.

Current Price (3/18/20)	$0.33
Valuation	**$3.00**

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 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 target NASH.

The lead product, Tlando, resubmitted an NDA in March 2020 after incorporating reanalysis of existing data requested by the FDA. The FDA subsequently provided a PDUFA date of August 28, 2020. While it appears that Lipocine has answered all of the agency's questions sufficiently to support approval, we have a low degree of confidence of approval and assign a 10% chance of success given the prior hurdles the FDA has placed in front of approval. LPCN's other TRT product, LPCN 1111 and LPCN 1107 for pre-term birth are on hold. 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 in March 2020 & will launch the trial after receiving additional funding.

SUMMARY DATA

52-Week High	**$3.45**
52-Week Low	**$0.30**
One-Year Return (%)	**-84.4**
Beta	**-0.2**
Average Daily Volume (sh)	**1,632,898**
Shares Outstanding (mil)	**47.8**
Market Capitalization ($mil)	**$15.9**
Short Interest Ratio (days)	**2.16**
Institutional Ownership (%)	**17.7**
Insider Ownership (%)	**3.2**
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 A	$0.2 A
2020					$6.5 E
2021					$137.6 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	-$0.11 A	-$0.50 A
2020					-$0.20 E
2021					$0.82 E

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WHAT'S NEW

2019 Operational and Financial Results

On March 13, 2020 Lipocine (NASDAQ: LPCN) filed its fiscal year 2019 10-K and posted its earnings release for the twelve month period ending December 31, 2019. The company reported $165,000 in revenues and a net loss per share of ($0.50) compared to prior year revenues of $428,000 and loss of ($0.55) per share. Despite receiving a Complete Response Letter (CRL) for Tlando on November 8th, management quickly requested and conducted a Post Action meeting with the FDA to identify an appropriate response to address the Cmax related deficiency. The agency and company agreed that a reanalysis of existing information would be sufficient and resubmitted the new drug application (NDA) in February 2020. Development continues with 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 streamlining of the Clarus lawsuit and additional capital raising.

Lipocine reported $165,000 in revenues from Spriaso related to the cough and cold field. Operational expenses of $13.1 million were up 11% and net loss totaled ($13.0) million or ($0.50) per share. Research and development expenses totaled $7.5 million, with the 16% rise reflecting increased costs related to the LiFT study partially offset by lower expenditures for Tlando. General and administrative costs rose 6% to $5.6 million on higher legal fees related to the Clarus litigation and inflation of corporate insurance partially offset by a variety of other items.

Cash and marketable securities balance was $19.1 million as of December 31, 2019 which includes $5 million of restricted[1] cash. Current and non-current debt totals $7.1 million. Cash burn for 2019 was approximately ($11.7) million and net cash provided by financing was $10.3 million representing two stock offerings partially offset by loan repayments to Silicon Valley Bank.

Tlando

Last May, 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 related to the application. 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.

Following the Post Action meeting with the FDA, Lipocine was advised to address the outstanding deficiencies with a reanalysis of existing data. This approach avoided the time and cost of an additional trial and also allowed the resubmission of the Tlando NDA in February. We were favorably surprised to see the rapid resubmission and the assigned PDUFA date of August 28, 2020, as it was ahead of our anticipated timeline. While the resubmission is a positive, Tlando has faced significant hurdles obtaining the favor of the FDA. We published a note on February 25th that discussed details regarding the resubmission.

We assign a 10% likelihood of approval for Tlando given the previous difficulties the product has faced with the FDA. While there is a high degree of uncertainty, it appears that most of the requirements for approval have been met and we see some probability that the product will be approved.

[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.

LPCN 1144

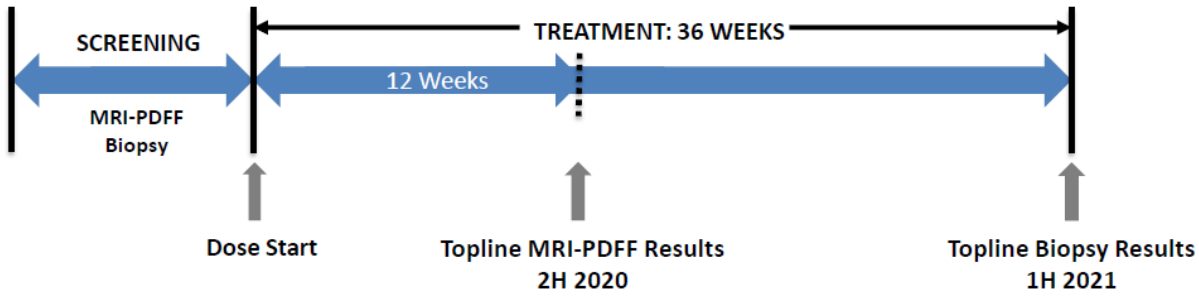
Lipocine announced in August 2018 the pursuit of a new indication in nonalcoholic steatohepatitis (NASH). We discuss the indication and Lipocine's efforts in an earlier piece that can be accessed here. Further work was pursued late last year and full enrollment of 36 subjects was achieved in November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

In January 2019, 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 was allowed to perform 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 1Q:19 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 NASH Topline article.

Lipocine has launched its Phase II clinical study for LPCN 1144 and dosed its first patient last 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[2] 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 in the first half of 2021.

Exhibit I – LiFT Study Timeline[3]



LPCN 1144 Poster Presentation

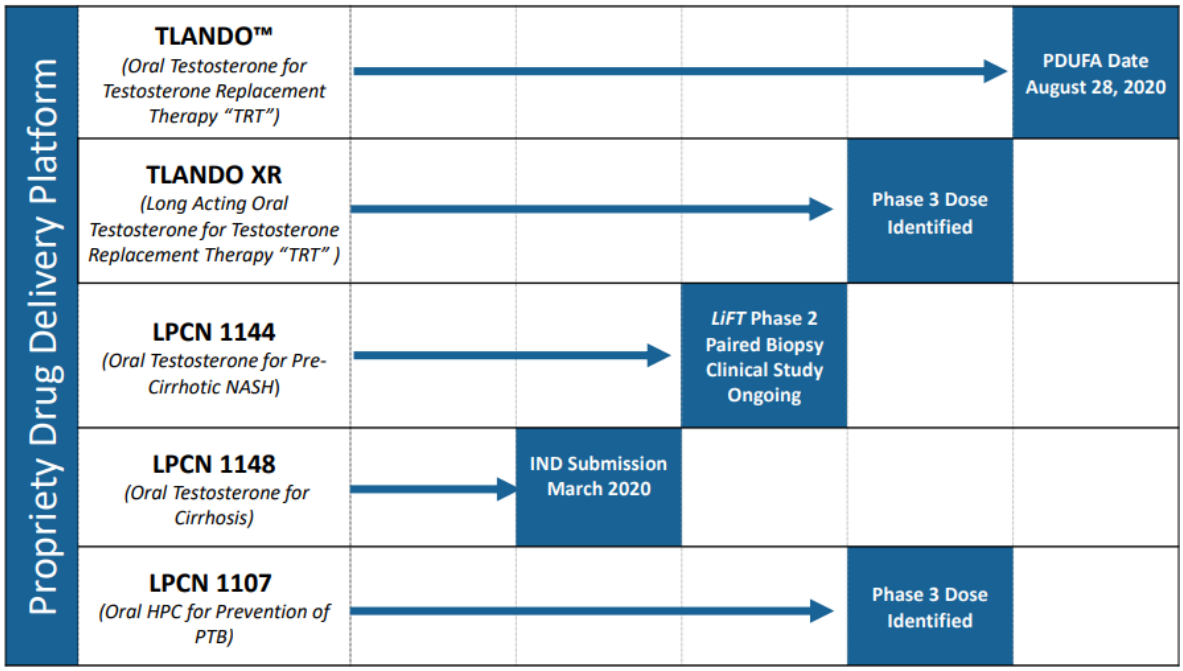
Lipocine presented a poster at the Liver Meeting 2019 entitled "LPCN 1144 Resolves Non-alcoholic Fatty Liver Disease" on November 11th. The poster highlights the correlation between lower free testosterone for NASH as compared to NAFLD patients. Levels of free testosterone decrease significantly with 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.

[2] NAS: NAFLD (Non-alcoholic fatty liver disease) Activity Score. Discussion of the metric can be found here.
[3] Source: Lipocine Corporate Presentation March 2020.

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 in March 2020.

Exhibit II – Lipocine Pipeline[4]



Data Exclusivity

Lipocine added a new risk factor in their 10-K related to the FDA's treatment of data exclusivity. The statement in the filing noted that the three years of exclusivity granted Clarus' Jatenzo could interfere with "the potential full approvability of TLANDO." Based on our understanding, in this unlikely event, the exclusivity characteristics that the FDA relied upon for granting Jatenzo exclusivity would have to be the same exclusivity characteristics that Tlando also relies upon for approval. Management has stated that the FDA has not raised this as an issue for Lipocine's product.

The event precipitating this change in perspective was a 2019 ruling on a case between Braeburn Pharmaceuticals and Indivior PLC. In December 2018, the FDA tentatively approved Braeburn's weekly and monthly Brixadi but did not finalize the approval. The agency found that competitor Sublocade's unexpired clinical investigation exclusivity prevented the approval of monthly Brixadi until November 30, 2020 due to the agency's previous grant of the protection to Sublocade. The FDA did not make clear the factor on which they based the exclusivity granted to Indivior's Sublocade. Braeburn went to court to fight the grant of exclusivity, and was given a summary judgment in its favor and the court remanded the matter back to the FDA. The court found that the FDA was inconsistent in its application of a definition for exclusivity and in July 2019 ruled that its three year grant of exclusivity was arbitrary and capricious. The court further outlined an expectation that the FDA would provide increased clarity on the innovation standards used to grant exclusivity and provide clarification regarding their decision.

In a follow up response, on November 7, 2019, the FDA upheld the exclusivity granted to Sublocade based on the particular characteristics that were relied upon for its approval. In this case, the periodicity of treatment (a monthly administration), was relied upon for the grant of exclusivity. The FDA did tentatively approve the weekly version of Brixadi, which was not subject to Sublocade's exclusivity. While there is some risk that Jatenzo's exclusivity could interfere with Tlando's marketing approval, we believe that our probability of success adjustment addresses it.

[4] Source: Lipocine Corporate Presentation March 2020.

Capital Raise

Lipocine raised $6.0 million in gross proceeds in November 2019 and another $6.0 million in gross proceeds in February 2020. The November raise issued 10,450,000 shares and 1,550,000 prefunded warrants at $0.50 per share with each share and prefunded warrant having a common warrant attached with a $0.50 exercise price. The February registered direct offering transacted 10,084,034 shares, each of which had a half warrant attached. Warrant exercise price and share transaction price were $0.595.

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
- Tlando FDA post action meeting – January 2020
- Resubmission of Tlando NDA – February 2020
- File Investigational New Drug (IND) application for LPCN 1148 – March 2020
- Tlando PDUFA date – August 28, 2020
- Primary endpoint results for LiFT – 2H:20
- Complete Phase II LPCN 1144 – 1H:21

Summary

Faced with another CRL in November, management quickly conducted a meeting with the FDA and found an efficient pathway forward for Tlando which avoids further clinical work. Lipocine reanalyzed existing data and then resubmitted the NDA for Tlando in February. After receipt of the package, the FDA assigned a PDUFA date of August 28, 2020. We add back a valuation component for Tlando; but at a low probability of 10%. This doubles our target price given the relatively low enterprise value we previously assigned. The Phase II LiFT trial continues to be a bright spot for the company and is potentially able to address a large unmet need in NASH patients. The Phase II 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 program entering the clinic until sufficient capital can be raised, we do think it will advance if Phase II data for LPCN 1144 are positive. We modify our target price to reflect the NDA submission for Tlando and the ongoing work for LPCN 1144. Our target price moves from $1.50 to $3.00.

PROJECTED FINANCIALS

Lipocine Inc. - Income Statement

Lipocine Incorporated	2018 A	Q1 A	Q2 A	Q3 A	Q4 A	2019 A	2020 E	2021 E
Total Revenues ($MM)	**$0.4**	**$0.0**	**$0.0**	**$0.2**	**$0.0**	**$0.2**	**$6.5**	**$137.6**
R&D	$6.5	$1.9	$2.0	$1.7	$1.8	$7.5	$8.2	$9.4
G&A	$5.3	$1.2	$1.4	$1.4	$1.6	$5.6	$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)	($3.4)	($12.9)	($10.6)	$73.2
Operating Margin	-					-	-	-
Total Other Income	($0.3)	($0.1)	($0.1)	($0.1)	$0.2	($0.1)	($0.5)	($0.9)
Pre-Tax Income	$11.7	($3.2)	($3.4)	($3.1)	($3.3)	($13.0)	($11.1)	$72.3
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)	($3.3)	($13.0)	($11.1)	$72.3
Reported EPS	**($0.55)**	**($0.14)**	**($0.14)**	**($0.12)**	**($0.11)**	**($0.50)**	**($0.20)**	**$0.82**
YOY Growth	-					-	-	-
Shares Outstanding	21.4	23.4	24.6	24.9	30.0	25.9	54.6	88.0

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

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HISTORICAL STOCK PRICE

Lipocine Inc. – Share Price Chart



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