

Diffusion Pharmaceuticals, Inc.

(DFFN-NASDAQ)

DFFN: TSC Causes Dose Dependent Increase in Tissue Oxygenation in TCOM Trial...

Based on our probability adjusted DCF model that takes into account potential future revenues from TSC in select hypoxia-related indications, 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 (07/06/21) **\$0.68**
Valuation **\$2.00**

OUTLOOK

On June 30, 2021, Diffusion Pharmaceuticals, Inc. (DFFN) announced topline results from the Phase 1 transcutaneous oxygen monitoring (TCOM) trial of its lead development product, trans sodium crocetin (TSC). The results showed that compared to placebo, there was a positive dose-dependent response trend in TCOM readings after TSC administration that persisted throughout the measurement period. Diffusion will be following up these results with two additional oxygenation studies: the Altitude Trial, which will evaluate the effect of TSC on oxygen levels and maximal oxygen consumption in those exposed to hypoxic conditions while exercising; and the DLCO Trial, which will evaluate the effect of TSC on improving gas diffusion from the lungs into the bloodstream in patients with ILD. We anticipate both of those trials to complete in the second half of 2021 with results within two months following their completion.

SUMMARY DATA

52-Week High **\$1.70**
52-Week Low **\$0.60**
One-Year Return (%) **-23.16**
Beta **1.60**
Average Daily Volume (sh) **1,717,675**

Shares Outstanding (mil) **102**
Market Capitalization (\$mil) **\$74**
Short Interest Ratio (days) **N/A**
Institutional Ownership (%) **12**
Insider Ownership (%) **0.2**

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-Value**
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 A	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	-\$0.06 A	-\$0.04 E	-\$0.04 E	-\$0.04 E	-\$0.18 E
2022					-\$0.16 E
2023					-\$0.14 E

WHAT'S NEW

Business Update

Positive Trends Seen in TCOM Trial

On June 30, 2021, Diffusion Pharmaceuticals, Inc. (DFFN) **announced** topline results from the Phase 1 transcutaneous oxygen monitoring (TCOM) study of its lead development product trans sodium crocetinate (TSC). This study was designed to evaluate the exposure-reponse relationship between TSC and oxygenation through direct measurement of oxygen movement through peripheral tissues. It was a randomized, double blind, placebo controlled, pharmacokinetic and pharmacodynamic study in which thirty healthy volunteers received 100% O₂ at a rate of 6L/min before and after dosing with one of five doses of TSC (range from 0.5 mg/kg to 2.5 mg/kg) or placebo. 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).

Topline results from the TCOM trial showed that, compared to placebo, there was a positive dose-dependent trend in TCOM readings after TSC administration that persisted through the measurement period. The results were not statistically significant, due in part to the small number of subjects in each cohort and the inherent variability of tcpO₂ measurements, however the trends indicated an improvement in peripheral oxygenation compared to placebo with no evidence of hyperoxygenation. Importantly, TSC was safe and well-tolerated at all doses tested with no serious adverse events or dose-limiting toxicities.

To follow up on the TCOM study, Diffusion will be conducting two additional oxygenation trials as it collects data on how TSC affects oxygenation, which will inform the company's strategy moving forward.

- **Altitude 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 after exercise under 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 (i.e., simulated altitude). The study will be designed (or modeled) to evaluate the difference in effect of TSC versus placebo on oxygen availability and consumption.
- **Diffusing Capacity of the Lungs (DLCO) Trial:** 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. This trial will be a double-blind, randomized, placebo-controlled study which will evaluate the effects of TSC on DLCO in patients with previously diagnosed interstitial lung disease who have a baseline DLCO test result that is abnormal. The study will be statistically powered to evaluate the difference in effect of TSC versus placebo on improvement in DLCO as well as improvement in a standardized 6 minute walk test (6MWT).

We anticipate the Altitude Trial and DLCO Trial to initiate and be completed in the second half of 2021. For each study, we anticipate topline results approximately one to two months following their completion. The company expects to announce the initial hypoxia-related indications in which TSC will be studied in the fourth quarter of 2021 and for clinical trials in those indications to be initiated in the first half of 2022.

Conclusion

We are glad to see that the TCOM study successfully showed a positive trend between TSC administration and tissue oxygenation and we look forward to the results of the Altitude and DLCO Trials in the second half of 2021. Diffusion is sufficiently financed to conduct the remaining planned trials and we believe by the end of 2021 the company will have enough data in hand to decide which indication(s) to pursue. With no changes to our model our valuation remains at \$2.00.

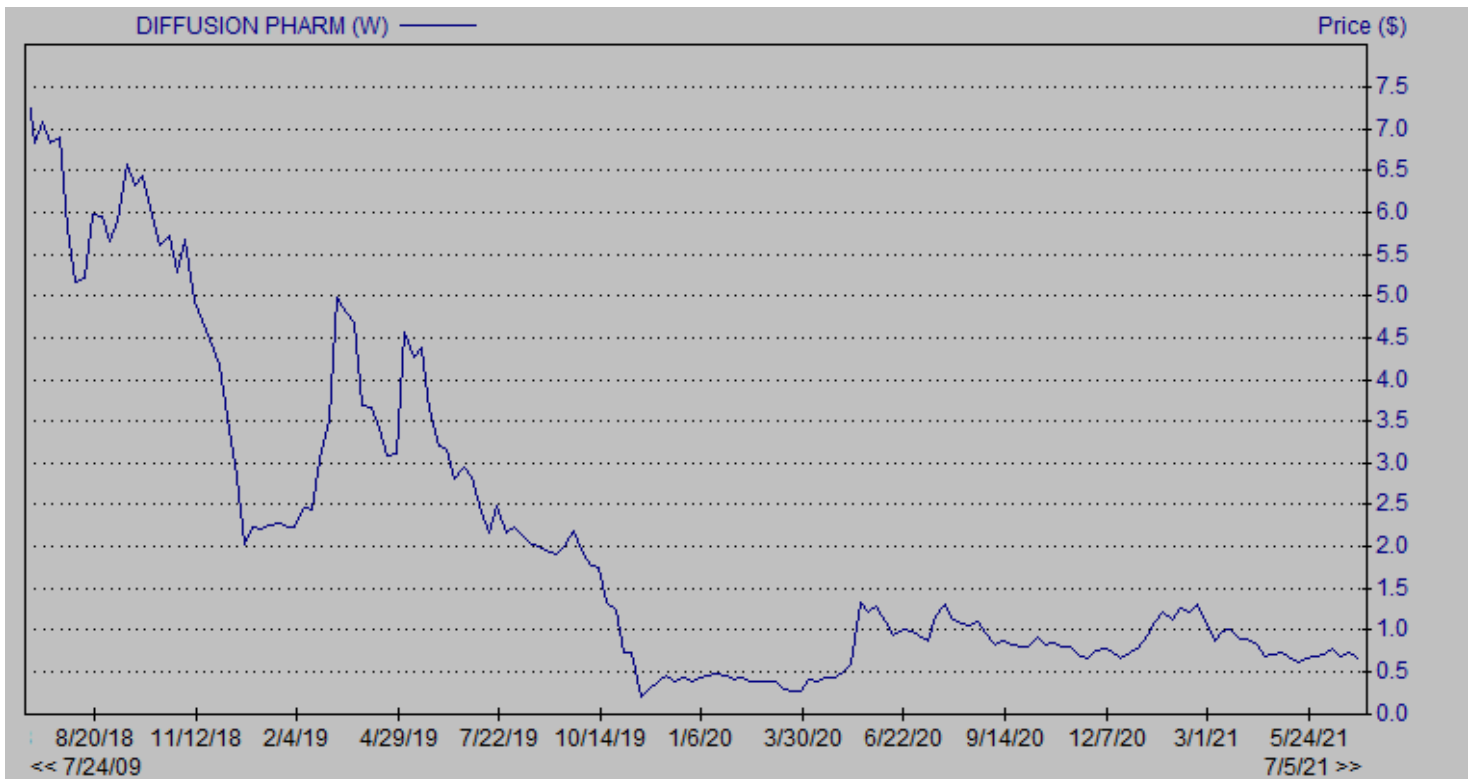
PROJECTED FINANCIALS

Diffusion Pharmaceuticals, Inc.	2020 A	Q1 A	Q2 E	Q3 E	Q4 E	2021 E	2022 E	2023 E
TSC (COVID)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
TSC (Stroke)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
Grants & Collaborative Revenue	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
Total Revenues	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
Cost of Sales	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>Product Gross Margin</i>	-	-	-	-	-	-	-	-
Research & Development	\$9.4	\$2.9	\$2.4	\$2.6	\$2.6	\$10.5	\$12.0	\$12.5
General & Administrative	\$6.4	\$1.7	\$1.8	\$1.8	\$1.8	\$7.1	\$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)	(\$4.7)	(\$4.2)	(\$4.4)	(\$4.4)	(\$17.8)	(\$19.6)	(\$20.6)
<i>Operating Margin</i>	-	-	-	-	-	-	-	-
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)	(\$4.6)	(\$4.2)	(\$4.4)	(\$4.4)	(\$17.8)	(\$19.6)	(\$20.6)
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)	(\$4.6)	(\$4.2)	(\$4.4)	(\$4.4)	(\$17.8)	(\$19.6)	(\$20.6)
<i>Net Margin</i>	-	-	-	-	-	-	-	-
Reported EPS	(\$0.30)	(\$0.06)	(\$0.04)	(\$0.04)	(\$0.04)	(\$0.18)	(\$0.16)	(\$0.14)
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
Basic Shares Outstanding	53.8	83.4	101.9	102.0	102.1	97.4	120.0	150.0

Source: Zacks Investment Research, Inc.

David Bautz, PhD

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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