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Lipocine Inc. (LPCN-NASDAQ)

PDUFA Delay: Now November 30?

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 given to LPCN 1148 prior to entry in the clinic.

Current Price (11/19/20)	$1.38
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. Five drugs 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 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 which has been delayed to at least November 30, 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	**$2.39**
52-Week Low	**$0.30**
One-Year Return (%)	**246**
Beta	**0.57**
Average Daily Volume (sh)	**2,646,555**
Shares Outstanding (mil)	**65.7**
Market Capitalization ($mil)	**$90.6**
Short Interest Ratio (days)	**4.45**
Institutional Ownership (%)	**11.0**
Insider Ownership (%)	**5.5**
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 A	$0.0 A	$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	-$0.13 A	-$0.07 A	-$0.05 E	-$0.35 E
2021					$1.24 E
2022					$1.62 E

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WHAT'S NEW

Third Quarter 2020 Operational and Financial Results

On November 10, 2020 Lipocine (NASDAQ: LPCN) filed its third quarter 2020 10-Q and posted its earnings release for the three month period ending September 30, 2020. The company reported zero revenues and a net loss per share of ($0.07) compared to prior year third quarter revenues of $0.2 million and loss of ($0.12) per share. Attention since the second quarter report has been dominated by the target action date delay imposed by the FDA on Tlando. The FDA is now expected to provide its response to Lipocine's new drug application around the week of November 30. The company accomplished several commitments since the middle of the year including enrollment completion and journal publication of the LPCN 1144 Liver Fat Study results and presentation of materials at scientific and investor conferences. The company's shares exceeded $1.00 in June, and have remained above this level, allowing Lipocine to regain compliance with NASDAQ minimum bid requirements in July.

We expect to hear a response from the FDA on Tlando before year end. Assuming approval, Lipocine will likely find a partner to commercialize Tlando and use associated upfront and milestone payments to further develop the existing pipeline. Potential licensees will presumably wait until approval is granted before performing their due diligence. This suggests that a deal would take some time to be constructed and an announcement would come in the months following a positive answer from the FDA.

Operational expenses for 3Q:20 were $4.4 million, up 39% from the prior year period and net loss totaled ($4.3) million or ($0.07) per share. Research and development expenses totaled $2.5 million. The 45% rise in R&D over prior year amounts reflects increased costs related to the LiFT study and greater manufacturing costs related to Tlando and higher personnel expenditures. General and administrative costs rose 32% over last year's third quarter levels to $1.9 million on an expansion in legal expenditures related to the Clarus dispute and an increase in personnel costs related to stock compensation, partially offset by lower marketing expenses and administrative travel. A decline in the share price since the prior quarter end reduced the warrant liability and required the recognition of a small gain, while net interest expense was lower due to lower interest rates.

Cash and marketable securities balance was $18.8 million as of September 30, 2020. There is another $5 million of restricted[1] cash which will remain on hold until Tlando is approved. Current and non-current debt is carried on the balance sheet at $6.4 million. Cash burn for 3Q:20 was approximately ($4.2) million and net cash provided by financing was $4.7 million representing funds raised through the at-the-market facility and the exercise of warrants.

Tlando

On November 11 of last year, Lipocine announced that it had received a complete response letter (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 these 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. A target action date of August 28th was provided but has subsequently been extended. A company press release provided FDA estimates of an approximately three month delay (around November 30) in the Prescription Drug User Fee Act (PDUFA) date. Tlando has faced significant hurdles gaining the favor of the FDA, but we are hopeful for a favorable result in the next few weeks. We published a note on February 25th that discussed details regarding the resubmission.

[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.

LPCN 1144

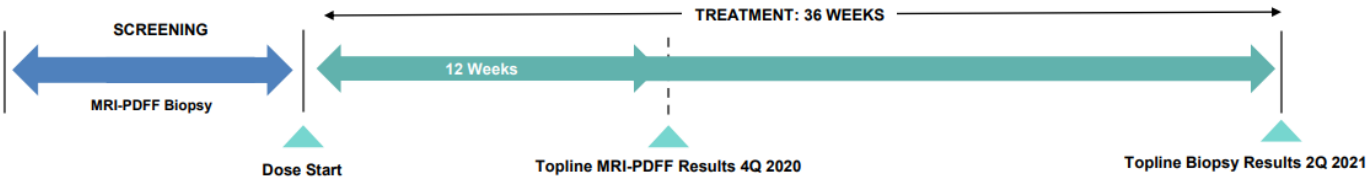
Lipocine announced in August 2018 the pursuit of a new indication in nonalcoholic steatohepatitis (NASH). We discuss the indication and Lipocine's efforts in an earlier piece that can be accessed here. Full enrollment of 36 subjects was achieved in November 2018.

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 studies completed, Lipocine 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 enrolled its last patient in September 2020 and is expected to report topline in January 2021 and 36 biopsy and MRI-PDFF data in mid-2021.

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]



NASH Environment

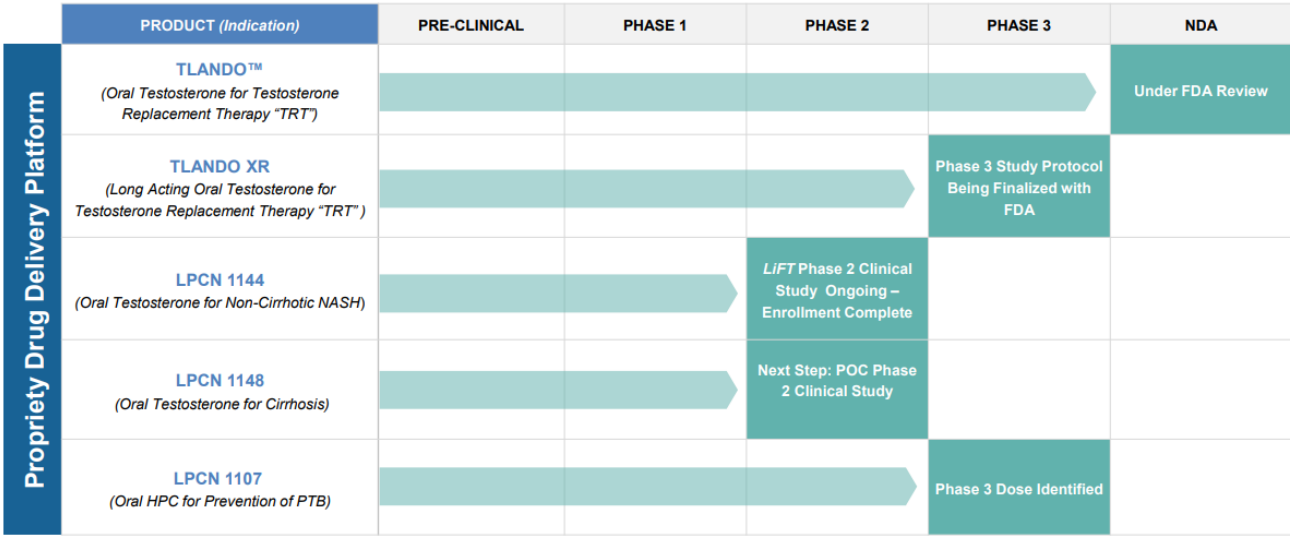
A lot has happened in the NASH space in 2020. Genfit (GNFT) announced that it will halt development of elafibranor after it failed to distinguish itself compared to placebo earlier this year. CymaBay (CBAY) announced that the FDA had lifted the hold on seladelpar's Phase II study last month. No evidence was found for liver injury for the drug and the trial is expected to resume. Intercept's (ICPT) OCA received a complete response letter from the FDA in late June noting that the agency remains uncertain that the benefits of the drug outweigh the risks. Viking (VKTX) is conducting the Phase IIb VOYAGE trial for VK2809, which is still ongoing. A bright spot in the space has been results from Akero's (AKRO) Phase IIb trial for efruxifermin in NASH which were announced June 30. The study found that 48% of patients had fibrosis improvement of at least one stage with a 62% response rate. Fibrosis improved by at least two stages for 28% of the group with a 38% response rate and 48% experienced NASH resolution without worsening of fibrosis across all dose groups.

[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.

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 inverse relationship between testosterone and sarcopenia and the increased risks of advancing NASH cirrhosis validates this pursuit. 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 it.

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. Due to delays related to the coronavirus, this date may be delayed. 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.

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.

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

Publications and Abstracts

Results from Lipocine's Liver Fat Study were published in Hepatology Communications in an article entitled "LPCN 1144 Resolves Non-Alcoholic Fatty Liver Disease In Hypogonadal Males." The study served to identify the prevalence of non-alcoholic fatty liver disease (NAFLD) in hypogonadal males and quantify the beneficial impact of LPCN 1144 on hypogonadism. 36 hypogonadal males were evaluated using MRI-PDFF measurements for liver fat. 81% of those with baseline liver fat equal to or greater than 5% showed improvement in liver fat content and NAFLD resolved in one-third of the group at six weeks and 48% after 16 weeks. The paper concluded that treatment with LPCN 1144 resolved NAFLD in about half of affected patients without any safety signals.

Lipocine submitted several abstracts to the American Urological Association (AUA) Virtual Experience, which took place from May 15 to 17, 2020. Three titles were presented.

- "Impact of a new oral testosterone undecanoate on blood pressure and cardiovascular risk" was presented by Dr. Mohit Khera, which investigated the chronic use of testosterone replacement therapy (TRT) on cardiovascular risk. Jatenzo, Xyosted and Tlando were assessed in terms of their impact on blood pressure and cardiovascular risk in hypogonadal men. Marginal increases in blood pressure were observed and no meaningful impact on cardiovascular risk was noted.
- "A novel oral testosterone therapy restores testosterone to eugonadal levels without dose titration" was presented by Dr. Martin Miner and highlighted the shortcomings of dose titration when prescribing TRT. The abstract concluded that fixed dose Tlando normalizes testosterone levels in hypogonadal patients while avoiding the potential problems associated with titrated TRT.
- "Effects of a new oral testosterone undecanoate (TLANDO) therapy on liver" was presented by Dr. Irwin Goldstein and compares oral methyltestosterone (MT) with TRT in males deficient in endogenous testosterone. The study results suggested that unlike MT, Tlando has no adverse effects on liver and can be used for an extended period to potentially reduce liver fat.

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
- Wajda v. Patel shareholder suit dismissed – July 2020
- Tlando target action date – Expected week of November 30, 2020
- Primary endpoint results for LiFT (LPCN 1144) – January 2020
- Patent Infringement trial – February 2021
- Complete Phase II LiFT (LPCN 1144) – 2Q:21
- 36-week biopsy data in mid-2021 (LPCN 1144)

Summary

Since our previous update, the FDA has extended its deadline to provide a response for the Tlando new drug application by at least three months. Since then, Lipocine has participated in several conferences, including the HC Wainwright investment conference and the Sexual Medicine Society of North American and Liver Meeting scientific conferences. Assuming a favorable outcome for the application, Lipocine will seek a commercialization partner and should receive upfront and milestone proceeds in conjunction with a deal. 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 in contrast to competing programs which have met with difficulty. Management has guided towards a January 2021 readout of LiFT 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 is available, 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

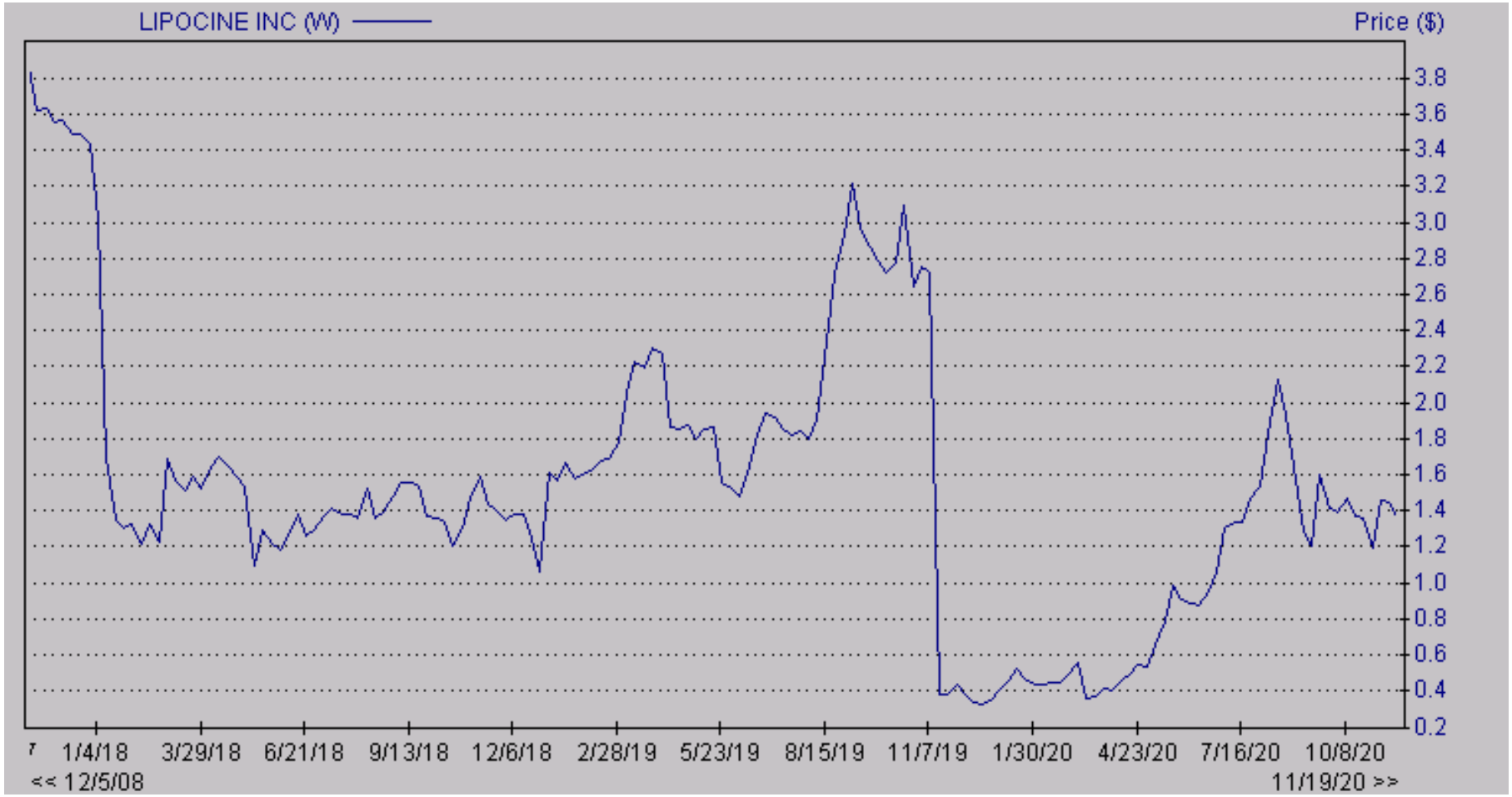
Lipocine Incorporated	2019 A	Q1 A	Q2 A	Q3 A	Q4 E	2020 E	2021 E	2022 E
Total Revenues ($MM)	**$0.2**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$111.3**	**$148.8**
R&D	$7.5	$2.5	$2.3	$2.5	$1.2	$8.5	$9.4	$10.0
SG&A	$5.6	$2.1	$2.0	$1.9	$1.7	$7.6	$7.2	$8.0
Other expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($12.9)	($4.6)	($4.2)	($4.4)	($2.9)	($16.1)	$94.7	$130.8
Operating Margin	-					-	-	-
Total Other Income	($0.1)	($1.2)	($2.1)	$0.1	($0.1)	($3.4)	($5.6)	($9.5)
Pre-Tax Income	($13.0)	($5.8)	($6.4)	($4.3)	($3.0)	($19.5)	$89.1	$121.3
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)	($6.4)	($4.3)	($3.0)	($19.5)	$89.1	$121.3
Reported EPS	**($0.50)**	**($0.14)**	**($0.13)**	**($0.07)**	**($0.05)**	**($0.35)**	**$1.24**	**$1.62**
YOY Growth	-					-	-	-
Shares Outstanding	25.9	41.3	49.8	64.8	65.7	55.4	72.0	75.0

Source: Company Filing // Zacks Investment R

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HISTORICAL STOCK PRICE

Lipocine Inc. – Share Price Chart



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