

Zacks Small-Cap Research

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Diffusion Pharmaceuticals, Inc.

(DFFN-NASDAQ)

DFFN: Three Studies to Guide Clinical Development of TSC...

Based on our probability adjusted DCF model that takes into account potential future revenues from TSC in stroke and ARDS, DFFN is valued at \$2.00/share. This model is highly dependent upon the continued clinical success of TSC and will be adjusted accordingly based upon future clinical results.

...

Current Price (03/25/21) \$0.91
Valuation \$2.00

OUTLOOK

On February 17, 2021, Diffusion Pharmaceuticals, Inc. (DFFN) announced the completion and topline data for the open label, Phase 1b clinical trial of trans sodium crocetinate (TSC) in hospitalized COVID-19 patients with confirmed hypoxia. The external safety monitoring board reviewed the safety data for the final dose (1.5 mg/kg) and determined no dose-limiting toxicities or serious adverse events were observed. We anticipate secondary endpoint data from the trial to be available in the second quarter of 2021.

The company will be conducting three upcoming studies of TSC: The TCOM study has completed enrollment and dosing, an induced hypoxia trial will initiate in the third quarter of 2021, and the DLCO study will initiate in the third quarter of 2021, with results of the TCOM trial in the second quarter of 2021 and the other data from the other trials available in the second half of 2021. The data generated by these studies will guide development strategies for TSC going forward, with an anticipated announcement on the specific hypoxia-related conditions the company will target beginning in 2022.

SUMMARY DATA

52-Week High \$1.70
52-Week Low \$0.29
One-Year Return (%) 209.05
Beta 1.73
Average Daily Volume (sh) 5,050,800

Shares Outstanding (mil) 102
Market Capitalization (\$mil) \$93
Short Interest Ratio (days) N/A
Institutional Ownership (%) 8
Insider Ownership (%) 1

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

Risk Level High
Type of Stock Small-Blend
Industry Med-Biomed/Gene

ZACKS ESTIMATES

Revenue

(In millions of \$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	0 A	0 A	0 A	0 A	0 A
2021	0 E	0 E	0 E	0 E	0 E
2022					0 E
2023					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	-\$0.07 A	-\$0.10 A	-\$0.07 A	-\$0.06 A	-\$0.30 A
2021	-\$0.05 E	-\$0.04 E	-\$0.05 E	-\$0.05 E	-\$0.18 E
2022					-\$0.16 E
2023					-\$0.15 E

WHAT'S NEW

Business Update

No Safety Signals for Phase 1b Trial of TSC in COVID-19 Patients

On February 16, 2021, Diffusion Pharmaceuticals, Inc. (DFFN) [announced](#) the completion and topline results for the Phase 1b clinical trial of trans sodium crocetinate (TSC) in hospitalized COVID-19 patients. The primary objective of this trial was to test the safety and tolerability of TSC when administered on a more frequent basis than had been done in previous clinical trials. Secondary endpoints include pharmacokinetic measurements, improvements in blood oxygen levels, and other clinical parameters related to COVID-19.

For the trial, patients were administered intravenous doses of TSC at 0.25 mg/kg, 0.5 mg/kg, 1.0 mg/kg, or 1.5 mg/kg every six hours for a minimum of five days and up to 15 days. On Feb. 12, 2021, the external safety monitoring committee reviewed the safety data for the 1.5 mg/kg dose cohort and determined that there were no dose-limiting toxicities or serious adverse events. This is consistent with what had been seen for the other dosing cohorts in the trial. We anticipate results for the second endpoints in the second quarter of 2021.

Next Planned Trials for TSC

Now that the safety and tolerability of TSC has been established at a more frequent dosing interval, the company will next test the ability of TSC to affect oxygenation through three separate clinical studies.

- **Transcutaneous Oxygen Monitoring (TCOM) Study:** TCOM measures local oxygen tension in tissue below the skin and provides an objective measure of oxygen release and diffusion into tissues from vasculature (tcpO₂). This study is designed to evaluate the exposure-reponse relationship between TSC and oxygenation through direct measurement of oxygen movement in tissues. It will be a Phase 1 biphasic, single ascending dose trial in healthy volunteers in which all subjects will be on 100% O₂ before and after a TSC dose. The objectives of the trial are to identify the time to increase in tcpO₂ following a TSC dose along with magnitude and duration of the effect. Results from this study will inform dose selection for future TSC trials.
- **TSC Induced Hypoxia Trial:** This will be a double blind, randomized, placebo controlled trial to evaluate the effects of TSC on maximal oxygen consumption (VO₂) and partial pressure of blood oxygen (PaO₂) in normal healthy volunteers exposed to simulated altitude conditions that induce hypoxia. The primary endpoints will examine the change from baseline in VO₂ and PaO₂ after receiving a single intravenous dose of TSC following incremental levels of physical exertion in hypoxic and hypobaric conditions. The study is designed to detect if escalating doses of TSC exhibit a dose-reponse relationship on oxygen consumption and availability.
- **Diffusing Capacity of the Lungs (DLCO) Study:** DLCO is a pulmonary function test that measures gas diffusion (carbon monoxide, CO, as a surrogate for oxygen) from the lungs to the bloodstream and is a standard tool for examining pulmonary disease etiology. The current protocol consists of a Phase 1b dose-ranging, single dose trial in patients with interstitial lung disease (ILD) in which pre-dose baseline DLCO will be compared with serial post-dose DLCO readings in order to determine optimal Phase 2 dosing. In the Phase 2 portion of the study, hospitalized patients with acute ILD exacerbations will be randomized to either TSC or placebo with outcome measurements examining the need for mechanical ventilation, oxygen requirement, length of stay in the ICU, mortality, and safety.

The TCOM study has completed enrollment and dosing and we anticipate data in the second quarter of 2021. The induced hypoxia and DLCO studies should initiate in the third quarter of 2021 and complete in the second half of 2021. For each study, we anticipate topline results approximately one to two months following completion of the study.

Financial Update

On March 17, 2021, Diffusion announced financial results for the fourth quarter and full year 2020. As expected, the company did not report any revenues in 2020. R&D expenses in 2020 were \$9.4 million, compared to \$6.6 million in 2019. The increase was primarily due to the company's clinical trial evaluating TSC in hospitalized COVID-19 patients, which included increased manufacturing and clinical trial related expenses. G&A expenses were \$6.4 million in 2020, compared to \$4.8 million in 2019. The increase was primarily due to increased professional fees, salaries, and non-cash stock-based compensation.

The company exited 2020 with approximately \$18.5 million in cash and cash equivalents. In February 2021, Diffusion raised net proceeds of approximately \$31.2 million from an underwritten public offering of 33,658,538 shares at an offering price of \$1.025 per share. In addition, from January 1, 2021 to March 15, 2021, the company raised approximately \$2.2 million from the exercise of 4.23 million warrants. We estimate that the company currently has approximately \$48 million in cash and cash equivalents. As of March 12, 2021, Diffusion had approximately 101.9 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 110.7 million.

Conclusion

Now that the safety and tolerability of TSC at a more frequent dosing regimen has been established we are eager to see data for the secondary endpoints from the Phase 1b trial of TSC in COVID-19 patients and whether any positive signals such as increased oxygenation are seen. We're also glad to see that the management team has a clear plan in place about how best to move TSC forward into additional clinical indications with the three oxygenation studies and we look forward to the results of those trials later in 2021. Following the recent financing, Diffusion is very well capitalized to conduct the planned studies and potentially additional studies beyond that. Our current valuation is \$2.00.

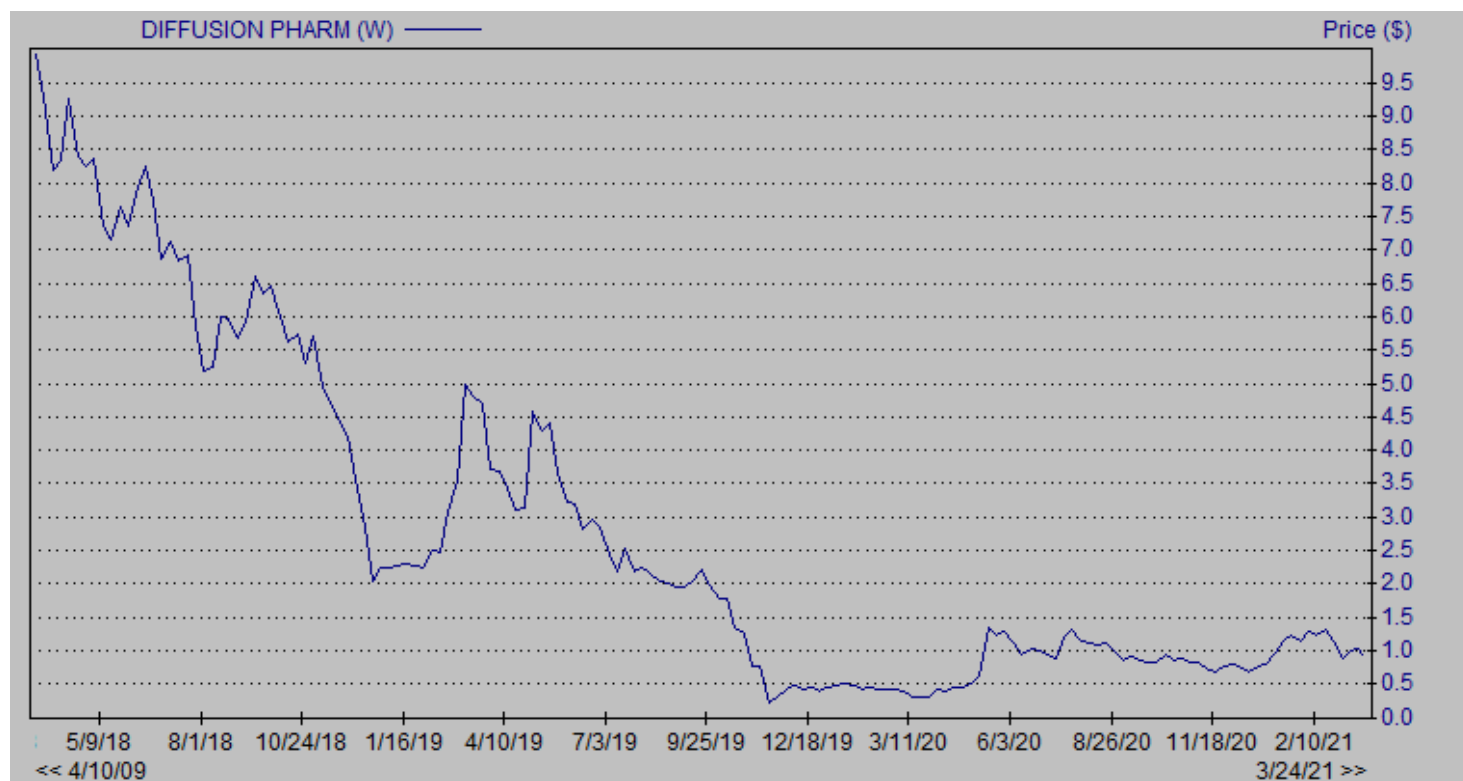
PROJECTED FINANCIALS

Diffusion Pharmaceuticals, Inc.	2020 A	Q1 E	Q2 E	Q3 E	Q4 E	2021 E	2022 E	2023 E
TSC (COVID)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
YOY Growth	-	-	-	-	-	-	-	-
TSC (Stroke)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
YOY Growth	-	-	-	-	-	-	-	-
Grants & Collaborative Revenue	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
YOY Growth	-	-	-	-	-	-	-	-
Cost of Sales	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Product Gross Margin	-	-	-	-	-	-	-	-
Research & Development	\$9.4	\$2.5	\$2.6	\$2.8	\$3.0	\$10.9	\$12.0	\$15.0
General & Administrative	\$6.4	\$1.6	\$1.8	\$1.8	\$1.8	\$7.0	\$7.5	\$8.0
Goodwill Impairment	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Depreciation	\$0.1	\$0.0	\$0.0	\$0.0	\$0.0	\$0.1	\$0.1	\$0.1
Operating Income	(\$16.0)	(\$4.1)	(\$4.4)	(\$4.6)	(\$4.8)	(\$18.0)	(\$19.6)	(\$23.1)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	\$0.1	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Pre-Tax Income	(\$15.9)	(\$4.1)	(\$4.4)	(\$4.6)	(\$4.8)	(\$18.0)	(\$19.6)	(\$23.1)
Income Taxes	(\$1.7)	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Accretion of Series A preferred dividends	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Deemed Dividend from warrant exchange	\$2.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Net Income	(\$16.1)	(\$4.1)	(\$4.4)	(\$4.6)	(\$4.8)	(\$18.0)	(\$19.6)	(\$23.1)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	(\$0.30)	(\$0.05)	(\$0.04)	(\$0.05)	(\$0.05)	(\$0.18)	(\$0.16)	(\$0.15)
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	53.8	90.0	102.0	102.5	103.0	99.4	120.0	150.0

Source: Zacks Investment Research, Inc.

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HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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