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Diffusion Pharmaceuticals, Inc. (DFFN-NASDAQ)

DFFN: Phase 2 GBM Trial to Initiate 2H22…

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 $40.00/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 (08/17/22)	$6.90
Valuation	**$40.00**

OUTLOOK

On August 11, 2022, Diffusion Pharmaceuticals, Inc. announced financial results for the second quarter of 2022 and provided a business update. The company recently announced it had aligned with the U.S. FDA on the design of an open label, dose escalation, Phase 2 safety and efficacy study of it lead product candidate, trans sodium crocetinate (TSC), administered with standard of care to patients newly diagnosed with glioblastoma multiforme (GBM). We anticipate the trial initiating before the end of 2022 and the first patient being dosed in the first quarter of 2023. In addition, Diffusion recently announced positive results from the Altitude Trial, which showed that a higher dose of TSC decreased blood acidity and enhanced metabolic recovery at 10 minutes after completion of exercise in simulated high altitude. These data further support the development of TSC for the treatment of hypoxic solid tumors

SUMMARY DATA

52-Week High	**$30.31**
52-Week Low	**$5.66**
One-Year Return (%)	**-72.28**
Beta	**1.59**
Average Daily Volume (sh)	**25,332**
Shares Outstanding (mil)	**2**
Market Capitalization ($mil)	**$14**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**9**
Insider Ownership (%)	**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	**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)
2021	0 A	0 A	0 A	0 A	0 A
2022	0 A	0 A	0 E	0 E	0 E
2023					0 E
2024					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	-$2.78 A	-$1.85 A	-$6.21 A	-$1.67 A	-$12.34 A
2022	-$2.22 A	-$2.06 A	-$2.14 E	-$2.22 E	-$8.71 E
2023					-$7.33 E
2024					-$6.37 E

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WHAT'S NEW

Business Update

Phase 2 GBM Trial to Initiate in 2H22

In July 2022, Diffusion Pharmaceuticals, Inc. (DFFN) announced that the company had aligned with the U.S. Food and Drug Administration (FDA) on the design of an open label, dose escalation, Phase 2 safety and efficacy study (Study 200-208) of its lead development compound, trans sodium crocetinate (TSC), in patients with newly diagnosed glioblastoma multiforme (GBM).

The trial will utilize a dose escalation phase in a 3+3+3 design and will test 1.5 mg/kg, 2.0 mg/kg, and 2.5 mg/kg TSC administered in combination with standard of care (SOC) radiotherapy plus temozolomide (TMZ). An additional 17 patients will be treated at the highest tolerated dose identified in the dose escalation phase. The primary endpoint of the study is to evaluate the safety and efficacy of TSC when administered with SOC therapy in newly diagnosed GBM patients. Secondary objectives include evaluation of progression-free survival at six months by MRI, assessment using Response Assessment in Neuro-Oncology criteria, and to evaluate overall survival at 12 months.

Diffusion previously tested TSC in a Phase 1/2 study of 59 newly diagnosed GBM patients (Gainer *et al*., 2016). The 1.5 mg/kg to 2.5 mg/kg to be used in the upcoming Phase 2 trial will be 6-10-fold higher than the 0.25 mg/kg dose used in the Phase 1/2 trial. TSC will be administered five days per week approximately 30-60 minutes before radiotherapy, which is in contrast to the three days per week it was administered in the Phase 1/2 study.

The upcoming trial will include PET scans to directly measure the oxygen enhancing effects of TSC on tumor hypoxia using one of two radiotracers (18F-FMISO or 18F-FAZA). Data from the PET scans should be available within one year of the study's initiation.

We anticipate the trial initiating before the end of 2022 and the first patient should be dosed in the first quarter of 2023.

Positive Results for Altitude Trial

In June 2022, Diffusion announced positive results from the Altitude Trial, the company's second Oxygenation Trial. The Altitude Trial was a double blind, randomized, placebo controlled trial that evaluated the effects of TSC on maximal oxygen consumption (VO2) and partial pressure of blood oxygen (PaO2) in normal healthy volunteers subjected to incremental levels of physical exertion while exposed to simulated altitude conditions that induce hypoxia.

The results of the study showed that following exercise under hypoxic conditions, an increase in pH and a decrease in lactate were observed in the study subjects treated with the highest dose of TSC (2.5 mg/kg), both at the end of the exercise period and at 10 minutes post-exercise. The data suggest that the 2.5 mg/kg dose of TSC decreased blood acidity through a decrease in lactic acid accumulation and enhanced metabolic recovery at 10 minutes after exercise was complete. TSC was safe and well tolerated at all doses tested (0.5 mg/kg, 1.5 mg/kg, 2.5 mg/kg) and there were no serious adverse events reported.

Financial Update

On August 11, 2022, Diffusion announced financial results for the second quarter of 2022. As expected, the company did not report any revenues in the second quarter of 2022. R&D expenses for the three months ending June 30, 2022 were $2.1 million, compared to $2.0 million for the second quarter of 2021. The decrease was primarily due to the timing of clinical trials and drug manufacturing, offset by an increase in salaries and stock-based compensation. G&A expenses for the second quarter of 2022 were $2.1 million, compared to $1.8 million for the second quarter of 2021. The increase was primarily due to an increase in professional fees along with increased salaries.

As of June 30, 2022, Diffusion had approximately $28.5 million in cash, cash equivalents, and marketable securities. We anticipate the company has sufficient capital to fund operations into the first quarter of 2024. As of

August 10, 2022, Diffusion had approximately 2.0 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximatley 2.3 million.

Conclusion

We're glad to see that the company has a clinical trial plan in place for a new Phase 2 clinical trial in GBM. The company's previous Phase 1/2 trial in GBM yielded very encouraging results, and we believe with a higher dose of TSC and a more frequent dosing schedule those results have the potential to be bested in the upcoming Phase 2 trial. In addition, the positive effects seen in the TCOM Trial, the Altitute Trial, and the COVID-19 Trial add to our conviction that TSC could be an effective adjuvant therapy for hypoxic tumors such as GBM. With no changes to our model our valuation remains at $40 per share.

PROJECTED FINANCIALS

Diffusion Pharmaceuticals, Inc.	2021 A	Q1 A	Q2 A	Q3 E	Q4 E	2022 E	2023 E	2024 E
TSC (Hypoxic Tumors)	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
TSC (Other Indications)	$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	$8.5	$2.4	$2.1	$2.4	$2.6	$9.5	$10.0	$11.0
General & Administrative	$7.4	$2.1	$2.1	$1.9	$1.9	$8.1	$7.5	$8.0
Impairment Charge	$8.6	$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	($24.7)	($4.6)	($4.2)	($4.4)	($4.5)	($17.7)	($17.6)	($19.1)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.1	($0.0)	($0.1)	$0.0	$0.0	($0.1)	$0.0	$0.0
Pre-Tax Income	($24.5)	($4.5)	($4.2)	($4.4)	($4.5)	($17.8)	($17.6)	($19.1)
Income Taxes	($0.4)	$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	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Net Income	**($24.1)**	**($4.5)**	**($4.2)**	**($4.4)**	**($4.5)**	**($17.8)**	**($17.6)**	**($19.1)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($12.34)**	**($2.22)**	**($2.06)**	**($2.14)**	**($2.22)**	**($8.71)**	**($7.33)**	**($6.37)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	2.0	2.0	2.0	2.0	2.0	2.0	2.4	3.0

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

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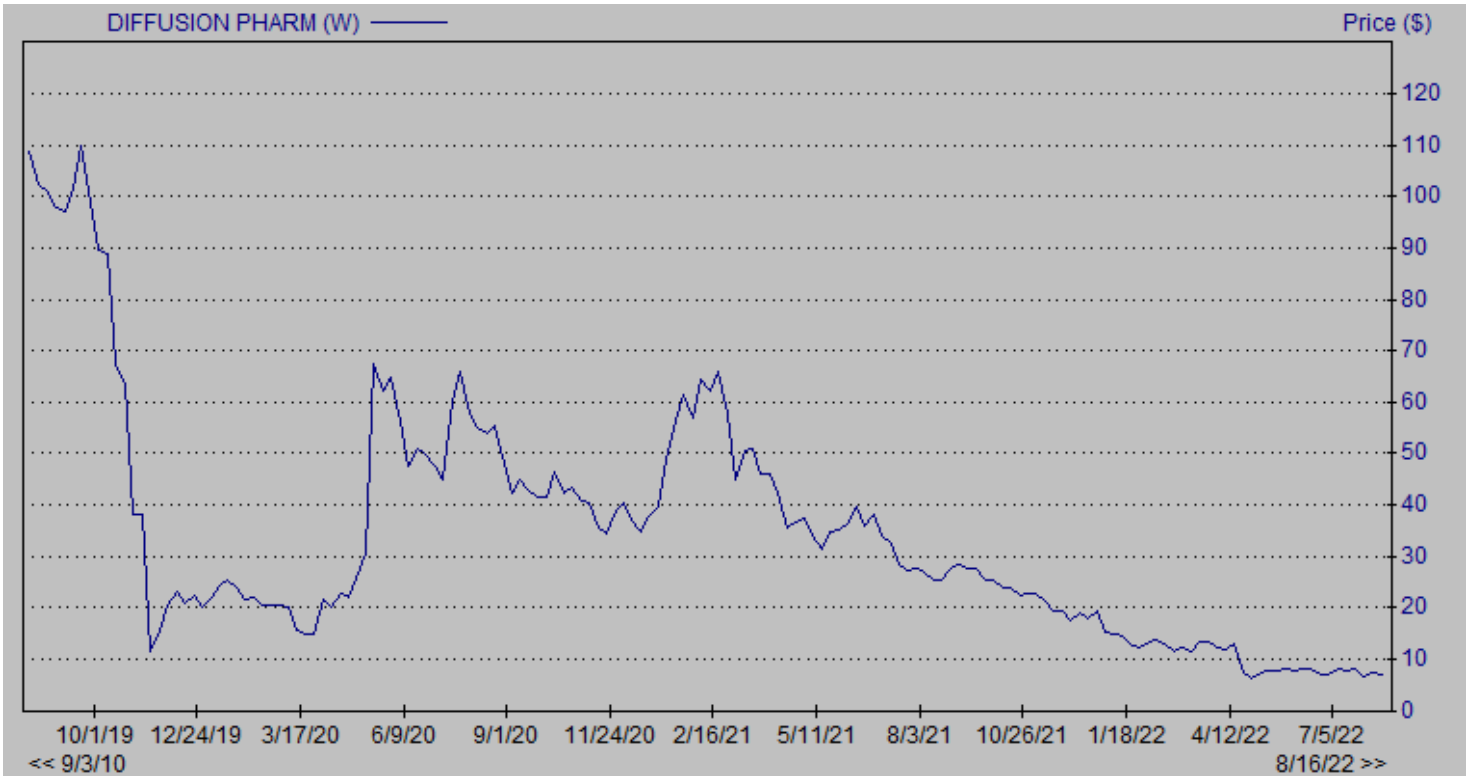
HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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