Zacks Small-Cap Research

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Lipocine Inc. (LPCN-NASDAQ)

Resubmission Complete; Preparing for AdCom

Based on our DCF model and a 20% discount rate, LPCN is valued at approximately $9.00 per share. We apply a 50% probability of eventual sales of LPCN 1021 (TLANDO), a 15% probability to LPCN 1111 and a 10% probability to LPCN 1107.

Current Price (11/9/17)	$3.63
Valuation	**$9.00**

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 due to concerns regarding the titration approach used in the trial compared to the proposed label. Since then a DV and DF study were completed supporting the dosing and titration employed in the Ph 3 study and the NDA was resubmitted in August 2017. We anticipate a mid-year 2018 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	**$3.12**
One-Year Return (%)	**4.6**
Beta	**1.70**
Average Daily Volume (sh)	**191,544**
Shares Outstanding (mil)	**21.2**
Market Capitalization ($mil)	**$77.0**
Short Interest Ratio (days)	**6.01**
Institutional Ownership (%)	**26.8**
Insider Ownership (%)	**5.9**
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					$38.9 E
2019					$136.2 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					$0.25 E
2019					$2.12 E

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WHAT'S NEW

Third Quarter Operational and Financial Results

Lipocine made progress addressing its CRL for Tlando in the third quarter and resubmitted its NDA for the product receiving a February 8, 2018 PDUFA date. The FDA also scheduled an advisory committee meeting for Tlando on January 10, 2018. The other highlight of 3Q:17 related to the USPTO 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.

On November 8th Lipocine Inc. (NASDAQ: LPCN) filed its third quarter 2017 10-Q in conjunction with a press release highlighting recent achievements. The company reported a 3Q:17 net loss of ($4.7) million which equates to ($0.22) on a per share basis. This compares to our estimates of ($6.0) million and ($0.28) per share.

Third quarter 2017 R&D expenses were $2.0 million, increasing from the $1.5 million spent in 3Q:16 but they fell sequentially. Higher spend for all three product candidates contributed to the year over year increase while the wind down of the DV and DF studies explains the sequential drop. G&A expenses of $2.7 million were up both year over year and sequentially due to market research and pre-commercialization activities on behalf of Tlando. The recognition of severance benefits also contributed to the increase.

End of third quarter cash and equivalents and investment securities totaled $25.7 million down from $27.8 million in 2Q:17 and $26.8 million at the end of 2016. Cash burn for the third quarter was ($4.6) million offset by a net increase in cash from financing of $2.4 million due to the equity issuance under the controlled equity offering sales agreement with Cantor Fitzgerald.

Advisory Committee Required and USPTO Issues Motion for Tlando

On September 20, Lipocine announced that an Advisory Committee (AdCom) will be convened to review Tlando following the August submission of data in the Dosing Validation and the Dosing Flexibility studies which evaluated the efficacy and tolerability of Tlando. The Bone, Reproductive and Urologic Drugs Advisory Committee (BRUDAC) will review the submission. While the date of the AdCom has not yet been scheduled, it will conform to the PDUFA goal date of February 8, 2018. Lipocine expects to spend an additional $2.5 million of research and development costs for Tlando as of November 2017.

While there is additional cost and effort required to present before an AdCom, we believe that this is a positive as the FDA would not go through the effort and expense required to schedule one unless there was a degree of confidence Tlando has met the requirements for approval.

Patent Litigation

On September 21 Lipocine announced that the Patent Trial and Appeal Board (PTAB) issued a motions decision in the interference case between Lipocine and Clarus. The PTAB denied both parties' initial priority dates which had the result of switching senior party status from Lipocine to Clarus. Following the decision, Lipocine has an accorded priority date of May 15, 2015 and Clarus has a date of April 26, 2014. Despite the apparent shift in balance to Clarus, the important factor for Lipocine was that the original 2006 priority date for Clarus was discarded.

Prior to the PTAB motions decision, Clarus was using a patent filed in 2006 and Lipocine was using evidence from 2002 and 2003 to support their claim. The PTAB responded that there was no embodiment of all the elements asserted in the earlier dates that both Lipocine and Clarus were citing. As a result, the PTAB did not allow either of their earlier asserted priority dates.

Lipocine has patents issued in 2009 (8,865,695 and 8,778,922) which contain the specific formulation that is in dispute. Lipocine believes that the strength of these 2009 filed patents are sufficient to support their claim of priority and easily invalidate Clarus' 8,828,428 ('428) patent. Through either *ex parte* reexamination or *inter partes* review, which are the two primary administrative procedures available to challenge a patent, Lipocine expects to obtain a ruling in their favor based on the strength in their 2009 filings.

Patent Litigation Timeline

- May 15, 2015 Lipocine filed a request for interference using their owned patent application against Clarus' patent
- November 2, 2015, Clarus filed a complaint against Lipocine alleging that Tlando NDA filing will infringe upon the Clarus' patent
- December 4, 2015, PTAB declared interference between Clarus' patent and Lipocine's application
- January 5, 2016 Lipocine filed a motion to dismiss the complaint with the court
- October 6, 2016 the court dismissed the complaint as there was no actionable infringement since Tlando had not received FDA approval
- September 20, 2017 PTAB issued motions decision
- October 4, 2017 conference call with PTAB
    - Lipocine was the only party that filed a priority statement, therefore, only Lipocine will be able to put on a priority case as per the order
    - Lipocine's priority statement included a claimed date of invention prior to Clarus' earliest allowed priority date of April 2014

Highlighted Events Year to Date

- Entry into a Controlled Equity Offering agreement with Cantor Fitzgerald where up to $20 million in stock may be sold under an at-the-market offering.
- During the first nine months of 2017, 2.52 million shares were sold under the offering agreement raising net proceeds of $10.6 million.
- On October 13, 2017 Lipocine filed an updated Form S-3 to register the sale of an additional $150 million in securities.
- On April 24th Lipocine announced it had completed enrollment of the LPCN 1021 fixed dose trials.
- Topline results from DV and DF study were announced on June 19, 2017.
- Lipocine submitted its SPA for LPCN 1107 (Pre-term birth) to the FDA in June 2017.

Competition Update

On June 26, 2017, Clarus Therapeutics, Inc. announced that it had completed its Phase 3 clinical trial for Jatenzo, a twice-daily oral softgel capsule of testosterone undecanoate, and submitted an NDA to the FDA. However, no PDUFA date has been announced as of yet. If Jatenzo is approved by the FDA before LPCN 1021, Clarus may launch Jatenzo before LPCN 1021, providing a commercial advantage to this competitor.

On July 6, 2017, the Australian Acrux confirmed that a generic version of Axiron Topical Solution, 30 mg/1.5 mL (Testosterone Topical Solution, 30 mg/1.5 mL) has been launched in the United States by Perrigo. Acrux also confirmed the availability of an authorized generic version of Axiron in the United States, through an agreement between Eli Lilly and another generics company. We do not see this as materially impacting the competitive environment as there are a number of topical competitors in the market and LPCN 1021 as an oral solution is not competing directly with other methods of administration.

On October 20, 2017, the FDA issued a CRL for Antares Pharma's (ATRS) Xyosted, an injectable version of testosterone enanthate. Based on the press release provided by Antares, the FDA sought additional information regarding a clinically meaningful increase in blood pressure and raised concerns regarding the occurrence of depression and suicidality.

Update on LPCN 1107 (Pre-term Birth)

Lipocine submitted its special protocol assessment (SPA) to the FDA for LPCN 1107 in June and is continuing its interactions with the agency. Due to the small patient population size, the FDA has granted orphan status to LPCN 1107, which provides several benefits that will lower trial costs and duration.

During the end of Phase 2 meeting, the FDA agreed to a randomized, open-label, two-arm clinical study to include LPCN 1107 and intramuscular comparator with treatment for up to 23 weeks. The agency also had a favorable view on the proposed 800 mg, twice per day dosing for the trial. The FDA and Lipocine agreed on a surrogate endpoint of a rate of delivery less than 37 weeks rather than clinical outcomes for the infant and a non-inferiority

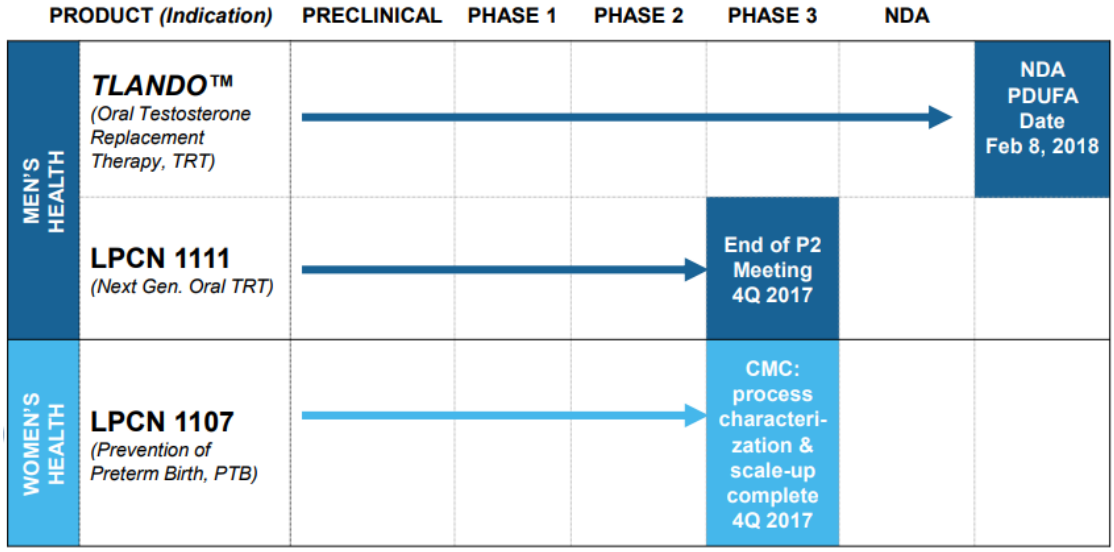
study margin of 7%, with interim analyses. Based on the proposed endpoints and 90% powering, a full study may require as many as 1,100 subjects per treatment arm, however, the ability to conduct interim analyses may enable the study to enroll fewer subjects. A food effect trial will also be required.

Lipocine will work with the FDA to determine the best trial design that meets the agency's needs and we expect the design of the Phase 3 trial to develop by the end of the year. Manufacturing (CMC) scale up work, agreement on the protocol with the FDA and additional funding are required before the Phase 3 for LPCN 1107 can begin.

Update on LPCN 1111 (Once-daily Oral Testosterone)

LPCN 1111 has completed the preclinical toxicity study, finding that the toxicological profile is closely aligned with general androgenic class pharmacology based on a preliminary evaluation.following a Phase 2a and 2b study that were completed in 2016. The FDA has scheduled a meeting in 1Q:18 to discuss Phase 3 trial design and potentially other pre-clinical or clinical trials that may be required.

Exhibit I – Lipocine Pipeline



Summary of Milestones

- Resubmission of Tlando NDA in August 2017
- Advisory Committee for Tlando January 10, 2018
- PDUFA date for Tlando February 8, 2018
- First sales of Tlando anticipated before 3Q:18
- LPCN 1111 preclinical toxicology study completed
- LPCN 1111 end of Phase 2 meeting with FDA 1Q:18
- Continued FDA interaction for developing Phase 3 protocol for LPCN 1107
- CMC process characterization and scale completed for LPCN 1107

Summary

LPCN has resubmitted its NDA for Tlando and has been assigned both a PDUFA and AdCom date. We are optimistic that Lipocine can successfully navigate both of these regulatory requirements and obtain FDA approval. Following the anticipated approval, Lipocine will develop the required sales force and find an appropriate partner to commercialize the primary care segment over the following 90 days. Based on this timeline, first sales are anticipated to take place near mid-year 2018. Lipocine will then be able to launch its first product and 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 50%, 15% and 10% respectively. Based on our estimates of sales, expenses, risk, and updates provided in company documents, our target price remains $9.00 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**	**$38.9**	**$136.2**
CoGS	$0	$0	$0	$0	$0	$0	$14	$48
Product Gross Margin							*65.0%*	*65.0%*
R&D	$8.1	$3.1	$4.1	$2.0	$4.0	$13.2	$22.0	$22.0
G&A	$10.4	$1.8	$2.0	$2.7	$2.5	$9.1	$19.0	$25.4
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)	($15.8)	$41.0
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)	($15.8)	$41.0
Taxes & Other	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$21.4	$7.2
Tax Rate	*0%*	*$0.0*	*0%*	*0%*	*0%*	*0%*	*136%*	*-18%*
Net Income	($19.0)	($4.9)	($6.1)	($4.7)	($6.5)	($22.4)	$5.7	$48.3
Reported EPS	**($1.04)**	**($0.26)**	**($0.31)**	**($0.22)**	**($0.30)**	**($1.11)**	**$0.25**	**$2.12**
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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