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Lipocine Inc. (LPCN-NASDAQ)

New Candidate in Postpartum Depression

Based on our DCF model and a 20% discount rate, LPCN is valued at approximately $10.00 per share. We include a valuation component for tentatively approved TLANDO (95% probability) and Phase II asset LPCN 1144 (15% probability). Despite a cleared investigational new drug application (IND), no valuation is given to LPCN 1148 or LPCN 1154 prior to entry in the clinic.

Current Price (8/5/21)	$1.32
Valuation	**$10.00**

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. Six 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, 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 anticipated March 2022. Several factors could advance this date but appear less likely as court dates are delayed due to the pandemic. These options include a favorable outcome of the patent lawsuit against Clarus or a settlement and an appeal to the FDA's decision to delay Tlando due to exclusivity for the competitors' oral testosterone product. LPCN's other candidates, Tlando XR and LPCN 1107 are on hold. LPCN 1144 is in development for pre-cirrhotic NASH and completed 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	**$2.42**
52-Week Low	**$1.09**
One-Year Return (%)	**-32.7**
Beta	**0.38**
Average Daily Volume (sh)	**1,020,573**
Shares Outstanding (mil)	**88.3**
Market Capitalization ($mil)	**$117**
Short Interest Ratio (days)	**3.39**
Institutional Ownership (%)	**9.5**
Insider Ownership (%)	**2.5**
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 2020 Estimate	**N/A**
P/E using 2021 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(in millions of $US)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2021	$0.0 A	$0.0 A	$0.0 E	$0.0 E	$0.0 E
2022					$116.9 E
2023					$145.2 E

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	-$0.14 A	-$0.13 A	-$0.07 A	-$0.07 A	-$0.38 A
2021	-$0.04 A	-$0.08 A	-$0.05 E	-$0.06 E	-$0.23 E
2022					$1.09 E
2023					$1.29 E

WHAT'S NEW

Second Quarter 2021 Financial and Operational Results

On August 5th, 2021 Lipocine (NASDAQ: LPCN) filed its Form 10-Q and posted its earnings release for the three month period ending June 30, 2021.

Highlights for the second quarter 2021 and to-date include:

- Summary judgment in patent infringement lawsuit – May 2021
- IND clearance for LPCN 1154 in PPD – June 2021
- Settlement with Clarus Therapeutics - July 2021

Lipocine continued advancing the ongoing Phase II LiFT study, with 36-week biopsy data expected August 2021, and further enrolled into LiFT's open-label extension. The company is also in the process of evaluating commercial options for TLANDO.

Lipocine generated no revenue from its products in 2Q:21 or 2Q:20. It reported net loss of $6.8 million, or ($0.08) per diluted share for the second quarter 2021 compared with net loss of ($6.4) million, or ($0.13) per diluted share for the prior year period.

For the first quarter ending March 31, 2021 and versus the first quarter ending March 31, 2020:

- Research & development (R&D expense totaled $1.46 million, down 35% from $2.27 million driven primarily by reduction in contract research organization cost and outside consulting costs for LPCN 1144 and TLANDO. Personnel expenses declined due to lower stock compensation and bonus. These trends were offset by a rise in expenditures for LPCN 1154, LPCN 1107 and other R&D expense;
- General & administrative (G&A) expenses fell 22% to $1.53 million from $1.95 million, on lower stock compensation and bonus expense as well as decreased legal activities. The declines were in part offset by increases in corporate insurance and other G&A expenses;
- Net interest expense fell to ($40,000) from ($81,000) on lower loan balances and a gain was recognized on warrant liability tied to share price movements;
- A litigation settlement with Clarus of ($4.0) million was recognized in the quarter with no corresponding charge in the prior year;
- Net loss was ($6.81) million or ($0.08) per diluted share compared with net loss of ($4.22) million or ($0.13) per diluted share.

As of June 30, 2021, marketable securities, cash and equivalents totaled $46.6 million, compared to $18.2 million twelve months earlier. In January 2021, Lipocine raised gross proceeds of $28.7 million through a public offering.

Summary Judgement Spurns Lipocine

Hopes for Lipocine to secure damages from Clarus related to the ongoing patent infringement lawsuit patents faded on Tuesday, May 25th, when the US District Court for the District of Delaware granted Clarus Therapeutics a motion for summary judgment against the patents in the suit advanced by Lipocine in the patent infringement case. Judge William Bryson found all of the asserted Lipocine patent claims invalid noting that Lipocine's claims were not specific enough and lacked sufficient written description.[1]

Clarus's motion for Summary Judgment proposed that there was a clear, straightforward outcome for the suit and it would only require Judge Bryson to rule on the decision, not a jury. The judge's decision found Lipocine's patents lacked description and enablement, or in other words, that Lipocine's patents used language that was too broad to make a case for infringement.

[1] We did not have access to primary resources and relied on management commentary and notes in the press for the judge's rationale. The details of the case remain sealed as of the date of this note.

Lipocine's patent claims for Lipocine's U.S. patents 9,034,858; 9,205,057; 9,480,690; and 9,757,390, were all found invalid. Federal Circuit Judge William Bryson, Senior Circuit Judge of the U.S. Court of Appeals for the Federal Circuit made the call.

The summary judgment does not affect the anticipated commercialization calendar for Tlando, which we continue to anticipate will begin first sales in March 2022.[2] The testosterone replacement therapy was granted tentative approval by the FDA on December 8, 2020. Tlando met all required quality, safety and efficacy standards necessary for approval; however, final approval will not be granted until the expiration of Jatenzo's exclusivity period. Jatenzo was granted a three-year period of exclusivity on March 27, 2019.

Settlement with Clarus Therapeutics

Following the summary judgement, Lipocine announced that it had entered into a global settlement and license agreement with Clarus Therapeutics to resolve all outstanding claims in the on-going IP litigation between the two companies. Under the terms of the settlement, the two companies agreed to dismiss *Lipocine Inc. v Clarus Therapeutics, Inc., No 19-cv-622 (WCB)* litigation that was still pending, in the U.S. District Court for the District of Delaware, before the announcement. Both parties also reached an agreement on the interference proceedings, Interference No. 106,128 that was pending in the U.S. Patent and Trademark system. The terms of the settlement are confidential; however, on July 15, 2021, Clarus announced itself that the intellectual property litigation and patent interference were resolved at no cost to Clarus.

In an update provided in the second quarter 2021 Form 10-Q filing, Lipocine noted that a $4.0 million payment was made by the company to Clarus to resolve all outstanding claims of the litigation as well as the ongoing USPTO interference case. Lipocine will pay $2.5 million immediately, $1.0 million on July 13, 2022 and $500,000 on July 13, 2023 to satisfy the terms of the settlement. No future royalties are owed to either party. The US District Court for the District of Delaware dismissed both Lipocine's and Clarus' claims and the Patent Trial and Appeal Board (PTAB) granted Lipocine's request for adverse judgment in the interference case.

LPCN 1154 IND Cleared

On June 14, 2021, Lipocine announced that its IND application to initiate a Phase II study in postpartum depression had been cleared. LPCN 1154 represents the latest addition to Lipocine's clinical portfolio, and is an oral neurosteroid. Lipocine has completed a pharmacokinetic (PK) study and will analyze results before embarking on a Phase II study. The PK study began in July 2021 with topline results expected in 3Q:21. Following the PK study, the Phase II will be a proof-of-concept to evaluate safety, tolerability and efficacy of the oral neurosteroid in adult female subjects diagnosed with postpartum depression. Management expects the first patient to be dosed in 4Q:21.

Postpartum depression is a major depressive disorder that impacts an estimated 1 in 7 women after giving birth. There is no specific oral therapy approved for treatment of postpartum depression. The mother's physician may prescribe common oral antidepressants such as citalopram, escitalopram, fluvoxamine, paroxetine, fluoxetine and sertraline.[3] However, these agents may not take effect for several weeks.

The first and only drug approved specifically for postpartum depression is Zulresso (brexanolone) which is delivered via intravenous infusion.[4] Oral delivery of the underlying hormone as in LPCN 1154 would alleviate the inpatient burden associated with Zulresso infusion as a treatment that can be administered at home.

The active moiety of LPCN 1154 is a synthetic precursor of allopregnanolone, a positive allosteric modulator of $GABA_A$ (γ-aminobutyric acid) receptor, which is metabolized into the endogenous molecule in the body. Lipocine's Lip'ral technology has been combined with this hormone as a vehicle for addressing PPD.[5]

Postpartum Depression (PPD): A New Target

With the latest IND clearance for LPCN 1154, Lipocine adds to its portfolio of clinical indications with postpartum depression (PPD) combining its Lip'ral technology with an oral neurosteroid. The PPD market is substantial. PPD

[2] TLANDO has not received final approval and is not eligible for final approval to market in the U.S. until the expiration of the exclusivity period previously granted to Clarus Therapeutics for Jatenzo, which expires on March 27, 2022.
[3] Postpartum Antidepressants - Postpartum Depression Treatments
[4] Treatment for PPD | ZULRESSO™ (brexanolone) CIV
[5] https://en.wikipedia.org/wiki/Allopregnanolone

is believed to be underreported, estimated to affect at least 10-15% of all adult mothers per year, lasting more than 6 months in up to half of them.[6] One report estimates that only 20% of women with symptoms of PPD actually report their symptoms to health care providers. With an estimated 3.6 million births[7] in 2020, this could indicate an incidence of 400,000 to 500,000 patients per year.

Symptoms of PPD are frequently dismissed by both those who suffer from this disorder and health care providers as natural consequences of childbirth.[8] Similar to other forms of depression, PPD patients suffer low mood, sleep disturbance, change in appetite, diurnal variation in mood, poor concentration and irritability but also experience guilt about their inability to care for their new baby. Hospital admission is reserved for cases with severe symptoms to minimize the risk of suicide and infanticide.

Exhibit I - Three Categories of Postpartum Affective Disorders[9]

Disorder	Prevalence	Onset	Duration	Treatment
Blues	30 – 75%	Day 3 or 4	Hours to days	No treatment required other than reassurance
Postpartum Depression	10 – 15%	Within 12 months	Weeks – months	Treatment usually required
Puerperal Psychosis	0.1 – 0.2 %	Within 2 weeks	Weeks - months	Hospitalization usually required

Oral anti-depressant treatment using selective serotonin reuptake inhibitors (SSRIs) poses several shortcomings, including an extended period (on average 4-8 weeks) prior to onset of action and negative side effects. Brexanolone[10] is a synthetic neurosteroid $GABA_A$ receptor modulator that is used to treat postpartum depression approved for use by the FDA in March 2019. However, the drug is administered intravenously over 60 hours on an inpatient basis, creating difficulties for new mothers to adhere to the regimen and care for their child including breastfeeding.

Various treatment options are used for tackling PPD including pharmacological, psychological, psychosocial, and hormonal among others. Psychosocial strategies include supportive cognitive therapy and support group therapy for mothers and couples. Even electroconvulsive therapy has been used. Patients with severe symptoms, and who are deemed to have a higher risk for suicide, may require hospital admission.[11]

In addition to the usual concerns about safety, drug interactions and systemic side effects, PPD patients present an additional challenge with a higher need for an immediate resolution of their symptoms to assure the best outcome for both the mother and the baby. Pharmacokinetic and clinical studies of LPCN 1154 will investigate these issues further as a component of the safety assessment.

The major competitor in this field is another positive allosteric modulator of $GABA_A$ receptors, being developed by Biogen in partnership with Shionogi branded Zuranolone (SAGE-217). In addition to PPD, this oral formulation is being investigated for major depressive disorder in a Phase III clinical trial.[12] As opposed to the endogenous active ingredient of LPCN 1154, the active molecule in SAGE-217 is a synthetic neurosteroid and positive allosteric modulator activity on $GABA_A$ receptors.[13]

A second competitor in the PPD treatment area as a nasal formulation is S-ketamine (esketamine), which is being investigated in an interventional clinical trial in China. Although it has an entirely different mechanism of action and does not belong to the neurosteroid family, the molecule received a Breakthrough Therapy and Fast Track FDA approval for use in treatment of resistant depressive disorder as a combination therapy with other oral antidepressants in 2019.[14] Esketamine is a more potent form of ketamine which is a common general anesthetic and an NMDA receptor antagonist with anti-depressant action in low doses.

[6] Beck CT, Records K, Rice M. Further development of the postpartum depression predictors inventory-revised. J Obstet Gynecol Neonatal Nurs. 2006;35(6):735–45
[7] Source: Vital Statistics Rapid Release, Report No. 012 May 2021.
[8] Nonacs R, Cohen LS. Postpartum mood disorders: diagnosis and treat- ment guidelines. J Clin Psychiatry. 1998;59:34–40
[9] https://www.who.int/mental_health/prevention/suicide/lit_review_postpartum_depression.pdf
[10] Sage Therapeutics sponsored the new drug application for Brexanolone (Zulresso).
[11] Nonacs R, Cohen LS. Postpartum mood disorders: diagnosis and treatment guidelines. J Clin Psychiatry. 1998;59:34–40
[12] https://clinicaltrials.gov/ct2/show/NCT04442490
[13] Gunduz-Bruce H, Silber C, Kaul I, Rothschild AJ, Riesenberg R, Sankoh AJ, Li H, Lasser R, Zorumski CF, Rubinow DR, Paul SM, Jonas J, Doherty JJ, Kanes SJ. Trial of SAGE-217 in Patients with Major Depressive Disorder. N Engl J Med. 2019 Sep 5;381(10):903-911.
[14] https://www.fda.gov/news-events/press-announcements/fda-approves-new-nasal-spray-medication-treatment-resistant-depression-available-only-certified

Mechanism of Action

Brexanolone, also known as allopregnanolone is a naturally produced (endogenous) inhibitory pregnane neurosteroid made from progesterone. The exact mechanism of action of brexanolone as an antidepressant is unknown. It acts as a positive allosteric modulator of $GABA_A$ receptors. GABA (gamma-aminobutyric acid) is an inhibitory neurotransmitter in the brain. Naturally produced brexanolone exerts a neurophysiological role through the fine-tuning of $GABA_A$ receptors and modulating the action of several positive allosteric modulators and agonists at $GABA_A$ receptors. It has a biphasic action on the $GABA_A$ receptors. At high levels, it can produce paradoxical effects such as negative mood, anxiety, irritability and aggression. Moderate levels of increased brexanolone inhibit the receptor activity, whereas lower or higher concentrations stimulate it. This is a common effect of many positive allosteric modulators of $GABA_A$ receptors.[15,16]

Administration

Approved by the FDA in 2019, Zulresso offers relief for those who suffer from PPD.[17,18] Despite its efficacy, the drug's intravenous route of administration limits its use to in-patient clinics and hospitalized patients. Zulresso is administered via intravenous infusion under continuous monitoring throughout the duration of the infusion. Administration comprises a continuous infusion over 60 hours (2.5 days) in controlled dosages for initiation, upscaling and finally gradual tapering of the dose towards the end of the infusion period. The patient is constantly monitored for excessive sedation and hypoxia due to the risk of respiratory depression.[19] As a vehicle, Lip'ral technology could offer a new more convenient oral solution for providing adequate and safe bioavailability of the underlying endogenous hormone via oral administration.

Studies Underway

Lipocine is currently conducting a pharmacokinetic (PK) and dose proportionality study to identify to optimal dosing to deliver sufficient levels of the hormone to produce efficacy. Following a topline report to investors and analysis of this data, the company expects to launch a Phase IIa proof of concept trial in 4Q:21 in what we think could be around eight patients. If successful, a Phase IIb would be launched to further determine efficacy.

Exhibit II – Key Factors For Lipocine's PPD Pursuit[20]

~ 1 in 7 women suffer from PPD after giving birth	Only 50% (~400,000) of patients are currently diagnosed and treated in US	Negative impact on maternal and infant outcomes	Negative impact on spouse

Positive Topline Phase II Results from Ongoing LiFT Study

On January 12, 2021, Lipocine announced positive topline data from LiFT, a Phase II study of its candidate LPCN 1144 in biopsy-confirmed, non-cirrhotic male NASH patients with F1-F3 fibrosis, a patient population with outstanding clinical need. Results are positive and show statistical significance in the primary endpoint of change in hepatic fat fraction, quantified via MRI-PDFF[21] at week 12. The results succeed a string of failed NASH treatment attempts by other companies, including Gilead, whose anti-fibrosis drug selonsertib failed in Phase III, Ionis, with its delayed

[15]Bäckström T, Haage D, Löfgren M, Johansson IM, Strömberg J, Nyberg S, et al. (September 2011). "Paradoxical effects of GABA-A modulators may explain sex steroid induced negative mood symptoms in some persons". *Neuroscience*. **191**: 46-54. doi: 10.1016/j.neuroscience.2011.03.061. PMID 21600269. S2CID 38928854.
[16] Andréen L, Nyberg S, Turkmen S, van Wingen G, Fernández G, Bäckström T (September 2009). "Sex steroid induced negative mood may be explained by the paradoxical effect mediated by GABAA modulators". *Psychoneuroendocrinology*. **34** (8): 1121–32. doi:10.1016/j.psyneuen.2009.02.003. PMID 19272715. S2CID 22259026.
[17] https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/211371lbl.pdf
[18] https://en.wikipedia.org/wiki/Allopregnanolone
[19] https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/211371lbl.pdf
[20] Source: Lipocine Corporate Presentation June 2021
[21] Magnetic Resonance Imaging Proton Density Fat Fraction

result release for their antisense gene therapy, and Intercept, whose Ocaliva failed to achieve statistical significance in the clinic. In contrast, Lipocine's LPCN 1144, an oral pro-drug of endogenous testosterone, has shown robust, statistically significant efficacy in not only its primary endpoint of reduction of hepatic fat fraction, but secondary endpoints as well, some of which were published in an update on January 12, 2021.

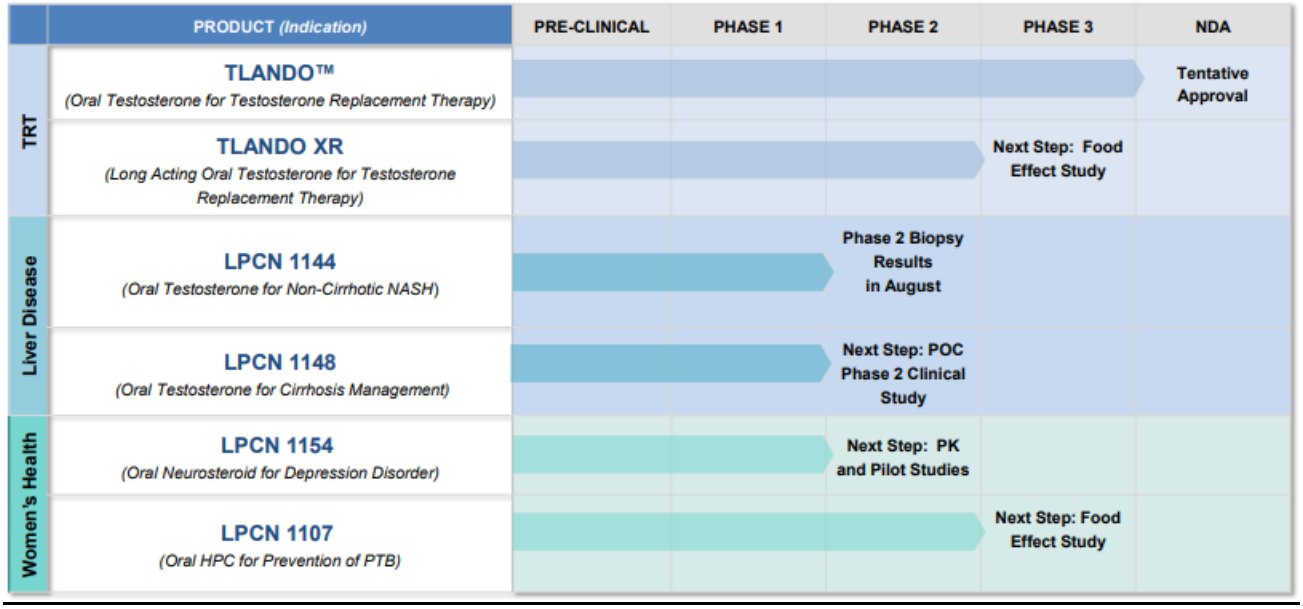
FDA Grants Tentative Approval to Tlando

After multiple extensions from the August 2020 target action date, the FDA granted tentative approval of Lipocine's Tlando on December 8th, 2020 Tlando met all required quality, safety and efficacy standards necessary for approval; however, marketing of Tlando will not be allowed until the expiration of the exclusivity period for Clarus' Jatenzo. Jatenzo, also an oral form of testosterone undecanoate, was granted a three year period of exclusivity as of March 27, 2019.

Upon full approval, on Tlando's behalf, Lipocine must assess the safety and effectiveness of the product in pediatric patients and conduct post-marketing studies. One of the studies requires that the label is designed appropriately so that patients understand the risk disclosures and the other requires a one-year trial to assess adrenal insufficiency with chronic Tlando therapy. We discuss the tentative approval of Tlando and its implications for future commercialization in our previous report.

Lipocine is in the process of identifying possible partners for commercialization of Tlando and is considering two approaches. The first is to outlicense commercialization of the drug where Lipocine would not participate in the marketing effort. The second is to enter into a risk sharing agreement where profits are shared after costs are covered by the collaborative entity. Lipocine is in discussions with multiple prospects and we anticipate further information will be provided when the path forward is clarified.

Exhibit III - Lipocine Clinical Pipeline[22]



[22] Source: Lipocine Corporate Presentation June 2021

Milestones

- NDA filed for Tlando – February 2020
- IND clearance for Phase II study of LPCN 1148 – May 2020
- Tentative approval of Tlando – December 2020
- LiFT Study
    - Primary endpoint – January 2021
    - Last patient, last visit for biopsy data – June 2021
    - Presentation of biopsy data – August 2021
- Abstract presentation at EASL – June 2021
- Male cirrhosis trial first subject dosed for LPCN 1148 – 4Q:21
- Topline announcement for PK study for LPCN 1154 – 3Q:21
- Launch of Phase IIa proof of concept PPD trial – 4Q:21
- Tlando eligible for final approval – 2Q:22

Summary

Highlights for Lipocine's second quarter are a summary judgment in the patent infringement lawsuit, IND clearance for LPCN 1154 and settlement of the Clarus litigation. We also expect the launch of a Phase IIa trial in PPD and first subject dosed in the LPCN 1148 trial before year end. The primary valuation driver for the company is Tlando, which must wait for full approval and first sales until the expiration of its competitor's exclusivity. In the interim between now and anticipated full approval, Lipocine will be meeting with prospects to identify a path forward for commercialization. We maintain our target price of $10.00.

PROJECTED FINANCIALS

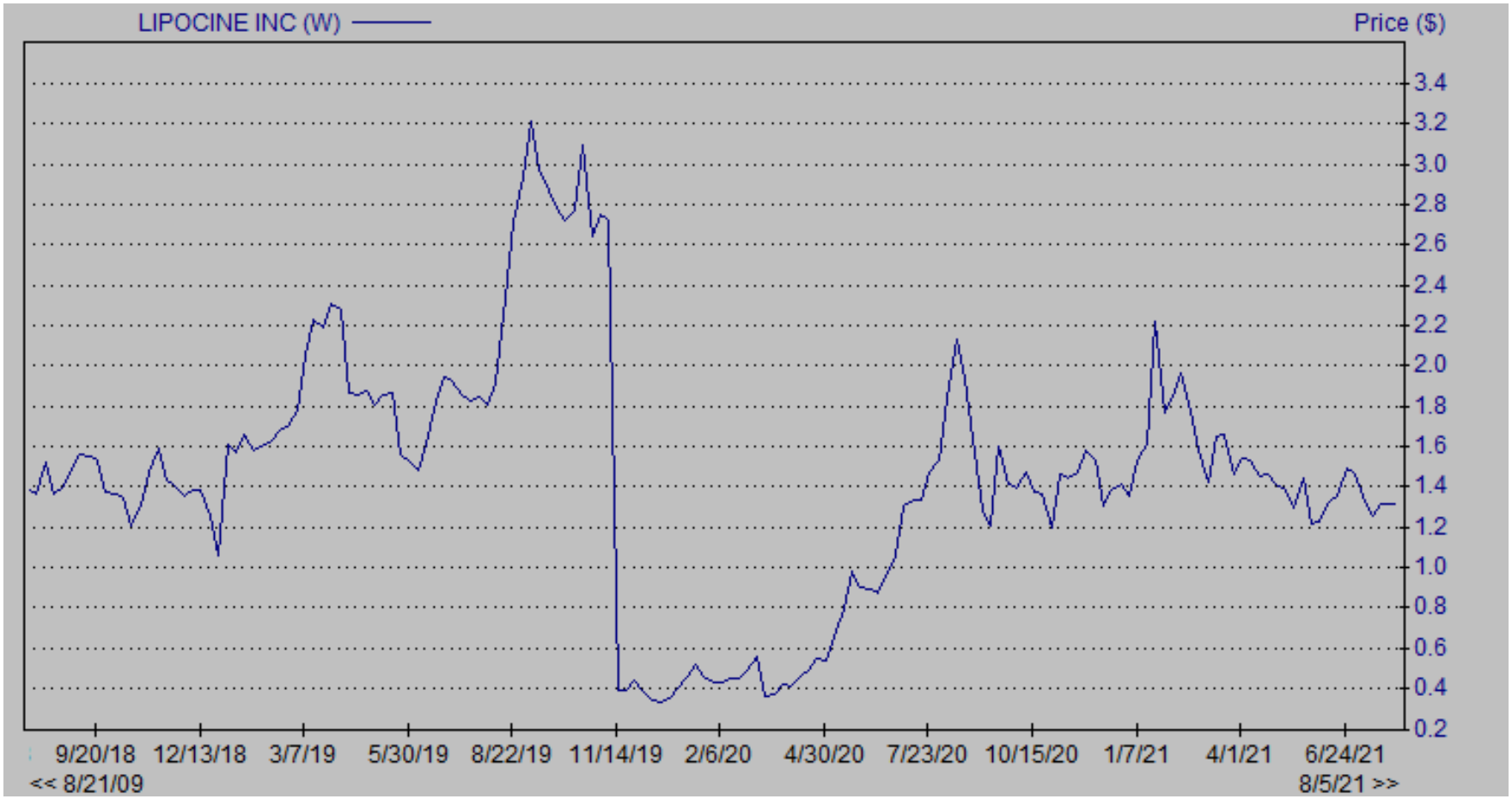
Lipocine Inc. - Income Statement

Lipocine Incorporated	2020 A	Q1 A	Q2 A	Q3 E	Q4 E	2021 E	2022 E	2023 E
Total Revenues ($MM)	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$116.9**	**$134.0**
R&D	$9.7	$1.6	$1.5	$2.5	$2.8	$8.3	$10.0	$10.0
G&A	$8.2	$1.5	$1.5	$2.1	$2.3	$7.5	$8.3	$6.0
Other expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$1.1
Operating Income	($18.0)	($3.1)	($3.0)	($4.6)	($5.1)	($15.8)	$98.6	$116.9
Operating Margin	-					-	-	-
Total Other Income	($3.0)	($0.3)	($3.8)	($0.1)	($0.1)	($4.3)	($0.5)	($0.5)
Pre-Tax Income	($21.0)	($3.4)	($6.8)	($4.7)	($5.2)	($20.1)	$98.1	$116.4
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	($21.0)	($3.4)	($6.8)	($4.7)	($5.2)	($20.1)	$98.1	$116.4
Reported EPS	**($0.38)**	**($0.04)**	**($0.08)**	**($0.05)**	**($0.06)**	**($0.23)**	**$1.09**	**$1.29**
YOY Growth	-					-	-	-
Shares Outstanding	55.7	81.9	88.3	88.5	88.7	86.8	90.0	90.0

Source: Company Filing // Zacks Investment R

HISTORICAL STOCK PRICE

Lipocine Inc. – Share Price Chart



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