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March 15, 2018
John D. Vandermosten, CFA
312-265-9588 / jvandermosten@zacks.com

10 S. Riverside Plaza, Chicago, IL 60606

Lipocine Inc. (LPCN-NASDAQ)

Coming at the FDA Like a Spider Monkey

Based on our DCF model and a 20% discount rate, LPCN is valued at approximately $7.00 per share. We apply a 30% probability of eventual sales of LPCN 1021 (TLANDO), a 15% probability to LPCN 1111 and a 10% probability to LPCN 1107.

Current Price (3/14/18)	$1.51
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 three drugs in development that employ this technology. Two are for the treatment of male hypogonadism and the third for the prevention of pre-term birth.

The lead product, LPCN 1021 (Tlando), received a CRL in June 2016 and a negative AdCom vote in January 2018. Currently Tlando has a May 2018 PDUFA date, however, we anticipate this will be delayed based on the AdCom result and proactive action by Lipocine. Our updated estimates anticipate a mid-2019 launch of Tlando assuming FDA approval. LPCN's other TRT product, LPCN 1111, which provides 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	**$5.33**
52-Week Low	**$1.15**
One-Year Return (%)	**-66.1**
Beta	**-0.51**
Average Daily Volume (sh)	**783,730**
Shares Outstanding (mil)	**21.3**
Market Capitalization ($mil)	**$32.2**
Short Interest Ratio (days)	**6.8**
Institutional Ownership (%)	**18.0**
Insider Ownership (%)	**5.8**
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 2016 Estimate	**N/A**
P/E using 2017 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 $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2017	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2018					$0.0 E
2019					$68.1 E

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	-$0.38 A	-$0.32 A	-$0.18 A	-$0.16 A	-$1.04 A
2017	-$0.26 A	-$0.31 A	-$0.22 A	-$0.25 A	-$1.05 A
2018					-$0.90 E
2019					$0.04 E

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WHAT'S NEW

2017 Operational and Financial Results

Lipocine Inc. (NASDAQ: LPCN) filed its 2017 10-K and posted its earnings release on March 12, summarizing an volatile year which included new dosing studies for Tlando and a resubmission of the drug to the FDA. Several key events have taken place year to date with additional financing secured and an advisory committee meeting that sought additional information for the company's testosterone replacement therapy product. Progress was also made on patent rights and class action lawsuits, placing Lipocine in a stronger position overall with respect to Clarus' patent.

As expected, no revenues were reported in 2017. Total expenses were $21.2 million, up 11% over the prior year, with $11 million of this total allocated to R&D and $10.2 million allocated to G&A. R&D rose 36% as Lipocine conducted two important dose validation studies, increased manufacturing capabilities and prepared for the January 2018 advisory committee meeting. G&A fell slightly on lower Tlando commercialization costs and lower legal expenses.

Cash stood at $21.5 million at December 31, 2017 and during the first quarter, the company entered into a loan agreement, drawing an additional $10 million.[1] Cash burn for the year was ($16.7) million, an improvement over 2016 levels of ($18.3) million.

The most important effort during 2017 and year to date 2018 was the progress made on Tlando with the FDA. In mid-2016, Lipocine received a CRL which identified an anomaly in the titration scheme that required further study. Following a post-action meeting, the company launched a dosing flexibility and dosing validation study which were completed and announced in June 2017. In August 2017, Lipocine resubmitted its new drug application for Tlando to the FDA and an advisory committee date of January 10th 2018 was set along with a PDUFA date of May 8th 2018. At the meeting, the committee voted six to thirteen against the benefit/risk profile for Tlando citing blood pressure concerns, the need for an ambulatory blood pressure study and whether testosterone concentrations measured in serum tubes were reliable.[2]

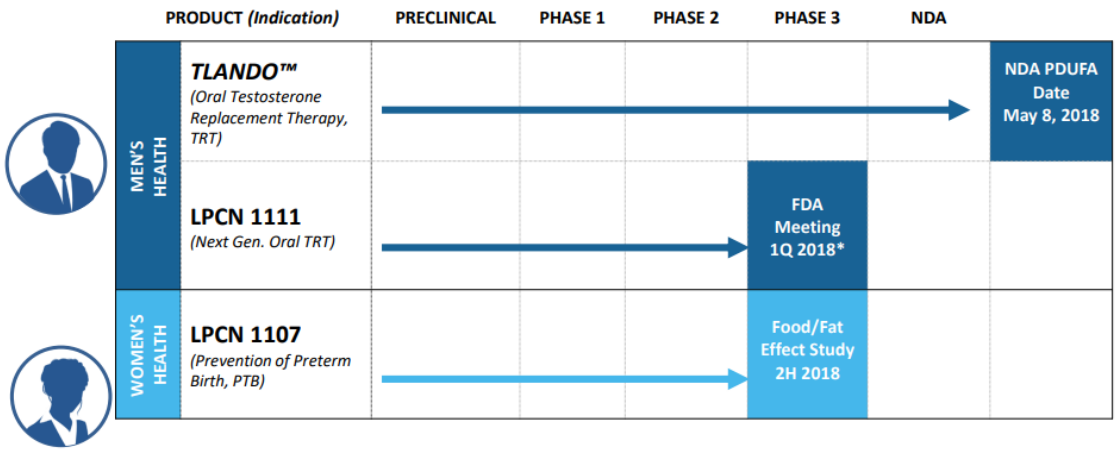
To address these concerns, Lipocine has begun preparing to conduct an ambulatory blood pressure monitoring (ABPM) study and a phlebotomy study. Both protocols have been submitted to the FDA under an IND for comments. Lipocine will be ready to begin immediately following input from the agency. The phlebotomy study should be a relatively short and inexpensive effort,[3] however, the ABPM is not expected to be finished prior to the May 8th PDUFA date and Lipocine would agree to conducting the work after approval. In conjunction with the efforts to address the concerns of the AdCom, Lipocine is also meeting with congressional members with oversight of the FDA making the case that the FDA outlined everything it needed in study design during its 2017 meeting, and should not bring up new concerns that are not justified by the data at this late stage in the approval process. The company is also drafting letters with legal counsel to deliver to the FDA making the case that no other approved product was required to perform the studies. These will be delivered if necessary following FDA action. See our January 11 report[4] for additional discussion of the AdCom.

Lipocine is coming at the FDA from multiple directions[5] on the regulatory, congressional and legal fronts with the goal of focusing attention on the original pathway, protocol and processes developed. While we are not sure of the likelihood of success for this approach, we see Lipocine's all-in efforts as a strong positive.

And finally, our previous commentary[6] regarding the Clarus patent dispute left off with the USPTO granting a motion for Lipocine's and Clarus' initial priority dates regarding Tlando. This change shifted the focus to Lipocine's 2009 patent, which the company believes contains sufficient evidence to support their claim of priority and is dated prior to the earliest priority that will be accorded Clarus. Management expects that the court should have all of the documentation by the required July deadline, after which the court will deliver a ruling. There is no mandated timeline for the court's action, but we expect a response before year end 2018.

[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.
[2] Based on our reading of the AdCom notes, none of these concerns were raised based on data provide by Lipocine or related to Tlando.
[3] Management believes the study can be completed in a few weeks for ~$100,000.
[4] http://s1.q4cdn.com/460208960/files/News/2018/Jan-12-2018_LPCN_Vandermosten.pdf
[5] Like a spider monkey
[6] http://s1.q4cdn.com/460208960/files/News/2017/Nov-10-2017_LPCN_Vandermosten.pdf

Exhibit I – Lipocine Pipeline



* Meeting occurred and awaiting FDA meeting minutes

Highlighted Events Year for 2017 and Year to Date

- Completion of enrollment of the LPCN 1021 fixed dose trials – April 2017
- Topline results from DV and DF study - June 2017
- SPA for LPCN 1107 (Pre-term birth) submitted to FDA - June 2017
- Resubmission of Tlando to FDA – August 2017
- USPTO Motions decision – September 2017
- Updated form S-3 filed registering $150 million in securities – October 2017
- AdCom delivers a 6:13 vote against the benefit/risk profile for Tlando – January 2018
- Entry into a $10 million load agreement with Silicon Valley Bank – January 2018
- Settlement of Securities Class Action Lawsuit – February 2018

Valuation

While the negative outcome from the AdCom regarding Tlando reduced our valuation (discussed in our prior report), we anticipate that Lipocine will continue to pursue the approval of Tlando by developing yet another study in conjunction with the FDA to address the advisory committee's concerns relating to blood pressure and quality of samples. We believe that Lipocine can take a proactive stance but despite their efforts, there may be a delay in FDA consideration. Until the FDA has a chance to clarify the information needed to satisfy potential concerns, timing is uncertain. Based on these factors, we have assumed that first sales will commence after a 2019 approval and there will be approximately $6 million in R&D expended to support the necessary work. We also maintain our 30% probability estimate of ultimate approval. The delay of Tlando will result in LPCN 1111 being delayed by another year; however, LPCN 1107 maintains its 2020 launch date in our estimates, with both probabilities of ultimate sales remaining the same for these two pipeline candidates. We update our model for two additional items which advance our NPV model by one year and reflect the change in US corporate tax rate. The net of our NPV and tax rate changes increases our target price from $6.00 to $7.00 per share.

Summary

LPCN is working through the hurdles created by the AdCom and we adjust our model to reflect our view on success and timing for Tlando's commercialization. We forecast a 30% probability that Lipocine can successfully navigate the regulatory requirements and obtain FDA approval for the drug. Following approval, Lipocine will develop a sales force and find an appropriate partner to commercialize the primary care segment and we anticipate will be able to commence first sales within 90 days of the regulatory nod. Based on this timeline, first sales should commence in 2019. Lipocine will then be able to shift its development efforts towards LPCN 1111 and 1107.

Our target price is derived using a 20% discount rate, and probability of eventual sales for LPCN 1021, LPCN 1111 and LPCN 1107 of 30%, 15% and 10% respectively. Based on our estimates of sales, expenses, risk, and updates provided in company documents, and adjustments of our NPV model and anticipated tax rates, our target price increases to $7.00 per share.

PROJECTED FINANCIALS

Lipocine Inc. - Income Statement

Lipocine Incorporated	2016 A	Q1 A	Q2 A	Q3 A	Q4 A	2017 A	2018 E	2019 E
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0.0**	**$0.0**	**$68.1**
CoGS	$0	$0	$0	$0	$0	$0	$0	$24
Product Gross Margin							*# DIV/0!*	*65.0%*
R&D	$8.1	$3.1	$4.1	$2.0	$1.8	$11.0	$6.8	$22.0
G&A	$10.4	$1.8	$2.0	$2.7	$3.6	$10.2	$12.6	$21.3
Other expenses	$0.7	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($19.2)	($4.9)	($6.1)	($4.8)	($5.40)	($21.2)	($19.4)	$0.97
Operating Margin	-					-	-	-
Total Other Income	$0.2	$0.0	$0.1	$0.1	$0.1	$0.2	$0.0	$0.0
Pre-Tax Income	($19.0)	($4.9)	($6.1)	($4.7)	($5.3)	($21.0)	($19.4)	$1.0
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	($19.0)	($4.9)	($6.1)	($4.7)	($5.3)	($21.0)	($19.4)	$1.0
Reported EPS	**($1.04)**	**($0.26)**	**($0.31)**	**($0.22)**	**($0.25)**	**($1.05)**	**($0.90)**	**$0.04**
YOY Growth	-					-	-	-
Shares Outstanding	18.3	18.7	19.4	20.9	21.2	20.1	21.5	21.9

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

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