NEWS RELEASE

Diffusion Pharmaceuticals Reports Third Quarter 2022 Financial Results and Provides Business Update

11/14/2022

- Announced Thorough Evaluation of a Range of Potential Strategic Opportunities
- Continued GBM Study Start-up Activities
- Ended Quarter with $25.9 million in Cash, Cash Equivalents and Marketable Securities

CHARLOTTESVILLE, Va., Nov. 14, 2022 (GLOBE NEWSWIRE) -- Diffusion Pharmaceuticals Inc. (NASDAQ: DFFN) ("Diffusion" or the "Company"), a biopharmaceutical company developing novel therapies that may enhance the body's ability to deliver oxygen to areas where it is needed most, today announced financial results for the quarter ended September 30, 2022, and provided a business update.

"As previously announced, we formalized our efforts to identify and evaluate strategic opportunities during the third quarter, and with our current assets, including trans sodium crocetinate ("TSC") and our strong balance sheet, we believe these activities will effectively position us to meet the challenges of this dynamic market," commented Robert Cobuzzi, Jr., Ph.D., President and Chief Executive Officer of Diffusion.

Dr. Cobuzzi continued, "While our process to evaluate strategic opportunities is ongoing, the Diffusion organization remains focused on executing our strategy to create value for our shareholders. We continue to prioritize progress towards the initiation of Study 200-208 and further exploration of potential accelerated pathways for regulatory approval of TSC, while taking steps to preserve capital without sacrificing meaningful growth opportunities."

Business & Development Updates

Commenced Process to Evaluate Potential Strategic Opportunities: In October 2022, Diffusion announced that its Board of Directors authorized a thorough review and evaluation of a range of potential strategic opportunities in the interest of enhancing stockholder value including transactional opportunities to better leverage the potential of TSC and the Company's other assets. The Company retained Canaccord Genuity LLC as its financial advisor and Dechert LLP as its legal counsel to assist with the review process.

Announced Plans for a Phase 2 Glioblastoma Trial: In July 2022, Diffusion announced alignment with the United States Food and Drug Administration ("FDA") on the design of Diffusion's Phase 2 clinical trial entitled "Open-Label, Dose-Escalation, Phase 2 Safety and Efficacy Study of TSC in Newly Diagnosed Glioblastoma ("GBM") Patients when Administered with Standard of Care." The study will include up to 9 patients in a dose-escalation phase, enrolling patients in a 3+3+3 design, to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of TSC at doses of 1.5 mg/kg, 2.0 mg/kg and 2.5 mg/kg administered in combination with concomitant standard of care radiotherapy plus temozolomide. An additional 17 subjects will be treated at the highest tolerable dose identified in the dose escalation phase. The primary objective of the study is to evaluate the overall survival of patients with newly diagnosed GBM when treated with TSC administered with standard of care. Secondary objectives of the study are to evaluate progression-free survival at six months and seven months by magnetic resonance imaging, assessment using Response Assessment in Neuro-Oncology criteria. The trial will incorporate an innovative use of Positron Emission Tomography ("PET") imaging to obtain an early read on TSC's effects by directly evaluating the effects of TSC on tumor hypoxia, with initial data readouts from the dose-escalation phase of the study expected to be available within one year of the first patient being dosed.

Financial Updates

Research and development expenses in the third quarter of 2022 were $0.8 million, compared to $2.1 million in the prior year period. This decrease was attributable to the timing of clinical trials and drug manufacturing, as well as a vendor-related refund.

General and administrative expenses were $2.1 million during the third quarter of 2022 versus $1.9 million in the comparable quarter last year. The increase primarily reflects a rise in outside services related to the ongoing business development activities.

As of September 30, 2022, Diffusion had $25.9 million in cash, cash equivalents, and marketable securities, which the Company currently expects will enable it to fund its operating expenses and capital expenditure requirements into the first quarter of 2024, without giving effect to the outcome and timing of the Company's ongoing strategic review process.

About Diffusion Pharmaceuticals Inc.

Diffusion Pharmaceuticals Inc. is a biopharmaceutical company developing novel therapies to enhance the body's ability to deliver oxygen to areas where it is needed most. Diffusion's lead product candidate, TSC, is being investigated to enhance the diffusion of oxygen to tissues with low oxygen levels, also known as hypoxia, a serious complication of many of medicine's most intractable and difficult-to-treat conditions, including hypoxic solid tumors like GBM. For more information, please visit us at **www.diffusionpharma.com**.

Forward-Looking Statements

This press release includes express and implied forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including: the timing and potential outcome of the Company's ongoing strategic alternative review process; the potential therapeutic value of TSC in cancer and non-cancer indications; anticipated timelines for the initiation, completion, and announcement of data from Study 200-208; the Company's ongoing and planned clinical trials; the Company's near-term strategic priorities with respect to the development of TSC and otherwise; and the Company's anticipated cash runway. The Company may, in some cases, use terms such as "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately," or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Although the Company believes that it has a reasonable basis for each forward-looking statement contained herein, forward-looking statements by their nature involve risks and uncertainties, known and unknown, many of which are beyond the Company's control and, as a result, the Company's actual results could differ materially from those expressed or implied in any forward-looking statement. Particular risks and uncertainties include, among other things, those related to: the Company's ongoing strategic alternative review process and the Company's ability to identify, evaluate and execute potential business development transactional opportunities, if any; the novelty of the Company's Study 200-208 design, the relevance of trends observed in any PET scan data readouts the Company may obtain, and the therapeutic value of TSC; the optimal doses and dosing regimens of TSC in connection with the potential treatment of any particular disease or indication; the Company's ability to design, initiate, enroll, execute, and complete its ongoing and planned studies evaluating TSC, including Study 200-208; the likelihood and timing of regulatory approval of TSC, if any, for the treatment of solid tumors complicated by hypoxia or any other indication, or the nature of any feedback the Company may receive from the FDA or other regulatory bodies; the impact of global supply chain disruptions on the Company's drug product manufacturing capabilities, clinical development program, and associated timelines;; the Company's ability to protect and expand its intellectual property portfolio; the availability of cash resources; general economic, political, business, industry, and market conditions, including the ongoing COVID-19 pandemic, inflationary pressures, and geopolitical conflicts; and the other factors discussed under the heading "Risk Factors" in the Company's filings most recent Annual Report on Form 10-K, subsequent Quarterly Reports on Form 10-Q, and other filings with the U.S. Securities and Exchange Commission. Any forward-looking statements in this press release speak only as of the date hereof (or such earlier date as may be identified) and, except as required by applicable law, rule, or regulation, the Company undertakes no obligation to update any such statements after the date hereof.

Contacts

Investors:

Tiberend Strategic Advisors, Inc.

Daniel Kontoh-Boateng/Jonathan Nugent

dboateng@tiberend.com

jnugent@tiberend.com

Balance Sheet

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 6,587,018	$ 37,313,558
Marketable securities	19,270,940	—
Prepaid expenses, deposits and other current assets	464,884	510,015
Total current assets	26,322,842	37,823,573
Other assets	—	15,578
Total assets	$ 26,322,842	$ 37,839,151
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 807,372	$ 947,495
Accrued expenses and other current liabilities	1,463,280	1,980,189
Total current liabilities	2,270,652	2,927,684
Stockholders' Equity:		
Common stock, $0.001 par value: 1,000,000,000 shares authorized: 2,038,592 and 2,038,185 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	2,039	2,038
Additional paid-in capital	165,657,681	164,914,540
Accumulated other comprehensive loss	(86,955)	—
Accumulated deficit	(141,520,575)	(130,005,111)
Total stockholders' equity	24,052,190	34,911,467
Total liabilities and stockholders' equity	$ 26,322,842	$ 37,839,151

Statement of Operations

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 798,247	$ 2,105,815	$ 5,332,698	$ 6,994,866
Intangible asset impairment charge	-	8,639,000	—	8,639,000
General and administrative	2,124,785	1,930,082	6,390,663	5,510,365
Depreciation	-	19,100	—	67,302
Loss from operations	2,923,032	12,693,997	11,723,361	21,211,533
Interest income	(124,710)	(50,710)	(207,897)	(146,354)
Loss from operations before income tax benefit	(2,798,322)	(12,643,287)	$ (11,515,464)	$ (21,065,179)
Income tax benefit	-	(443,893)	-	(443,893)
Net loss	$ (2,798,322)	$ (12,199,394)	$ (11,515,464)	$ (20,621,286)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (1.37)	$ (5.99)	$ (5.65)	$ (10.76)

Weighted average shares outstanding, basic and diluted	2,039,089	2,037,978	2,038,716	1,916,107
Comprehensive loss:				
Net loss	$ (2,798,322)	$ (12,199,394)	$ (11,515,464)	$ (20,621,286)
Unrealized loss on marketable securities	(372)	-	(86,955)	-
Comprehensive loss:	$ (2,798,694)	$ (12,199,394)	$ (11,602,419)	$ (20,621,286)

Source: Diffusion Pharmaceuticals Inc.