Zacks Small-Cap Research
Sponsored – Impartial - Comprehensive

December 4, 2020
David Bautz, PhD
312-265-9471
dbautz@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Diffusion Pharmaceuticals, Inc. (DFFN-NASDAQ)

DFFN: Planning for Additional Studies 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 (12/04/20)	$0.75
Valuation	**$2.00**

OUTLOOK

On November 12, 2020, Diffusion Pharmaceuticals, Inc. (DFFN) announced financial results for the third quarter of 2020 and provided a business update. The company is currently conducting a Phase 1 safety and PK study of trans sodium crocetinate (TSC) in hospitalized COVID-19 patients. We anticipate an update on this study in the first quarter in 2021. In addition, Diffusion is also planning to evaluate TSC in other clinical studies to quantify the effect of TSC on tissue oxygenation in an effort to determine potential patient populations and indications for future clinical development. We anticipate an update on TSC's clinical pathway in early 2021. The company exited the third quarter of 2020 with approximately $21.9 million in cash and cash equivalents, which we estimate is sufficient to fund operations into the fourth quarter of 2022.

SUMMARY DATA

52-Week High	**$1.50**
52-Week Low	**$0.26**
One-Year Return (%)	**58.51**
Beta	**1.35**
Average Daily Volume (sh)	**1,259,241**
Shares Outstanding (mil)	**64**
Market Capitalization ($mil)	**$48**
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	**Above Avg.**
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)
2019	0 A	0 A	0 A	0 A	0 A
2020	0 A	0 A	0 A	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	-$0.07 A	-$0.05 E	-$0.22 E
2021					-$0.19 E
2022					-$0.20 E

© Copyright 2020, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

Business Update

Update on COVID-19 Trial

Diffusion Pharmaceuticals (DFFN) is currently conducting the 100-303 COVID trial of trans sodium crocetinate (TSC) in hospitalized COVID-19 patients in Romania (NCT04573322). This is primarily a safety and tolerability study of TSC when it is administered four times a day for up to 15 days. The trial is designed to have four dosing cohorts of six patients. Previous clinical trials of TSC have shown the compound to be safe and well tolerated when administered once daily, thus the protocol for the 100-303 study calls for an independent safety monitoring committee to review the safety data following the completion of each dosing cohort. In addition to determining safety and tolerability, secondary endpoints will examine clinical endpoints such as oxygen saturation, change in WHO ordinal severity scale, and mortality, although given the limited number of patients (n=24) we don't anticipate statistically significant differences being detected. Rather, we would view a promising signal (e.g., safe and tolerable at escalating and more frequent dosing than studied previously) to be a positive outcome that could lead to testing TSC in additional clinical indications.

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 oxygen diffusion should help 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 can involve oxygen therapy non-invasively or invasively (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 soon after administration without affecting the lungs (Gainer *et al*., 2005). This is in addition to multiple other examples of TSC increasing oxygen diffusion 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.

Additional Studies of TSC in Hypoxia

The company is currently in the early planning stages for additional clinical studies to evaluate the pharmacodynamics of TSC. These are likely to be short-term studies that could examine oxygenation models in either healthy volunteers or patients with any number of different conditions. The ultimate outcome of these studies is to quantitatively determine a dose response relationship for TSC and tissue oxygenation, which should provide clarity on future clinical indications. The final details of these studies should be available early in 2021 and the planned clinical trials are likely to initiate in the first half of 2021.

Financial Update

On November 12, 2020, Diffusion announced financial results for the third quarter of 2020. As expected, the company did not report any revenues. R&D expenses were $3.1 million for the third quarter of 2020 compared to $1.7 million during the third quarter of 2019. The increase was due to expenses related to the initiation of the 100-303 trial. G&A expenses were $2.1 million for the third quarter of 2020 compared to $1.3 million for the third quarter of 2019. The increase was primarily due to increased professional expenses and salaries.

As of September 30, 2020, Diffusion had approximately $21.9 million in cash and cash equivalents. We estimate the company has sufficient capital to fund operations into the fourth quarter of 2022.

As of November 11, 2020, Diffusion had approximately 64 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 75.2 million shares.

Conclusion

We are glad to see that management has a clear plan in place about how best to move TSC forward into additional clinical indications and we look forward to an update on these plans in early 2021. In addition, we will be eager to see topline data from the 100-303 trial in COVID-19 patients, particularly safety and tolerability at higher and more frequent dosing, and if there are any positive signs such as increased oxygenation that could lead to potential trial expansion. Lastly, Diffusion is very well capitalized and will be able to fund the planned studies with cash on hand, thus we don't foresee a financing being necessary in the near future. With no changes to our model our valuation remains at $2.00.

PROJECTED FINANCIALS

Diffusion Pharmaceuticals, Inc.	2019 A	Q1 A	Q2 A	Q3 A	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	$3.1	$2.0	$8.8	$8.0	$10.0
General & Administrative	$4.8	$1.4	$1.5	$2.1	$1.3	$6.3	$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)	($5.3)	($3.3)	($15.2)	($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)	($5.2)	($3.3)	($13.3)	($13.5)	($15.8)
Income Taxes	$0.3	($0.4)	($0.5)	($0.8)	$0.0	($1.7)	$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)**	**($4.4)**	**($3.3)**	**($11.6)**	**($13.5)**	**($15.8)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.76)**	**($0.07)**	**($0.10)**	**($0.07)**	**($0.05)**	**($0.22)**	**($0.19)**	**($0.20)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	6.7	34.5	52.0	64.0	64.0	53.6	70.0	80.0

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

© Copyright 2020, Zacks Investment Research. All Rights Reserved.

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

© Copyright 2020, Zacks Investment Research. All Rights Reserved.

DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, David Bautz, PhD, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.
Zacks SCR has received compensation from the issuer directly, from an investment manager, or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

CANADIAN COVERAGE

This research report is a product of Zacks SCR and prepared by a research analyst who is employed by or is a consultant to Zacks SCR. The research analyst preparing the research report is resident outside of Canada, and is not an associated person of any Canadian registered adviser and/or dealer. Therefore, the analyst is not subject to supervision by a Canadian registered adviser and/or dealer, and is not required to satisfy the regulatory licensing requirements of any Canadian provincial securities regulators, the Investment Industry Regulatory Organization of Canada and is not required to otherwise comply with Canadian rules or regulations.