NRx Pharmaceuticals Provides Business Update and Reports Second Quarter 2022 Results Focusing on Reactivation & Advancement of its Psychiatry Franchise

August 15, 2022

Company to Host Conference Call and Webcast August 15, 2022, at 8:30am ET

RADNOR, Pa., Aug. 15, 2022 /PRNewswire/ -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP), ("NRx Pharmaceuticals" or the "Company"), a clinical-stage biopharmaceutical company, today announced its financial results for the second quarter of 2022 and provided a business and clinical update.

Newly Appointed Proven Bio CEO, Stephen Willard, Leads Q2-22 Earnings Report & Reinitiated Franchise Focus in Psychiatry

"During our second quarter, we reactivated clinical development in our psychiatry franchise around our lead compound, NRX-101. NRX-101 has been awarded Breakthrough Therapy designation and a Special Protocol Agreement for severe bipolar depression with acute suicidal ideation and behavior (ASIB) by the U.S. Food and Drug Administration (FDA), said Stephen Willard, Chief Executive Officer of the Company. "We anticipate initiation of the study in severe bipolar depression with acute suicidal ideation and behavior (ASIB) to commence at the end of 2022 or at the beginning of 2023.

During this quarter, we commenced enrollment in our Phase 2 trial of NRX-101 in patients with Bipolar Depression and Sub-Acute Suicidal Ideation & Behavior (SSIB)", said Willard. "The purpose of this trial is to expand our potential indication from bipolar depression in patients with acute suicidality to the significantly larger population of patients with bipolar depression and sub-acute suicidality, who are being treated in the ambulatory setting. We are evaluating the adequacy of the protocol to support approval for the treatment of the larger SSIB population. We project a readout of the data from this trial by the end of the year or early Q1 of next year".

"We expect to release commercial-stage material of NRX-101 in the coming weeks. This material will be used in our phase 2b/3 trial of NRX-101 for severe bipolar depression in patients with acute suicidal ideation & behavior (ASIB) under the FDA Special Protocol Agreement, which we expect to start in Q4," said Mr. Willard.

Many approved drugs for bipolar depression have warning labels for increased risk of suicide. To our knowledge, NRX-101 is the only oral antidepressant in the bipolar segment that targets patients with active suicidality, which typically is an exclusion criterion in clinical studies of depression and PTSD. Phase 2 STABIL-B trial1 data of NRX-101 demonstrated a significant reduction in both depression and suicidality compared to standard therapy in acutely suicidal patients who were first stabilized with ketamine. We have released non-clinical findings demonstrating that, unlike ketamine, both components in NRX-101 have not shown potential for addiction and are not neurotoxic (i.e., do not cause death of brain cells in FDA-required assays).2

In Q2, we repatriated the manufacture of NRX-101 drug supply to North Carolina and are currently manufacturing clinical supplies for P3 as part of the commercial readiness program.

Our psychiatry franchise builds on a strong scientific and intellectual property foundation with 47 granted patents and 43 pending applications around the world. Our focus is to address this major unmet medical need for which the only currently approved treatment is electroshock therapy. It is estimated that 50% of individuals with bipolar disorder attempt suicide over their lifetime. We believe NRX-101 is a potentially life-saving medicine that could change the treatment paradigm for individuals with bipolar depression that are also experiencing suicidality."

We expect to evaluate the options for ZYESAMI® in COVID-19 Respiratory Failure and other lung disorders once we receive the full data set from NIH towards the end of Q3 or early Q4 and have conducted our own analysis.

Although we are not funding additional clinical trials of ZYESAMI® at this time, we have completed manufacture of phase 3/commercial ready ZYESAMI®. We also received an independent assessment of chest X-ray data from a sub-study that included a subgroup of approximately 80 patients that had survived to day 10 in our Phase 2b/3 study of ZYESAMI®. The sub-study showed a statistically significant improvement in chest X-rays using the RALES score in patients with COVID-19 respiratory failure, compared to a worsening in patients treated with placebo (P<.05). This exploratory data will further guide our assessment of future options for ZYESAMI®.

Key Business & Clinical Highlights

- Announced new leadership with the appointment of Stephen Willard, JD, as CEO and member of the Board of Directors, and Seth Van Voorhees, PhD, MBA, as CFO
- Repositioned company to focus on psychiatry franchise and our Breakthrough Therapy designated drug NRX-101 for Bipolar Depression in Patients with Suicidality. NRX-101 has additionally been awarded a Special Protocol Agreement by the FDA
- Repatriated manufacture of NRX-101 to a leading North Carolina-based manufacturer, completed technology transfer, and manufactured first batch of phase 3/commercial-ready NRX-101 capsules
- Initiated a Phase 2b trial of NRX-101 in patients with Bipolar Depression and Sub-Acute Suicidality (SSIB); 10 planned clinical sites are activated and are actively enrolling patients, with topline data readout anticipated at the end of Q4 22/Q1 23
- Received independent grading of chest x-rays from a subgroup of patients that survived to day 10 from the intravenous ZYESAMI® trial. Top line analysis shows a statistically significant change between baseline and day 10 on the RALES score (i.e., improvement in ZYESAMI®-treated patients and worsening in placebo-treated patients). Ongoing data analysis is continuing.

Financial Results for Quarter ended June 30, 2022

- Research and development expenses for the three months ended June 30, 2022, totaled $3.0 million, compared to $4.7 million for the quarter ended June 30, 2021. The decrease of $1.7 million related primarily to a decrease clinical trials and development expenses related to ZYESAMI®.
- General and administrative expenses for the three months ended June 30, 2022, totaled $6.6 million, compared to $12.5 million for the three months ended June 30, 2021. The decrease of $5.8 million was primarily related to a decrease in stock-based compensation and consultant fees, partially

offset by an increase in higher insurance related expenses.

- Other income for the three months ended June 30, 2022, totaled $2.6 million, compared to $17.0 million for the three months ended June 30, 2021. The decrease of $14.4 million 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 three months ended June 30, 2022, was $7.0 million compared with a net loss of $0.1 million for the three months ended June 30, 2021.

Financial Results for Six Months ended June 30, 2022

- Research and development expenses for the six months ended June 30, 2022, totaled $8.4 million, compared to $7.6 million for the six months ended June 30, 2021. The increase of $0.9 million related primarily to an increase in regulatory and process development expenses.

- General and administrative expenses for the six months ended June 30, 2022, totaled $16.9 million, compared to $14.6 million for the six months ended June 30, 2021. The increase of $2.3 million was primarily related to an increase in legal, professional and insurance expenses partially offset by a decrease in consultant fees and stock-based compensation expenses.

- Other Income for the six months ended June 30, 2022, totaled $4.9 million, compared to $17.1 million for the recently restated six months ended June 30, 2021. The decrease of $12.2 million 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 six months ended June 30, 2022, was $20.4 million compared with a net loss of $25.6 million for the three months ended June 30, 2021.

- As of June 30, 2022, cash was $24.5 million compared to $27.6 million as of December 31, 2021. We believe that we have sufficient funds and if necessary, the ability to reduce expenditures, to support operations through August 2023. The Company may also seek to reduce certain expenditures if needed to reduce cash consumption in support of operations.

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 (844) 826-3033 (U.S.), (412) 317-5185 (International) Conference ID: 10170239, or through the webcast link NRx Pharmaceuticals Second 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-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, fixed dose combination of D-cycloserine and lurasidone, neither of which has shown addiction potential. Based on the results of a Phase II study, NRX-101 received Breakthrough Therapy designation (BTD) 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.

About NRx Pharmaceuticals

NRx Pharmaceuticals, Inc. draws upon decades of collective, scientific, and drug-development experience applying innovative science to known molecules to address very high unmet needs and bring improved health to patients. NRx Pharmaceuticals is led by executives who have held 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.

CORPORATE CONTACT
Molly Cogan
Sr. Director, Global Communications
mcogan@nrxpharma.com

INVESTOR RELATIONS
Tim McCarthy
Investor Relations
tim@lifesciadvisors.com

###tables to follow###

NRX PHARMACEUTICALS, INC.

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

(Unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 2,958	$ 4,659	$ 8,441	$ 7,568
General and administrative	6,642	12,458	16,864	14,558
Settlement expense	—	—	—	21,366
Reimbursement of expenses from Relief Therapeutics	—	—	—	(771)
Total operating expenses	9,600	17,117	25,305	42,721
Loss from operations	(9,600)	(17,117)	(25,305)	(42,721)
Other (income) expenses:				
Gain on extinguishment of debt	—	—	—	(121)
Interest income	(23)	—	(23)	—
Interest expense	—	5	3	10
Change in fair value of warrant liabilities	(116)	(17,359)	(273)	(17,359)
Change in fair value of Earnout Cash liability	(2,479)	355	(4,582)	355
Total other (income) expenses	(2,618)	(16,999)	(4,875)	(17,115)
Net loss	(6,982)	(118)	(20,430)	(25,606)
Deemed dividend	—	(255,822)	—	(255,822)
Net loss attributable to common stockholders	$ (6,982)	$ (255,940)	$ (20,430)	$ (281,428)

NRX PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	June 30, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 24,548	$ 27,605
Prepaid expenses and other current assets	7,866	5,109
Total current assets	32,414	32,714
Other assets	19	15
Total assets	$ 32,433	$ 32,729
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,078	$ 3,687
Accrued and other current liabilities	3,326	2,375
Accrued clinical site costs	658	469
Earnout Cash liability	—	4,582
Warrant liabilities	19	292
Note payable and accrued interest	—	518
Total liabilities	$ 7,081	$ 11,923
Preferred stock, $0.001 par value, 50,000,000 shares authorized; 0 shares issued and outstanding at June 30, 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 June 30, 2022 and December 31, 2021, respectively	67	59
Additional paid-in capital	228,958	203,990
Accumulated deficit	(203,673)	(183,243)
Total stockholders' equity	25,352	20,806
Total liabilities and stockholders' equity	$ 32,433	$ 32,729

NRX PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

(Unaudited)

	Six months ended June 30,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (20,430)	$ (25,606)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	2	1
Stock-based compensation	2,321	4,655
Gain on extinguishment of debt	—	(121)
Change in fair value of warrant liabilities	(273)	(17,359)
Change in fair value of earnout cash liability	(4,582)	355
Non-cash interest expense	—	10
Non-cash settlement expense	—	21,366
Non-cash consulting expense	—	4,850
Changes in operating assets and liabilities:		
Account receivable	—	831
Prepaid expenses and other assets	(2,757)	(4,849)
Accounts payable	(609)	2,563
Accrued expenses and other liabilities	1,157	(1,105)
Net cash used in operating activities	(25,171)	(14,409)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of computer equipment	(6)	(3)
Net cash used in investing activities	(6)	(3)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of common stock, net of transaction costs	—	8,489
Proceeds from issuance of common stock for exercise of warrant	—	7,500
Effect of Merger, net of transaction costs	—	11,050
Repayment of note payable	(518)	—
Proceeds from issuance of common stock and warrants issued in private placement, net of issuance costs	22,638	—
Repayment of notes payable assumed in Merger	—	(1,100)
Repayment of notes payable - related party	—	—
Net cash provided by financing activities	22,120	25,939
Net increase in cash and cash equivalents	(3,057)	11,527
Cash and cash equivalents at beginning of period	27,605	1,859
Cash and cash equivalents at end of period	$ 24,548	$ 13,386

1 NRX-101 (D-cycloserine plus lurasidone) vs. lurasidone for the maintenance of initial stabilization after ketamine in patients with severe bipolar depression with acute suicidal ideation and behavior: A randomized prospective phase 2 trial | medRxiv
2 https://www.biorxiv.org/content/10.1101/2022.06.18.496662v1

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