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Diffusion Pharmaceuticals, Inc. (DFFN-NASDAQ)

DFFN: Strategic Review Underway; Planning to Initiate Phase 2 GBM Trial in 1Q23…

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 (12/01/22)	$6.50
Valuation	**$40.00**

OUTLOOK

On November 14, 2022, Diffusion Pharmaceuticals, Inc. announced financial results for the third quarter of 2022 and provided a business update. The company is currently in the process of identifying and evaluating various strategic opportunities to better leverage the potential of its lead asset, trans sodium crocetinate (TSC). The company has given no timeline for this review and will provide updates as necessary.

While the review is ongoing, Diffusion is continuing to focus on initiating Study 200-208 of TSC in patients with newly diagnosed glioblastoma (GBM) in the first quarter of 2023, however the outcome and timing of the strategic review process will impact when the first patient is dosed and subsequent milestones in the trial.

SUMMARY DATA

52-Week High	**$20.20**
52-Week Low	**$4.64**
One-Year Return (%)	**-64.19**
Beta	**1.56**
Average Daily Volume (sh)	**10,342**
Shares Outstanding (mil)	**2**
Market Capitalization ($mil)	**$13**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**10**
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 A	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	-$1.37 A	-$2.20 E	-$7.93 E
2023					-$7.33 E
2024					-$6.37 E

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WHAT'S NEW

Business Update

Evaluating Strategic Opportunities

On November 14, 2022, Diffusion Pharmaceuticals, Inc. (DFFN) provided an update for its previously announced evaluation of strategic opportunities, which may include a sale, merger, divestiture, recapitalization, or other strategic transaction.

Since announcing its intention to evaluate various strategic opportunities, Diffusion has met with multiple parties in an effort to identify the potential for both short- and long-term value amongst the various potential transactions. While the company believes that its lead asset, trans sodium crocetinate (TSC), has the potential to be beneficial for patients, it may be in the best interest of Diffusion shareholders to seek a near-term opportunity to allow for a more effective use of company resources.

Diffusion has already rejected an unsolicited offer from LifeSci Captial on behalf of one of its clients since the offer was "woefully inadequate". LifeSci has informed Diffusion that it intends to commence a proxy contest and nominate its own slate of directors for election at the 2022 Annual Meeting. Diffusion is open to engaging with all shareholders, however it intends to oppose the Proxy Contest effort by LifeSci as it believes it will ultimately undermine the ongoing strategic review process. The company's Annual Meeting is currently scheduled for December 30, 2022.

Phase 2 GBM Trial to Initiate in 2H22

While the strategic review process continues, Diffusion continues to focus on the initiation of an open label, dose escalation, Phase 2 safety and efficacy study (Study 200-208) of 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 combination with standard of care therapy 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 positron emission tomography (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 obtained during the dose escalation phase of the study should be available within one year of the study's initiation.

At this point the company is planning to initiate the trial in the first quarter of 2023, however this will be subject to the outcome and timing fo the strategic review process.

Financial Update

On November 14, 2022, Diffusion announced financial results for the third quarter of 2022. As expected, the company did not report any revenues in the third quarter of 2022. R&D expenses for the three months ending September 30, 2022 were $0.8 million, compared to $2.1 million for the third quarter of 2021. The decrease was primarily due to the timing of clinical trials and drug manufacturing. G&A expenses for the third quarter of 2022 were

$2.1 million, compared to $1.9 million for the third quarter of 2021. The increase was primarily due to an increase in outside services related to ongoing business development activities.

As of September 30, 2022, Diffusion had approximately $25.9 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 November 14, 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 will be very interested to learn the outcome of the company's strategic review process, however there can be no assurance of what the outcome of that process will be or when the company will make an announcement regarding it. In the meantime, the company is preparing for the Phase 2 trial in GBM, which we currently anticipate initiating in the first quarter of 2023. However, this will be subject to the timing and outcome of the strategic review process. We have made no changes to our model and our valuation remains at $40 per share.

PROJECTED FINANCIALS

Diffusion Pharmaceuticals, Inc.	2021 A	Q1 A	Q2 A	Q3 A	Q4 E	2022 E	2023 E	2024 E
TSC (GBM)	$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	$0.8	$2.6	$7.9	$10.0	$11.0
General & Administrative	$7.4	$2.1	$2.1	$2.1	$1.9	$8.3	$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	$0.0	$0.1	$0.1
Operating Income	($24.7)	($4.6)	($4.2)	($2.9)	($4.5)	($16.2)	($17.6)	($19.1)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$0.1	($0.0)	($0.1)	$0.1	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($24.5)	($4.5)	($4.2)	($2.8)	($4.5)	($16.2)	($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)**	**($2.8)**	**($4.5)**	**($16.2)**	**($17.6)**	**($19.1)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($12.34)**	**($2.22)**	**($2.06)**	**($1.37)**	**($2.20)**	**($7.93)**	**($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



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