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Lipocine Inc. (LPCN-NASDAQ)

Another CRL: Updated Timeline Points to 1Q:19 FDA Response

Based on our DCF model and a 20% discount rate, LPCN is valued at approximately $6.00 per share. We apply a 25% probability of eventual sales of LPCN 1021 (TLANDO), a 15% probability to LPCN 1111 and a 10% probability to LPCN 1107.

Current Price (5/9/18)	$1.14
Valuation	**$6.00**

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 second CRL in May 2018 and Lipocine is working to address the deficiencies. We expect a 3Q:18 resubmission and FDA response by 1H:19 followed by a 2H:19 launch of Tlando. We apply a 25% probability of FDA approval and eventual sales. 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	**$1.03**
One-Year Return (%)	**-71.4**
Beta	**-0.32**
Average Daily Volume (sh)	**462,896**
Shares Outstanding (mil)	**21.3**
Market Capitalization ($mil)	**$24.3**
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)
2017	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2018	$0.4 A	$0.0 E	$0.0 E	$0.0 E	$0.4 E
2019					$54.5 E
2020					$186.0 E

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-$0.26 A	-$0.31 A	-$0.22 A	-$0.25 A	-$1.05 A
2018	-$0.13 A	-$0.22 E	-$0.22 E	-$0.27 E	-$0.85 E
2019					$0.24 E
2020					$2.90 E

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WHAT'S NEW

May 8 Complete Response Letter

Lipocine Inc. (NASDAQ: LPCN) received a complete response letter (CRL) from the FDA on May 8, 2017 which identified four deficiencies related to the New Drug Application submitted for Tlando, an oral testosterone product for testosterone replacement therapy. The deficiencies mirrored the concerns highlighted by the January AdCom meeting and include:

- Determining the extent, if any, of *ex vivo* conversion of testosterone undecanoate ("TU") to testosterone ("T") in serum blood collection tubes to confirm the reliability of T data;
- Obtaining definitive evidence pre-approval via an ambulatory blood pressure monitoring (ABPM) study as to whether TLANDO causes a clinically meaningful increase in blood pressure in hypogonadal men;
- Verifying the reliability of Cmax data and providing justification for non-applicability of the agreed-upon and prespecified Cmax secondary endpoints for TLANDO; and,
- Determining the appropriate stopping criteria that can reproducibly and accurately identify those patients who should discontinue use of TLANDO.

Lipocine was already aware of the deficiencies identified in the CRL following the meeting with the January Advisory Committee. Prior to the CRL, the company had initiated work on the ABPM and serum measurement reliability studies and is waiting for a response from the FDA on the design of the study which should come in the next week. Additionally, the company will also schedule a Type A meeting with the FDA in response to the CRL for further guidance on how to proceed. We anticipate a few weeks to prepare the materials, followed by a request and a meeting prior to the end of June. The ABPM study should take approximately three months and could potentially start in the next couple weeks and prior to the Type A meeting. After results are available, a Class 2 resubmission to the FDA is next. The Class 2 resubmission requires a six month review cycle which sets the stage for a 1H:19 FDA response.

We reduce our probability of FDA approval and ultimate sales for Tlando from 30% to 25% and also adjust our model to reflect the anticipated ~$3 million in cost for the ABPM. Our revenue estimates also reflect a later launch of Tlando to 2H:19.

1Q:18 Operational and Financial Results

Prior to the May 8 PDUFA date, the company filed its 1Q:18 10-Q and posted its earnings release. Highlights for the quarter included the AdCom in early January, a capital raise of $10 million, and the settlement of the class action lawsuit related to the first CRL.

License revenues were $428,000 in the first quarter related to royalty payments from Spriaso in the cough and cold space. Total expenses in the first quarter were $3.1 million, down 38% over the prior year, due to lower R&D and G&A costs, related predominantly to deceleration in Tlando development costs. Research and development costs were $1.4 million in 1Q:18 down from $3.1 million in the same quarter in the prior year. $2.0 million of the decline was due to lower expenses for Tlando, which was partially offset by slightly higher expenditures on the other two programs in the portfolio and higher outside service costs of $362,000 related to the Tlando AdCom meeting. General and administrative expenses fell 8% to $1.7 million due to lower compensation and bonus expense as well as lower overhead costs partially offset by higher professional fees.

Cash stood at $27.8 million at March 31, 2018 and during the first quarter, which was an increase over end of year levels due to the Silicon Valley Bank loan of $10 million.[1] Cash burn for the quarter was ($3.7) million compared to ($3.1) million in 1Q:17.

[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.

Litigation

A lawsuit was filed against Lipocine in July 2016 related to the FDA's issuance of a CRL in the prior month. In February 2018, Lipocine entered into a memorandum of understanding (MOU) regarding a settlement which is expected to be approved by the court. The MOU has identified a settlement of $4.3 million. Lipocine carries insurance for this type of claim and $3.6 million of the settlement will be covered by insurance.

TLANDO

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]

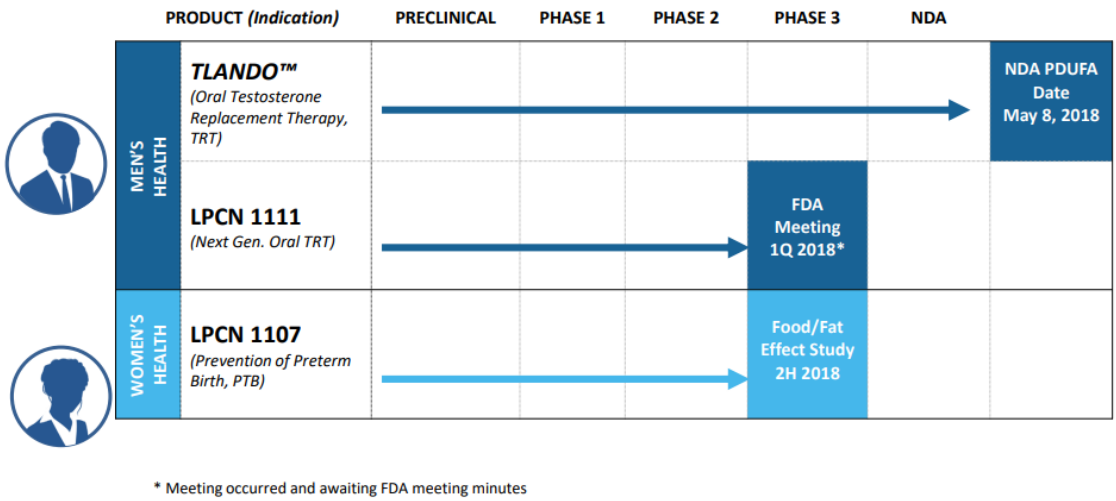
To address these concerns, Lipocine has prepared to conduct an ambulatory blood pressure monitoring (ABPM) study and a phlebotomy study. Both protocols have been submitted to the FDA under an IND for comments and a response should be received in the first half of May. Lipocine will be ready to begin immediately following input from the agency. The phlebotomy study should be a relatively short and inexpensive effort, however, the ABPM is not expected to start until feedback is provided from the agency in the first half of May. 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[3] for additional discussion of the AdCom.

Lipocine is coming at the FDA from multiple directions 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[4] 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.

[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] http://s1.q4cdn.com/460208960/files/News/2018/Jan-12-2018_LPCN_Vandermosten.pdf
[4] 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

Recent and Future Milestones

- 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
- CRL Issued for Tlando – May 8, 2018
- FDA comments on ABPM – May 2018
- Type A Meeting – June 2018
- Resubmission of Tlando NDA – 3Q:18
- Anticipated FDA Response for Tlando NDA – 1H:19

Valuation

While the negative outcome from the CRL regarding Tlando reduced our valuation, we anticipate that Lipocine will continue to pursue the approval of Tlando by addressing the advisory committee's concerns relating to blood pressure and quality of samples. Until the FDA has a chance to clarify the information needed to satisfy potential concerns in the ABPM study and the Type A meeting, timing is uncertain but based on our assumptions discussed above, the FDA could provide a response by 1H:19. We have assumed that first sales will commence in 2H:19. Our probability of approval and ultimate sales declines from 30% to 25%. The push back of first sales of Tlando by approximately a quarter and reduction in probability of success reduce our target price from $7.00 to $6.00 per share.

Summary

LPCN has a head start addressing the discrepancies raised in the CRL and we adjust our model to reflect our view on success and timing for Tlando's commercialization. We forecast a 25% probability that Lipocine will obtain FDA approval and commercialize Tlando. 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 2H:19. 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 25%, 15% and 10% respectively. Based on our estimates of sales, expenses, risk, and updates provided in company documents, our target price moves to $6.00 per share.

PROJECTED FINANCIALS

Lipocine Inc. - Income Statement

Lipocine Incorporated	2017 A	Q1 A	Q2 E	Q3 E	Q4 E	2018 E	2019 E	2020 E
Total Revenues	**$0.0**	**$0.4**	**$0.0**	**$0.0**	**$0.0**	**$0.4**	**$54.5**	**$186.0**
CoGS	$0.0	$0.0	$0.0	$0.0	$0.0	$0.1	$5.4	$65.1
Product Gross Margin							*90.0%*	*65.0%*
R&D	$11.0	$1.4	$1.7	$1.7	$1.7	$6.5	$22.0	$23.0
G&A	$10.2	$1.7	$2.8	$3.0	$4.0	$11.5	$21.3	$32.9
Other expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$1.1
Operating Income	($21.2)	($2.6)	($4.5)	($4.7)	($5.7)	($17.7)	$5.7	$63.9
Operating Margin	-					-	-	-
Total Other Income	$0.2	($0.1)	($0.1)	($0.1)	($0.1)	($0.5)	($0.5)	($0.5)
Pre-Tax Income	($21.0)	($2.7)	($4.6)	($4.8)	($5.8)	($18.1)	$5.2	$63.4
Taxes & Other	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$1.6
Tax Rate	*0%*	*$0.0*	*0%*	*0%*	*0%*	*0%*	*0%*	*-3%*
Net Income	($21.0)	($2.7)	($4.6)	($4.8)	($5.8)	($18.1)	$5.2	$65.1
Reported EPS	**($1.05)**	**($0.13)**	**($0.22)**	**($0.22)**	**($0.27)**	**($0.85)**	**$0.24**	**$2.90**
YOY Growth	-					-	-	-
Shares Outstanding	20.1	21.3	21.4	21.5	21.6	21.5	21.9	22.4

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

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