

## Diffusion Pharmaceuticals, Inc.

(DFFN-NASDAQ)

### **DFFN: Initial Indication for TSC to be Announced 4Q21...**

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 (08/19/21) **\$0.51**  
Valuation **\$2.00**

### OUTLOOK

On August 11, 2021, Diffusion Pharmaceuticals, Inc. (DFFN) announced financial results for the second quarter of 2021 and provided a business update. The company recently announced positive results from both its Phase 1b COVID-19 study and the Phase 1b TCOM Study. In the second half of 2021, we anticipate the company performing two more oxygenation trials – The Altitude Trial, designed to evaluate trans sodium crocetin (TSC) versus placebo on maximal oxygen consumption and partial pressure of blood oxygen while participants are exposed to hypoxic and hypobaric conditions; and the DLCO Trial, designed to evaluate the effect of TSC on diffusion of carbon monoxide through the lungs (“DLCO”), which will act as a surrogate measure of oxygen transfer. Both trials should initiate in the fourth quarter of 2021 with topline results available one to two months following study completion.

### SUMMARY DATA

52-Week High **\$1.70**  
52-Week Low **\$0.49**  
One-Year Return (%) **-54.87**  
Beta **1.55**  
Average Daily Volume (sh) **1,206,147**

Shares Outstanding (mil) **102**  
Market Capitalization (\$mil) **\$52**  
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 A	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 A	-\$0.04 E	-\$0.04 E	-\$0.18 E
2022					-\$0.16 E
2023					-\$0.14 E

## WHAT'S NEW

### Business Update

#### *Preparing for Two Additional Oxygenation Trials in 4Q21*

Diffusion Pharmaceuticals, Inc. (DFFN) is in the process of evaluating its lead development compound, trans sodium crocetinate (TSC), in a series of oxygenation trials to better understand TSC's mechanism of action and clinical potential. The company has successfully completed the first of three planned studies, the TCOM study, and we anticipate the other two trials, Altitude Trial and DLCO Trial, initiating in the fourth quarter of 2021.

- 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 (tcpO<sub>2</sub>). This study was designed to evaluate the exposure-reponse relationship between TSC and oxygenation through direct measurement of oxygen movement in tissues. It was a randomized, double blind, placebo controlled, pharmacokinetic and pharmacodynamic study in which thirty healthy volunteers received 100% O<sub>2</sub> 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.

Topline results 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 tcpO<sub>2</sub> 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.

- Altitude Trial: This will be a double blind, randomized, placebo controlled trial to evaluate the effects of TSC on maximal oxygen consumption (VO<sub>2</sub>) and partial pressure of blood oxygen (PaO<sub>2</sub>) in normal healthy volunteers subjected to incremental levels of physical exertion while exposed to simulated altitude conditions that induce hypoxia. The study will be statistically powered to evaluate the difference in effect of TSC versus placebo on maximal oxygen consumption and partial pressure of blood oxygen. Topline results should be available 1-2 months following study completion.
- ILD-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 (ILD) 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 in a standard six-minute walk test. This study is likely to initiate late in the fourth quarter of 2021 and completing in the first quarter of 2022, with results available 1-2 months following study completion.

In the fourth quarter of 2021, we expect the company to announce the initial indication for which TSC will be studied to support the planned pathway for regulatory approval. We then anticipate the company initiating a controlled, clinical outcome study evaluating TSC in the chosen indication in the first half of 2022. That study will be funded with cash on hand.

### Financial Update

On August 11, 2021, Diffusion announced financial results for the second quarter of 2021. As expected, the company did not report any revenues in the second quarter of 2021. R&D expenses for the three months ending June 30, 2021 were \$2.0 million, compared to \$2.2 million for the three months ending June 30, 2020. The decrease was primarily due to winding down the clinical trial of TSC in glioblastoma brain cancer and the COVID-19 Trial. G&A expenses were \$1.8 million in the second quarter of 2021, compared to \$1.5 million in the second quarter of 2020. The increase was primarily due to increased professional fees, salaries, non-cash stock-based compensation, and costs associated with the separation of former employees.

The company exited the second quarter of 2021 with approximately \$43.3 million in cash and cash equivalents. This was due in part to a public offering in February 2021 in which Diffusion raised net proceeds of approximately \$31.2 million. As of August 11, 2021, Diffusion had approximately 101.9 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 111.5 million.

### **Conclusion**

With one positive trial completed Diffusion will now turn its attention to conducting the remaining two oxygenation trials, both of which will be funded with cash on hand. In addition, we look forward to the company announcing the initial clinical indication for TSC in the fourth quarter of 2021 and starting that clinical program in the first half of 2022. With no changes to our model our valuation remains at \$2.00.

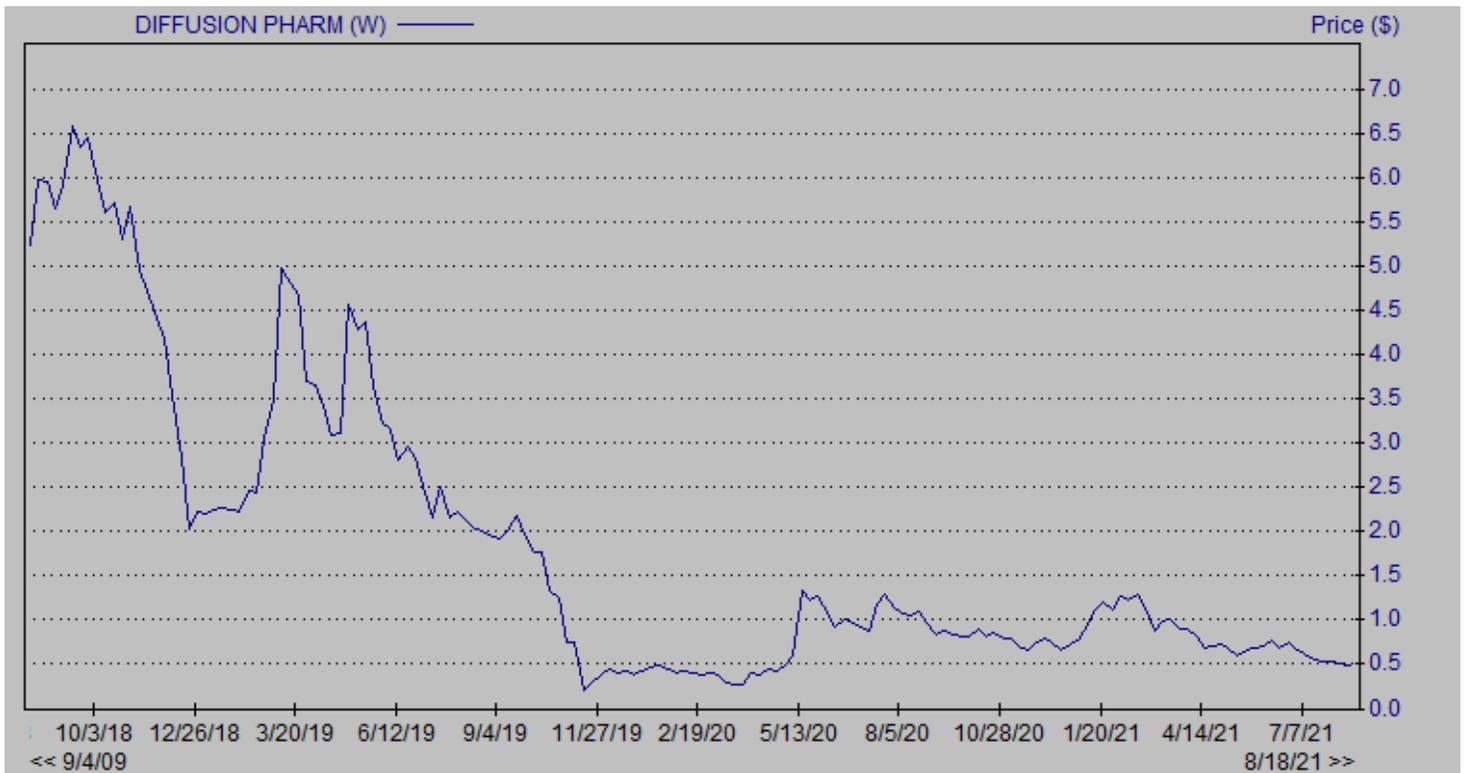
## PROJECTED FINANCIALS

Diffusion Pharmaceuticals, Inc.	2020 A	Q1 A	Q2 A	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 (Other Indications)	\$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>	-	-	-	-	-	-	-	-
<b>Total Revenues</b>	<b>\$0</b>							
<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	\$2.0	\$2.6	\$2.6	\$10.1	\$12.0	\$12.5
General & Administrative	\$6.4	\$1.7	\$1.8	\$1.8	\$1.8	\$7.2	\$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
<b>Operating Income</b>	<b>(\$16.0)</b>	<b>(\$4.7)</b>	<b>(\$3.8)</b>	<b>(\$4.4)</b>	<b>(\$4.4)</b>	<b>(\$17.4)</b>	<b>(\$19.6)</b>	<b>(\$20.6)</b>
<i>Operating Margin</i>	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	\$0.1	(\$0.0)	(\$0.1)	\$0.0	\$0.0	(\$0.1)	\$0.0	\$0.0
<b>Pre-Tax Income</b>	<b>(\$15.9)</b>	<b>(\$4.6)</b>	<b>(\$3.8)</b>	<b>(\$4.4)</b>	<b>(\$4.4)</b>	<b>(\$17.5)</b>	<b>(\$19.6)</b>	<b>(\$20.6)</b>
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
<b>Net Income</b>	<b>(\$16.1)</b>	<b>(\$4.6)</b>	<b>(\$3.8)</b>	<b>(\$4.4)</b>	<b>(\$4.4)</b>	<b>(\$17.5)</b>	<b>(\$19.6)</b>	<b>(\$20.6)</b>
<i>Net Margin</i>	-	-	-	-	-	-	-	-
<b>Reported EPS</b>	<b>(\$0.30)</b>	<b>(\$0.06)</b>	<b>(\$0.04)</b>	<b>(\$0.04)</b>	<b>(\$0.04)</b>	<b>(\$0.18)</b>	<b>(\$0.16)</b>	<b>(\$0.14)</b>
<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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