# Zacks Small-Cap Research

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## Lipocine Inc. (LPCN-NASDAQ)

***ABPM Results Expected Before Quarter End***

Based on our DCF model and a 20% discount rate, LPCN is valued at approximately $6.00 per share. We apply a 25% probability of eventual sales of Tlando, a 15% probability to LPCN 1111 and a 10% probability to LPCN 1107. No valuation is provided yet for LPCN 1144.

| | |
|---|---|
| Current Price (3/6/19) | $1.98 |
| **Valuation** | **$6.00** |

## 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 pharmocokinetic profile facilitates lower dosing, reduces side effects and eliminates gastrointestinal interactions that limit absorption. Currently, the company has four drugs in development that employ this technology. Two are for the treatment of male hypogonadism, the third for the prevention of pre-term birth and the most recent candidate targets NASH.

The lead product, LPCN 1021 (Tlando), received a second CRL in May 2018 and Lipocine is working to address the deficiencies. We expect a 1H:19 resubmission and FDA response by 2H:19 followed by a 2H:19 launch of Tlando. We apply a 25% probability of FDA approval and eventual sales. LPCN's other TRT product, LPCN 1111, which requires a once daily regimen, is undergoing an end-of-Phase 2 meeting in preparation for a Ph 3 study and is expected to eventually replace the twice daily product. LPCN 1107 for pre-term birth has received an orphan designation and is developing a protocol for conducting an eventual Ph 3 trial.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$2.64** |
| **52-Week Low** | **$1.03** |
| **One-Year Return (%)** | **24.5** |
| **Beta** | **0.10** |
| **Average Daily Volume (sh)** | **638,723** |
| **Shares Outstanding (mil)** | **23.9** |
| **Market Capitalization ($mil)** | **$47.3** |
| **Short Interest Ratio (days)** | **0.09** |
| **Institutional Ownership (%)** | **9.8** |
| **Insider Ownership (%)** | **5.8** |
| **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 2018 Estimate** | **N/A** |
| **P/E using 2019 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) |
|---|---|---|---|---|---|
| 2017 | $0.0 A | $0.0 A | $0.0 A | $0.0 A | $0.0 A |
| 2018 | $0.4 A | $0.0 A | $0.0 A | $0.0 A | $0.4 A |
| 2019 | | | | | $0.0 E |
| 2020 | | | | | $157.4 E |

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2017 | -$0.26 A | -$0.31 A | -$0.22 A | -$0.25 A | -$1.05 A |
| 2018 | -$0.13 A | -$0.15 A | -$0.12 A | -$0.15 A | -$0.55 A |
| 2019 | | | | | -$1.38 E |
| 2020 | | | | | $2.90 E |

## WHAT'S NEW

**2018 Operational and Financial Results**

On March 6, 2019 Lipocine (NASDAQ: LPCN) filed its 2018 10-K and posted its earnings release for the full year ending December 31, 2018. The company reported revenues of $0.4 million, matching our estimate and net loss per share of ($0.55) which compares to our estimate of ($0.56). The most important highlights for 2018 and to date include the May complete response letter (CRL) for Tlando which highlighted deficiencies, two of which required additional study. In response to the CRL, Lipocine launched and completed a definitive phlebotomy study and began the ambulatory blood pressure monitoring (ABPM) study. The company announced and achieved early milestones with LPCN 1144, which is intended for non-alcoholic fatty liver disease (NAFLD) patients. In legal and administrative matters, progress was achieved in the patent dispute with Clarus and the United States Patent and Trademark Office (USPTO) granted Lipocine's Priority Motion.

Revenues for the year were $428,000, representing license payments from Spiraso related to the filing of an NDA. Research and development expenses were $6.5 million for 2018, falling from $11.0 million due to reduced costs related to Tlando development and the completion of the dosing validation (DV) and dosing flexibility (DF) studies that wrapped up earlier in the year as well as lower contract manufacturing and consulting costs compared to 2017 figures. Declines in these areas were offset by an increase in expenditures for LPCN 1144. General and administrative expenses were $5.3 million for the year, contracting from $10.2 million in 2017. These changes were due to a reduction in headcount and fewer pre-commercialization, marketing and sales activities related to Tlando. Professional fees were also lower in the most recent period and a legal settlement in 2017 did not recur in 2018. Net loss for the year was ($11.7) million, or ($0.55) per share.

Cash balance was $20.2 million as of December 31, 2018 which includes $5 million of restricted cash. Cash burn for 2018 was approximately ($12.1) million and cash from financing was $10.7 million representing a $10 million loan from Silicon Valley Bank[1] and $652,000 from proceeds raised on the issuance of equity through the at-the-market (ATM) facility with Cantor Fitzgerald. Cash burn for the year improved by $4.6 million compared to 2017 on reduced R&D and G&A expenses as discussed above.

**Tlando**

After completing the Advisory Committee meeting in January 2018 and suffering the 6 to 13 unfavorable vote from its members, Tlando received a CRL from the FDA in May. The agency identified several deficiencies in its response and identified the following requirements:

- determine the extent, if any, of clinically meaningful *ex vivo* conversion of testosterone undecanoate (TU) to testosterone (T) in serum blood collection tubes to confirm the reliability of T data;
- obtain definitive evidence pre-approval via an ABPM study as to whether Tlando causes a clinically meaningful increase in blood pressure in hypogonadal men, which is a surrogate marker of predicting cardiovascular outcomes;
- verify the reliability of $C_{max}$ data and provide justification for non-applicability of the agreed-upon and pre-specified $C_{max}$ secondary endpoints for Tlando; and,
- determine the appropriate stopping criteria that can reproducibly and accurately identify those patients who should discontinue use of Tlando

The CRL identified additional comments that were not considered approvability issues and not discussed. Following a Post Action meeting with the FDA, two additional trials were designed: the definitive phlebotomy study and ABPM which were designed to determine any clinically meaningful conversion of TU to T and to identify whether or not a clinically meaningful increase in blood pressure was associated with Tlando.

Lipocine reported the successful completion of its phlebotomy study on the last day of 2018, concluding one of the two required studies to resubmit TLANDO to the FDA. The phlebotomy study measured testosterone concentrations in blood samples in plain serum separation tubes at there and five hour intervals after collection. There were 24 observations from 12 patients who were dosed a single oral 225 mg dose of TLANDO. Concentration levels at the indicated intervals were compared to immediately processed concentrations to

[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.

determine any observed variation. The mean percentage difference of testosterone concentrations was -1.0% with a standard deviation of 9.2%. The difference was not statistically significant, demonstrating that there was no significant *ex vivo* TU to T conversion over the time period observed. Recall that this concern was raised by the advisory committee as a result of Clarus' use of special tubes for blood collection for its AdCom in January of 2018 rather than a specific concern over TU to T conversion for Lipocine's data collection. We believe that the results of the study will put to rest this concern that was raised in last year's AdCom.

The ABPM study was launched in June following the Post Action meeting and completed enrollment in November. 138 subjects are participating in the study and results are anticipated prior to the end of the first quarter 2019. The FDA has a broad concern over the risks of increasing blood pressure and has held public workshops on the topic[2] for all medications, with particular focus on high risk categories.

Lipocine anticipates approximately $1.9 million in additional expenditures related to Tlando development, which includes the finalization of the phlebotomy study and the completion of the ABPM study

**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. Further work was undertaken late last year and full enrollment of 36 subjects was achieved in November.

In January, Lipocine announced meaningful liver fat reduction in patients participating in its Liver Fat Study and informed investors that they 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 have been numerous safety studies completed, LPCN was able to perform a proof of concept (POC) clinical study under the original IND to assess liver fat changes. This 36 person study was conducted 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. Interim results from the study were announced in January and demonstrated an absolute mean reduction of 7.6 percentage points in liver fat from baseline and a 38% relative mean liver fat reduction from baseline. The POC work demonstrated an 86% responder rate where subjects showed a minimum of a 4.1% absolute reduction in liver fat compared to baseline and a 71% responder rate where subjects showed a minimum of a 29% reduction in liver fat compared to baseline.

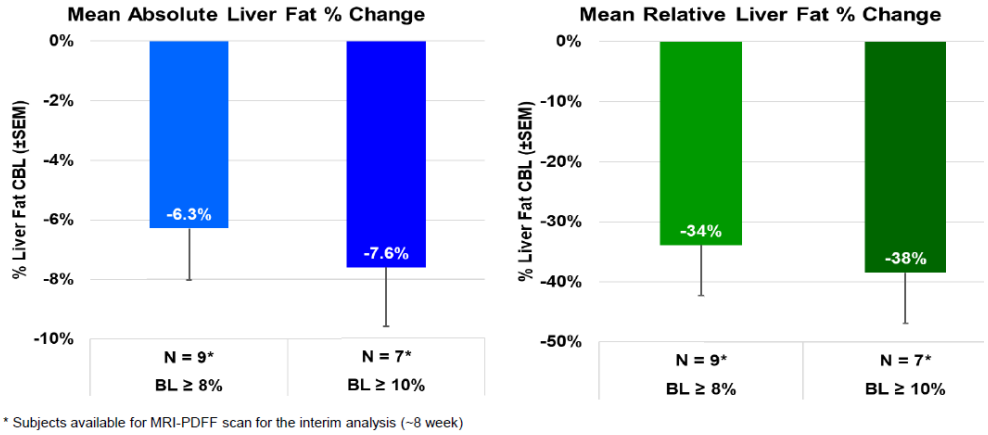
**Exhibit I – Interim Data Summary from Liver Fat Study**

| | |
|---|---|
| Starting Liver Fat | 21.0% |
| Ending Liver Fat | 13.4% |
| % Point Δ in liver fat | 7.6 |
| Reduction in liver fat | 38% |
| n= | 7 |

The reduction in liver fat is comparable with other NASH studies and testosterone undecanoate, in contrast to other novel molecules, is well understood from a safety perspective. While these are interim results from a small study and the data was collected using imaging techniques (MRI-PDFF) rather than biopsy, they are supportive of advancing LPCN 1144 to the next stage. Data were presented at the NASH-TAG Conference in January.

[2] On February 4, 2019, the FDA held a public workshop entitled, "Evaluating the Pressor Effects of Drugs & Ambulatory Blood Pressure Monitoring Studies". The purpose of the workshop was to bring together the stakeholder community, including company sponsors, FDA, and key opinion leaders, to discuss the premarketing assessment of a drug's effect on blood pressure. Topics discussed by the FDA included: study design considerations to definitively assess a drug's effect on blood pressure and appropriate regulatory action; the need to raise physician and patient awareness via labeling or risk mitigation strategies based on blood pressure effects and associated increased cardiovascular risks; the assessment of clinical meaningfulness of blood pressure changes based on findings; appropriately identifying the population at risk; and, a drug's benefit risk analyses.

**Exhibit II – LPCN 1144 Liver Fat Reduction at 8 Weeks[3]**




* Subjects available for MRI-PDFF scan for the interim analysis (~8 week)

Additional results from the POC liver imaging study and the biopsy confirmed *in-vivo* POC study are expected in the first quarter of 2019.

Lipocine filed an IND in January 2019 to conduct a Phase II clinical study of LPCN 1144 in NASH with biopsy confirmed subjects. The company later announced that they had received clearance from the agency to start the Phase II study. It will be a prospective, multi-center, randomized, placebo controlled, multiple-arm study in male, hypogonadal, biopsy-confirmed NASH patient with grade F2 or F3 fibrosis and an anticipated 36-week treatment period. We anticipate that the company will seek additional capital and determine the study design over the next few months, launching the Phase II mid-year 2019.

Applying some quick, back of the napkin math to this space, with a global market size of $20 to $40 billion and a disease that affects from 10 to 40 million Americans,[4] assuming even a 5% market penetration could generate revenues in the $1 to $2 billion range. Now that Lipocine has the go-ahead to start a Phase II study, we anticipate they will seek capital to support the program before it starts. We see management turning its attention to the LPCN 1144 program after resubmitting the NDA for Tlando.

**Clarus Patent Dispute**

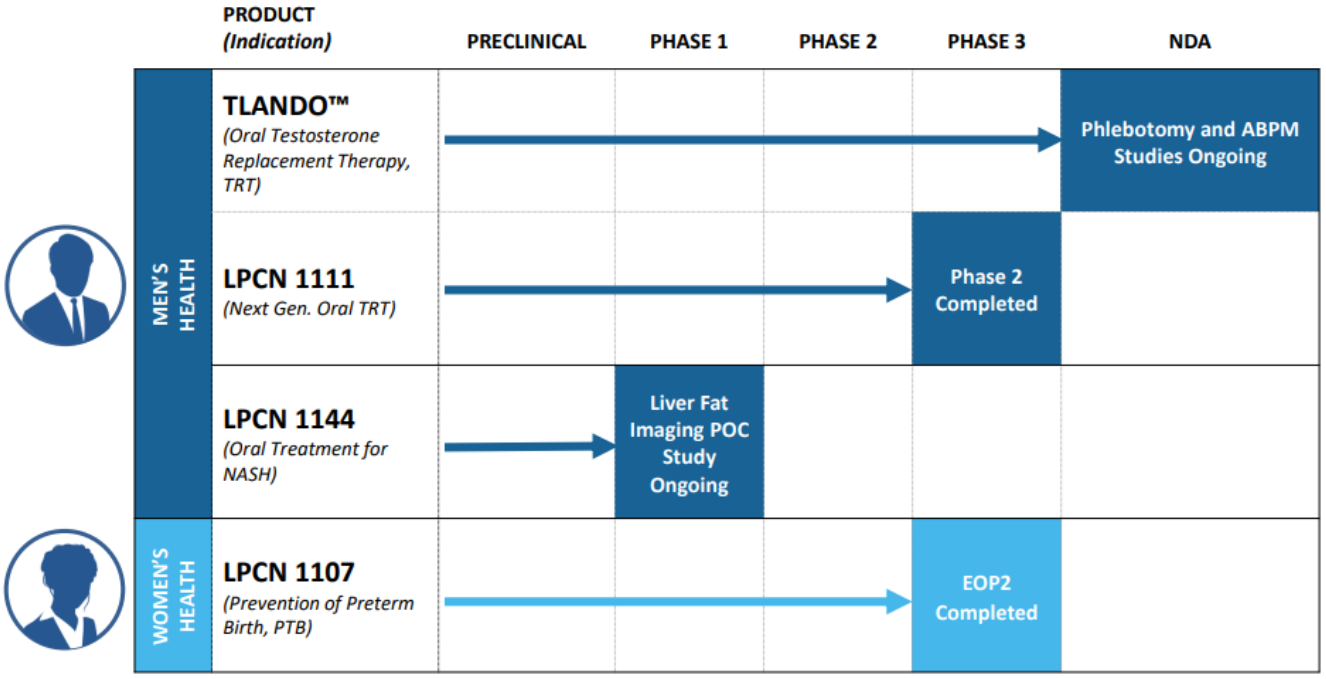
Lipocine has also seen continued success in its patent dispute against Clarus regarding patent number 8,828,428. The United States Patent and Trademark Office (USPTO) granted Lipocine's Priority Motion in the case and entered an adverse judgment against Clarus. This cancels Clarus' claims to the '428 patent. On February 19th, 2019 Clarus filed an appeal of the ruling, as expected. This initial action is inexpensive and quickly completed. However, if Clarus wants to continue the fight against Lipocine, they must subsequently file a brief, which will require greater expense and effort. This will require Lipocine to file a rebuttal brief, then the appeal will be heard at the federal circuit level, rather than by the USPTO. Based on our understanding, it is rare for a federal court to overturn a USPTO ruling. We are hopeful that Clarus will accept the USPTO ruling and avoid filing the brief, thereby reducing additional costs for both parties and clearing the way for TLANDO to be commercialized following approval.

[3] Kim, Kilyoung, et al. Hypogonadism is Associated with NAFLD: LPCN 1144 MRI-PDFF Clinical Results. Keystone Symposia on Integrated Pathways of Disease in NASH and NAFLD Conference. Santa Fe, New Mexico, January 22, 2019.
[4] See our previous report for citations: LPCN: ANDROGEN THERAPY IN NASH: A COMPREHENSIVE APPROACH

**Milestones**

- Executed $10 million loan agreement with Silicon Valley Bank – January 2018
- CRL Issued for Tlando – May 8, 2018
- Type A/Post Action Meeting – July 19, 2018
- Tlando phlebotomy study results – 4Q:18
- Anticipated Tlando ambulatory blood pressure results – 1Q:19
- Resubmission of Tlando NDA – 1H:19
- Complete in-vivo model POC study in biopsy-confirmed NASH – 1Q:19
- POC clinical study results in imaging-confirmed NAFLD/NASH patients – 1Q:19
- Anticipated FDA Response for Tlando NDA – 2H:19
- Launch Tlando – 2020
- Launch Phase II LPCN 1144 – 2019/2020

**Exhibit III – Lipocine Pipeline**




**Summary**

LPCN has initiated two studies to address the discrepancies raised in the CRL for Tlando. The phlebotomy study has been completed and the ABPM study is expected to complete in the next few weeks. Depending on the composition of the data, we anticipate that all the necessary information for resubmission will be available from one to three months after completion of the ABPM study. We forecast a 25% probability that Lipocine will obtain approval and commercialize Tlando. Based on our estimates, first sales should commence in early 2020. Lipocine will then be able to shift its development efforts towards other candidates in the pipeline. We are optimistic on the opportunity for LPCN 1144 given the large end market, promising preliminary data and well known safety profile for TU. We will add a valuation component for LPCN 1144 when it begins its Phase II study.

Our target price is derived using a 20% discount rate and probability of eventual sales for LPCN 1021, LPCN 1111 and LPCN 1107 of 25%, 15% and 10% respectively. Based on our estimates of sales, expenses, risk, and updates provided in company documents, our target price remains at $6.00 per share.

## PROJECTED FINANCIALS

### Lipocine Inc. - Income Statement

| Lipocine Incorporated | 2017 A | Q1 A | Q2 A | Q3 A | Q4 A | 2018 A | 2019 E | 2020 E |
|---|---|---|---|---|---|---|---|---|
| **Total Revenues** | **$0.0** | **$0.4** | **$0.0** | **$0.0** | **$0.0** | **$0.4** | **$0.0** | **$157.4** |
| R&D | $11.0 | $1.4 | $1.5 | $1.4 | $2.2 | $6.5 | $22.0 | $23.0 |
| G&A | $10.2 | $1.7 | $1.7 | $0.9 | $1.0 | $5.3 | $7.6 | $28.6 |
| Other expenses | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $1.1 |
| Operating Income | ($21.2) | ($2.6) | ($3.2) | ($2.4) | ($3.2) | ($11.33) | ($29.6) | $49.6 |
| *Operating Margin* | - | | | | | - | - | - |
| Total Other Income | $0.2 | ($0.1) | ($0.1) | ($0.1) | ($0.1) | ($0.3) | ($0.5) | ($0.5) |
| Pre-Tax Income | ($21.0) | ($2.7) | ($3.3) | ($2.5) | ($3.2) | $11.7 | ($30.1) | $49.1 |
| Taxes & Other | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $5.2 |
| *Tax Rate* | *0%* | *$0.0* | *0%* | *0%* | *0%* | *0%* | *0%* | *-11%* |
| Net Income | ($21.0) | ($2.7) | ($3.3) | ($2.5) | ($3.2) | ($11.7) | ($30.1) | $54.3 |
| | | | | | | | | |
| **Reported EPS** | **($1.05)** | **($0.13)** | **($0.15)** | **($0.12)** | **($0.15)** | **($0.55)** | **($1.38)** | **$2.43** |
| *YOY Growth* | - | | | | | - | - | - |
| Shares Outstanding | 20.1 | 21.3 | 21.3 | 21.3 | 21.6 | 21.4 | 21.9 | 22.4 |

*Source: Company Filing // Zacks Investment Research, Inc. Esti*

## HISTORICAL STOCK PRICE

**Lipocine Inc. – Share Price Chart[5]**


[5] Price chart courtesy of barchart.com

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