November 14, 2022

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

- Completed a technology transfer, submitted a new manufacturing file to the United States ("U.S.") Food and Drug Administration ("FDA"), and released new drug produced with processes designed to support commercial-stage manufacturing of a Phase 3 investigational drug
- On track to report data from ongoing Phase 2 clinical trial of NRX-101 in patients with bipolar depression with sub-acute suicidal ideation and behavior (SSIB) in 1Q 2023
- Company has received numerous partnering inquiries for NRX-101
- Plan to initiate registrational Phase 3 clinical trial of NRX-101 in patients with bipolar depression with acute suicidal ideation and behavior (ASIB) by year-end; data readout expected in 3Q 2023
- Commenced Phase 2 clinical trial planning of NRX-101 for post-traumatic stress disorder ("PTSD")
- Ended quarter with $18.2 million in cash and cash equivalents and announced completion of a subsequent unsecured debt financing on November 7, 2022, providing net proceeds of $10.0 million to support the NRx Pharmaceuticals' pipeline of life-saving therapeutics

RADNOR, Pa., Nov. 14, 2022 /PRNewswire/ -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) ("NRx Pharmaceuticals", the "Company"), a clinical-stage biopharmaceutical company, today announced its financial results for the third quarter of 2022 and provided a business and clinical update.

"In recent months, NRx Pharmaceuticals has made substantial progress advancing our clinical development plans for our lead investigational compound, NRX-101, in multiple psychiatric indications," said Stephen Willard, J.D., Chief Executive Officer and Director of NRx Pharmaceuticals. "Today, someone in the U.S. someone attempts suicide every 27 seconds, and someone dies of suicide every 11 minutes and there is no approved medication for suicidal bipolar depression or PTSD. The only FDA-approved treatment for suicidal bipolar depression remains electroshock therapy. The FDA has granted NRX-101 a Breakthrough Therapy Designation with an accompanying Special Protocol Agreement for treatment of patients with bipolar depression and acute suicidality. If approved, we aim to offer this potentially transformative medicine to patients in 2024. During this exciting time at NRx Pharmaceuticals, we remain committed to our mission of meeting the needs of underserved patients with life-threatening central nervous system ("CNS") disorders."

NRx Pharmaceuticals plans to advance NRX-101 to approval with multiple near-term catalysts on track for the fourth quarter, including the initiation of a Phase 2b/3 SPA trial (a registrational Phase 3 clinical trial) for NRX-101 in patients with bipolar depression with acute suicidality and a Phase 2 trial for NRX-101 in PTSD, a secondary indication recently announced in September. Additionally, the Company expects to report top-line clinical data for the Phase 2 trial of NRX-101 in patients with bipolar depression with sub-acute suicidality in the first quarter of 2023.

Third Quarter Clinical and Regulatory Highlights

In March 2022, NRx Pharmaceuticals announced a primary focus on its psychiatry franchise and the late-stage development of NRX-101 for the treatment of bipolar depression in patients with suicidality. NRX-101 is a fixed dose combination of D-cycloserine, an NMDA antagonist, and lurasidone, a 5-HT2A atypical antipsychotic and antidepressant, for the maintenance of remission from severe bipolar depression following initial stabilization

with ketamine. The previously undiscovered synergy between these two drug classes in the treatment of CNS disorders, combined with the efficacy of D-cycloserine in the treatment of depression and PTSD, is the subject of 47 issued patents and more than 43 pending patents owned by or licensed to NRx Pharmaceuticals.

NRX-101 Lead Indication – Severe Bipolar Depression in Patients with Acute Suicidal Ideation and Behavior (ASIB) After Initial Stabilization with ketamine

- In 2017, NRX-101 received an investigational new drug (IND) clearance by the U.S. Food and Drug Administration (FDA) and a Phase 2b/3 clinical trial commenced for bipolar depression with ASIB. Later that year, the FDA granted NRX-101 a Fast Track designation for the same indication.
- In 2018, the FDA provided a Letter of Support to the Company encouraging the development of Glutamine+Glutamate (Glx) as a pharmacodynamic biomarker for depression. The letter referenced published and unpublished data demonstrating a significant association between clinical symptoms of depression and levels of brain Glx.
- In the STABIL-B Phase 2 trial, the Phase 2 portion of the Phase 2b/3 trial, patients with bipolar depression and ASIB received either NRX-101 or lurasidone after an intravenous infusion of NRX-100 (ketamine). The proof-of-concept data presented at the American Congress of Neuropsychopharmacology in 2018 demonstrated with statistical significance that NRX-101 treated patients experienced lower depression scores and did not relapse.
- Based on STABIL-B findings, the FDA granted NRX-101 Breakthrough Therapy Designation and a Special Protocol Agreement ("SPA") for bipolar depression in patients with ASIB, which affects ~150K-180K patients per year in the U.S. The Breakthrough Therapy Designation allows for an expedited rolling submission of a new drug application ("NDA") for investigational drugs that have demonstrated substantial improvement over existing approved therapies, and the SPA allows for a single registrational trial of NRX-101 in severe bipolar depression in patients with ASIB after stabilization with ketamine, using a protocol similar to the STABIL-B trial with a patient population of less than 100.
- NRx Pharmaceuticals plans to initiate the registrational Phase 3 portion of the Phase 2b/3 clinical trial of bipolar depression in patients with ASIB in 4Q 2022. The trial is designed as a double-blind, adaptive trial with a 2:1 randomization of NRX-101 vs. lurasidone alone in 72 patients. The study is expected to find that following initial stabilization with a single infusion of ketamine (NRX-100), treatment with NRX-101 is superior to lurasidone alone in maintaining remission from symptoms of depression and suicidality as measured by the MADRS-10 depression scale and the CGI suicidality scale.
- NRx Pharmaceuticals announced that it has transferred Phase 3 commercial drug manufacturing processes to the U.S. and released Phase 3 drug manufactured via the expected commercial-stage processes. NRx Pharmaceuticals has submitted its manufacturing file to the FDA. This investigational drug manufactured according to these new processes will be used in the upcoming Phase 3 trial.
- A data readout from the registrational Phase 3 clinical trial is expected in 3Q 2023. Assuming that efficacy endpoints and safety are met, NRx Pharmaceuticals plans to initiate submission of a NDA to the FDA by year-end 2023, as allowed under Breakthrough Therapy Designation.
- Company has received numerous partnering inquiries for NRX-101

NRX-101 Indication – Bipolar Depression in Patients with Sub-acute Suicidal Ideation and Behavior (SSIB)

- A Phase 2 double-blind study completed in 2018 demonstrated the ability of NRX-101 to improve depression and suicidality over 6 weeks when taken twice daily over lurasidone alone after an initial stabilization with ketamine. The current study involving patients with bipolar depression and sub-acute suicidality (not requiring hospitalization) does not include the use of ketamine; all patients are being treated in an outpatient setting.
- Insights from this study will guide NRx Pharmaceuticals in the potential expansion of the indication for NRX-101 to bipolar depression with SSIB, which represents a significantly 2-3x larger patient population than those with bipolar depression and ASIB. A data readout of this study is expected by 1H 2023.

NRX-101 Indication – Post Traumatic Stress Disorder

- In September 2022, NRx announced plans to investigate PTSD as an additional indication. The Company expects to commence Phase 2 clinical trial planning of NRX-101 in PTSD in 4Q 2022.
- 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.

Corporate Updates

- In August 2022, the Company appointed Mr. Willard as Chief Executive Officer and as a member of the Board of Directors. Mr. Willard brings a wealth of experience in the management of publicly traded biotechnology companies, together with his background in law and finance. Most recently, Mr. Willard previously served as CEO of Cellphire Therapeutics, where he grew the company and shepherded their revolutionary human platelet platform through key clinical trials, growing the company and enhancing shareholder value. For eight years prior to that he served as CEO of NASDAQ traded Flamel Technologies.
- Completed agreement with Relief Therapeutics Holding SA regarding pending litigation. Further information was contained in a joint press release issued on November 13, 2022, and will be included in the form 8-K to be filed with the Securities and Exchange Commission upon settlement.

Third Quarter 2022 Financial Results

Financial Results for the Third Quarter ended September 30, 2022

- Research and development (R&D) expenses for the third quarter totaled $4.1 million compared to $6.3 million for the comparable quarter in 2021. The decrease in R&D expenses related primarily to a decrease clinical trials and development expenses related to ZYESAMI®.
- General and administrative (G&A) expenses for the third quarter totaled $5.0 million compared to $13.8 million for the comparable quarter in 2021. The decrease in G&A expenses was primarily related to a decrease in stock-based compensation and consultant fees.
- Other income for the third quarter totaled $0.06 million compared to $17.0 million for the comparable quarter in 2021. The decrease in other income was primarily related to a decrease in the fair value of certain Substitute Warrants and the Placement Warrants assumed pursuant to the Merger Agreement because of lower stock price levels.
- Net loss for the third quarter was $9.1 million compared with a net loss of $37.0 million for the comparable quarter in 2021.

Financial Results for Nine Months ended September 30, 2022

- R&D expenses for the nine months ended September 30, 2022, totaled $12.6 million compared to $13.8 million for the nine months ended September 30, 2021. The decrease in R&D expenses related primarily to a decrease in regulatory and process development expenses related to ZYESAMI® and the BriLife vaccine.
- G&A expenses for the nine months ended September 30, 2022, totaled $21.9 million compared to $28.4 million for the nine months ended September 30, 2021. The decrease in G&A expenses was primarily related to a decrease in consultant fees and stock-based compensation.
- Settlement expenses for the nine months ended September 30, 2022, totaled $0.0 million compared to $21.4 million for the nine months ended September 30, 2021, related to the GEM Warrant reflecting the incremental value through the date of issuance.
- Other income for the nine months ended September 30, 2022, totaled $4.9 million compared to $0.2 million for the nine months ended September 30, 2021. The increase in other income was primarily related to a decrease in the fair value of the Earnout Cash liability compared to the nine months ended September 30,

2021.

- Net loss for the nine months ended September 30, 2022, was $29.5 million compared with a net loss of $62.7 million for the nine months ended September 30, 2021.
- As of September 30, 2022, cash was $18.2 million compared to $27.6 million as of December 31, 2021. NRx Pharmaceuticals announced completion of a subsequent unsecured debt financing on November 7, 2022, with net proceeds of $10.0 million. The Company intends to use the net proceeds to support its NRX-101 development programs for the treatment of suicidal bipolar depression and PTSD. The Company believes that it has sufficient funds to support our ongoing clinical development plans for at least the next 12 months, and if necessary, the ability to reduce non-core G&A operating expenses.

Conference Call and Webcast Details

A live webcast of the conference call will be available on the Company's website at NRx Pharmaceuticals Third Quarter Earnings Webcast/Call. An archive of the webcast will be available on the Company's website.

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 bipolar depression and acute suicidal ideation & behavior (ASIB) remains electroconvulsive therapy (ECT). 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. 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.

NRx Pharmaceuticals expects to begin its registration trial for NRX-101 under a SPA in 4Q 2022 or early Q1 2023.

About NRx Pharmaceuticals

NRx Pharmaceuticals is a clinical-stage biopharmaceutical company developing therapeutics for the treatment of central nervous system disorders, specifically suicidal depression 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 NMDA receptor and is being investigated in a Phase 3 trial under a Food and Drug Administration ("FDA") Special Protocol Agreement and Breakthrough Therapy Designation in patients with bipolar depression and acute suicidal ideation, an indication for which the only approved treatment is electroshock therapy. NRx Pharmaceuticals has also initiated a Phase 2b clinical trial in patients with Sub-Acute Suicidality, potentially a substantially broader indication. The Breakthrough Therapy Designation and Special Protocol Agreement were awarded by the FDA based on the Company's prior STABIL-B trial that demonstrated 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.

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

	September 30, 2022	December 31, 2021
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 18,249	$ 27,605
Prepaid expenses and other current assets	6,552	5,109
Total current assets	24,801	32,714
Other assets	23	15
Total assets	$ 24,824	$ 32,729
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,168	$ 3,687
Accrued and other current liabilities	5,067	2,375
Accrued clinical site costs	751	469
Earnout Cash liability	—	4,582
Warrant liabilities	56	292
Note payable and accrued interest	—	518
Total liabilities	$ 8,042	$ 11,923
Preferred stock, $0.001 par value, 50,000,000 shares authorized; 0 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	—	—
Common stock, $0.001 par value, 500,000,000 shares authorized; 67,641,314 and 58,810,550 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	68	59
Additional paid-in capital	229,470	203,990
Accumulated deficit	(212,756)	(183,243)
Total stockholders' equity	16,782	20,806
Total liabilities and stockholders' equity	$ 24,824	$ 32,729

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

NRX PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except share and per share data)

(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2022	**2021**	**2022**	**2021**
Operating expenses:				
Research and development	$ 4,129	$ 6,276	$ 12,571	$ 13,844
General and administrative	5,012	13,823	21,876	28,382
Settlement expense	—	—	—	21,366
Reimbursement of expenses from Relief Therapeutics	—	—	—	(771)
Total operating expenses	9,141	20,099	34,447	62,821
Loss from operations	(9,141)	(20,099)	(34,447)	(62,821)
Other (income) expenses:				
Gain on extinguishment of debt	—	—	—	(121)
Interest income	(95)	—	(119)	—
Interest expense	—	5	3	16
Change in fair value of warrant liabilities	37	16,537	(236)	(823)
Change in fair value of Earnout Cash liability	—	408	(4,582)	763
Total other (income) expenses	(58)	16,950	(4,934)	(165)
Net loss	(9,083)	(37,049)	(29,513)	(62,656)
Deemed dividend	—	—	—	(255,822)
Net loss attributable to common stockholders	$ (9,083)	$ (37,049)	$ (29,513)	$ (318,478)
Net loss per share:				
Basic	$ (0.14)	$ (0.72)	$ (0.45)	$ (1.45)
Diluted	$ (0.14)	$ (0.72)	$ (0.45)	$ (1.45)
Net loss per share attributable to common stockholders:				
Basic	$ (0.14)	$ (0.72)	$ (0.45)	$ (7.36)
Diluted	$ (0.14)	$ (0.72)	$ (0.45)	$ (7.36)
Weighted average common shares outstanding:				
Basic and diluted	66,449,593	51,739,452	65,532,409	43,290,675

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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