Zacks Small-Cap Research
*Sponsored – Impartial - Comprehensive*

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# Cerecor Inc

**(CERC-NASDAQ)**

***CERC: Positive Results for Phase 1 Trial of CERC-301…***

Based on our probability adjusted DCF model that takes into account potential future revenues from CERC-301, CERC-611, commercial operations, and sales of PRVs, using a 12% discount rate CERC is valued at $8.50/share.

| | |
|---|---|
| Current Price (04/17/19) | $5.18 |
| **Valuation** | **$8.50** |

## OUTLOOK

On April 15, 2019, Cerecor, Inc. (CERC) announced positive topline results from the Phase 1 trial of CERC-301 in Parkinson's Disease patients with neurogenic orthostatic hypotension (nOH). nOH is caused by decreased release of norepinephrine from sympathetic vasomotor neurons that can result in both inadequate vasoconstriction and heart rate upon standing and occurs in neurodegenerative diseases. The company reported that all doses showed a clinically meaningful increase over placebo and a robust increase in systolic blood pressure from baseline to 6 hours. There were no serious adverse events and all doses were well tolerated. We anticipate topline results from the full study by the end of the second quarter of 2019.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$7.22** |
| **52-Week Low** | **$3.02** |
| **One-Year Return (%)** | **48.42** |
| **Beta** | **2.26** |
| **Average Daily Volume (sh)** | **103,380** |
| **Shares Outstanding (mil)** | **43** |
| **Market Capitalization ($mil)** | **$221** |
| **Short Interest Ratio (days)** | **N/A** |
| **Institutional Ownership (%)** | **50** |
| **Insider Ownership (%)** | **80** |
| **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** | **-7.6** |
| **P/E using 2019 Estimate** | **-6.8** |

| | |
|---|---|
| **Risk Level** | **High** |
| **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) |
|---|---|---|---|---|---|
| 2018 | 4.5 A | 4.8 A | 4.1 A | 5.0 A | 18.3 A |
| 2019 | 5.0 E | 5.1 E | 5.3 E | 5.6 E | 21.0 E |
| 2020 | | | | | 23.0 E |
| 2021 | | | | | 25.0 E |

**Earnings per Share**

| | Q1 (Mar) | Q2 (Jun) | Q3 (Sep) | Q4 (Dec) | Year (Dec) |
|---|---|---|---|---|---|
| 2018 | -$0.12 A | -$0.19 A | -$0.71 A | -$0.18 A | -$1.20 A |
| 2019 | -$0.18 E | -$0.18 E | -$0.18 E | -$0.17 E | -$0.70 E |
| 2020 | | | | | -$0.64 E |
| 2021 | | | | | -$0.65 E |

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## WHAT'S NEW

*Positive Interim Results for CERC-301 in nOH*

On April 15, 2019, Cerecor, Inc. (CERC) announced positive interim results for the Phase 1 study of CERC-301 in Parkinson's Disease (PD) patients suffering from neurogenic orthostatic hypotension (nOH). The Phase 1 trial is a double blind, randomized, placebo controlled trial with a target enrollment of 20 Parkinson's patients with nOH. Each patient will have five visits in which they will receive four single escalating doses of drug (8, 12, 16, or 20 mg) or placebo. Patients then complete six orthostatic standing tests over a six hour period: blood pressure is recorded while in supine position with the head elevated, immediately before standing, and then one minute, three minutes, and five minutes after standing. This is repeated every hour for six hours. While the primary endpoints of the study are safety, tolerability, and pharmacokinetics, a key secondary endpoint is the effect of CERC-301 on blood pressure. An overview of the trial is given below.

**Phase 1 SAD in PD patients with nOH**

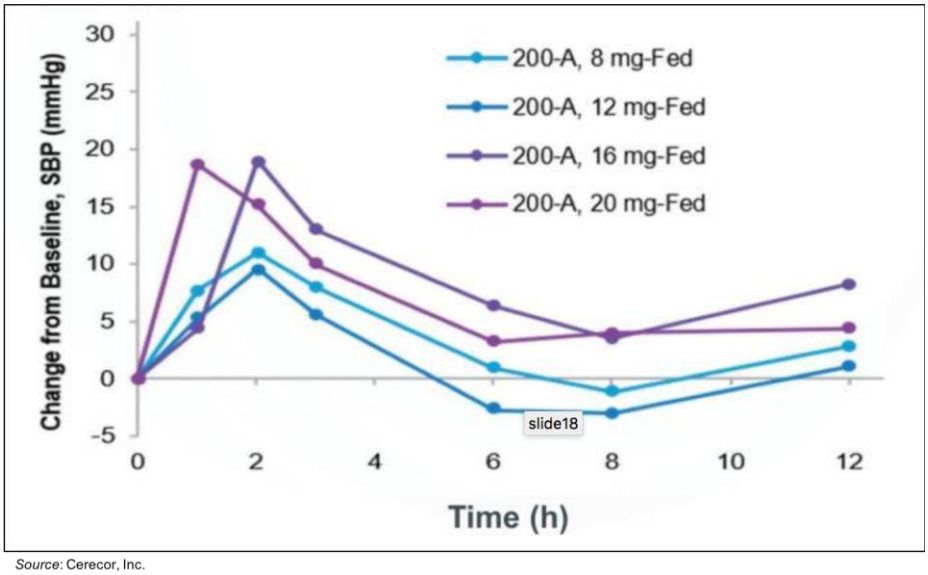
| | |
|---|---|
| **Enrollment** | • 12 active centers in US |
| **Design** | • N = 20 (8, 12, 16 & 20 mg)<br>• Double-blind, randomized, pbo-controlled<br>• Interim Analysis at 10 patients |
| **Endpoints** | • Safety, Tolerability & PK<br>• BP measurement<br>• Symptomatic assessment |

| | Visit 1 | Visit 2 | Visit 3 | Visit 4 | Visit 5[a] |
|---|---|---|---|---|---|
| Arm 1 (n = 5) | pbo | 8 mg | 12 mg | 16 mg | 20 mg |
| Arm 2 (n = 5) | 8 mg | pbo | 12 mg | 16 mg | 20 mg |
| Arm 3 (n = 5) | 8 mg | 12 mg | pbo | 16 mg | 20 mg |
| Arm 4 (n = 5) | 8 mg | 12 mg | 16 mg | pbo | 20 mg |

*Source:* Cerecor, Inc.

The company reported interim data from half of the patients that are intended to enroll. The data showed that the highest dose demonstrated an improvement in systolic blood pressure (SBP) of 15.6 mmHg at one-hour post-dose that ultimately reached 26.7 mmHg in SBP over baseline at the 6-hour timepoint. Whether the company will test additional doses above 20 mg will be determined after the trial is complete. Importantly, all doses tested were safe and well tolerated, just as was seen in previous trials of the drug. We anticipate the trial completing and topline data being reported by the end of the second quarter of 2019.

CERC-301 is an orally available specific antagonist against the NMDA receptor subunit 2B (NR2B). It has previously been studied in approximately 400 patients and healthy volunteers. The following chart shows the rapid and sustained change in systolic blood pressure that occurs upon taking CERC-301, which is the basis for its use in nOH.




*Source:* Cerecor, Inc.

Background on nOH

Orthostatic hypotension (OH) occurs due to an inability to maintain blood pressure upon standing. The technical definition of OH is a sustained reduction in systolic blood pressure of at least 20 mm Hg or diastolic blood pressure of at least 10 mm Hg within three minutes of standing. OH can result from either non-neurogenic or neurogenic causes and be either acute or chronic. Non-neurogenic causes include dehydration, cardiac abnormalities (bradycardia/tachyarrhythmia/myocardial infarction), and prolonged standing.

nOH is caused by decreased release of norepinephrine from sympathetic vasomotor neurons that can result in both inadequate vasoconstriction and heart rate upon standing (Freeman *et al*., 2011). The disorder occurs mostly in those with specific diseases caused by accumulation of alpha-synuclein, including Parkinson's disease (PD), multiple system atrophy (MSA), Lewy body dementia, and pure autonomic failure (PAF). It can also occur in patients with peripheral neuropathies, including diabetic neuropathy, amyloidosis, and Guillan-Barre syndrome.

In contrast to OH, which is relatively common in elderly patients (prevalence of 15% in those aged 65 to 69 to 26% in those aged 85 years or older, Rutan *et al*. 1992), nOH is a rare disorder and is considered as an orphan disease, affecting approximately 80,000 individuals with PD, MSA, and PAF in the U.S. (FDA briefing documents for Northera®).

Few studies have examined the prognosis for patients with nOH, however a study of 104 nOH patients over a 14-year period in Italy showed that the condition increased the risk of death three-fold compared to the general population in that area (Maule *et al*., 2012). On a day to day basis, the condition can result in severe morbidity for patients that includes significant drops in blood pressure during the day. This can lead to an interference in normal daily activities, with the increased debilitation potentially leading to a poor quality of life (QOL).

Non-pharmacological therapies for nOH include drinking more water (to help increase blood volume), increase salt in the diet, avoid carbohydrate-heavy meals, elevating the head of the bed, slowly rising when standing, and getting regular exercise. There are currently two therapies approved in the U.S. for the treatment of nOH: midodrine, which was approved in 1996, and droxidopa (Northera®), which was approved in 2014.

- Midodrine (ProAmatine®): This is a peripherally acting $\alpha$-andrenergic agonist. The drug was originally approved based on clinical data showing an effect on the surrogate endpoint of increase in standing blood pressure, which is thought to confer clinical benefit. It is currently available as a generic.

- Droxidopa (Northera®): This is a synthetic amino acid precursor for norepinephrine that is capable of crossing the blood-brain barrier. Droxidopa was originally approved in Japan for the treatment of hypotension and nOH in 1989. Chelsea Therapeutics acquired the rights to droxidopa and following approval of the compound by the FDA the company was acquired by Lundbeck for $658 million. Lundbeck reported 2017 revenues for Northera® of DKK 1,644 (approximately $270 million).

*Leadership Changes*

On April 11, 2019, Cerecor announced that Simon Pedder, PhD has been appointed Executive Chairman of the Board, with the ultimate goal being his transition to the role of CEO to replace Peter Greenleaf. Dr. Pedder is currently the Chief Business and Strategy Officer at Athenex, Inc. (ATNX) and has served on the Board of Directors for Cerecor since April 2018. Dr. Pedder was previously the President and CEO of Chelsea Therapeutics and was responsible for the development and approval of Northera®, the most recent drug to be approved for the treatment of nOH.

**Conclusion and Valuation**

We're encouraged by the interim data announced by Cerecor regarding CERC-301 in nOH patients. Unfortunately, a direct comparison with Northera® isn't possible at this time as studies similar to the one currently being conducted by Cerecor were not done for that compound, however the fact that CERC-301 is able to have a sustained effect on increasing blood pressure is a good sign. Based on these initial results we have slightly increased the probability for approval, which has resulted in an increase to our valuation to $8.50.

## PROJECTED FINANCIALS

| Cerecor, Inc. | 2018 A | Q1 E | Q2 E | Q3 E | Q4 E | 2019 E | 2020 E | 2021 E |
|---|---|---|---|---|---|---|---|---|
| Commercial Group | $18.3 | $5.0 | $5.1 | $5.3 | $5.6 | $21.0 | $23.0 | $25.0 |
| CERC-301 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| CERC-611 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| CERC-406 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| LIcense Revenue | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| Grant Revenue | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| **Total Revenues** | **$18.3** | **$5.0** | **$5.1** | **$5.3** | **$5.6** | **$21.0** | **$23.0** | **$25.0** |
| Cost of Sales | $7.5 | $2.0 | $2.1 | $2.1 | $2.2 | $8.4 | $8.9 | $9.8 |
| *Product Gross Margin* | *59%* | *60%* | *59%* | *60%* | *61%* | *60%* | *61%* | *61%* |
| Research & Development | $5.8 | $3.6 | $3.8 | $4.0 | $4.2 | $15.6 | $17.0 | $19.0 |
| Acquired in-process R&D | $18.7 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| General & Administrative | $10.7 | $2.3 | $2.3 | $2.4 | $2.5 | $9.5 | $10.0 | $10.5 |
| Sales and Marketing | $8.5 | $3.0 | $3.0 | $3.0 | $3.0 | $12.0 | $13.0 | $14.0 |
| Amortization Expense | $4.5 | $1.2 | $1.2 | $1.2 | $1.2 | $4.8 | $4.8 | $4.8 |
| Impariment of Intangible Assets | $1.9 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| Change in fair value of contingent consideration | $0.1 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 |
| Operating Income | ($39.3) | ($7.1) | ($7.3) | ($7.4) | ($7.5) | ($29.3) | ($30.7) | ($33.1) |
| *Operating Margin* | *-215%* | - | - | - | - | *-140%* | *-133%* | *-132%* |
| Other (expense) income | ($0.8) | ($0.4) | ($0.3) | ($0.3) | ($0.3) | ($1.2) | ($1.2) | ($1.2) |
| Pre-Tax Income | ($40.1) | ($7.5) | ($7.6) | ($7.7) | ($7.8) | ($30.5) | ($31.9) | ($34.3) |
| Income Taxes Paid | ($0.0) | $0.0 | $0.0 | $0.0 | $0.0 | $0.1 | $0.1 | $0.1 |
| **Net Income** | **($40.1)** | **($7.5)** | **($7.6)** | **($7.8)** | **($7.8)** | **($30.6)** | **($32.0)** | **($34.4)** |
| *Net Margin* | | - | - | - | - | | | |
| **Reported EPS** | **($1.20)** | **($0.18)** | **($0.18)** | **($0.18)** | **($0.17)** | **($0.70)** | **($0.64)** | **($0.65)** |
| *YOY Growth* | | - | - | - | - | | | |
| Basic Shares Outstanding | 34.8 | 42.0 | 43.0 | 43.5 | 46.0 | 43.6 | 50.0 | 53.0 |

*Source: Zacks Investment Research, Inc.* *David Bautz, PhD*

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## HISTORICAL STOCK PRICE




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