



NRx Pharmaceuticals Provides Business Update and Reports First Quarter 2022 Financial Results

Company to Host Conference Call and Webcast May 16, 2022, at 8:30am ET

RADNOR, Pa., May 16, 2022 /PRNewswire/ -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP, NRx Pharmaceuticals), a clinical-stage biopharmaceutical company, today announced its financial results for the quarter ended March 31, 2022 and provided a business and clinical update.

NRX-101 Dosed the First Patient in Phase II Study. "During our first quarter of 2022 we continued to make progress on our strategic priorities for our two key compounds, namely advancing NRX-101 for bipolar depression with Acute and Sub-Acute Suicidal Ideation & Behavior and intravenous ZYESAMI® for COVID-19," said Robert Besthof, Interim Chief Executive Officer of NRx Pharmaceuticals.

COVID-19 has also significantly affected the mental health status of the United States. "We have all heard about the recent loss of lives due to suicide of well-known people, and those only known to few. Hence, we are pleased to have restarted development of our psychiatry franchise with the initiation of a Phase II clinical study of NRX-101 for patients with bipolar depression and sub-acute suicidal ideation & behavior (SSIB) for which the first patient was enrolled on May 12, 2022," continued Mr. Besthof. "We expect to initiate our registrational Phase IIb/III study for Bipolar Depression in patients with acute suicidal ideation & behavior (ASIB) in the second half of this year with commercial level material."

Having an effective therapeutic for Critical COVID-19 is of the utmost importance, as [the U.S. is still losing nearly 300 Americans to COVID-19 daily](#). ZYESAMI® is the only remaining drug for Critical COVID-19 in the NIH sponsored ACTIV-3b Trial. NRx Pharmaceuticals made important progress to further improve its proprietary formulation of aviptadil and has now achieved refrigerated stability of up to 8 months and expected multi-year frozen stability (-20°C).

Though infections have gone down since earlier this year, the White House recently issued a [warning of up to 100 million new infections in the fall and winter](#). For the ongoing ZYESAMI® NIH Phase III ACTIV-3b Trial, the next DSMB meeting is scheduled for May 25, 2022, instead of an originally planned meeting in April. The NIH ACTIV-3b Trial leadership indicated to NRx Pharmaceuticals that this new timing would allow the vast majority of patients enrolled to date to have reached the 90-day observation period endpoint. Additionally, the Company submitted filings for Emergency Use Authorization and a Breakthrough Therapy designation request to the U.S. Food & Drug Administration (FDA) both focused on a narrower group of patients with Critical COVID-19, based on a post-hoc analysis of those who progressed despite treatment with remdesivir and other therapies. These filings were supplemented by cumulative safety data of approximately 750 patients treated with intravenous ZYESAMI®. The Company continues to collaborate with the NIH ACTIV-3b Trial leadership in the quest to enable data read out by the end of 2022.

"Overall, we continue to execute on our commitment to bring hope to life by applying innovative science to known molecules in the quest to address very high unmet medical needs," concluded Robert Besthof.

Recent Business Highlights

- Submitted a new Emergency Use Authorization request to the FDA for ZYESAMI® in patients with Critical COVID-19 who are at immediate risk of death from respiratory failure despite treatment with approved therapies including remdesivir.
- Submitted an updated Breakthrough Therapy designation request to the FDA for ZYESAMI® in patients with Critical COVID-19 with respiratory failure that continued to progress despite treatment with remdesivir. This submission included safety data of approximately 750 patients treated with intravenous ZYESAMI® for Critical COVID-19.
- NIH ACTIV-3b Trial DSMB continues to enroll patients and enrollment is expected to rise as infections rise.
- Further advanced commercial manufacturing capabilities for ZYESAMI®, enabling stability of up to eight months, and expected multi-year frozen stability (minus -20°C) based on data to date.
- Restarted development in Psychiatry Franchise by initiating a Phase II study of NRX-101 for bipolar depression with SSIB, and patient enrollment in this study has commenced.
- Preparing to start a new registrational study of NRX-101 for severe bipolar depression with ASIB using commercial level material in the second half of 2022.
- Completed \$25 Million private placement in February 2022.

- Research and development expenses for the three months ended March 31, 2022, totaled \$5.5 million, compared to \$2.9 million for the quarter ended March 31, 2021. The increase of \$2.6 million was primarily driven by an increase of \$2.1 million in clinical trials and development expenses related to ZYESAMI®.
- General and administrative expenses for the three months ended March 31, 2022, totaled \$10.2 million, compared to \$2.1 million for the three months ended March 31, 2021. The increase of \$8.1 million was primarily related to an increase of \$4.4 million in legal, professional, and accounting fees, an increase of \$2.2 million in insurance expense, an increase of \$0.8 million in stock-based compensation expense and an increase of \$0.7 million in other general and administrative expense. The \$10.2 million and \$2.1 million of general and administrative expenses for the three months ended March 31, 2022, and 2021, respectively, include \$1.1 million and \$0.3 million, respectively, of non-cash stock-based compensation.
- For the three months ended March 31, 2022, NRx Pharmaceuticals recorded gains of \$2.1 million and \$0.2 million for the change in fair value of Earnout Cash liability and warrant liability, respectively. NRx Pharmaceuticals recorded no such gains in the three months ended March 31, 2021.
- For the three months ended March 31, 2021, NRx Pharmaceuticals recorded reimbursement of expenses from Relief Therapeutics of \$0.8 million, a \$0.1 million gain on extinguishment of debt, and a non-cash settlement expense of \$21.4 million related to the GEM Warrant. NRx Pharmaceuticals had no reimbursement of expenses from Relief Therapeutics, gain from extinguishment of debt or settlement expense in the three months ended March 31, 2022.
- Net loss for the three months ended March 31, 2022, was \$13.4 million, or \$0.21 per share, compared with a net loss of \$25.5 million, or \$0.71 per share for the three months ended March 31, 2021.
- During the three months ended March 31, 2022, NRx Pharmaceuticals used \$10.4 million of cash in operating activities compared to \$3.0 million during the three months ended March 31, 2021.
- As of March 31, 2022, cash was \$40.2 million compared to \$27.6 million as of December 31, 2021. NRx Pharmaceuticals believes it has sufficient cash to support operations for at least the next 12 months.

Conference Call and Webcast Details

Investors and the general public are invited to listen to a live audio webcast of the conference call, which may be accessed five minutes before the start of the call by dialing (877) 705-6003 (U.S.), (201) 493-6725 (International) Conference ID: 13729829, or through the webcast link [NRx Pharmaceuticals First Quarter 2022 Earnings Call](#). A replay will be available from the NRx Pharmaceuticals website for thirty days following the call at www.nrxpharma.com.

About NRx Pharmaceuticals

NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) ("NRx Pharmaceuticals" or the "Company") draws upon decades of collective, scientific, and drug-development experience to bring improved health to patients. The U.S. Food and Drug Administration ("FDA") has granted Breakthrough Therapy designation, a Special Protocol Agreement, and a Biomarker Letter of Support for NRX-101, an investigational medicine for the treatment of severe bipolar depression in patients with acute suicidal ideation and behavior after initial stabilization with ketamine or other effective therapy. In addition, ZYESAMI® (aviptadil), for patients with COVID-19, has been granted Fast Track designation by the FDA and is in a Phase III trial for Critical COVID-19 patients which is sponsored and managed by the US National Institutes of Health.

NRx Pharmaceuticals is led by executives who have held senior leadership roles at Lilly, Pfizer, and Novartis as well as major investment banking institutions.

Cautionary Note Regarding Forward-Looking Statements

This announcement of NRx Pharmaceuticals, Inc. includes "forward-looking statements" within the meaning of the "safe harbor" provisions of the U.S. Private Securities Litigation Reform Act of 1995, which may include, but are not limited to, statements regarding our financial outlook, product development, business prospects, and market and industry trends and conditions, as well as the Company's strategies, plans, objectives, and goals. These forward-looking statements are based on current beliefs, expectations, estimates, forecasts, and projections of, as well as assumptions made by, and information currently available to, the Company's management.

The Company assumes no obligation to revise any forward-looking statement, whether as a result of new information, future events or otherwise. Accordingly, you should not place reliance on any forward-looking statement, and all forward-looking statements are herein qualified by reference to the cautionary statements set forth above.

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NRX PHARMACEUTICALS, INC.			
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS			
(in thousands, except share and per share data)			
	Three months ended		
	March 31,		
	2022	2021	
Operating expenses:			
Research and development	\$ 5,483	\$	2,909
General and administrative	10,222		2,101
Settlement expense	—		21,366
Reimbursement of expenses from Relief Therapeutics	—		(771)
Total operating expenses	15,705		25,605
Loss from operations	(15,705)		(25,605)
Other (income) expenses:			
Gain on extinguishment of debt	—		(121)
Interest expense	3		5
Change in fair value of warrant liability	(157)		—
Change in fair value of Earnout Cash liability	(2,103)		—
Total other (income) expenses	(2,257)		(116)
Net loss	\$ (13,448)	\$	(25,489)
Net loss per share:			
Basic and diluted	\$ (0.21)	\$	(0.71)
Weighted average common shares outstanding:			
Basic and diluted	63,667,468		35,658,216

NRX PHARMACEUTICALS, INC.			
CONDENSED CONSOLIDATED BALANCE SHEETS			
(in thousands, except share and per share data)			
	March 31, 2022	December 31, 2021	
	(Unaudited)		
ASSETS			
Current assets:			
Cash	\$ 40,202	\$	27,605
Prepaid expenses and other current assets	3,382		5,109
Total current assets	43,584		32,714
Other assets	17		15
Total assets	\$ 43,601	\$	32,729
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities:			
Accounts payable	\$ 4,311	\$	3,687
Accrued and other current liabilities	4,001		2,375
Accrued clinical site costs	466		469
Earnout Cash liability	2,479		4,582
Warrant liabilities	135		292
Note payable and accrued interest	520		518
Total liabilities	\$ 11,912	\$	11,923
Stockholders' equity:			
Preferred stock, \$0.001 par value, 50,000,000 shares authorized; 0 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	—		—
Common stock, \$0.001 par value, 500,000,000 shares authorized; 66,641,314 and 58,810,550 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	67		59
Additional paid-in capital	228,313		203,990
Accumulated deficit	(196,691)		(183,243)
Total stockholders' equity	31,689		20,806
Total liabilities and stockholders' equity	\$ 43,601	\$	32,729

NRX PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)
(Unaudited)

	Three months ended March 31,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (13,448)	\$ (25,489)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	1	—
Stock-based compensation	1,334	372
Gain on extinguishment of debt	—	(121)
Change in fair value of warrant liabilities	(157)	—
Change in fair value of earnout cash liability	(2,103)	—
Non-cash interest expense	2	5
Non-cash settlement expense	—	21,366
Changes in operating assets and liabilities:		
Accounts receivable	—	831
Prepaid expenses and other assets	1,727	(50)
Accounts payable	624	1,229
Accrued expenses and other liabilities	1,640	(1,158)
Net cash used in operating activities	(10,380)	(3,015)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of computer equipment	(3)	—
Net cash used in investing activities	(3)	—
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of common stock, net of transaction costs	—	6,927
Proceeds from issuance of common stock for exercise of warrant	—	7,500
Proceeds from issuance of common stock and warrants issued in private placement, net of issuance costs	22,980	—
Net cash provided by financing activities	22,980	14,427
Net increase in cash	12,597	11,412
Cash at beginning of period	27,605	1,859
Cash at end of period	\$ 40,202	\$ 13,271

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