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Lipocine Inc. (LPCN: NASDAQ)

LPCN: 1148 Shows Muscle Loss Reversal

Our DCF model employs a 15% discount rate for Tlando royalty cash flows and a 20% discount rate and a 21% probability adjusted DCF valuation for LPCN 1144, LPCN 1148 and LPCN 1154. We model all of Lipocine's assets to eventually be developed by partners and Lipocine to receive upfronts, milestones and royalties.

Current Price (7/28/2023)	$4.91
Valuation	**$40.00**

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. Tlando, is being commercialized by partner Halozyme and royalties are expected. Lipocine is developing treatments for CNS disorders with its LPCN-1154, -1148 and -2101 assets. Other assets are intended for partnerships including those for the treatment of male hypogonadism; the prevention of pre-term birth, NASH and cirrhosis.

Tlando's US commercialization activities began in June 2022 while ex-US rights remain available. Lipocine's R&D is focused on several indications including -1154 (postpartum depression), -1148 (cirrhosis) & -2101 (epilepsy).

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 making it a primary candidate for partnership. LPCN-1107, -1148 & -1154 have various PK and food effect studies required before beginning the next stage of studies.

SUMMARY DATA

52-Week High	**14.28**
52-Week Low	**3.30**
One-Year Return (%)	**-62.6**
Beta	**1.0**
Average Daily Volume (sh)	**173,299**
Shares Outstanding (mil)	**5.21**
Market Capitalization ($mil)	**25.6**
Short Interest Ratio (days)	**6.9**
Institutional Ownership (%)	**12.0**
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 2023 Estimate	**N/A**
P/E using 2024 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)
2022	$0.0 A	$0.5 A	$0.0 A	$0.0 A	$0.5 A
2023	$0.1 A	$0.0 E	$0.0 E	$0.0 E	$0.1 E
2024					$0.0 E
2025					$0.0 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2022	-$0.67 A	-$0.51 A	-$0.46 A	-$0.43 A	-$2.07 A
2023	-$0.74 A	-$0.64 E	-$0.57 E	-$0.53 E	-$2.47 E
2024					-$2.26 E
2025					-$2.41 E

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WHAT'S NEW

LPCN 1148 Phase II Study Topline Results

Lipocine Inc. (NASDAQ: LPCN) provided a pleasant surprise to investors with its strong Phase II results from its LPCN 1148 study as presented in a July 27th press release. A slide presentation was concurrently provided which can be accessed here. A The study was intended to measure the efficacy, safety and tolerability of LPCN 1148 in adult men with cirrhosis of the liver and sarcopenia on the liver transplant waitlist. The primary endpoint was the increase in the L3 skeletal muscle index (L3-SMI)[1] relative to placebo at week 24. Secondary endpoints included rates of decompensation events including hepatic encephalopathy and participant-reported change in symptoms using the Patient Global Impression of Change (PGI-C) scale.[2]

Subjects in the LPCN 1148 arm demonstrated a material and statistically significant improvement in their muscle mass as measured by the L3-SMI. Active arm participants, with a baseline of 47.8 cm^2/m^2 produced a 3.62 cm^2/m^2 improvement in muscle mass whereas the placebo group saw a slight 0.74 cm^2/m^2 decline from their 45.8 cm^2/m^2 baseline measurement.

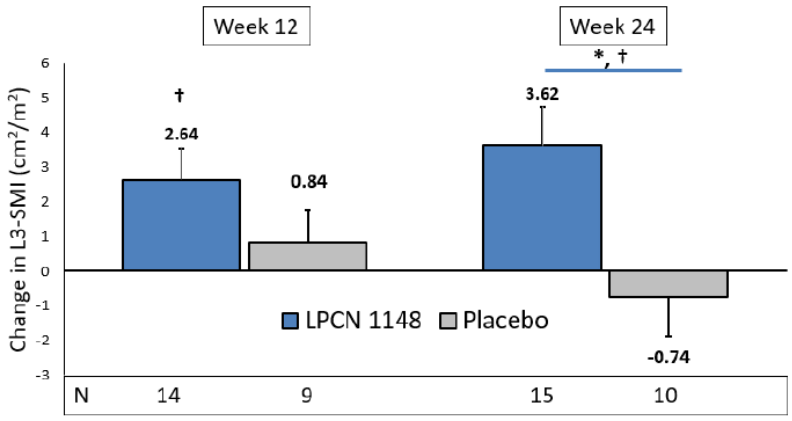
Exhibit I – L3-SMI Change from Baseline[3]

Timepoint	LPCN 1148 (N=15)	Placebo (N=10)	P-value	
			1148 CFB	1148 vs. Placebo
Baseline (cm^2/m^2)	47.8 (1.8)	45.8 (2.3)	N/A	NS
Week 24 CFB (cm^2/m^2)	3.62 (0.93)	- 0.74 (1.14)	<0.001	0.007

LS mean (SE). CFB – Change from baseline

Results from the L3-SMI metric also showed improvement after 12 weeks of therapy. Subjects in the active arm produced a 2.64 cm^2/m^2 improvement after 12 weeks, which was statistically significant at the 5% level of significance.

Exhibit II – L3-SMI Absolute Change from Baseline[4]



LS mean (SE), †P<0.05 for change from baseline; * P=0.007 vs. placebo

[1] The L3 skeletal muscle index (L3-SMI) is a measurement used to estimate skeletal muscle mass and diagnose sarcopenia (age-related loss of muscle mass and strength). It is calculated using a CT scan is done at the L3 vertebral level to measure the cross-sectional area of skeletal muscle. The cross-sectional muscle area is normalized for stature by dividing it by height in meters squared. The resulting value is the L3 skeletal muscle index (L3-SMI) measured in cm2/m2. Normal L3-SMI values are above 55 cm2/m2 for men and above 39 cm2/m2 for women. Sarcopenia is diagnosed if the L3-SMI is below 55 cm2/m2 for men and below 39 cm2/m2 for women. The L3-SMI allows quantification of muscle mass and identification of sarcopenia, which can guide treatment to prevent muscle loss and related adverse health outcomes.
[2] The PGI-C scale is a patient-reported outcome measure used to assess symptoms in patients with chronic conditions. The scale allows patients to rate how their symptoms have changed compared to a recall period, usually the past week. Patients select one of the seven following options with responses scored from 1 to in the following order: 1) Substantially improved, 2) Moderately improved, 3) Slightly improved, 4) No change, 5) Slightly worse, 6) Moderately worse, 7) Substantially worse.
[3] Source: June 27, 2023 Corporate Presentation: LPCN 1148 Phase 2 Study Week 24 Topline Results
[4] Source: June 27, 2023 Corporate Presentation: LPCN 1148 Phase 2 Study Week 24 Topline Results

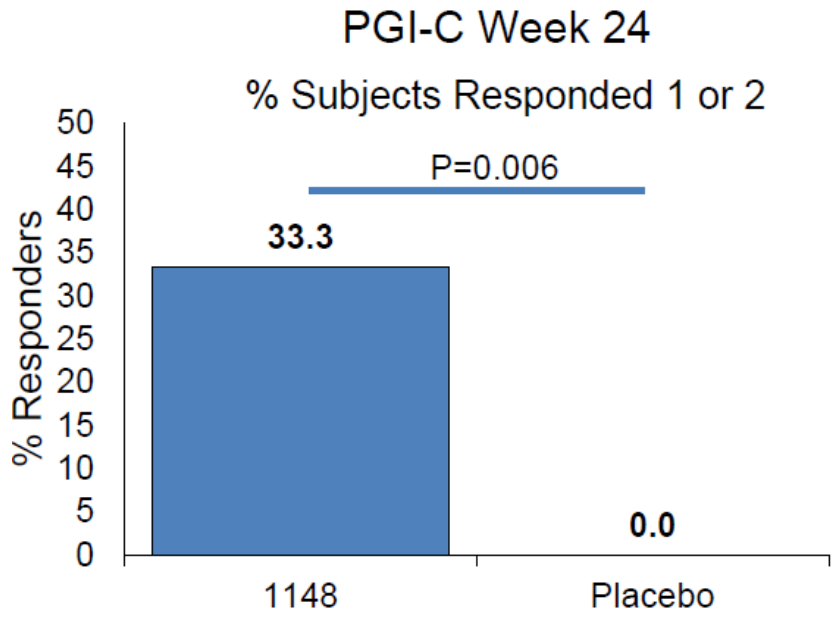
Secondary endpoints examined decompensation events,[5] including hepatic encephalopathy and change in patient reported symptoms. The number of decompensation events were lower in the active arm, both in terms of number and percentage of total. Subjects administered LPCN 1148 had fewer major decompensation events as compared to the placebo group. There were seven major decompensation events in the active arm and ten in the placebo arm. There were also fewer recurrences of hepatic encephalopathy in the active arm with a longer delay to recurrence.

Exhibit III – LPCN 1148 Therapy Produced Fewer Decomposition Events[6]

Parameter	LPCN 1148 (N=15)	Placebo (N=14)	Total (N=29)
Total decompensation events	7	10	17
Total decompensation events > Grade 1	6	10	16
Hepatic Encephalopathy	3	6	9
HE > Grade 1*	2	6	8
Recurrence of HE > Grade 1*	1	6	7
Time to first recurrence of HE > Grade 1 (days)	115	39**	54**

In addition to the objective measures of muscle mass increase and decompensation events, subjective measures were also taken. Individuals enrolled in the trial reported significant improvement in symptoms as measured by the PGI-C scale. At week 24, one third of LPCN 1148 subjects reported that they felt moderately or very much better. Lipocine's principal investigators noted that significantly more 1148-treated subjects reported feeling better and that the mean PGI-C score was significantly lower for 1148 subjects at week 24.

Exhibit IV – PGI-C Week 24[7]



The study also observed two hematological benefits using biomarkers. Hemoglobin improved relative to baseline for 1148 subjects while remaining essentially flat for those in the placebo group. The trial also observed resolution of anemia in four patients at week 24 in the active arm compared with no net change in the placebo group.

[5] Decompensation events in the context of cirrhosis refer to acute episodes where the liver's function suddenly worsens. This is usually due to complications from the underlying cirrhosis. Some key decompensation events include ascites, hepatic encephalopathy, variceal hemorrhage, spontaneous bacterial peritonitis, hepatorenal syndrome, hepatopulmonary syndrome. Decompensation events often require hospitalization for management. They indicate worsening liver dysfunction and that the cirrhosis is progressing. Goals of treatment are to stabilize the acute event and prevent further decompensation. The number of decompensation events and their severity are strong predictors of morbidity and mortality in cirrhosis. Preventing decompensation is a major goal of therapy for patients with stable compensated cirrhosis.
[6] Source: June 27, 2023 Corporate Presentation: LPCN 1148 Phase 2 Study Week 24 Topline Results
[7] Source: June 27, 2023 Corporate Presentation: LPCN 1148 Phase 2 Study Week 24 Topline Results

Exhibit V – Hematologic Benefits[8]

Hemoglobin **Timepoint**	**LPCN 1148 (N=15)**	**Placebo (N=14)**	P-value	
			Change from Baseline	Vs. Placebo
Baseline (g/dL)	11.39 (0.75)	13.04 (0.8)	N/A	NS
Week 24 CFB (g/dL)	1.20 (0.33)	-0.05 (0.35)	0.001	0.02

LS Mean (SE)

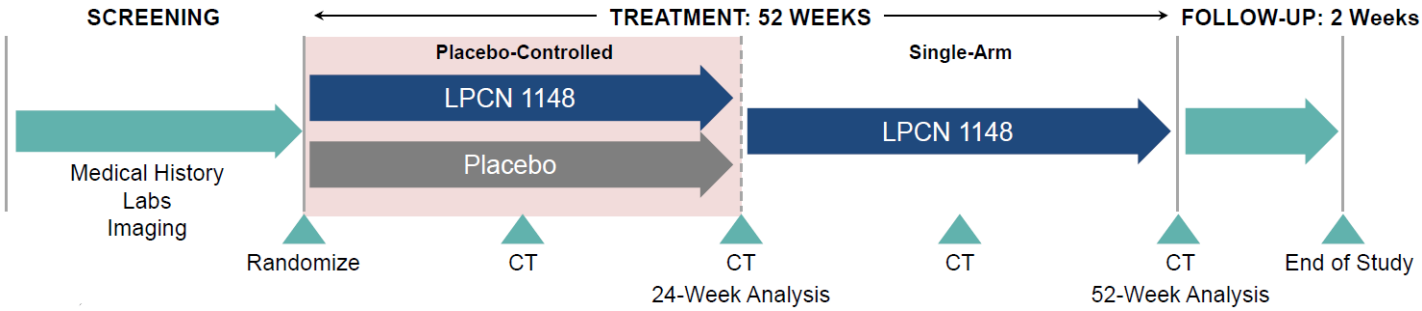
Anemia Status	**LPCN 1148 (N=15)**	**Placebo (N=14)**
Anemic at baseline	11 (73%)	7 (50%)
Anemic at W24	7 (47%)	7 (54%)
Resolution	4 (36%)	1 (14%)
New onset	0 (0%)	1 (14%)

More subjects had resolution of anemia* at Week 24

LPCN 1148 Trial Design

Lipocine's 1148 study design was a Phase II, multicenter, double-blinded, placebo-controlled study that enrolled male subjects with liver cirrhosis and sarcopenia on the liver transplant waitlist. The two-arm, 1:1 randomized study enrolled 29 subjects of which 25 remained in the modified intent to treat (mITT) population.

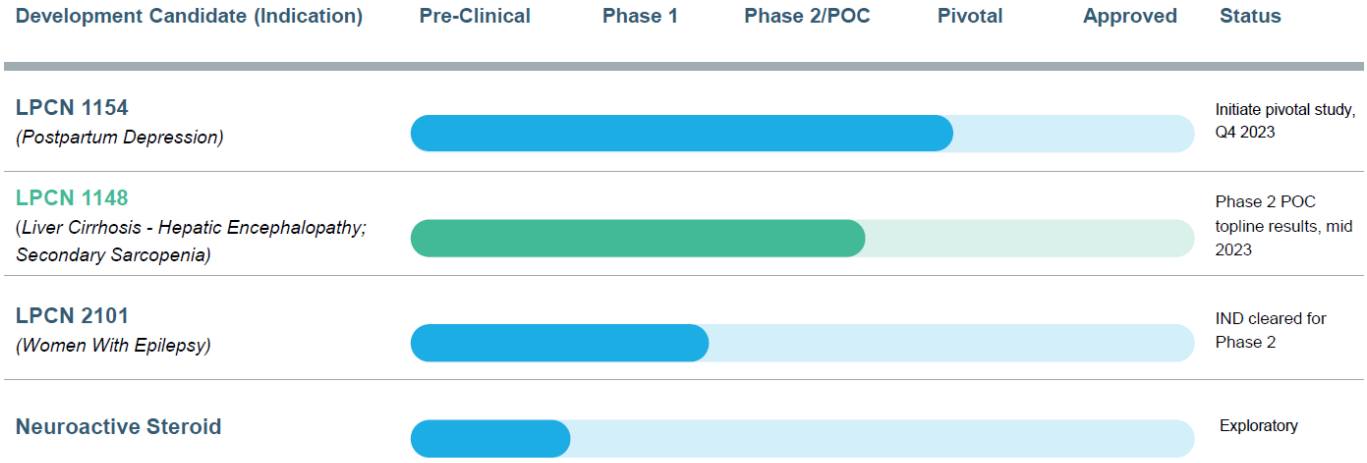
Exhibit VI – LPCN 1148 Proof of Concept Phase II Study Design[9]



Results from the Phase II LPCN 1148 trial were quite good in our opinion, with material and statistically significant improvement in the primary endpoint as well as observed improvement in decompensation events including hepatic encephalopathy and patient symptom perception. The strong results support pursuit of either an additional pivotal study or other accelerated development path to approval with the FDA. Lipocine plans to set up a Type C meeting with the FDA in the second half of 2023, present its findings and determine next steps. With no other approved treatment for cirrhosis, if these results persist in a pivotal or confirmatory study, LPCN 1148 could become standard of care for patients on the liver transplant list and potentially reduce the risk of and the need for liver transplant.

[8] Source: June 27, 2023 Corporate Presentation: LPCN 1148 Phase 2 Study Week 24 Topline Results
[9] Source: June 27, 2023 Corporate Presentation: LPCN 1148 Phase 2 Study Week 24 Topline Results

Exhibit VII - Lipocine Active Pipeline[10]



Summary

On the heels of favorable data from the LPCN 1154 pharmacokinetic study which showed that the oral formulation of brexanolone was within parameters set by the FDA, Lipocine presents data for its LPCN 1148 intended for men with cirrhosis of the liver and sarcopenia. Results of the Phase II study were favorable with a statistically significant increase in the primary endpoint of L3-SMI and improvements in secondary endpoints of decomposition events, particularly hepatic encephalopathy and patient perception of improvement in symptoms. Subjects also exhibited hematologic benefits in terms of anemia status and hemoglobin levels. Next steps for Lipocine are consultation with the FDA to clarify the clinical pathway forward and potential partnership to advance the candidate to the next stage. Lipocine recently shifted its focus towards a CNS-focused strategy and with the positive results for the active arm of the trial in hepatic encephalopathy, the company is well on its way in identifying a valuable asset in this area.

[10] Lipocine June 2023 Corporate Presentation

PROJECTED FINANCIALS

Lipocine Inc. - Income Statement

Lipocine Incorporated	2022 A	Q1 A	Q2 E	Q3 E	Q4 E	2023 E	2024 E	2025 E
Total Revenues ($MM)	**$0.5**	**$0.1**	**$0.0**	**$0.0**	**$0.0**	**$0.1**	**$0.0**	**$0.0**
R&D	$8.6	$3.1	$2.1	$2.1	$1.9	$9.2	$10.0	$10.0
G&A	$4.1	$1.3	$1.1	$0.9	$0.9	$4.2	$5.6	$6.0
Other expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($12.1)	($4.3)	($3.2)	($3.0)	($2.8)	($13.3)	($15.6)	($17.0)
Operating Margin	-					-	-	-
Total Other Income	$1.4	$0.5	($0.1)	($0.1)	($0.1)	$0.1	($0.5)	($0.5)
Pre-Tax Income	($10.8)	($3.9)	($3.3)	($3.1)	($2.9)	($13.2)	($16.1)	($17.5)
Taxes & Other	$0.0	($0.0)				$0.0	$2.0	$3.0
Tax Rate	*0%*	*$0.0*	*0%*	*0%*	*0%*	*0%*	*-12%*	*-17%*
Net Income	($10.8)	($3.9)	($3.3)	($3.1)	($2.9)	($13.2)	($18.1)	($20.5)
Reported EPS	**($2.07)**	**($0.74)**	**($0.64)**	**($0.57)**	**($0.53)**	**($2.47)**	**($2.26)**	**($2.41)**
YOY Growth	-					-	-	-
Shares Outstanding	5.204	5.207	5.210	5.500	5.510	5.357	8.000	8.500

Source: Company Filing // Zacks Investment Research, Inc. Estimates

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HISTORICAL STOCK PRICE

Lipocine Inc. – Share Price Chart



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