Zacks Small-Cap Research

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# Lipocine Inc. (LPCN-NASDAQ)

***FDA Issues CRL; Updating Target Price***

Based on our DCF model and a 20% discount rate, LPCN is valued at approximately $9.00 per share. We apply a 50% probability of eventual sales of LPCN 1021 (TLANDO), a 15% probability to LPCN 1111 and a 10% probability to LPCN 1107.

| | |
|---|---|
| Current Price (6/29/16) | $3.10 |
| **Valuation** | **$9.00** |

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

The lead product, LPCN 1021 (Tlando), received a CRL on June 28, 2016 due to concerns regarding the titration approach used in the trial compared to what is recommended on the label. We anticipate a one year delay as a result. LPCN's other TRT product, LPCN 1111, which provides a once daily regimen, is 2 years behind 1021 and is expected to eventually replace the twice daily product. LPCN 1170 for pre-term birth has received an orphan designation and is currently in Phase 1 trials.

While a setback, we do not see the FDA's concerns as fatal for Tlando and reduce our price target to $9.00.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$19.23** |
| **52-Week Low** | **$3.10** |
| **One-Year Return (%)** | **-62.0** |
| **Beta** | **1.47** |
| **Average Daily Volume (sh)** | **305,169** |
| **Shares Outstanding (mil)** | **18.3** |
| **Market Capitalization ($mil)** | **$56.6** |
| **Short Interest Ratio (days)** | **5.74** |
| **Institutional Ownership (%)** | **49** |
| **Insider Ownership (%)** | **16** |
| **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 2016 Estimate** | **N/A** |
| **P/E using 2017 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 $)

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2015 | $0.0 A | $0.0 A | $0.0 A | $0.0 A | $0.0 A |
| 2016 | $0.0 A | $0.0 E | $0.0 E | $0.0 E | $0.0 E |
| 2017 | | | | | $0.0 E |
| 2018 | | | | | $58.3 E |

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2015 | -$0.23 A | -$0.26 A | -$0.35 A | -$0.25 E | -$1.11 E |
| 2016 | -$0.38 A | -$0.35 E | -$0.40 E | -$0.40 E | -$1.54 E |
| 2017 | | | | | -$1.77 E |
| 2018 | | | | | $0.69 E |

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## WHAT'S NEW

**FDA Issues Complete Response Letter Regarding LPCN 1021**

On June 29, 2016, Lipocine Inc. (NASDAQ:LPCN) announced that the Food and Drug Administration (FDA) had issued a Complete Response Letter (CRL) for LPCN 1021 (Tlando). The CRL means that the FDA will not approve Tlando as it was presented in the New Drug Application (NDA).

The CRL highlighted deficiencies related to dosing as provided in the label. The Phase 3 trial had adjusting dosing based on 15 blood draws taken over a 24 hour period; however, the proposed label only relied on only one blood draw to determine the proper titration. The FDA felt that this inconsistency would lead to dosing errors and as a result will require evidence to support a single point window after administration of Tlando where the patient is evaluated and up-titrated or down-titrated to achieve the optimal dose. Prior to the letter, management felt that the trial design was sufficient as it was based on the Phase 3 trial for Axiron, an Eli Lilly topical testosterone product which was approved in 2010.

Lipocine noted that the CRL did not include any language that questioned LPCN 1021's efficacy, safety, adverse events, side effects or the effectiveness of Lipocine's proprietary Lip'ral drug delivery technology.

Lipocine will require additional clarity from the FDA before taking the next step and will request a Type A meeting, which we expect will occur within the next 30 days. Prior to the meeting there is a high degree of uncertainty as to what may be required to ultimately gain approval from the FDA. Based on our discussions with management, there may be several pathways of varying duration and expense required before a new application satisfies the regulatory agency.

In a best case scenario, a label bridging study using existing data may satisfy regulators. This approach tests the pharmacokinetics of a drug under different dosing titrations by extrapolating data that has already been collected. Under this scenario we anticipate only a minimal amount of additional expense and a delay of four to eight months. We estimate 30 days for the initial FDA meeting, a minimum of 30 days to conduct additional analysis and 60 days for a Class 1 resubmission response from the FDA.

If the FDA requires additional substantiation regarding an optimal titration point, then a 45-day safety and efficacy study may be required with costs ranging from $1 to $5 million depending upon the agency's needs. Under this scenario, we anticipate it could take from 12 to 15 months to obtain approval. We estimate 30 days for the initial FDA meeting, 2 to 3 months to enroll and set up for the trial, 45 days to conduct the trial, 2 to 3 months to analyze data and 6 months for a Class 2 resubmission response from the FDA.

It is possible that a longer study may be required with additional expense in excess of $5 million and a duration on par with the 15-month SOAR trial. However, we think this is unlikely given the narrow focus of the CRL on titration and dosing requirements.

We do not believe that the FDA's response threatens Lipocine's Lip'ral technology or will have a materially negative impact on the other two programs in the pipeline. Lipocine anticipates consulting with the FDA regarding trial design following the end of the Phase 2 trials for LPCN 1111 (once-daily testosterone) and LPCN 1107 (pre-term birth) and expects to meet with the agency in later this year. We anticipate that Lipocine will make any and all adjustments necessary to ensure that dosing and titration protocols satisfy the FDA's requirements for the other development programs.

**Our Estimates**

Compared to our previous estimates, we adjust our forecasts to reflect a one year delay in the launch of Tlando and anticipate additional costs of $4 million. Due to the heightened level of uncertainty regarding timeline, costs and FDA requirements, we increase our discount rate from 15% to 20% and reduce the likelihood of approval from 65% to 50%. These changes shrink the target price from $19.00 per share to $9.00 per share. We estimate that Lipocine will be able to achieve a 4% share of the TRT market with Tlando by 2020 at which time once-a-day testosterone (LPCN 1111) will take the reins of LPCN's testosterone franchise. Penetration of Lipocine's once-a-day product is anticipated to hold 4.5% of the target market by 2024 due to expanding salesforce productivity and increased awareness of the product.

We anticipate that expenses will increase in 2016, and assuming that LPCN 1021 is approved in 2017, we believe they will continue to rise in following years as well. Increased costs will come from the addition of an adequate sized sales force to promote the drug, maintenance, expansion and protection of the IP portfolio, and the addition of other activities to prepare for the commercialization launch.

Currently, management anticipates developing a 50-person sales force to focus on endocrinologists and urologists. The company is also contemplating working with a partner to focus on the primary care physician segment. Due to additional trial costs, we increase our total expenses forecast to $29 million in 2016 (up from $18 million in 2015 and up $2 million from our previous estimates), and to $37 million in 2017. Refer to our model at the end of the report for additional detail.

**Conclusion**

While the FDA's issuance of a complete response letter will delay the launch of Tlando and potentially increase trial costs by several million dollars, we believe that the narrow focus of the FDA's concerns and emphasis on dosing protocols rather than on a fundamental flaw with the Lip'ral technology support eventual approval. While the requirements to satisfy the FDA will only become clear after Lipocine meets with the agency, based on current information, we have conservatively estimated an additional twelve months will be required to launch Tlando placing first sales in 2018. We will adjust our model accordingly as additional details become available. Based on our updated estimates of sales, expenses and risk, our target price moves from $19.00 per share to $9.00 per share.

## PROJECTED FINANCIALS

**Lipocine Inc. -** Income Statement

| Lipocine Incorporated | 2015 A | Q1 A | Q2 E | Q3 E | Q4 E | 2016 E | 2017 E | 2018 E |
|---|---|---|---|---|---|---|---|---|
| **Total Revenues** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0** | **$0.0** | **$58.3** |
| CoGS | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $20 |
| *Product Gross Margin* | | | | | | | | *65.0%* |
| R&D | $12.6 | $2.7 | $3.8 | $4.8 | $4.9 | $16.2 | $22.0 | $22.0 |
| G&A | $5.8 | $4.4 | $2.8 | $2.8 | $2.8 | $12.8 | $15.0 | $19.0 |
| Other expenses | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.1 | $0.1 | $0.1 |
| Operating Income | ($18.4) | ($7.1) | ($6.6) | ($7.6) | ($7.7) | ($29.0) | ($37.1) | ($3.2) |
| *Operating Margin* | - | | | | | - | - | - |
| Total Other Income | $0.2 | $0.1 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| Pre-Tax Income | ($18.2) | ($7.0) | ($6.6) | ($7.6) | ($7.7) | ($29.0) | ($37.1) | ($3.1) |
| Taxes & Other | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $18.3 |
| *Tax Rate* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *581%* |
| Net Income | ($18.2) | ($7.0) | ($6.6) | ($7.6) | ($7.7) | ($29.0) | ($37.1) | $15.1 |
| **Reported EPS** | **($1.11)** | **($0.38)** | **($0.35)** | **($0.40)** | **($0.40)** | **($1.54)** | **($1.77)** | **$0.69** |
| *YOY Growth* | | | | | | - | - | - |
| Shares Outstanding | 16.5 | 18.3 | 18.7 | 19.0 | 19.2 | 18.8 | 21.0 | 22.0 |

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

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## HISTORICAL STOCK PRICE




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