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10 S. Riverside Plaza, Chicago, IL 60606

Lipocine Inc. (LPCN-NASDAQ)

Cirrhosis IND Cleared

Based on our DCF model and a 20% discount rate, LPCN is valued at approximately $3.00 per share. We include a valuation component for both recently resubmitted TLANDO and Phase II asset LPCN 1144. Despite a cleared investigational new drug application (IND). No valuation is attached to LPCN 1148 until it has entered the clinic.

Current Price (5/11/20)	$0.71
Valuation	**$3.00**

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 pharmacokinetic profile facilitates lower dosing, reduces side effects and eliminates gastrointestinal interactions that limit absorption. Currently, the company has five drugs in development that employ this technology; two are for the treatment of male hypogonadism; one is for the prevention of pre-term birth and the last two candidates target NASH and cirrhosis.

The lead product, Tlando, was resubmitted in an NDA in March 2020 after incorporating the FDA requested reanalysis of existing data. The FDA subsequently granted a PDUFA date of August 28, 2020. While it appears that Lipocine has sufficiently answered the agency's questions to support approval, we are cautious given the hurdles the FDA has raised in the past. LPCN's other products, Tlando XR and LPCN 1107 are on hold. LPCN 1144 is in development for pre-cirrhotic NASH and is enrolling a Phase II study. LPCN 1148's IND was cleared in March 2020 and will launch a Phase II after additional funding is obtained.

SUMMARY DATA

52-Week High	**$3.45**
52-Week Low	**$0.30**
One-Year Return (%)	**-60.6**
Beta	**-0.08**
Average Daily Volume (sh)	**1,287,262**
Shares Outstanding (mil)	**47.9**
Market Capitalization ($mil)	**$32.1**
Short Interest Ratio (days)	**4.6**
Institutional Ownership (%)	**17.8**
Insider Ownership (%)	**3.7**
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 2019 Estimate	**N/A**
P/E using 2020 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 $US)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	$0.0 A	$0.0 A	$0.2 A	$0.0 A	$0.2 A
2020	$0.0 A	$0.0 E	$0.0 E	$0.0 E	$0.0 E
2021					$111.3 E
2022					$148.8 E

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	-$0.14 A	-$0.14 A	-$0.12 A	-$0.11 A	-$0.50 A
2020	-$0.14 A	-$0.06 E	-$0.06 E	-$0.06 E	-$0.31 E
2021					$1.75 E
2022					$2.34 E

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WHAT'S NEW

First Quarter 2020 Operational and Financial Results

On May 7, 2020 Lipocine (NASDAQ: LPCN) filed its first quarter 2020 10-Q and posted its earnings release for the three month period ending March 31, 2020. The company reported zero revenues and a net loss per share of ($0.14) compared to prior year revenues of zero and loss of ($0.14) per share. Activity in the first quarter was dominated by a rapid response to Tlando's Complete Response Letter (CRL) received in late 2019. Management requested and held a Post Action meeting with the FDA to identify an appropriate response to address the Cmax related deficiency identified in the CRL. The agency and company agreed that a reanalysis of existing information would be sufficient leading to the resubmission of a new drug application (NDA) in February 2020. Development continues with LPCN 1144, which is currently being evaluated in the Phase II Liver Fat Intervention with oral Testosterone (LiFT) study. Other highlights year to date include a series of decisions favorable to Lipocine in their confrontation with Clarus. The company also received clearance for LPCN 1148 and may now start a Phase II trial for cirrhosis dependent on the availability of funding.

Operational expenses for 1Q:20 were $4.6 million, up 47% and net loss totaled ($5.8) million or ($0.14) per share. Research and development expenses totaled $2.5 million, with the 29% rise over prior year amounts reflecting increased costs related to the LiFT study, greater expense for Tlando XR development and greater personnel expense partially offset by lower expenditures for Tlando. General and administrative costs rose 77% over last year's first quarter to $2.1 million on a $1.0 million increase in legal fees related to the Clarus litigation partially offset by a decrease in personnel costs and lower travel expenses.

Cash and marketable securities balance was $15.6 million as of March 31, 2020. There is another $5 million of restricted[1] cash which will remain on hold until Tlando is approved. Current and non-current debt totals $6.4 million. Cash burn for 1Q:20 was approximately ($3.4) million and net cash provided by financing was $4.9 million representing $5.7 million in proceeds from a registered direct offering and repayment of $833 thousand of debt to Silicon Valley Bank.

Tlando

On November 11 of last year, Lipocine announced that it had received a CRL for Tlando. The CRL identified one deficiency stating that the trial did not meet one of the three secondary endpoints for maximal testosterone concentrations (Cmax). No deficiencies related to chemistry, manufacturing and controls were noted. FDA guidelines call for 85% of subjects to achieve a Cmax below 1500 ng/dL and no more than 5% of subjects presenting a Cmax between 1800 ng/dL and 2500 ng/dL and 0% above 2500 ng/dL. In the most recent dosing validation (DV) study, 85% of subjects were below 1500 ng/dL and 7% were between 1800 ng/dL and 2500 ng/dL. Although there were small variations from the FDA guidelines in the original SOAR study for subjects above 2500 ng/dL, the FDA did not identify this as a deficiency during the original New Drug Application (NDA) submission.

Following the Post Action meeting with the FDA, Lipocine was advised to address the outstanding deficiencies with a reanalysis of existing data. This recommendation relieved Lipocine of the time and cost of an additional trial and also allowed the resubmission of the Tlando NDA in February. We were pleasantly surprised to see the rapid resubmission and the assigned PDUFA date of August 28, 2020, as it was ahead of our anticipated timeline. While the resubmission is a positive, Tlando has faced significant hurdles gaining the favor of the FDA. We published a note on February 25th that discussed details regarding the resubmission.

LPCN 1144

Lipocine announced in August 2018 the pursuit of a new indication in nonalcoholic steatohepatitis (NASH). We discuss the indication and Lipocine's efforts in an earlier piece that can be accessed here. Full enrollment of 36 subjects was achieved in November 2018.

In January 2019, Lipocine announced meaningful liver fat reduction in patients participating in its Liver Fat Study and informed investors that the company had filed an investigational new drug (IND) application to begin a Phase II study for NASH. Since LPCN 1144 is the same molecule as TLANDO, for which there were numerous safety

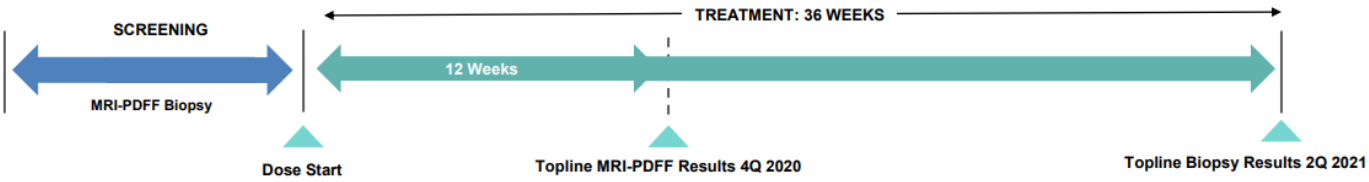
[1] Tlando was not approved by the FDA by May 31, 2018, and therefore Lipocine is required to maintain $5.0 million of cash collateral at Silicon Valley Bank (the lender) until such time as it is approved by the FDA.

studies completed, LPCN was allowed to perform a proof of concept (POC) clinical study under the original IND to assess liver fat changes. This 36-person study was conducted in hypogonadal men at risk of developing non-alcoholic steatohepatitis (NASH) and results were measured using the magnetic resonance imaging proton density fat fraction (MRI-PDFF) technique. Topline results were announced in 1Q:19 demonstrating a 4.0% to 8.2% percentage point reduction in liver fat depending on baseline liver fat category. We discussed the results in further detail in our NASH Topline article.

Lipocine launched its Phase II clinical study for LPCN 1144 and dosed its first patient last September. Prior to the start of the trial, Lipocine announced that the FDA would allow the Phase II LiFT trial to enroll eugonadal patients in addition to the NASH patients that were initially targeted. This expansion was based on research that we discussed in a July 29th note. The study is anticipated to last for 18 months and cost approximately $8 million.

LiFT, an acronym of Liver Fat intervention with oral Testosterone, is a paired biopsy Phase II study in NASH subjects. The study design will employ a three-arm, double-blind, placebo-controlled structure and enroll approximately 75 biopsy confirmed male NASH subjects with a NAS[2] score of greater or equal to four. The primary endpoint for the study is 12-week MRI-PDFF liver fat reduction and the first patient was enrolled in 3Q:19. As for the anticipated timeline, Lipocine expects top line liver fat reduction data in 4Q:20 as measured by MRI-PDFF at 12 weeks. Biopsy data at 36 weeks is expected to be available in the second quarter of 2021.

Exhibit I – LiFT Study Timeline[3]



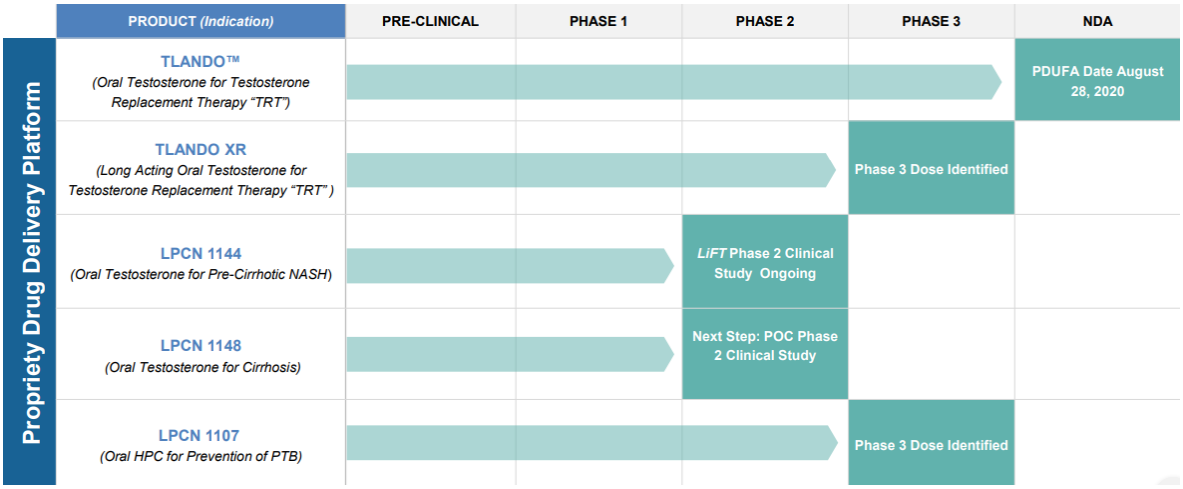
On May 11th, the competitive environment for the NASH space was thinned by one with the announcement that Genfit's (GNFT) elafibranor had failed in a Phase III trial that enrolled over 1,000 NASH patients. The drug was not better than placebo at improving NASH symptoms without worsening of fibrosis and did not achieve its primary endpoint. While elafibranor's failure is not helpful for the patients that were hoping for its success, its likely withdrawal as a contender clears a potential competitor from the space. The leader in the space, Intercept Pharmaceuticals (ICPT), is expecting a response from the FDA in late June for its candidate, Obeticholic acid, or OCA.

LPCN 1148

Lipocine is preparing to develop its testosterone molecule to treat NASH cirrhosis patients. While the target market is smaller than that of pre-cirrhotic NASH, there are no other FDA approved products available. The positive relationship between testosterone and sarcopenia and the increased risks of advancing NASH cirrhosis makes this pursuit worthwhile. Pending funding, Lipocine plans to initiate a proof of concept trial to evaluate the potential of this candidate. The company's Investigational New Drug (IND) application was cleared by the FDA in May 2020. We anticipate Lipocine will launch the Phase II trial after the start of commercialization of Tlando and upon availability of sufficient capital to fund the trial. Management has guided to a 4Q:20 or 1Q:21 start.

[2] NAS: NAFLD (Non-alcoholic fatty liver disease) Activity Score. Discussion of the metric can be found here.
[3] Source: Lipocine Corporate Presentation May 2020.

Exhibit II – Lipocine Pipeline[4]



Markman Hearing

On March 26th, Lipocine announced the outcome of the Markman Hearing, also known as a claim construction hearing. This meeting is an important precursor to a patent infringement lawsuit and provides the definitions of terms critical for a jury's determination on whether or not a patent has value. A patent should not be too specific, as it provides insufficient protection to an invention, or too broad, in which case a court may rule it indefinite. In the hearing order,[5] Judge Bryson did not agree with most of Clarus' claims and sided with Lipocine on the majority of definitions and clarifications. While the terms and definitions are subject to an "evolving" construction, the order is favorable to Lipocine's dispute against Clarus. While this order could be appealed again, it is unlikely in the opinion of Lipocine's counsel. Lipocine and Clarus are currently engaged in the fact discovery phase of the lawsuit and the jury trial is anticipated to take place in February 2021. Lipocine need only prevail on one claim to merit damages, which places them in a strong position to succeed in the trial or provide incentive for Clarus to settle.

Citizen's Petition

Clarus filed a Citizen's Petition with the FDA in October of 2019 requesting that the agency provide clear, written guidance regarding safety and efficacy standards for oral testosterone drugs. The petition also requested that the FDA not approve any other oral testosterone drugs until the requested guidance was given. This was an effort to limit competition for oral testosterone candidates in development such as Lipocine's Tlando. The FDA denied the petition without comment on February 27, 2020.

USPTO Decision Affirmed

The US Court of Appeals affirmed the decision of the USPTO in April 2020 to grant Lipocine's Priority Motion in the interference case that cancelled Clarus' claims to the '428 patent in January 2019. The USPTO, through its Patent Trial and Appeal Board (PTAB), had granted Lipocine's priority motion in the related interference case and entered adverse judgment against Clarus. As we have previously shared, this outcome was expected as it is rare for a federal court to overturn a USPTO ruling. As a reminder, in 2Q:19 Lipocine filed suit against Clarus alleging that Jatenzo infringed on six of Lipocine's patents. The injunction filing may slow down commercialization of Jatenzo and force Clarus to come to the table to negotiate a settlement. While the cost of pursuing such legal action could be high, we anticipate by the time the case works its way through the courts, cash flow from Tlando could be sufficient to support the legal efforts.

Capital Raise

Lipocine raised $6.0 million in gross proceeds in November 2019 and another $6.0 million in gross proceeds in February 2020. The November raise issued 10,450,000 shares and 1,550,000 prefunded warrants at $0.50 per share with each share and prefunded warrant having a common warrant attached with a $0.50 exercise price. The February registered direct offering transacted 10,084,034 shares, each of which had a half warrant attached. Warrant exercise price and share transaction price were $0.595.

[4] Source: Lipocine Corporate Presentation May 2020.
[5] A link to the Markman Hearing Order can be found on this page: https://ir.lipocine.com/presentations

Milestones

- Tlando CRL – November 9, 2019
- Tlando FDA post action meeting – January 2020
- Resubmission of Tlando NDA – February 2020
- Investigational New Drug (IND) clearance for LPCN 1148 – May 2020
- Tlando PDUFA date – August 28, 2020
- Primary endpoint results for LiFT – 4Q:20
- Patent Infringement trial – February 2021
- Complete Phase II LPCN 1144 – 2Q:21

Valuation Model

We update our model to reflect Tlando and LPCN 1144's commercialization through a partnership. Generally, a company is indifferent between self-commercialization and using a partner to develop a new product as the net value to the company is similar. Allowing a partner with a sales force in place allows a more efficient extraction of value and a larger pie, but is offset by a smaller cut of the pastry for the licensor. In this case there was little difference in equity value between the two approaches. We assume a 35% royalty for Tlando and LPCN 1144 reflecting upfront, milestone and royalty payments. We anticipate that there will be upfront amounts paid to Lipocine that will be used to advance other pipeline candidates; however, we do not estimate their value at this time and will adjust the model to reflect the structure of the agreement when available. We remove cost of goods sold and selling and marketing costs from the model and continue to use a 25% combined federal and state tax cash rate following the use of accumulated net operating losses. We maintain our $3.00 valuation and will update it based on the FDA's response to Tlando's resubmission and advancement of portfolio candidates.

Summary

Since our previous update, Lipocine has prevailed in several decisions involving Clarus. A favorable ruling on defining terms in the Markman Hearing, the affirmation of the USPTO decision and the denial of Clarus' Citizen Petition have all improved Lipocine's position. This will make the path forward easier in the coming quarters as the company launches Tlando (assuming approval) and give the company the high ground in the ultimate ruling on patent infringement or leverage in a settlement. The target action date for Tlando is only three months away and we are hopeful for a favorable response. The Phase II LiFT trial continues to be a bright spot for the company and is potentially able to address a large unmet need in NASH patients. Management has guided towards a year-end readout of these trial results. Lipocine is also developing LPCN 1148 for cirrhosis patients which was recently given clearance to begin a Phase II study. While we do not see this program entering the clinic until sufficient capital can be raised, we do think it will advance if Phase II data for LPCN 1144 are positive. We maintain our target price of $3.00 per share.

PROJECTED FINANCIALS

Lipocine Inc. - Income Statement

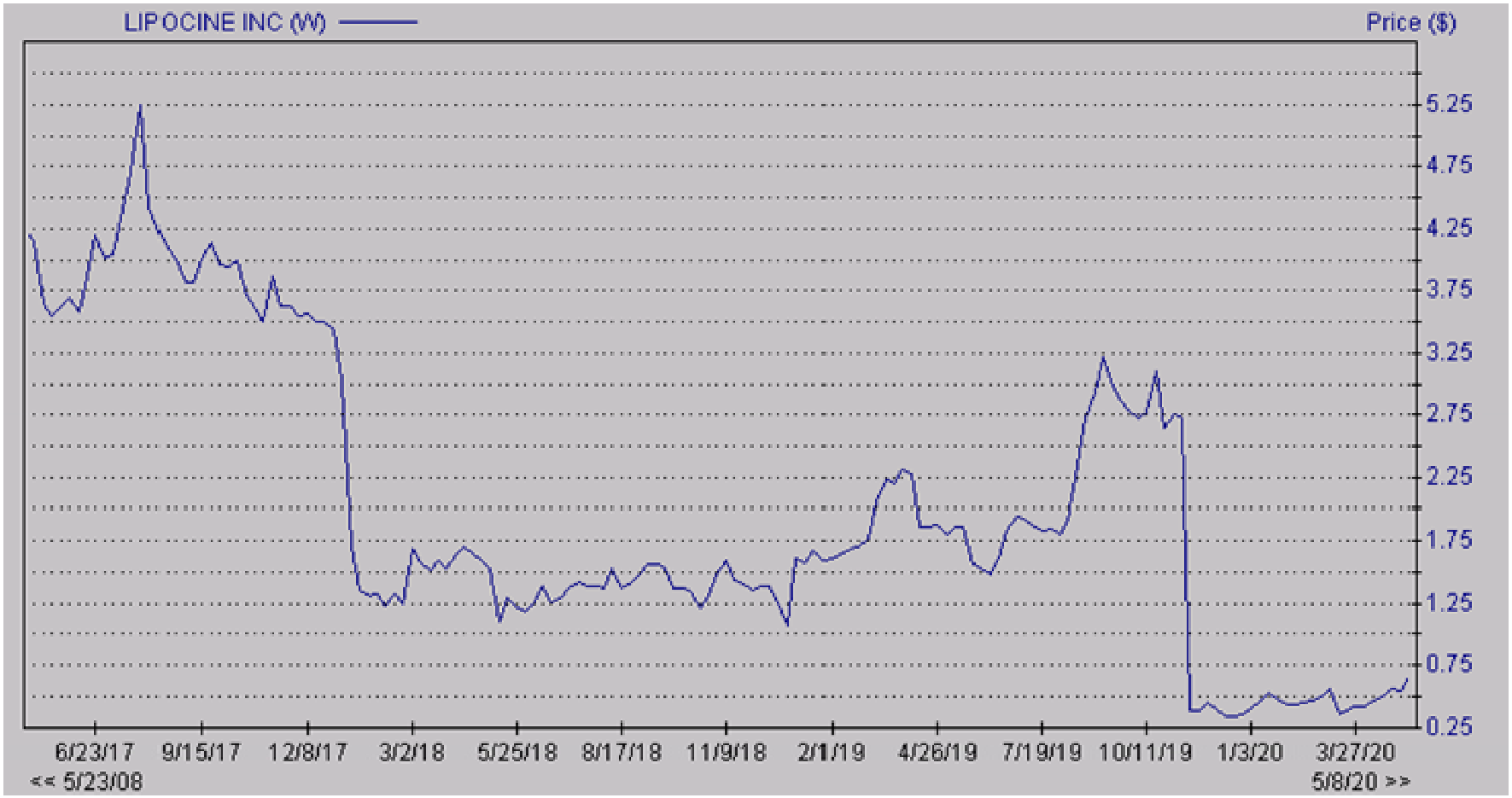
Lipocine Incorporated	2019 A	Q1 A	Q2 E	Q3 E	Q4 E	2020 E	2021 E	2022 E
Total Revenues ($MM)	**$0.2**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$111.3**	**$148.8**
R&D	$7.5	$2.5	$1.2	$1.2	$1.2	$6.1	$9.4	$10.0
SG&A	$5.6	$2.1	$1.7	$1.7	$1.7	$7.2	$7.2	$8.0
Other expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($12.9)	($4.6)	($2.9)	($2.9)	($2.9)	($13.3)	$94.7	$130.8
Operating Margin	-					-	-	-
Total Other Income	($0.1)	($1.2)	($0.1)	($0.1)	($0.1)	($1.5)	($1.9)	($4.2)
Pre-Tax Income	($13.0)	($5.8)	($3.0)	($3.0)	($3.0)	($14.8)	$92.7	$126.6
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%*	*0%*
Net Income	($13.0)	($5.8)	($3.0)	($3.0)	($3.0)	($14.8)	$92.7	$126.6
Reported EPS	**($0.50)**	**($0.14)**	**($0.06)**	**($0.06)**	**($0.06)**	**($0.31)**	**$1.75**	**$2.34**
YOY Growth	-					-	-	-
Shares Outstanding	25.9	41.3	48.0	50.0	52.0	47.8	52.9	54.0

Source: Company Filing // Zacks Investment I

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HISTORICAL STOCK PRICE

Lipocine Inc. – Share Price Chart



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