Zacks Small-Cap Research
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Diffusion Pharmaceuticals, Inc. (DFFN-NASDAQ)

DFFN: First Patients Dosed in COVID-19 Trial…

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.

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Current Price (09/17/20)	$0.90
Valuation	**$2.00**

OUTLOOK

On September 10, 2020, Diffusion Pharmaceuticals, Inc. (DFFN) announced the first patients have been dosed in the Phase 1b clinical trial of trans sodium crocetinate (TSC) in patients hospitalized with COVID-19. The primary outcome of the trial is safety and tolerability, as TSC will be tested across a wide range of doses. The company will also be evaluating pharmacokinetics (PK) of TSC and its effect on arterial blood oxygenation. These data, which are expected in the fourth quarter of 2020, will be used to guide the design of a planned follow-on efficacy study, which should get underway in the first part of 2021.

SUMMARY DATA

52-Week High	**$2.20**
52-Week Low	**$0.22**
One-Year Return (%)	**-56.42**
Beta	**1.27**
Average Daily Volume (sh)	**1,390,444**
Shares Outstanding (mil)	**64**
Market Capitalization ($mil)	**$58**
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)
2019	0 A	0 A	0 A	0 A	0 A
2020	0 A	0 A	0 E	0 E	0 E
2021					0 E
2022					0 E

Earnings per Share
(Diluted)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	-$0.81 A	-$0.63 A	-$0.60 A	-$0.25 A	-$1.76 A
2020	-$0.07 A	-$0.10 A	-$0.05 E	-$0.05 E	-$0.19 E
2021					-$0.19 E
2022					-$0.20 E

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WHAT'S NEW

Business Update

First Patients Dosed in COVID-19 Trial

On September 10, 2020, Diffusion Pharmacueticals, Inc. (DFFN) announced that the first two patients have been dosed in the open-label Phase 1b clinical trial of trans sodium crocetinate (TSC) in hospitalized COVID-19 patients. The trial is taking place at the Romanian National Institute of Infectious Diseases. The primary outcome of the trial is the safety and efficacy of TSC, as the drug will be tested at a much wider range of doses and higher frequency of dosing compared to prior trials. Additional details of the trial include:

- Up to 24 patients being enrolled in this portion of the trial.
- Dosing will take place for a minimum of five days and a maximum of 15 days, depending on how the patient is doing.
- Patients will be eligible for the trial is they test positive for SARS-CoV-2 and are hospitalized with a blood oxygen concentration less than 94%.
- Patients will be eligible to receive remdesivir while a part of the trial.

After the results from this study are released, which we anticipate will be before the end of 2020, the company will use the data to design a planned follow on efficacy trial in approximately 400 patients. We anticipate that trial taking place at centers in both Europe and the U.S. and to likely initiate in the first part of 2021.

ARDS and TSC

The current coronavirus epidemic is resulting in severe disease for a small percentage of patients, many of which end up on a ventilator as a result of acute respiratory distress syndrome (ARDS), which is a condition where the small blood vessels of the lung leak fluid that fills up the alveoli, thus preventing proper oxygen exchange (Stevens *et al*., 2018). This can lead to a hypoxic environment in the patient signified by a low blood oxygen level and subsequent lack of oxygen in vital organs, thus a treatment that can increase oxygenation should help to alleviate these symptoms.

There are many causes of ARDS, including infections (e.g., pneumonia), severe burns, pancreatitis, inhalation of smoke or chemicals, or other serious illnesses. An excessive inflammatory response appears to be involved in the pathogenesis of ARDS (Li *et al*., 2019). Current treatment options involve supportive care while the lungs heal, which involves oxygen therapy supplied through a ventilator. There are no pharmacological treatments specifically for ARDS and approximately 40% of hospitalized patients die from it (Siegel *et al*., 2020).

In a model of acute lung injury that mimics ARDS, TSC was shown to increase arterial PO_2 immediately after administration without affecting the lungs (Gainer *et al*., 2005). This is in addition to multiple other examples of TSC increasing oxygenation in animal models, including in hemorrhagic shock (Giassi *et al*., 2002) and in a 10% oxygen environment (Singer *et al*., 2000). Thus, we believe there is ample support for testing TSC in the treatment of ARDS.

Conclusion

We look forward to the results from the Phase 1b clinical trial of TSC in COVID-19 patients before the end of 2020. These results will guide the design of the follow-on efficacy trial in a much larger population and could potentially guide the design and execution of other trials involving TSC. With no changes to our model our valuation remains at $2.00.

PROJECTED FINANCIALS

Diffusion Pharmaceuticals, Inc.	2019 A	Q1 A	Q2 A	Q3 E	Q4 E	2020 E	2021 E	2022 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	$6.6	$1.5	$2.2	$1.7	$2.0	$7.5	$8.0	$10.0
General & Administrative	$4.8	$1.4	$1.5	$1.3	$1.3	$5.4	$5.2	$5.5
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	($11.6)	($3.0)	($3.7)	($3.1)	($3.3)	($13.0)	($13.3)	($15.6)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.1	($0.0)	$1.9	$0.0	$0.0	$1.9	($0.2)	($0.2)
Pre-Tax Income	($11.5)	($2.9)	($5.6)	($3.1)	($3.3)	($11.1)	($13.5)	($15.8)
Income Taxes	$0.3	($0.4)	($0.5)	$0.0	$0.0	($0.9)	$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
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($11.8)**	**($2.6)**	**($5.1)**	**($3.1)**	**($3.3)**	**($10.2)**	**($13.5)**	**($15.8)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.76)**	**($0.07)**	**($0.10)**	**($0.05)**	**($0.05)**	**($0.19)**	**($0.19)**	**($0.20)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	6.7	34.5	52.0	64.0	65.0	53.9	70.0	80.0

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

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HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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