Zacks Small-Cap Research

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Lipocine Inc. (LPCN - NASDAQ)

Reports 2015 results with lower cash burn rate due to completion of Phase 3 trial for LPCN 1021; cash balance near 2x FY16 estimated expenses.

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	08/13/2014
Current Price (04/01/16)	$10.75
Target Price	**$19.00**

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 of them are for the treatment of male hypogonadism and the third for the prevention of pre-term birth.

The lead product, LPCN 1021, is a twice a day oral testosterone replacement therapy (TRT) which has a PDUFA date of June 28, 2016. If the FDA grants approval, we anticipate first sales of the product to commence in early 2017. LPCN's other TRT product, LPCN 1111, which provides a once daily regimen, is 2-3 years behind 1021 and is expected to eventually cannibalize the twice daily product. LPCN 1170 for pre-term birth has received an orphan designation and is currently in Phase 1 trials.

LPCN offers an attractive long-term investment opportunity at our price target of $19. We maintain our Buy rating and anticipate adjusting our valuation following the FDA's announcement on June 28 regarding LPCN 1021.

SUMMARY DATA

52-Week High	**$18.54**
52-Week Low	**$5.51**
One-Year Return (%)	**48.22**
Beta	**1.87**
Average Daily Volume (sh)	**120,742**
Shares Outstanding (mil)	**18**
Market Capitalization ($mil)	**$196**
Short Interest Ratio (days)	**11.25**
Institutional Ownership (%)	**49**
Insider Ownership (%)	**16**
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**

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)
2015	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2016	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2017					$61.7 E
2018					$194.5 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$0.23 A	-$0.26 A	-$0.35 A	-$0.25 E	-$1.11 E
2016	-$0.34 E	-$0.34 E	-$0.34 E	-$0.35 E	-$1.38 E
2017					-$0.02 E
2018					$3.19 E

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WHAT'S NEW

2015 Financial and Operational Results

On March 10, 2016, Lipocine Inc. (NASDAQ:LPCN) reported fiscal year 2015 results which include a loss of $18.2 million, or ($1.11) per share compared with a loss of $20.4 million in 2014. The company did not report any revenues.

Total research and development expenses were $12.6 million, a decline from the previous year's $15.5 million. Lower costs followed the conclusion of the Phase 3 clinical trial for LPCN 1021. Total R&D expense for LPCN 1021 was $8.3 million, including an NDA filing fee of $2.3 million. Expenses for LPCN 1111 and LPCN 1107 were both approximately $850,000. The balance of R&D costs were predominantly attributed to internal personnel expenses, which fell slightly from the prior year.

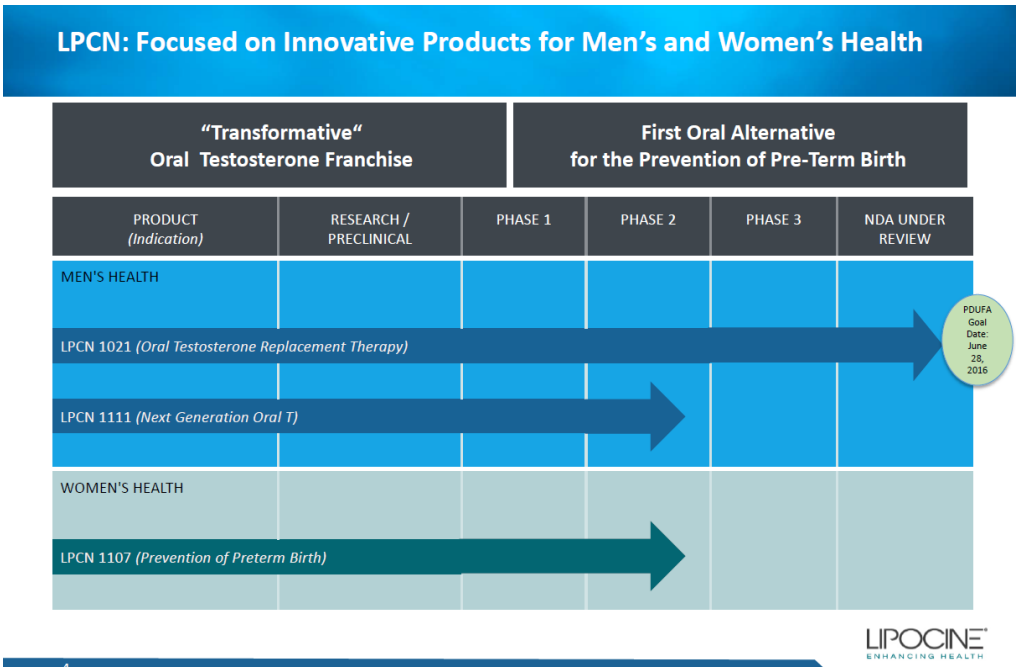
General and administrative expenditures of $5.8 million were higher than the prior year's $5.0 million. The $800,000 increase was due to higher personnel and market research costs as well as pre-commercialization activities on behalf of LPCN 1107.

Total cash and marketable securities increased to $44.8 million, compared to year end 2014 levels of $27.7 million. Cash levels rose due to the April 2015 stock offering which generated $32 million and was offset by $15 million of cash used in operating activities. Lipocine's balance sheet continues with no debt.

Manufacturing Agreement

Lipocine entered into a manufacturing agreement with M.W. Encap (Encap), a UK-based global contract manufacturing and development organization, to supply bulk commercial quantities of LPCN 1021 on March 3rd of this year. For the five years following FDA approval, LPCN is subject to a minimum purchase agreement. The agreement may be terminated prior to production beginning for a cancellation fee. Encap had previously provided the capsules which were used in Lipocine's Phase 3 study for LPCN 1021 and is now conducting an International Conference on Harmonization (ICH) Stability Study. This will examine how the compound will perform under the influence of variable temperature, humidity and light and to establish a shelf life for the product in support of Lipocine's NDA filing for this product.

Pipeline Update for LPCN 1021, 1107 & 1111[1]



[1] Lipocine corporate presentation as of March 10, 2016.

LPCN 1021 Status

On August 28, 2015, Lipocine Inc. submitted a 505(b)(2) New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for Lipocine's lead asset LPCN 1021. LPCN 1021 is a testosterone replacement therapy (TRT) designed for oral twice daily dosing in adult hypogonadal males with low testosterone. The FDA accepted the NDA on October 29, 2015, and subsequently on November 12, 2015, Lipocine announced that the FDA assigned a Prescription Drug User Fee Act (PDUFA) goal date of June 28, 2016 for completion of the review of the NDA, as we had expected according to the standard 10-month review period.

The FDA is not requiring an Advisory Committee prior to the PDUFA date. We view this as good news, and believe this means that the FDA does not need any independent expert advice regarding the LPCN 1021 data that Lipocine has submitted. We assume that the FDA did not identify any significant issues in its initial review to warrant an AdComm. We think there is always a small chance that the FDA could come back and ask for an AdComm, however we find this unlikely to occur at this point. Not having an AdComm will save Lipocine significant time and costs associated with hiring outside consultation for this activity. We believe that instead of preparing for an AdComm, Lipocine can instead focus on moving its pipeline forward and can continue to prepare for a potential commercial launch for LPCN 1021. We view all of this as good news for Lipocine, and continue to believe that LPCN 1021 is on track to receive approval.

Our previous updates discuss LPCN 1021 data from the Phase 3 SOAR trial, the food effect study, and 52-week safety extension arm study in depth. We continue to believe the oral formulation of LPCN 1021, if approved, may improve patient compliance as it appears to be a generally safe, effective, and a more convenient TRT option as compared to topical and injectable TRT products that are currently on the market. LPCN 1021 will have to adhere to all of the new regulations set forth by the FDA if approved. For instance, cautionary language will be required on the label for possible cardiovascular and stroke related risk with TRT, and the lack of benefit and safety of TRT in age-related hypogonadism. Additionally, if LPCN 1021 is approved, we are not sure what the post-approval obligations will be regarding a heart attack and stroke risk study. Lipocine may be have to contribute to an on-going industry-led heart attack and stroke risk study, or it may need to conduct a separate long-term study.

LPCN 1111 Status

On January 4, 2016, Lipocine announced that the first patient has been dosed in its Phase 2b clinical study for LPCN 1111, a once daily oral testosterone replacement therapy (TRT) product candidate. The primary objectives of the study will be to determine the optimal dose of LPCN 1111 along with the safety and tolerability of LPCN 1111 and its metabolites following oral administration of single and multiple doses of LPCN 1111 in hypogonadal males.

As a reminder, LPCN 1111 is the next-generation oral TRT version of LPCN 1021 that has the potential for once daily dosing through use of the company's proprietary Lip'ral solubilization technology that improves systemic absorption to give effective testosterone levels upon daily dosing. We expect to see top-line data from the Phase 2b study at some point during the second quarter of 2016.

With positive Phase 2a data of LPCN 1111 in place, and the Phase 2b trial now initiated, we believe an end-of-Phase 2 meeting with the FDA should occur at some point during the second half of 2016. As per management guidance, LPCN 1111 is 24 to 36 months behind LPCN 1021. In our opinion, this candidate provides compelling solutions for the weaknesses of currently approved TRT therapies in terms of convenience and compliance. If the Phase 3 data are positive, and trial milestones progress according to the timeline, we could see potential approval as early as 2018.

LPCN 1107 Status

On February 16, 2016, the company reported top-line results of its multi-dose pharmacokinetic dose finding clinical study of LPCN 1107, its oral hydroxyprogesterone caproate (HPC) candidate for the prevention of preterm birth in pregnant women. LPCN 1107 was granted orphan drug designation by the U.S. Food and Drug Administration (FDA) in June 2015, and has also been evaluated in two Phase 1 proof-of-concept studies in both pregnant and non-pregnant women.

On September 28, 2015, Lipocine announced initiation of its Phase 2 multi-dose PK dose finding clinical study with the first subject dosed with LPCN 1107. The primary objective of the study was to study pharmacokinetics over an extended period of time in pregnant women at multiple dose strengths of oral administration of LPCN 1107. The clinical study was an open-label, four-period, four-treatment, randomized, single and multiple dose, PK study in

pregnant women of three dose levels of LPCN 1107 and injectable HPC (Makena®). The study enrolled 12 healthy pregnant women (average age of 27 years) with a gestational age of approximately 16 to 19 weeks. Subjects received three dose levels of LPCN 1107 (400 mg twice-daily, 600 mg twice-daily, or 800 mg twice-daily) in a randomized, crossover manner during the first three treatment periods and then received five weekly injections of HPC during the fourth treatment period. During each of the LPCN 1107 treatment periods, subjects received a single dose of LPCN 1107 on Day 1 followed by twice daily administration from Day 2 to Day 8. Following completion of the three LPCN 1107 treatment periods and a washout period, all subjects received five weekly injections of HPC.

LPCN 1107 Receives Orphan Drug Designation

On June 2, 2015, Lipocine announced that the FDA granted orphan drug designation to LPCN 1107. In order to obtain orphan drug exclusivity upon approval, LPCN 1107 will need to demonstrate clinical superiority to the same drug already approved for the same orphan indication. This can be achieved, for instance, by demonstrating clinical superiority through establishing that the product offers a "major contribution to patient care."

Our Estimates

Our forecasts anticipate first revenues for LPCN 1021 when it is launched in 2017. We estimate that Lipocine will be able to attract 1% of the TRT market in the first full year of launch and generate revenues of approximately $62 million. Penetration is anticipated to increase to 3% in 2018 resulting in total sales of $194 million. Expenses will ramp up markedly in 2016. Assuming that LPCN 1021 is approved in 2016, we believe operating expenses will continue to rise as the company hires an adequate sized sales force to promote the drug, maintains, expands, and protects its IP portfolio, and undertakes other activities to prepare for the commercialization launch. Currently, management anticipates developing a 50-person sales force to focus on endocrinology and urology specialists. The company is also contemplating working with a partner to focus on the primary care physician segment. We forecast total expenses increasing to $25.5 million in 2016 (up from $18.4 million in 2015), and to $37 million in 2017. Refer to our model at the end of the report for additional detail.

Conclusion

We maintain a favorable view on Lipocine Inc. as an investment in the specialty pharmaceutical sector, and we believe the current share price presents investors with material upside. The company is currently developing three product candidates (LPCN 1021, LPCN 1111, and LPCN 1107) that utilize the patented Lip'ral oral drug delivery system. Lip'ral is designed to enhance the pharmacokinetic parameters of the drugs, facilitate lower dosing requirements, reduce side effects, and limit gastrointestinal interactions that would otherwise decrease effectiveness.

Below, we highlight the company's expected timing and key events as of March 10, 2016:

Event	Expected Timing
LPCN 1107: Request End of Phase 2 Meeting	2Q16
LPCN 1111: Top-line Results from Phase 2b Study	2Q16
LPCN 1021: FDA PDUFA Date	June 28, 2016
LPCN 1111: End of Phase 2 Meeting	2H16
LPCN 1021: File NDS in Canada	2H16

Source: Lipocine Inc.

Lipocine has made considerable progress with LPCN 1021. With the NDA accepted and PDUFA date assigned for June 28, 2016, we see LPCN 1021 as on track for mid-2016 approval. We model peak U.S. sales in the mid $300 million range, with this limitation due to anticipated cannibalization from the launch of the once-per-day solution, LPCN 1111. Additionally, we believe that Lipocine could file a New Drug Submission (NDS) in Canada during the second half of 2016. Although we do not currently factor Canadian sales of LPCN 1021 into our model, investors should know that this could offer additional upside to the story. We also believe that LPCN 1021 is much further ahead of any of its competitors, especially with news surrounding Repros Therapeutics Inc. (NASDAQ: RPRX)

receiving a Complete Response Letter (CRL) from the FDA for its NDA for enclomiphene citrate (formerly known as Androxal) for the treatment of secondary hypogonadism in overweight men wishing to restore normal testicular function.

Another potential competitor in the space, Apricus Biosciences, Inc. (NASDAQ: APRI), announced on March 28 that its Phase 2b study for secondary hypogonadism using the oral capsule Fispemifene failed to achieve either its primary or secondary endpoint. Apricus elected to discontinue development of Fispemifene and will pursue other products in its pipeline. This removes another potential competitor and places a cloud over the selective estrogen receptor modulator (SERM) class of testosterone therapy. The SERM class blocks the suppressive effect of estrogens upon lutenizing hormone production in the pituitary gland and in turn stimulates testosterone production. However, total testosterone levels have been insufficient to achieve desired endpoints and other research has shown that production of sex hormone binding globulin (SHBG) may render the testosterone circulating in the system inactive. This is due to the selective nature of SERM as both an agonist and antagonist of estrogen in the liver and the brain respectively. Where estrogen is produced it promotes the production of SHBG. While adverse events in Apricus' study were mild or moderate and no new or significant safety issues arose, the primary and secondary endpoints of erectile function and low libido, respectively, were not met with statistical significance. We believe that the SERM class of drugs will not be a threat to Lipocine's TRT franchise.

Topical products that are associated with poor patient compliance dominate the current testosterone market. We view patient compliance as one of several of serious issues with testosterone replacement products. This issue is not limited to just testosterone products as numerous studies have shown that once-daily dosing regimens have the highest rates of patient adherence (Claxton *et al*., 2001). Thus, the strategy with LPCN 1111 is to formulate a once daily oral dose of testosterone through a proprietary formulation coupled with the Lip'ral technology. An oral dosage testosterone would differentiate itself from gels, patches, and injections due to the convenience, discreteness, and lack of transference. We remind investors that the second-generation version of the drug, LPCN 1111, currently being evaluated in a dose-finding Phase 2b trial, could expand the potential peak U.S. sales to over $600 million. We believe that LPCN 1111 is approximately two to three years behind LPCN 1021 in development.

We believe that the positive top-line results from the Phase 2b study of LPCN 1107 for the prevention of preterm birth in pregnant women, and the candidate receiving U.S. orphan drug designation are significant positives for the company. Orphan designation not only protects the intellectual property of the drug, but also allows for aggressive pricing and reduced development and regulatory costs. We model peak U.S. sales of LPCN 1107 of approximately $275 million.

We would also like to point out that Lipocine adopted a poison pill on November 16, 2015. The plan was not adopted in response to any current takeover attempt, but is intended to ensure that if there is ever a party interested in acquiring Lipocine, that it will work through the board of directors as opposed to a hostile takeover.

Our NPV analysis on the three product candidates pegs fair value at almost $400 million. We continue to believe that the stock represents an attractive long-term investment opportunity at current levels. Our price target is $19, and we continue to rate the stock a Buy. We maintain a positive view on Lipocine shares as an investment in the specialty pharmaceutical sector based on the company's promising pipeline and Lip'ral technology.

PROJECTED FINANCIALS

Lipocine Inc. - Income Statement

Lipocine Incorporated	2015 A	Q1 E	Q2 E	Q3 E	Q4 E	2016 E	2017 E	2018 E
LPCN1021	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$61.7**	**$194.5**
YOY Growth	-	-	-	-	-	-	-	-
LPCN1111	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth								
LPCN1107	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth								
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$61.7**	**$194.5**
CoGS	$0	$0	$0	$0	$0	$0	$25	$68
Product Gross Margin						-	*60.0%*	*65.0%*
R&D	$12.6	$4.3	$4.4	$4.5	$4.7	$17.9	$20.0	$22.0
SG&A	$5.8	$2.0	$2.0	$2.0	$2.0	$7.5	$17.3	$34.2
Other expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.1	$0.1	$0.1
Operating Income	($18.4)	($6.3)	($6.4)	($6.5)	($6.7)	($25.5)	($0.4)	$70.1
Operating Margin	-					-	-	-
Total Other Income	$0.2	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($18.2)	($6.3)	($6.4)	($6.5)	($6.7)	($25.5)	($0.4)	$70.2
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%*
Net Income	($18.2)	($6.3)	($6.4)	($6.5)	($6.7)	($25.5)	($0.4)	$70.1
Reported EPS	**($1.11)**	**($0.34)**	**($0.34)**	**($0.34)**	**($0.35)**	**($1.38)**	**($0.02)**	**$3.19**
YOY Growth						-	-	-
Shares Outstanding	16.5	18.4	18.7	19.0	19.2	18.8	21.0	22.0

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

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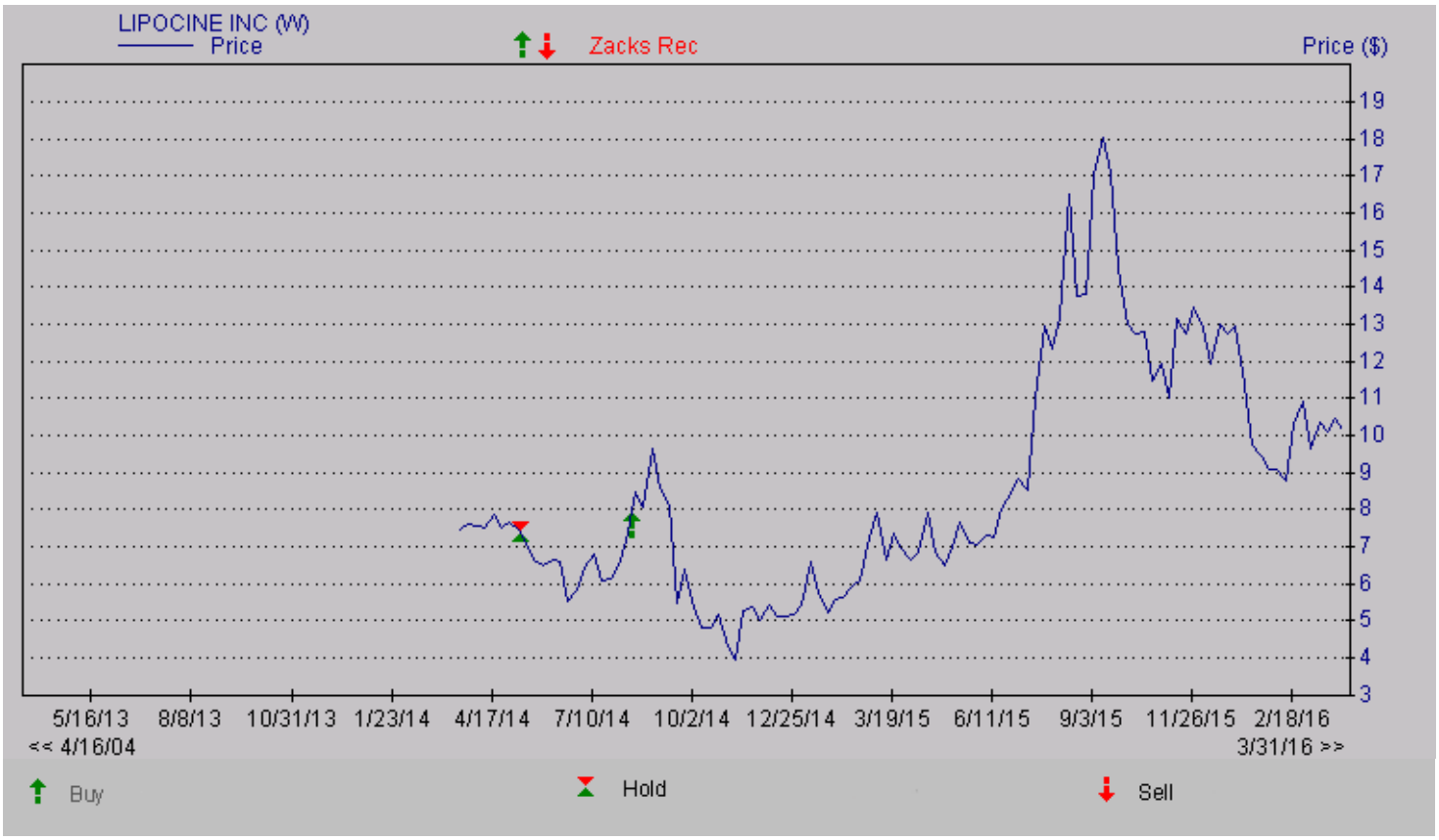

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