NRx Pharmaceuticals Reports First Quarter 2023 Financial Results and Provides Business Update

May 16, 2023

- Enrollment continues in the Phase 2b/3 clinical trial evaluating NRX-101 in Suicidal Treatment-Resistant Bipolar Depression; data expected in 4Q 2023
- National educational campaign launched to further accelerate enrollment in
- Breakthrough Therapy Designation meeting for NRX-101 in Suicidal Treatment-Resistant Bipolar Depression with the U.S. FDA planned for 2Q 2023; on track to report topline clinical data in 4Q 2023
- Ended quarter with $16.5 million in cash and cash equivalents
- Management to host a conference call and webcast today at 8:30 a.m. ET

RADNOR, Pa., May 16, 2023 /PRNewswire/ -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) ("NRx Pharmaceuticals", the "Company"), a clinical-stage biopharmaceutical company, today announced its financial results for the first quarter of 2023 and provided a business update.

"In the U.S. alone, nearly one million people suffer from Suicidal Treatment-Resistant Bipolar Depression, a lethal condition that ultimately leads to a suicide attempt in half of this patient population. Currently, there is no approved medicine for patients with this condition, and the only FDA-approved treatment is electroshock therapy, which has numerous known side-effects," said Stephen Willard, J.D., Chief Executive Officer and Director of NRx Pharmaceuticals. "We are committed to demonstrating the therapeutic benefit of NRX-101, the first oral NMDA-targeted medicine to be developed for patients with suicidal bipolar depression, for these patients facing significant unmet need, and we remain on track to report initial data from this integrated trial in the fourth quarter of this year. We look forward to working with the U.S. FDA on the upgraded Phase 2b/3 trial of NRX-101 in the broader indication of Suicidal Treatment-Resistant Bipolar Depression during a Breakthrough Therapy Designation meeting later this quarter."

First Quarter Clinical and Regulatory Highlights

NRX Pharma is engaged in the development of NRX-101, a fixed dose combination of D-cycloserine and lurasidone for the treatment of suicidal bipolar depression and potentially for other future indications. NRX-101 has been granted Fast Track Designation, Breakthrough Therapy Designation, a Special Protocol Agreement, and a Biomarker Letter of Support by the US Food and Drug Administration (FDA). In Q1 2023 the Company met with the FDA and was guided to expand its intended use of NRX-101 from the original population of patients with acute suicidality who might be treated in the hospital environment to the broader population of patients with subacute suicidal ideation (now described by the Company as Treatment-Resistant Bipolar Depression) who are treated in the outpatient setting. These patients are the current target population of the ongoing clinical trial.

Based on the guidance of FDA and the Company's completion of manufacturing for phase 3/commercial stage investigational product, the Company upgraded the ongoing clinical trial to a phase 2b/3 trial, the results of which have the potential to be used for registrational filings. The Company is engaged in that ongoing clinical trial of NRX-101 vs. lurasidone in patients with treatment-resistant bipolar depression with the objective of demonstrating a decreased in depression scores and scores of suicidal ideation in patients treated with NRX-101 compared to those treated with lurasidone alone.

The clinical trial was originally begun as an exploratory study in Q2 2022, as disclosed in prior filings. In Q1 2023 the study's independent Data Safety Monitoring Board (DSMB) reviewed both safety and unblinded efficacy data for the first 50 patients in the clinical trial and advised the Company that no safety concerns were identified. Moreover, the DSMB did not identify a futility signal, suggesting that the trial has potential to demonstrate a statistically significant outcome with additional enrollment. On this basis, the DSMB advised management to continue enrolling study participants.

During the first quarter of 2023, the Company refined its ability to validate the psychometric ratings that are used to assess the efficacy endpoints for the clinical trial. The Company relies upon a team of veteran raters who both train independent site rates and monitor the technical quality of each rating. A standard was set of 90% or better concordance between the Company's veteran rating team and site raters. This standard was met for all study participants whose ratings were obtained in their primary language and management believes that this standard can be maintained for the duration of the trial.

In April 2023, the Company contracted with 1nHealth to initiate a recruitment campaign that may cover up to 45 states in the US to recruit sufficient participants for this enlarged trial. The Company has similarly broadened its previously disclosed relationship with Science 37, a contract research organization that conducts decentralized clinical trials, to enroll participants identified by the 1nHealth recruitment initiative and randomize them to be treated within the broadened clinical trial. 1nHealth has additionally engaged a voice-of-the-patient organization with national reach to publicize the clinical trial to the 400,000+ subscribers who have indicated a focus on bipolar depression and suicidality.

In Q1 2023, the Company announced the participation of Prof. Andrew Nierenberg, M.D., Head of the Massachusetts General Hospital (MGH) Dauton Family Center for Bipolar Treatment Innovation as the Principal Investigator of the clinical trial. The Company has now initiated clinical trial sites at Northwestern University (Chicago) and University of Texas, Austin, in addition to commercial research sites.

NRX-101 Indication – Post Traumatic Stress Disorder (PTSD)

- NRx plans to investigate NRX-101 in PTSD as an additional indication. The Company expects to commence planning for a Phase 2 clinical trial in the second quarter of 2023 with the study expected to be open for enrollment in 2023.
- Depression in PTSD may be driven by pathways that are similar to those that drive depression in other conditions (NMDA and 5-HT2A). Additionally, approximately 10% of patients with PTSD may experience suicidality, especially those with severe PTSD.
- In a preclinical PTSD study, D-cycloserine, a component of NRX-101, demonstrated the ability to extinguish recurring images of traumatic events, also known as fear memory, in a validated WKY model of PTSD. Ketamine has demonstrated an effect on this debilitating symptom of PTSD. Should NRX-101 have a similar beneficial effect, it has the potential to be the first labeled medicine for PTSD symptoms.

First Quarter Corporate Updates

- In February 2023, the Company received notice of the issuance of a U.S. patent covering the lead formulation, NRX-101, a glycine site NMDA antagonist in clinical trials to treat bipolar depression with acute and subacute suicidality. This new patent covers the use of NRX-101 to treat patients suffering from depression, including bipolar depression or major depression (MDD) with or without suicidality and strengthens the Company's intellectual property position until at least 2033.
- In March 2023, the Company announced the close of a $2.9 million registered direct offering. Participants were existing investors, and the Company anticipates using the proceeds to initiate its national treatment protocol and safety database for NRX-101 for treatment-resistant bipolar depression with risk of self-harm under an FDA expanded access protocol, and to advance its pipeline of life-saving therapeutics.
- The Company has continued to engage in a strategic conversation focused on funding the drug approval and commercialization. In parallel, the Company has established an ongoing dialogue with Streeterville Capital LLC, the Company's current debt lender, to modify the Company's current debt facility to best support the ongoing needs of the clinical trial.

Financial Results for the First Quarter Ended March 31, 2023

- For the three months ended March 31, 2023, NRx Pharmaceuticals recorded $3.7 million of research and development expenses compared to $5.5 million for the year ended March 31, 2022. The decrease of $1.8 million is related primarily to a decrease of $1.8 million in clinical trials and development expenses related to ZYESAMI.
- For the three months ended March 31, 2023, NRx Pharmaceuticals recorded $5.8 million of general and administrative expenses compared to $10.2 million for the three months ended March 31, 2022. The decrease of $4.4 million was primarily, related to a decrease of $3.9 million in legal, professional and accounting fees, $0.6 million in insurance expenses, $0.5 million in stock-based compensation expense, partially offset by $0.3 million in employee expenses and $0.2 million in consultant fees.
- Assuming future debt payments can continue to be made in stock, the $16.5 million of cash and cash equivalents at the end of the first quarter of 2023 is expected to fund the Company's operations through the expected delivery of data in our Phase 2b/3 trial. Additionally, we are evaluating operational efficiencies associated with the completion of manufacturing activities to extend this runway.

Conference Call and Webcast Details

A live webcast of the conference call will be available on the Company's website today at 8:30 a.m. ET, at https://ir.nrxpharma.com/news-events/ir-calendar. An archive of the webcast will be available on the Company's website for 30 days. Participants that are unable to join the webcast can access the conference call via telephone by dialing domestically +1 (833) 630-1956 or internationally +1 (412) 317-1837.

About NRX-101

Up to 50% of individuals with bipolar disorder attempt suicide over their lifetime, and estimates indicate that up to 20% may succumb to suicide. The only FDA-approved treatment for patients with treatment-resistant suicidal bipolar depression remains electroconvulsive therapy.

Conventional antidepressants can increase the risk of suicide in certain patients; hence their labels contain a warning to that effect. NRX-101 is a patented, oral, fixed dose combination of D-cycloserine and lurasidone, neither of which has shown addiction potential in preclinical models. Based on the results of a Phase 2 proof-of-concept study, NRX-101 received Breakthrough Therapy Designation from the FDA for the treatment of severe bipolar depression in patients with ASIB after initial stabilization with ketamine or other effective therapy.

NRX-101 is one of the first oral antidepressants currently in late-stage clinical studies targeting the NMDA-receptor in the brain,

which represents potentially a key new mechanism to treat depression with and without suicidality, as well as PTSD and other indications. To date, NRX-101 is the only oral NMDA investigational medicine focused on bipolar depression in patients with acute and sub-acute suicidality.

About NRx Pharmaceuticals

NRx Pharmaceuticals is a clinical -stage biopharmaceutical company developing therapeutics for the treatment of central nervous system disorders, specifically bipolar depression with suicidality and post-traumatic stress disorder (PTSD). The company's lead program NRX-101, an oral, fixed-dose combination of D-cycloserine and lurasidone, targets the brain's N-methyl-D-aspartate (NMDA) receptor and is being investigated in a Phase 2b/3 clinical trial for Suicidal Treatment-Resistant Bipolar Depression, which includes patients with both acute and sub-acute suicidality, an indication for which the only approved treatment is electroshock therapy. The company's prior Phase 2 STABIL-B clinical trial evaluating NRX-101 in patients with Severe Bipolar Depression with Acute Suicidal Ideation & Behavior (ASIB) demonstrated a substantial improvement over available therapy in reducing depression and suicidality compared to placebo when patients were treated with NRX-101 after a single dose of ketamine. Based on the findings from the STABIL-B trial, the U.S. Food and Drug Administration (FDA) granted a Special Protocol Agreement and Breakthrough Therapy Designation for NRX-101 in patients with Severe Bipolar Depression with ASIB.

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.

NRX PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	March 31, 2023	December 31, 2022
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 16,506	$ 20,054
Prepaid expenses and other current assets	5,250	5,741
Total current assets	21,756	25,795
Other assets	24	21
Total assets	$ 21,780	$ 25,816
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		

Current liabilities:		
Accounts payable	$ 3,776	$ 2,076
Accrued and other current liabilities	5,054	4,855
Accrued clinical site costs	1,020	914
Convertible note payable and accrued interest - short term	12,189	7,703
Warrant liabilities	25	37
Total current liabilities	22,064	15,585
Convertible note payable and accrued interest - long term	—	2,822
Total liabilities	$ 22,064	$ 18,407
Preferred stock, $0.001 par value, 50,000,000 shares authorized; 0 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	—	—
Common stock, $0.001 par value, 500,000,000 shares authorized; 70,309,655 and 66,442,989 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	70	67
Additional paid-in capital	233,576	230,339
Accumulated other comprehensive income	106	—
Accumulated deficit	(234,036)	(222,997)
Total stockholders' (deficit) equity	(284)	7,409
Total liabilities and stockholders' (deficit) equity	$ 21,780	$ 25,816

NRX PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share data)

(Unaudited)

	Three months ended

	March 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 3,650	$ 5,483
General and administrative	5,785	10,222
Total operating expenses	9,435	15,705
Loss from operations	(9,435)	(15,705)
Other (income) expenses:		
Interest income	(156)	—
Interest expense	—	3
Change in fair value of convertible note payable	1,772	—
Change in fair value of warrant liabilities	(12)	(157)
Change in fair value of Earnout Cash liability	—	(2,103)
Total other (income) expenses	1,604	(2,257)
Net loss	$ (11,039)	$ (13,448)
Change in fair value of convertible note attributed to credit risk	(106)	—
Other comprehensive income	(106)	—
Comprehensive loss	$ (10,933)	$ (13,448)
Net loss per share:		
Basic and diluted	$ (0.16)	$ (0.21)
Weighted average common shares outstanding:		
Basic and diluted	67,453,897	63,667,468

SOURCE NRx Pharmaceuticals, Inc.