Zacks Small-Cap Research

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Lipocine Inc. (LPCN - NASDAQ)

LPCN: Remains on Track for Mid-2016 LPCN 1021 Approval…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	09/24/2014
Current Price (11/17/15)	$14.03
Target Price	**$20.00**

UPDATE

On November 12, 2015, Lipocine, Inc. (NASDAQ:LPCN) reported financial results for the third quarter 2015. The company reported no revenues as expected, and had a net loss of $6.4 million, or $0.35 per share.

On October 29, 2015, the FDA accepted the NDA for lead product candidate, LPCN 1021, which is a testosterone replacement therapy (TRT) designed for oral twice daily dosing in adult hypogonadal males with low testosterone. The PDUFA action date has been set for June 28, 2016, and the FDA is not requiring an Advisory Committee to take place prior to that date.

We continue to believe that the stock represents an attractive long-term investment opportunity, and are maintaining our price target of $20, and continue to rate the stock a 'Buy'.

SUMMARY DATA

52-Week High	**$18.54**
52-Week Low	**$4.87**
One-Year Return (%)	**167.78**
Beta	**1.17**
Average Daily Volume (sh)	**311,348**
Shares Outstanding (mil)	**18**
Market Capitalization ($mil)	**$262**
Short Interest Ratio (days)	**2.86**
Institutional Ownership (%)	**53**
Insider Ownership (%)	**15**
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 2015 Estimate	**N/A**
P/E using 2016 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)
2014	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2015	$0.0 A	$0.0 A	$0.0 A	$0.0 E	$0.0 E
2016					$0.0 E
2017					$74.8 E

Earnings per Share

(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$0.41 A	-$0.55 A	-$0.32 A	-$0.32 A	-$1.60 A
2015	-$0.23 A	-$0.26 A	-$0.35 A	-$0.44 E	-$1.32 E
2016					-$1.28 E
2017					$0.23 E

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WHAT'S NEW

We continue to believe Lipocine, Inc. (NASDAQ:LPCN) represents an attractive long-term investment opportunity, and will proceed to focus on third quarter 2015 financial and business highlights below. We believe LPCN 1021, the company's twice-daily oral testosterone replacement therapy candidate, has significant potential for commercial success and is on track for mid-2016 FDA approval.

Financial & Business Review

On November 12, 2015, Lipocine reported financial results for the third quarter ended September 30, 2015. As expected, the company did not report any revenues in the quarter. Net loss was $6.4 million, or $0.35 per share, for the third quarter 2015, as compared to a net loss of $4.1 million, or $0.32 per share, for the third quarter 2014.

Research and development expenses were $4.7 million for the third quarter 2015, compared with $3.2 million for the third quarter 2014. The increase was largely attributable to a one-time payment of $2.3 million to the FDA for the LPCN 1021 NDA filing, partially offset by decreased clinical research, consultant and manufacturing costs as Phase 3 study for LPCN 1021 was completed. General and administrative expenses were $1.7 million for the third quarter 2015, compared to $0.87 million for the same period in 2014. The increase was primarily due to increased personnel costs and costs related to market research and pre-commercialization activities. R&D expenses were less than our expectations, and G&A expenses were slightly above our expectations for the quarter.

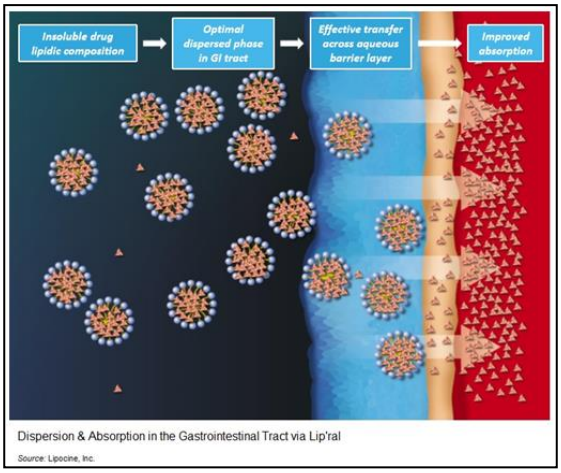
Operating burn for the third quarter 2015 was approximately $5.6 million. As of September 30, 2015, Lipocine had cash, cash equivalents, and marketable investment securities of $47.8 million, compared with cash and cash equivalents of $27.7 million as of December 31, 2014. As a reminder, this includes net proceeds (after fees) of $32.5 million from the public offering of 5.3 million shares of its common stock at $6.50 per share that Lipocine completed in April 2015.

We continue to believe the current cash balance is sufficient to fund operations past the PDUFA date for LPCN 1021, and into the third quarter 2016. We believe that the April 2015 completion of the public offering is allowing Lipocine to step up increased development efforts of LPCN 1111 and LPCN 1107, in addition to focusing on the on-going pre-commercial LPCN 1021 activities. Assuming that LPCN 1021 is approved in 2016, we believe operating expenses will continue to rise in anticipation of the company hiring an adequate sized sales force to promote the drug, in addition to expenses related to maintaining, expanding, and protecting its IP portfolio, and other activities to prepare for the commercialization launch.

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.

A Brief Overview of Lipocine Inc.

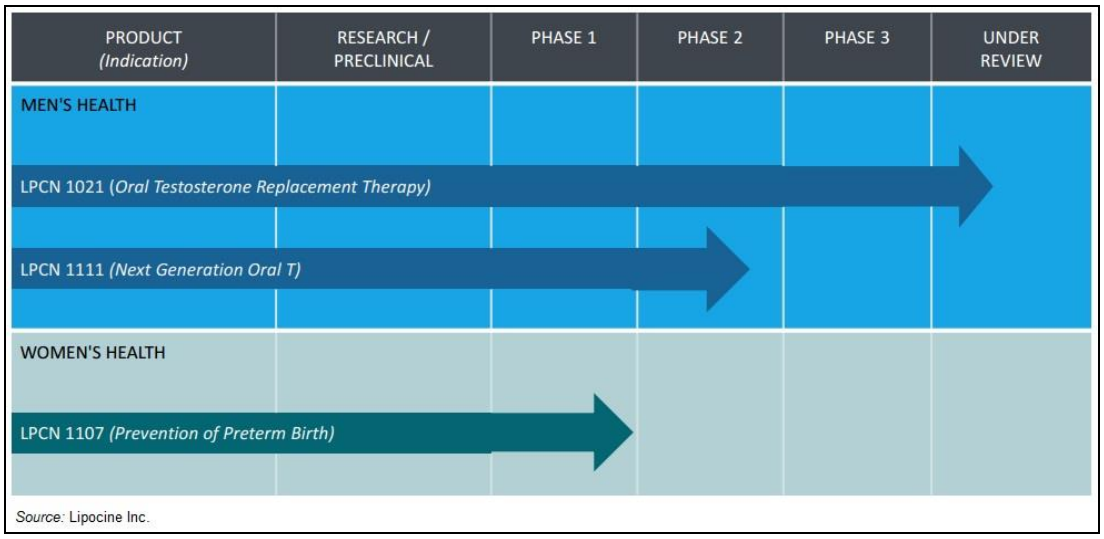
Lipocine is a specialty pharmaceutical company that has an oral drug delivery technology system, Lip'ral™, for products that affect the health of men and women. The Lip'ral™ promicellar technology is a patented platform based on lipid compositions which form an optimal dispersed phase in the gastrointestinal environment for improved absorption of insoluble drugs (*right*). The company is currently developing three product candidates in conjunction with this system (LPCN 1021, LPCN 1111, and LPCN 1107) that are designed to enhance the pharmacokinetic parameters of the drugs, facilitate lower dosing requirements, reduce side effects, and limit gastrointestinal interactions that would otherwise decrease the effectiveness of the compounds.



Dispersion & Absorption in the Gastrointestinal Tract via Lip'ral

Source: Lipocine, Inc.

Pipeline Update

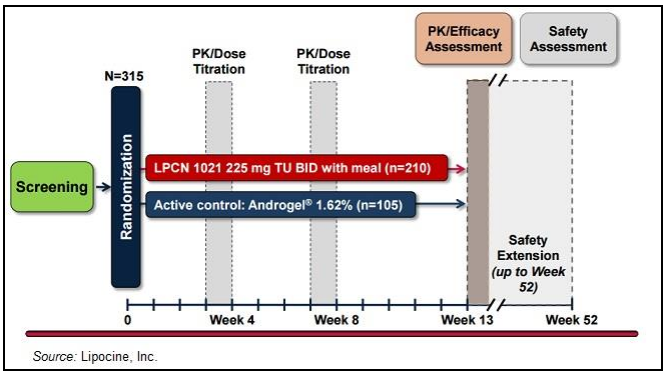


➢ LPCN 1021

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.

What we find most interesting is that the FDA is not requiring an Advisory Committee prior to the PDUFA date. We view this as good news, and in our opinion, we believe this means that the FDA does not need any independent expert advise 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.

As a reminder, results from the Phase 3 Study of Oral Androgen Replacement ("SOAR") trial was part of the NDA submission. SOAR was a randomized, parallel-group, active-controlled, open-label Phase 3 clinical study of oral testosterone replacement therapy (TRT) in hypogonadal males with low testosterone as indicated by a level of < 300 ng/dL. In total, 315 subjects at 40 different sites were randomized for a total of 52 weeks of treatment with 210 subjects randomized to receive LPCN 1021, while the remaining 105 subjects were randomized to receive the active control, Androgel®.



The study met its primary efficacy endpoint by successfully restoring testosterone levels to the normal range in 88% of the subjects. Additionally, 85% of the subjects reached their final dose with no more than one dose titration. LPCN 1021 treatment was well-tolerated with no hepatic, cardiac, gastrointestinal, or drug related serious adverse events. 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 1021 Competitive Landscape Update

There has been increased interest in developing oral testosterone replacement therapies (TRT) as well as testosterone therapies that are not considered testosterone replacement. We have discussed the competitive landscape for LPCN 1021 in previous updates, and would like to offer a quick update on both Repros Therapeutics Inc. ® (NASDAQ: RPRX) and Clarus Therapeutics, Inc. With Lipocine's NDA accepted and PDUFA date set, we believe that LPCN 1021 is much further ahead of any other product, and is on track to becoming the first oral TRT on the market.

Repros Therapeutics Inc. (enclomiphene citrate, formerly Androxal®)

Repros Therapeutics Inc.® is a development stage pharmaceutical company that develops drugs to treat reproductive system and hormonal disorders. The company currently has two pipeline candidates, one for male secondary hypogonadism (enclomiphene), and another for uterine fibroids and endometriosis (Proellex®).

Repros is developing enclomiphene (formerly known as Androxal®), an orally active, single isomer of clomiphene citrate that has been shown to be effective in treating secondary hypogonadism in overweight men of reproductive age with low testosterone wanting to restore normal testicular function. It is a small molecule compound that works by inhibiting the effects of estrogen on the pituitary gland thus stimulating the release of hormones that induce testosterone production. Unlike testosterone administration, it does not adversely affect the testes or fertility.

In our last update, with recent investor chatter surrounding Repros seeking U.S. approval for enclomiphene citrate (formerly known as Androxal®), we reiterated the differences between LPCN 1021 and enclomiphene citrate. Enclomiphene and LPCN 1021 have different mechanisms of action and different regulatory approval processes.

Since our last update, Repros suffered a huge setback following the announcement that the FDA had cancelled the Advisory Committee meeting for the company's enclomiphene product candidate just days before the panel was set to convene. The FDA's Bone, Reproductive and Urologic Products Advisory Committee was originally scheduled to meet on November 3, 2015 to review Repros' NDA for enclomiphene citrate for the treatment of overweight men with low testosterone due to secondary hypogonadism wishing to restore normal testicular function, with a PDUFA date of November 30, 2015. However, on October 29, 2015, Repros announced the cancellation of the FDA Adcom because of questions surrounding bioanalytical method validation that could have potentially affected how certain study data were interpreted. We are unclear about the path forward for the drug, but we think it will take a least one year for the FDA and Repros to redefine the intended target patient population and clearly define the disorder the drug is trying to treat. It has been a long road for Repros since it began developing the drug in 2002. We are thinking that the FDA will require a new trial design, but we will just have to wait and see. Since enclomiphene is not a TRT, we continue to believe that negative sentiments surrounding the drug should not affect Lipocine and should not impact LPCN 1021's approval or the fundamental valuation of Lipocine.

Clarus Therapeutics, Inc. (Rextoro®)

Clarus Therapeutics is developing Rextoro®, an oral formulation of testosterone undecanoate (TU). Rextoro® is formulated to aid absorption of TU via the intestinal lymphatic pathway. Lipocine's LPCN 1021 is TU formulated with the proprietary Lip'ral™ technology to aid in absorption, since TU has poor bioavailability.

The only recent news we have heard from Clarus was on November 2, 2015, fourteen months after the negative AdComm news, when the company filed a lawsuit against Lipocine for what Clarus claims to be an infringement of a Clarus patent (U.S. Patent 8,828,428) entitled "Pharmaceutical Delivery Systems for Hydrophobic Drugs and Compositions Comprising Same." This lawsuit states that the patent covers LPCN 1021, and Clarus is seeking injunction to prevent commercialization and sale of LPCN 1021. The Clarus press release regarding the lawsuit came out shortly after Lipocine announced that the NDA for LPCN 1021 had been accepted.

Lipocine filed a patent application with the U.S. Patent and Trademark Office (PTO) in May 2015, requesting that the PTO declare interference between its patent application and Clarus Therapeutics' patent mentioned above. Lipocine's request asks the PTO to determine that its patent application has priority over the Clarus '428 patent, the result of which would render the claims of the Clarus '428 patent invalid. The process is underway through the patent office. We believe that Lipocine intends to vigorously defend against these allegations. We will have to wait and see what happens with this lawsuit.

As a reminder, Clarus Therapeutics filed a new drug application (NDA) for Rextoro® on January 3, 2014. On September 18, 2014 there was a Joint Meeting of the Bone, Reproductive and Urologic Drugs Advisory Committee (BRUDAC) and the Drug Safety and Risk Management Advisory Committee (DSRM) to discuss the NDA for Rextoro® (see FDA Briefing Documents). The outcome of the FDA AdComm meeting was decidedly negative for Clarus, with the committee not ready to recommend approval of Rextoro® at the current time. Twelve of 21 committee members voted that there was insufficient evidence to conclude that TU was an effective TRT. Eighteen of 21 members voted that that the overall risk/benefit profile did not support approval of TU for TRT. Those members who voted against supporting approval did so based on the pivotal trial being small, food effects associated with Rextoro® dosing, a high number of dropouts in the pivotal study, missed secondary endpoints, and a lack of robust efficacy. The FDA originally assigned a PDUFA goal date of November 3, 2014; however, we have not heard of any recent updates on the process or the product. Since Clarus is a private company, we did not anticipate release of the complete response letter or a public comment ahead of the next steps. We are still waiting to hear how the company will proceed with Rextoro®.

We believe the negative views of Rextoro® were not due to the fact it was an oral formulation of TU but rather due to the data itself. We see Clarus issues as specific to Clarus, and do not believe they negatively impact Lipocine whatsoever. As the committee stated during the review of Rextoro®: "…it would be of great value to (hypogonadal) patients to have an oral treatment option…" We happen to agree with that opinion. We do not know how Clarus will get funding for Rextoro®, and at this point, we don't know if this drug will ever make it to the market. This further solidifies our belief that that the oral TRT market is Lipocine's to own with major competitor Clarus Therapeutics and Rextoro® having faced many issues. With Lipocine's NDA accepted, and our belief that Clarus will be required to perform additional clinical trials, we believe that LPCN 1021 is much further ahead of Rextoro® in becoming the first oral TRT on the market.

- **LPCN 1107**

Lipocine is developing LPCN 1107 as the first oral hydroxyprogesterone caproate (HPC) for the potential treatment of prevention of preterm birth (PTB) by formulating HPC with the Lip'ral™ technology. An oral formulation of HPC would offer a number of advantages over the current injectable formulation of the drug, including elimination of pain and reaction at the injection site as well as eliminating weekly trips to the doctor's office for administration of the compound. In approximately 12% of pregnancies, babies are born prior to 37 weeks gestation, which is the definition of preterm birth. Preterm birth is associated with a wide range of problems, including breathing issues, feeding difficulties, cerebral palsy, developmental delay, vision problems, and hearing impairment. In addition, preterm birth remains the leading cause of infant mortality, accounting for as many as 75% of perinatal deaths (Ananth *et al*., 2006).

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 will be to study pharmacokinetics over an extended period of time in pregnant women at multiple dose strengths of oral administration of LPCN 1107. With two Phase 1 proof-of-concept studies in both pregnant and non-pregnant women completed, we believed that this dose selection Phase 2 study would commence in the fourth quarter 2015 or first quarter 2016, so we are happy to report that the first patient has been dosed earlier than we expected during the third quarter 2015. We believe that top-line results will be reported during the first quarter 2016. Once this study is completed, Lipocine plans to schedule an End-of-Phase 2 meeting with the FDA regarding the Phase 3 development plan. We think this meeting will occur at some point during the second quarter 2016. If all goes well, we believe that LPCN 1107 will be Phase 3 ready by mid-late 2016. We continue to believe that the area of preterm birth, even in countries as developed as the

United States, is an area of unmet need, and at this point, we see a path forward for LPCN 1107 and look forward to watching the LPCN 1107 story unfold.

As a reminder, LPCN 1107 received orphan drug designation in June 2015 by the FDA and has the potential to become the first oral HPC product for the prevention of pre-term birth in women with a prior history of at least one pre-term birth. In order to obtain orphan drug exclusivity upon approval, we would like to mention that 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."

- **LPCN 1111**

LPCN 1111, is the next-generation oral TRT version of LPCN 1021, that has the potential for once daily dosing through the Lip'ral™ technology. With positive Phase 2a data in place, a Phase 2b trial is expected to begin in the fourth quarter of 2015, and an End-of-Phase 2 meeting with the FDA should occur at some point during the second quarter 2016. We believe that it should be Phase 3 ready by mid-2016. As per management guidance, LPCN 1111 is about 24 months behind LPCN 1021. We look forward to seeing the study commence in the near future. In our view, based on Phase 2a data, this drug looks like a potential game-changer for TRT.

Conclusion & Recommendation

With the NDA accepted and PDUFA date assigned, we see LPCN 1021 as having significant potential, and on track for mid-2016 approval. We believe that LPCN 1021 is much further ahead of its competitors, and we remain bullish on Lipocine shares as an investment in the specialty pharmaceutical sector because we think the company has a promising pipeline. We would like to bring attention to several near term value drivers, which are outlined below:

Event	Expected Timing
LPCN 1021: Anticipated NDA 74 day letter	November 2015
LPCN 1111: Initiate Phase 2b Study	4Q15
LPCN 1107: Top-line Results for Multi-Dose PK Study	1Q16
LPCN 1107: End of Phase 2 Meeting	2Q16
LPCN 1111: End of Phase 2 Meeting	2Q16
LPCN 1021: Expected FDA PDUFA Date	June 28, 2016

Source: Lipocine Inc.

If all goes well, we are expecting LPCN 1021 will see U.S. approval around the middle of 2016, and model peak U.S. sales in the $400 million range. We remind investors that there is a second-generation version of the drug, LPCN 1111, currently in Phase 2 trials that could expand the potential peak U.S. sales to over $600 million. We believe that LPCN 1111 is roughly 24 months behind LPCN 1021 in development. Additionally, it is important to point out that LPCN 1111 is intended to be a once daily dosing product, as compared to the twice-daily dosing profile of LPCN 1021.

We believe the news that LPCN 1107 has received U.S. orphan drug designation and that the first patient has been dosed in the dose selection Phase 2 study ahead of schedule 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.

Our NPV analysis on the three product candidates pegs fair value at over $400 million. We continue to believe that the stock represents an attractive long-term investment opportunity, and are maintaining our price target of $20, and continue to rate the stock a 'Buy'.

PROJECTED FINANCIALS

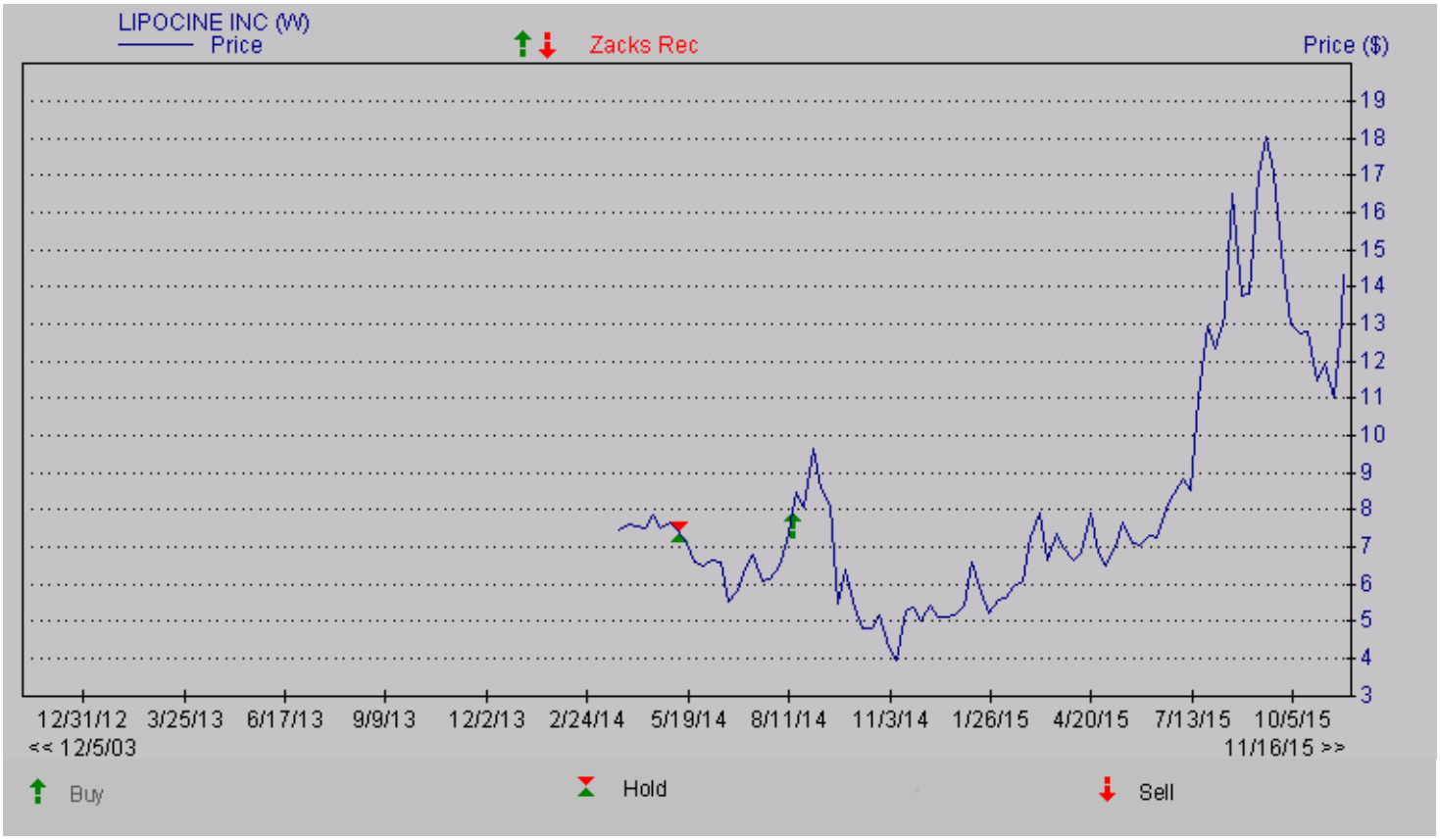
Lipocine Inc. - Income Statement

Lipocine Incorporated	2014 A	Q1 A	Q2 A	Q3 A	Q4 E	2015 E	2016 E	2017 E
LPCN 1021	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$74.8**
YOY Growth	-	-	-	-	-	-	-	-
LPCN 1111	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth								
LPCN 1107	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth								
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$74.8**
CoGS	$0	$0	$0	$0	$0	$0	$0	$30
Product Gross Margin	-						-	*60.0%*
R&D	$15.5	$1.9	$3.2	$4.7	$6.0	$15.8	$18.0	$20.0
SG&A	$5.0	$1.1	$1.1	$1.7	$2.0	$5.9	$7.5	$20.0
Other expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.1	$0.1	$0.1
Operating Income	($20.5)	($3.0)	($4.3)	($6.4)	($8.0)	($21.8)	($25.6)	$4.8
Operating Margin	-					-	-	-
Total Other Income	$0.1	$0.0	$0.0	$0.1	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($20.4)	($3.0)	($4.2)	($6.4)	($8.0)	($21.8)	($25.6)	$4.8
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	($20.4)	($3.0)	($4.2)	($6.4)	($8.0)	($21.8)	($25.6)	$4.8
Reported EPS	**($1.60)**	**($0.23)**	**($0.26)**	**($0.35)**	**($0.44)**	**($1.32)**	**($1.28)**	**$0.23**
YOY Growth	-						-	-
Shares Outstanding	12.8	12.8	16.5	18.2	18.3	16.5	20.0	21.0

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

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Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters.
Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

The current distribution is as follows: Buy/Outperform- 25.5%, Hold/Neutral- 55.2%, Sell/Underperform – 15.5%. Data is as of midnight on the business day immediately prior to this publication.