Zacks Small-Cap Research

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Lipocine Inc. (LPCN-NASDAQ)

AdCom Votes 6:13 Against Tlando

Based on our DCF model and a 20% discount rate, LPCN is valued at approximately $6.00 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 (1/11/18)	$2.01
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 pharmokinetic 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	**$1.67**
One-Year Return (%)	**-42.7**
Beta	**1.61**
Average Daily Volume (sh)	**319,504**
Shares Outstanding (mil)	**21.2**
Market Capitalization ($mil)	**$42.6**
Short Interest Ratio (days)	**6.8**
Institutional Ownership (%)	**19.8**
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 E	$0.0 E
2018					$0.0 E
2019					$109.0 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	-$0.30 E	-$1.11 E
2018					-$0.63 E
2019					$1.67 E

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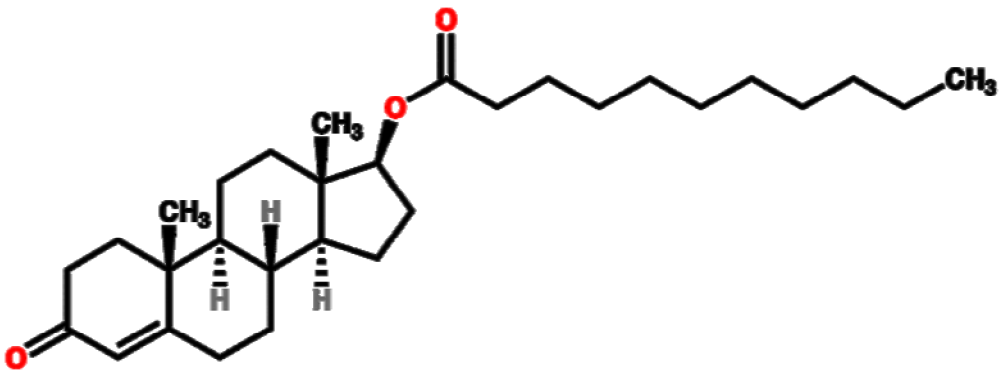
WHAT'S NEW

Advisory Committee Votes Against Tlando

On January 10, 2018 the 19 member Bone, Reproductive and Urologic Drugs Advisory Committee (BRUDAC) voted 13 to 6 against the benefit / risk profile for Lipocine Incorporated's (NASDAQ: LPCN) Tlando (Testosterone undecanoate). The panel's main focus was related to blood pressure concerns. While Lipocine did measure blood pressure during each visit for each study, this was insufficient to provide the data the panel sought. The lack of data prompted the BRUDAC to vote against the benefit / risk profile as they felt they had insufficient information to cast a positive vote. Other items raised during the meeting related to breakdown of testosterone undecanoate (TU) into testosterone in the collection tubes, and the data leading to the stopping of TRT.

Exhibit I – Testosterone Undecanoate[1]



The committee was formed to evaluate Lipocine's and Clarus' TU products currently before the FDA. The day before Tlando's review, the BRUDAC voted 10 to 9 against the benefit / risk profile for Clarus' Jatenzo (testosterone undecanoate). It appears that the panel and the FDA have taken a stricter stance against TRT and are concerned about the off-label use of the product. The BRUDAC considered that some of the off-label use would be for overweight men with a predilection for cardiovascular disease. With this population, high blood pressure, hematocrit and serum lipid levels are valid concerns.

Lipocine's AdCom voted only on whether or not the benefits of Tlando outweighed its risks in support of approval. The key factors considered for the benefit / risk question relate to elevated blood pressure and whether or not an ambulatory blood pressure assessment is required pre-approval. During the dosing validation (DV) and dosing flexibility (DF) studies one blood pressure reading was taken when the patient arrived for treatment. The panel felt this was insufficient to answer whether or not blood pressure was elevated in the Tlando arm. While the issue wasn't raised until the AdCom began, the panel wanted blood pressure readings both before and after administration of the drug that were measured over specific time intervals and performed relative to a comparator.

This concern was raised due to the blood pressure impact of Jatenzo, which did conduct a blood pressure study and did have a statistically higher level of blood pressure relative to its comparator arm. For Tlando, there was actually a decrease in blood pressure from baseline in Lipocine's 52-week study and their DV study; however, the DF study showed an increase. To satisfy the panel's concerns, we think Lipocine could conduct a small study lasting a few weeks with an Androgel comparator arm consisting of somewhere between 150 and 200 patients. We note that the blood pressure study conducted by Clarus included 166 patients on the Jatenzo arm, of which 135 had interpretable results.

One of the other issues raised by the AdCom was related to the collection vessels used for blood draws. Clarus had used tubes specially treated to prevent esterases in the blood sample from converting testosterone undecanoate (TU) to testosterone. The concern with using standard tubes is that more TU would convert to testosterone than what existed in the blood serum at the time of the draw, thereby resulting in higher testosterone read levels. This item was brought forward to Lipocine's AdCom as well, where it was discussed. Lipocine had its bioanalytical laboratory do a study to examine the impact of using the standard collection tubes and ensure this conversion from TU to testosterone was not occurring. While the committee may like to see more studies here, we

[1] Wikipedia Commons. https://commons.wikimedia.org/wiki/File:Testosterone_undecanoate.svg

do not anticipate this to be a safety issue even if it were occurring given the results would overestimate testosterone levels. Excessive testosterone levels would lead to discontinuation of use for Tlando, and hence no risk from the drug. In either case, these adjustments could easily be added to the blood pressure study.

Stopping criteria was the third area of questions posed to the AdCom by the FDA. How does a physician know if someone should stay on therapy or be discontinued? Lipocine suggested that a patient take a dose in the morning then come back to the physician's office and provide a blood sample seven to nine hours later. If results were outside the 300 ng/dL to 1080 ng/dL recommended range on the first draw, this discrepancy would be checked again with a second blood sample some period later. If still outside the required range in a later draw, this would indicate treatment should be halted. The FDA asked the AdCom's input regarding patients that are benefiting from the therapy being incorrectly removed from it. Based on the criteria provided for ceasing treatment, an estimated 30% of patients would be removed from treatment who were actually benefitting from it. Lipocine argued that subsequent blood draws for patients outside recommended ranges would substantially reduce this false positive rate.

Based on the commentary provided by the committee, a short study of a few weeks consisting of 150 to 200 patients with a comparator arm may be sufficient to address the items raised by the dissenting committee members. While the committee was the body that generated the negative vote, new data required and trial design will be determined by Lipocine and the FDA.

We use our estimated cost of last year's dosing validation (DV) and dosing flexibility (DF) studies, which ran about $2 million apiece to estimate the cost of work required to address the AdCom's concerns. Due to a shorter trial period of only a few weeks, costs could range from $500,000 to $1,000,000. We also believe that Lipocine will take a proactive stance, conduct studies to address the AdCom's concerns and submit this data to the FDA within a few months. This will likely be considered a major amendment by the FDA, which could delay a response by the agency by three to six months. While a further delay is a difficult hurdle, we believe this would be a faster path to approval compared to a CRL issuance in May, followed by a resubmission which could add a year or more to an eventual response by the agency.

Valuation

The negative outcome from the AdCom regarding Tlando will lower our valuation, reducing our target price by a third. 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 the breakdown of TU to testosterone in serum tubes. We believe that Lipocine can take a proactive stance and develop a short study lasting a few weeks with less than 200 patients, and include a control arm costing $1 million. The company could then supplement their NDA with this data to the FDA prior to the May 8 PDUFA date. We anticipate that the FDA will consider the submission of this data a major amendment and delay the PDUFA by several months. These assumptions, assuming ultimate approval, will push first sales into 2019 from 2H:18 and add an additional $1 million to 2018 R&D expenses. We also reduce the probability of ultimate approval and sales of Tlando from 50% to 30%. 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. The net of these changes reduces our target price from $9.00 to $6.00 per share.

PROJECTED FINANCIALS

Lipocine Inc. - Income Statement

Lipocine Incorporated	2016 A	Q1 A	Q2 A	Q3 A	Q4 E	2017 E	2018 E	2019 E
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0.0**	**$0.0**	**$109.0**
CoGS	$0	$0	$0	$0	$0	$0	$0	$38
Product Gross Margin							*#DIV/0!*	*65.0%*
R&D	$8.1	$3.1	$4.1	$2.0	$4.0	$13.2	$23.0	$22.0
G&A	$10.4	$1.8	$2.0	$2.7	$2.5	$9.1	$19.0	$21.3
Other expenses	$0.7	$0.0	$0.0	$0.0	$0.0	$0.1	$0.1	$0.1
Operating Income	($19.2)	($4.9)	($6.1)	($4.8)	($6.5)	($22.4)	($42.1)	$27.4
Operating Margin	-					-	-	-
Total Other Income	$0.2	$0.0	$0.1	$0.1	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($19.0)	($4.9)	($6.1)	($4.7)	($6.5)	($22.4)	($42.1)	$27.4
Taxes & Other	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$28.0	$10.6
Tax Rate	*0%*	*$0.0*	*0%*	*0%*	*0%*	*0%*	*67%*	*-39%*
Net Income	($19.0)	($4.9)	($6.1)	($4.7)	($6.5)	($22.4)	($14.1)	$38.1
Reported EPS	**($1.04)**	**($0.26)**	**($0.31)**	**($0.22)**	**($0.30)**	**($1.11)**	**($0.63)**	**$1.67**
YOY Growth	-					-	-	-
Shares Outstanding	18.3	18.7	19.4	20.9	21.9	20.2	22.3	22.8

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

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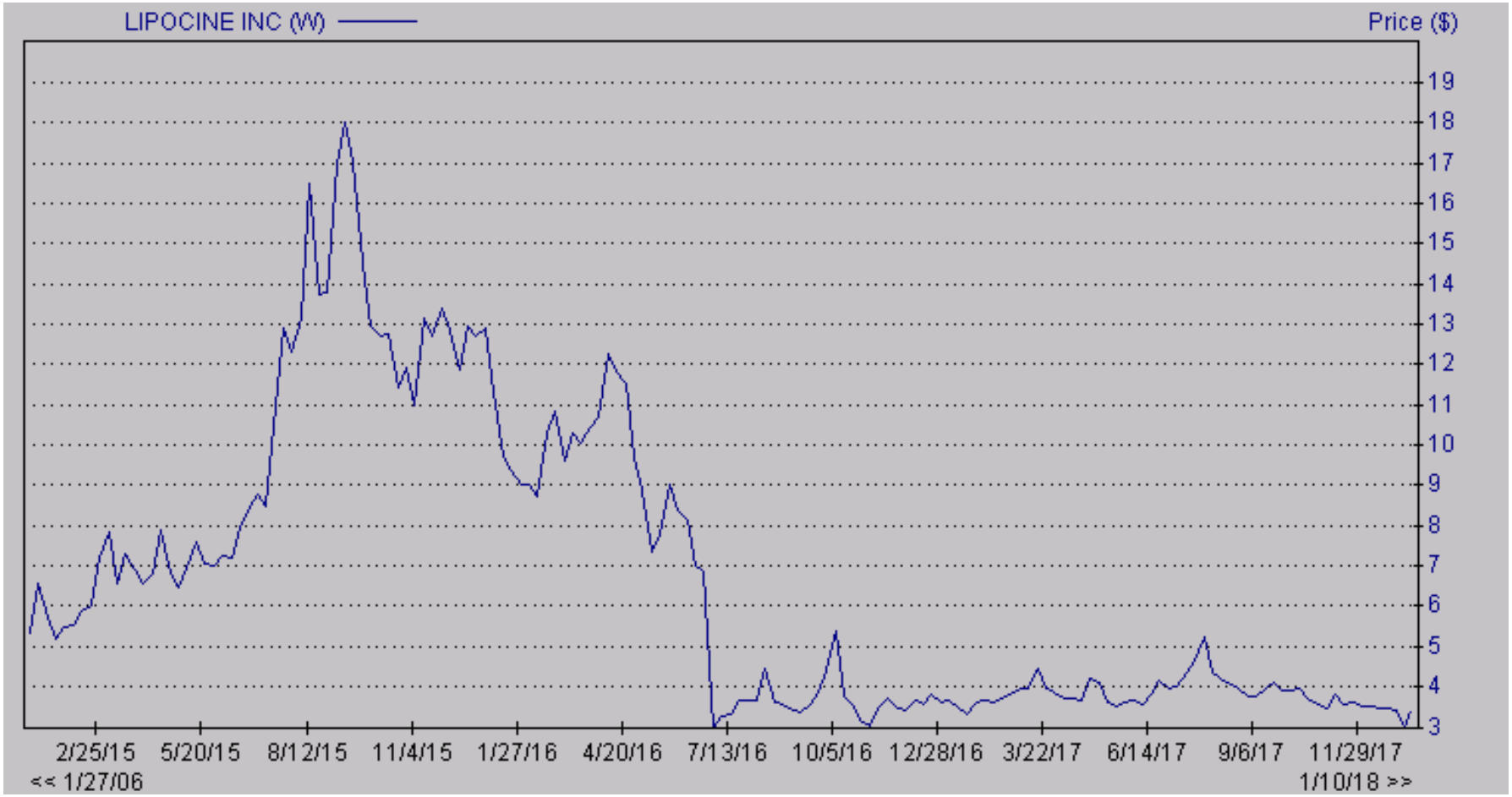
HISTORICAL STOCK PRICE



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