Zacks Small-Cap Research

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May 20, 2022
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Lipocine Inc. (LPCN: NASDAQ)

OLE Results

Based on our DCF model and a 20% discount rate, LPCN is valued at approximately $5.50 per share. We include a valuation component for tentatively approved TLANDO (95% probability) and Phase II assets LPCN 1144 (35%), LPCN 1148 (10%), LPCN 1154 (10%) & LPCN 1107 (15%). We model all of Lipocine's assets to eventually be developed by partners.

Current Price (5/19/2022)	$0.89
Valuation	**$5.50**

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. Many candidates are in development that employ the Lip'ral technology; two are for the treatment of male hypogonadism; one is for the prevention of pre-term birth, one for post-partum depression and two candidates target NASH and cirrhosis.

The lead product, Tlando, was tentatively approved in December 2020 with full approval granted in March 2022. Antares Pharma will commercialize the product and also holds rights to develop Tlando XR. We anticipate first sales in 2H:22.

LPCN 1144 for pre-cirrhotic NASH has shown promise in a space with no other approved treatment. Phase II data demonstrated reduction in liver fat and favorable safety data. LPCN 1107, LPCN 1148 & LPCN 1154 have various PK and food effect studies required before beginning the next stage of studies.

SUMMARY DATA

52-Week High	**1.89**
52-Week Low	**0.71**
One-Year Return (%)	**-35.5**
Beta	**0.5**
Average Daily Volume (sh)	**868,264**
Shares Outstanding (mil)	**88.5**
Market Capitalization ($mil)	**78.8**
Short Interest Ratio (days)	**2.2**
Institutional Ownership (%)	**13.5**
Insider Ownership (%)	**2.6**
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 2022 Estimate	**N/A**
P/E using 2023 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 USD)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	$0.0 A	$0.0 A	$0.1 A	$16.1 A	$16.1 A
2022	$0.0 A	$0.3 E	$1.0 E	$1.3 E	$2.6 E
2023					$10.7 E
2024					$19.7 E

Earnings per Share

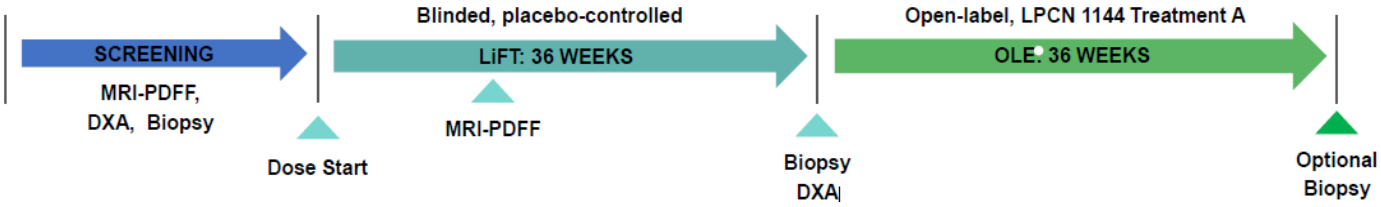
	Q1	Q2	Q3	Q4	Year
2021	-$0.04 A	-$0.08 A	-$0.03 A	$0.12 A	-$0.01 A
2022	-$0.04 A	-$0.04 E	-$0.03 E	-$0.04 E	-$0.15 E
2023					-$0.06 E
2024					$0.01 E

WHAT'S NEW

NASH Open Label Extension Study Results

On May 12, 2022 Lipocine (NASDAQ: LPCN) announced results from its NASH Open Label Extension (OLE) study. Safety was confirmed with no observed safety signals over the 72-week duration of exposure and liver injury markers were either maintained or reduced with the use of LPCN 1144. The data was sufficiently compelling to support further development in a pivotal trial. The OLE study was an extension of the 36 week Phase II LiFT study which produced topline results in August 2021 and was summarized in our report update here. Next steps are to hold an End of Phase II meeting with the FDA to identify trial design which will further determine Lipocine's next strategic step forward.

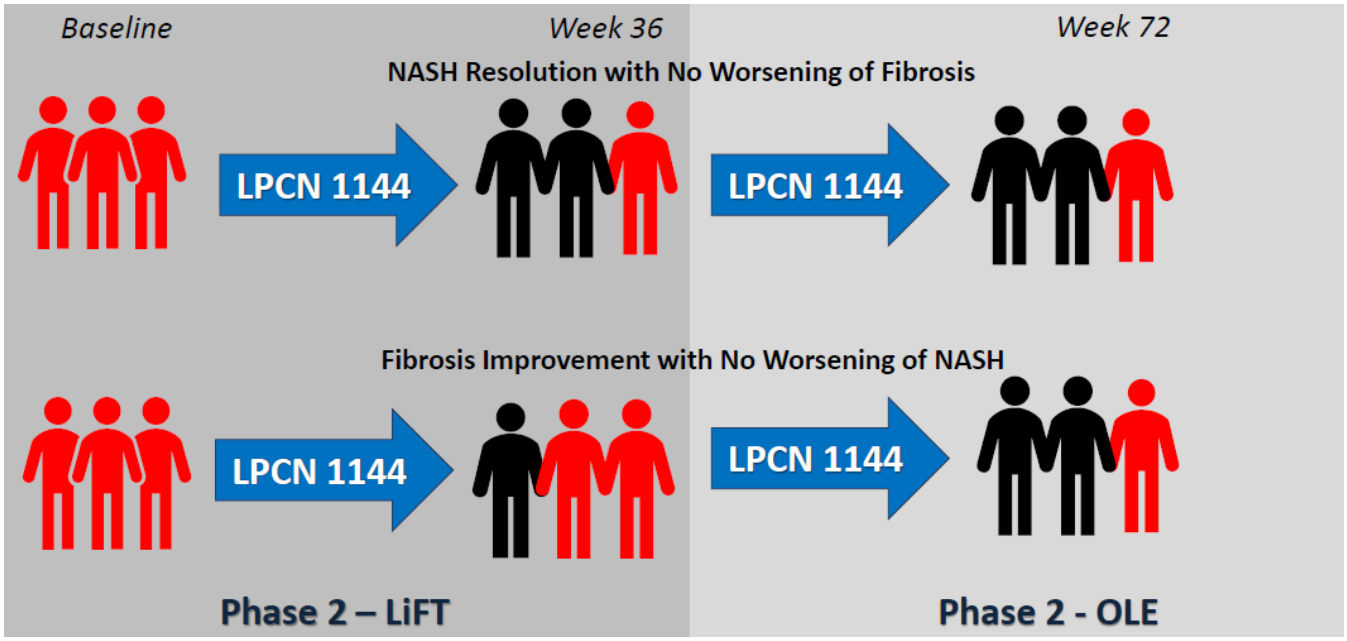
Exhibit I – LiFT and OLE Study Timeline[1]



Of the 25 subjects enrolled in the OLE safety set, 16 participants were in the LPCN 1144 arm of the LiFT study and the remainder were assigned to the placebo arm. 23 completed the OLE with two discontinuations due to a non-drug related treatment emergent adverse event (TEAE). The purpose of the extension was to evaluate safety and tolerability of LPCN 1144 and monitor subject health over the observation period. Adverse events that were observed, including a gastrointestinal (GI) event and pedal edema, were not considered related to the study drug. Furthermore, no clinically meaningful changes in lipids were observed. This is an important conclusion as many of the investigational drugs in development for non-alcoholic steatohepatitis (NASH) were associated with poorly-tolerated adverse effects.

Six subjects chose to undergo an optional liver biopsy at the end of the OLE to provide additional safety data. Three of the enrollees were on treatment for the full 72 weeks of treatment. In this group, NASH resolution with no worsening fibrosis and fibrosis improvement with no worsening of NASH was observed as detailed below.

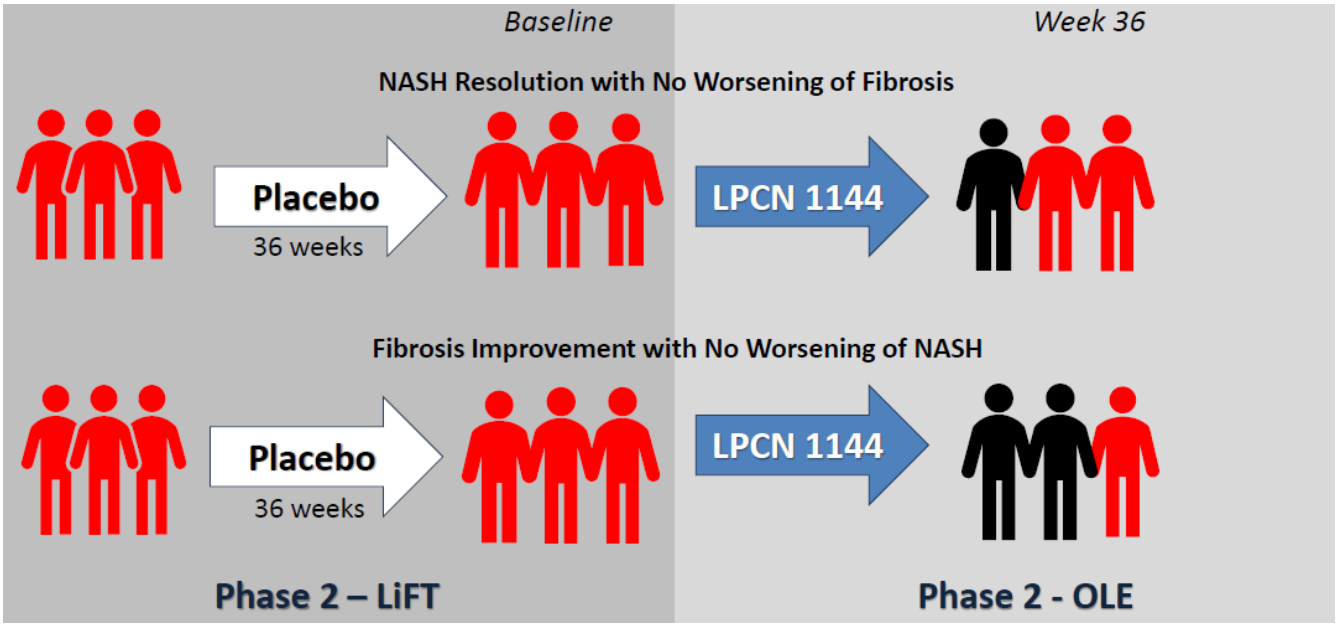
Exhibit II – Histological Changes in OLE Subjects with End of Period Biopsy[2]



[1] Source: LPCN Oral Neurosteroids Presentation, March 2022
[2] Source: LPCN Oral Neurosteroids Presentation, March 2022. Black = Improved individual subject; Red = Individual subject without improvement. Baseline was measured prior to LPCN 1144 treatment initiation. Biopsy changes in the subjects assessed utilizing NASH CRN (Clinical Research Network) scori

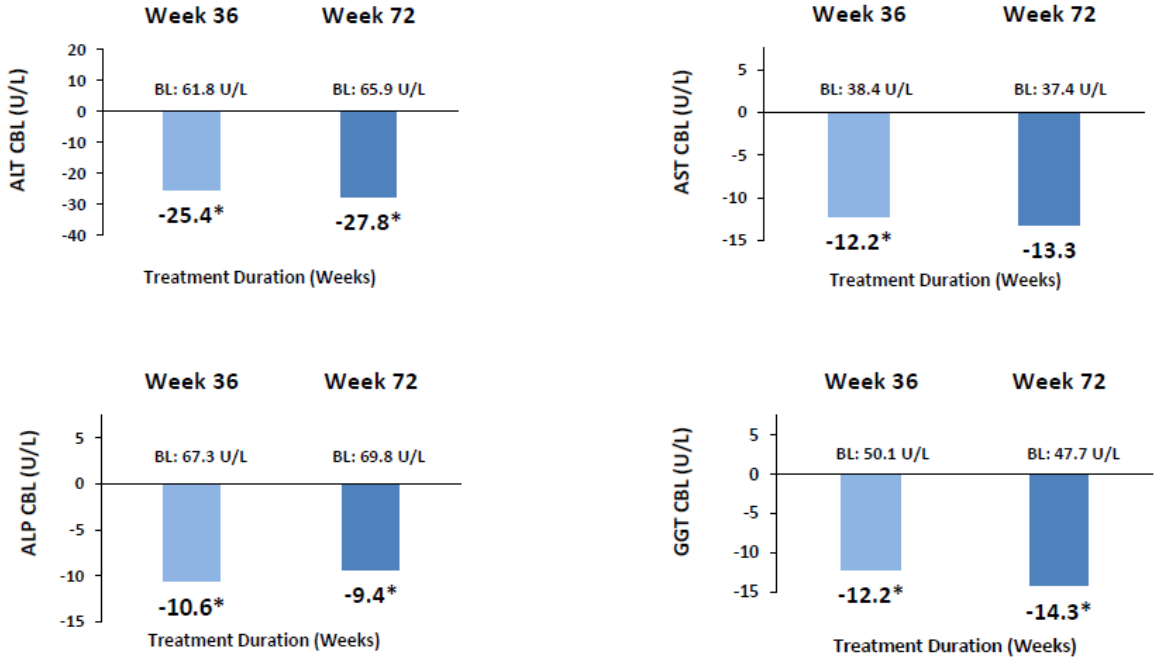
Three patients that started out in the placebo group for the LiFT portion of 36 weeks also received a biopsy to assess their status. Multiple individuals in this group also saw either an improvement in NASH resolution with no worsening fibrosis or fibrosis improvement with no worsening of NASH during the LPCN 1144 treatment period during the last 36 weeks of observation. Details of patients in each category are below.

Exhibit III – Histological Changes in OLE Subjects with End of Period Biopsy[3]



TEAEs for the OLE were comparable to what was observed in the LiFT study with no reported cases of cardiovascular events, thromboembolic events, hepatocellular carcinoma or drug induced liver injury. Liver injury in particular was significantly reduced during the OLE compared to baseline. Liver data is summarized below.

Exhibit IV – Liver Injury Markers Reduced in LPCN 1144 vs. Baseline[4]



CBL= Change from Baseline; Baseline was measured at LPCN 1144 pretreatment; * p<0.05; N = 25 for week 36 data and 16 for week 72 data

[3] Source: LPCN Oral Neurosteroids Presentation, March 2022. Black = Improved individual subject; Red = Individual subject without improvement. Baseline was measured prior to LPCN 1144 treatment initiation. Biopsy changes in the subjects assessed utilizing NASH CRN (Clinical Research Network) scori

[4] Source: LPCN Oral Neurosteroids Presentation, March 2022

Overall, the data was supportive of further development of LPCN 1144 in male patients with NASH. This has been a space with many dashed hopes as a number of candidates from other sponsors failed to generate strong enough data to merit a submission to the FDA due to either lack of efficacy or negative side effects. With the favorable safety data in hand, Lipocine's next step is to hold an End of Phase II meeting with the FDA to nail down trial design which will guide next steps forward.

Background for LPCN 1144: Treatment of Non-Cirrhotic NASH

Fast Track Designation

In a November 4th press release, Lipocine shared its success in obtaining the FDA's Fast Track Designation for LPCN 1144 for treatment of non-cirrhotic NASH. The designation is requested by a sponsor company for drug candidates that treat serious conditions and fill an unmet medical need. As no other NASH treatments have been approved and results from the LiFT trial were positive, the designation is welcome and not a surprise. The status should help Lipocine more efficiently design the Phase III program with closer guidance by the regulatory agency. It will also confer several benefits including more frequent interaction with the FDA, eligibility for accelerated approval, priority review and rolling review. Rolling review will allow Lipocine to submit portions of its NDA as they become ready rather than waiting until the entire package is ready thereby speeding the review process.

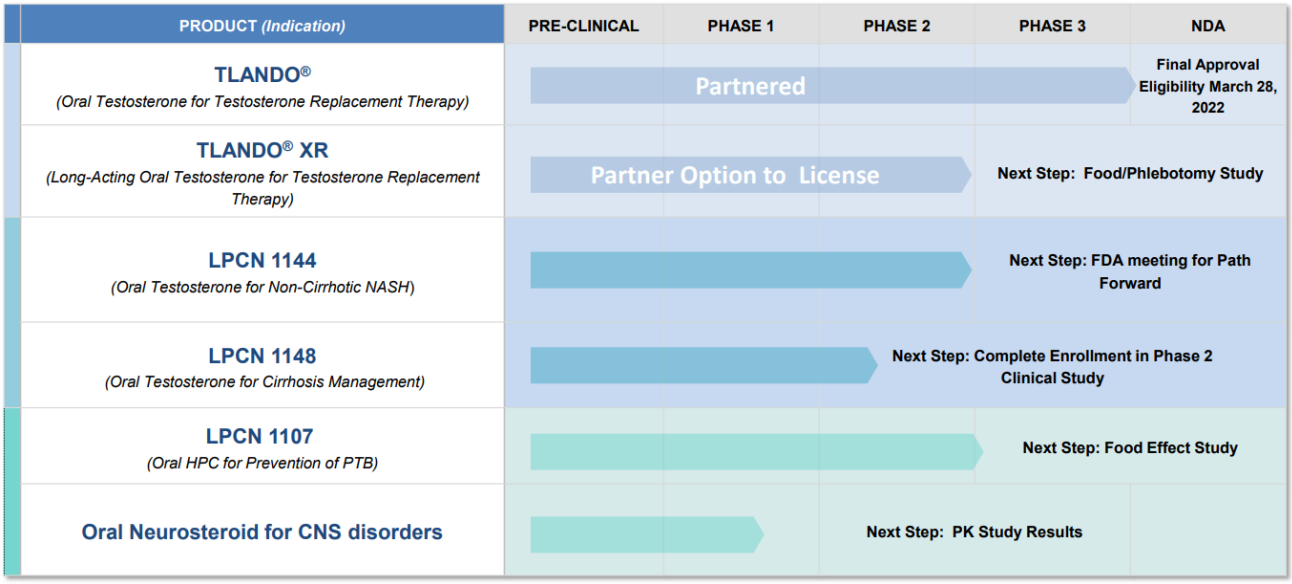
Regulatory Guidance on LPCN 1144

On March 1, 2022, Lipocine provided an update on its Type C meeting with the FDA regarding LPCN 1144's development. The FDA provided written response acknowledging that LPCN 1144's NDA would be submitted via 505(b)(2) regulatory pathway, that no additional nonclinical studies are needed to support the submission, and that Lipocine's Phase II LiFT study's multicomponent primary surrogate endpoint is acceptable for seeking approval under accelerated approval. The FDA recommended Lipocine either conduct a separate dose-ranging study prior to Phase III or evaluate multiple doses in the Phase III study and that the aforementioned multicomponent primary surrogate endpoint is acceptable. The FDA recommended Phase III study duration of 72 weeks. The FDA also recommended that Lipocine submit an updated Phase III protocol and discuss details further in an EoP2 which is expected to take place in 3Q:22.

Next Steps

Now that selected 72-week biopsy data has been presented to stakeholders and with the Fast Track Designation in its back pocket, Lipocine's next steps are to prepare a presentation for a scientific and medical conference and complete the extension study. With feedback from its Type C meeting with the FDA, Lipocine is now charged with redesigning and submitting an updated Phase III protocol to the FDA, and scheduling an EoP2 meeting with the FDA. In response to FDA guidance, Lipocine must decide whether it wishes to conduct a preliminary dose-ranging study, or to incorporate dose-ranging into the design of its Phase III trial. Management has voiced its desire to seek a partner to advance LPCN 1144 into a registrational study.

Exhibit V - Lipocine Pipeline[5]



[5] Lipocine Corporate Presentation January 2022

Summary

Lipocine provided results for its OLE of the LiFT trial which confirmed the safety profile that was reported in the LiFT trial. Improvements were noted in liver injury markers and adverse events were minor with the only TEAE not related to the study drug. In the six patients who consented to a biopsy, improvements in NASH and fibrosis were measured. The supportive data from the extension study will be helpful in the final stages of advancing LPCN 1144 through the regulatory process.

With $42 million in cash and equivalents and anticipated 2022 cash burn around ($13) million, we see a long runway for Lipocine as they continue to develop their diversified portfolio of assets. Growing revenues from TLANDO sales should reduce cash consumption in subsequent years.

Lipocine has several upcoming milestones in the next few months including first sales of TLANDO by partner Antares, an end of Phase II meeting for LPCN 1144, enrollment completion for the LPCN 1148 trial and an IND filing for LPCN 2101 in epilepsy among other items. Recent milestones include Lipocine's Phase II biopsy data for LPCN 1144, which yielded positive results and an update on its Type C meeting with the FDA regarding LPCN 1144's development. We modify our price target to $5.50 per share.

PROJECTED FINANCIALS

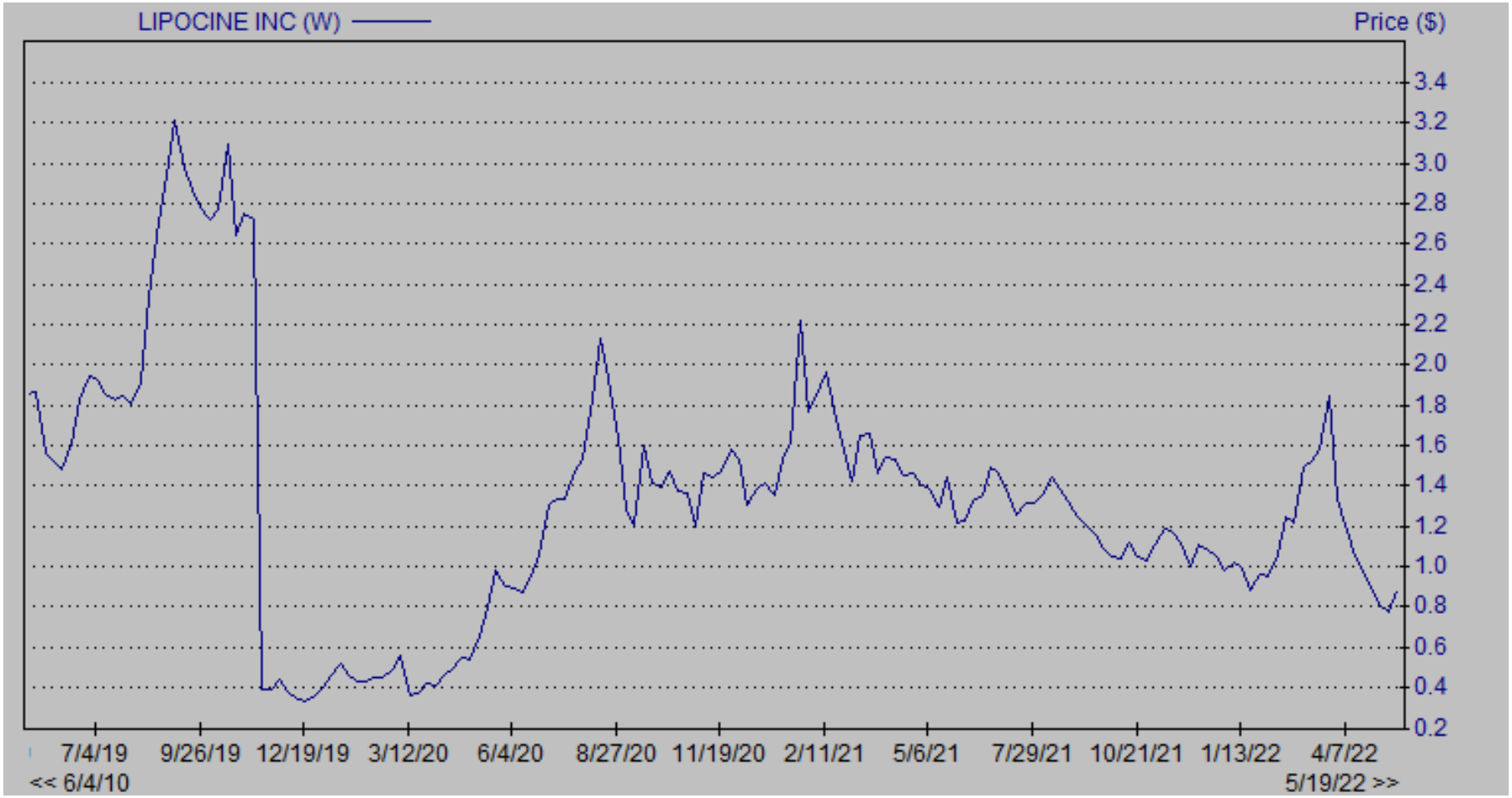
Lipocine Inc. - Income Statement

Lipocine Incorporated	2021 E	Q1 A	Q2 E	Q3 E	Q4 E	2022 E	2023 E	2024 E
Total Revenues ($MM)	**$16.1**	**$0.0**	**$0.3**	**$1.0**	**$1.3**	**$2.6**	**$10.7**	**$19.7**
R&D	$7.7	$1.9	$2.4	$2.1	$2.6	$9.0	$10.0	$10.0
G&A	$5.3	$1.2	$1.4	$1.5	$1.8	$5.9	$6.0	$6.0
Other expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	$3.1	($3.13)	($3.5)	($2.6)	($3.1)	($12.3)	($5.3)	$3.7
Operating Margin	-					-	-	-
Total Other Income	($3.8)	($0.4)	($0.1)	($0.1)	($0.1)	($0.7)	($0.5)	($0.5)
Pre-Tax Income	($0.6)	($3.5)	($3.6)	($2.7)	($3.3)	($13.1)	($5.8)	$3.2
Taxes & Other	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$2.0
Tax Rate	*0%*	*$0.0*	*0%*	*0%*	*0%*	*0%*	*0%*	*62%*
Net Income	($0.6)	($3.5)	($3.6)	($2.7)	($3.3)	($13.1)	($5.8)	$1.2
Reported EPS	**($0.01)**	**($0.04)**	**($0.04)**	**($0.03)**	**($0.04)**	**($0.15)**	**($0.06)**	**$0.01**
YOY Growth	-					-	-	-
Shares Outstanding	86.9	88.3	88.5	90.0	91.0	89.5	90.0	90.0

Source: Company Filing // Zacks Investment R

HISTORICAL STOCK PRICE

Lipocine Inc. – Share Price Chart



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