

Lipocine Inc.**(LPCN-NASDAQ)****Tentative Approval Granted, Target Up**

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 prior to entry in the clinic.

Current Price (12/9/20) **\$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. 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 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 including the outcome of 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 **\$2.39**
52-Week Low **\$0.30**
One-Year Return (%) **230**
Beta **0.8**
Average Daily Volume (sh) **1,732,767**

Risk Level

Type of Stock
Industry

Above Average
Small-Growth
Med-Biomed/Gene

Shares Outstanding (mil) **65.7**
Market Capitalization (\$mil) **\$86.7**
Short Interest Ratio (days) **4.35**
Institutional Ownership (%) **11.0**
Insider Ownership (%) **2.7**

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 2020 Estimate **N/A**
P/E using 2021 Estimate **N/A**

Zacks Rank **N/A**

ZACKS ESTIMATES**Revenue**

(in millions of \$US)

	Q1	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(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					\$0.0 E
2022					\$116.9 E

	Q1	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(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					-\$0.31 E
2022					\$1.19 E

WHAT'S NEW

FDA Grants Tentative Approval to Tlando

After multiple extensions from the August 2020 target action date, the FDA **granted** tentative approval of Lipocine's (NASDAQ: LPCN) Tlando on December 8th. 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.

Prior to the clarification provided by the FDA in conjunction with the tentative approval, it had been unclear if the exclusivity granted to Jatenzo would extend to Tlando. There had been other testosterone replacement therapies and multiple formulations, including an oral **methyltestosterone**; however, the FDA considers Jatenzo to be the first oral testosterone undecanoate and its exclusivity prevents Tlando from being commercialized in the United States until March 2022.

Lipocine has several alternatives that may allow for earlier marketing of Tlando prior to Jatenzo's 2022 exclusivity expiration; however, none of them are certain. One route may be to appeal the FDA decision through the court system. This could take several months. Another approach may involve a settlement related to the patent infringement lawsuit that is underway where Lipocine appears to have the advantage.¹ The two parties may come together and decide that in return for Lipocine dropping the infringement case, Clarus could waive its exclusivity with respect to Tlando among other adjustments. Lipocine could also progress forward with the patent infringement lawsuit and prevail, which would allow them to begin marketing and sue for damages. None of this is certain at this point and we expect that Lipocine will consult with the both the FDA and legal counsel to gain a better understanding of the tentative approval and possible options.

In parallel with efforts to advance the allowed marketing approval date, we believe that Lipocine will begin to look for a commercialization partner. In the following months, both Lipocine and a prospective partner will have time to determine a valuation, quantify upfronts, milestones and royalties and identify a commercial manufacturer among other prerequisites prior to launch. We had originally anticipated this effort would take several months as negotiation and due diligence takes place.

Valuation

While we had expected a traditional approval which would have supported a launch sometime in the first half of 2021, the tentative approval has extended this until March 2022, or about one year beyond our original expectation. Now that there is a high degree of certainty that Tlando will be commercialized, we increase the probability of this event to 95% and assume a start to sales in late first quarter 2022. First partial year penetration of the addressable market of 1.7 million is expected to be 2.2%, rising to 4.5% by year five. Annual pricing is expected to be just under \$9,000, growing at 3% inflation, as in our previous estimates. We maintain our previous forecasts for LPCN 1144 that assumes first sales in 2025 and a 15% probability of success. These modifications to our model generate a price target of \$10.00 per share.

Summary

After several FDA-issued complete response letters since 2016 and two delays to the latest target action date, the agency has finally decided to extend a tentative approval to Tlando. While at first glance the 15-month delay appears to be a disappointment, it only adds about a year to our previous expectations for marketing launch and allows Lipocine to carefully consider suitors if they choose to work with a partner. There are also several alternate routes which may allow for earlier sales that involve success in the courts or negotiation with Clarus. The approval has dramatically increased the likelihood of ultimate Tlando sales and we increase our estimate to 95%. The improvement in probability and delay by one year in first sales relative to our previous expectations has a net impact of raising our target price to \$10.00.

¹ See our May 28, 2020 [article](#) under Markman Hearing.

PROJECTED FINANCIALS

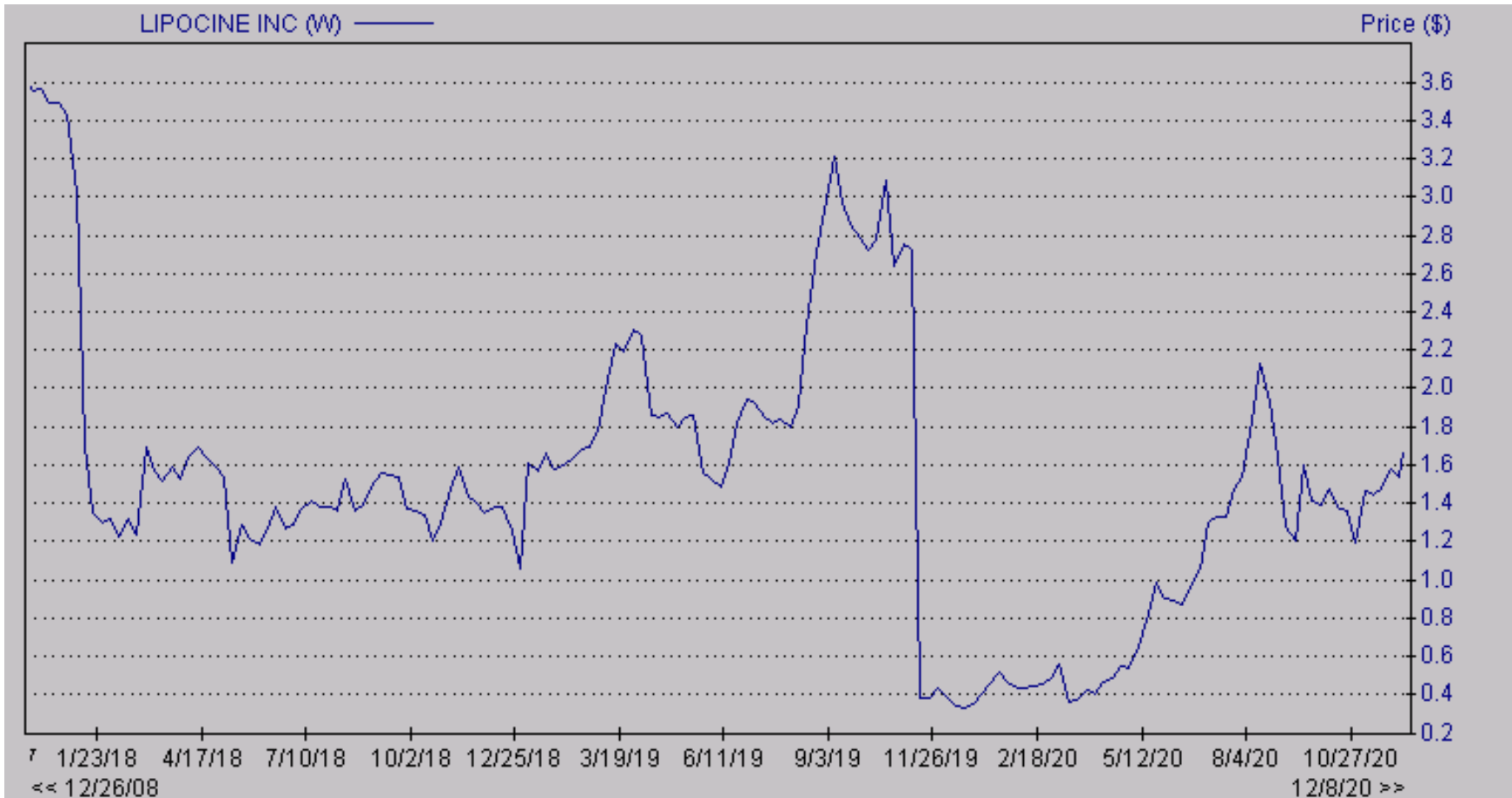
Lipocine Inc. - Income Statement

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	\$0.0	\$116.9
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)	(\$16.6)	\$98.9
<i>Operating Margin</i>	-					-	-	-
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)	(\$22.2)	\$89.4
Taxes & Other	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<i>Tax Rate</i>	0%	0.0	0%	0%	0%	0%	0%	0%
Net Income	(\$13.0)	(\$5.8)	(\$6.4)	(\$4.3)	(\$3.0)	(\$19.5)	(\$22.2)	\$89.4
Reported EPS	(\$0.50)	(\$0.14)	(\$0.13)	(\$0.07)	(\$0.05)	(\$0.35)	(\$0.31)	\$1.19
<i>YOY Growth</i>	-					-	-	-
Shares Outstanding	25.9	41.3	49.8	64.8	65.7	55.4	72.0	75.0

Source: Company Filing // Zacks Investment F

HISTORICAL STOCK PRICE

Lipocine Inc. – Share Price Chart



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