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

November 13, 2023

Four near-term milestones, including initiation of potential spinout initiatives expected in 2023/early 2024

- *Completing enrollment of the originally-targeted 70 patients in the Phase 2b/3 trial of NRX-101 in Treatment Resistant Bipolar Depression; enrollment to continue through November to increase study power; last patient visit expected in January. Data expected to be released shortly thereafter*
- *Opened the Investigational New Drug application (IND) with Food and Drug Administration (FDA) to treat chronic pain with NRX-101. Awaiting results of 200-person DOD-funded trial in treatment of chronic pain with D-cycloserine (DCS) from Northwestern University in the near term*
- *Received data from randomized, controlled trials demonstrating safety and efficacy of IV ketamine in treating suicidal depression, and established manufacturing partnership to enable filing of a New Drug Application (NDA) for what would be the first FDA-approved presentation of IV ketamine for this purpose in 1Q24.*
- *Planning a newly capitalized, publicly traded, ketamine-focused entity that will be owned by NRx, current NRx shareholders, and new investors; Term Sheet received from prospective anchor investor*
- *Submitted an IND application with FDA to treat complicated Urinary Tract Infection (cUTI) with NRX-101; Qualified Infectious Disease Product (QIDP) request response expected around year-end 2023.*
- *Management to address evidence of naked shorting of NRx securities*
- *Management to host a conference call tomorrow, November 14, 2023, at 4:30 PM ET*

RADNOR, Pa., Nov. 13, 2023 /PRNewswire/ -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) ("NRx Pharmaceuticals", the "Company"), a clinical-stage biopharmaceutical company, today announced its financial results for the quarter ended September 30, 2023 and provided a business update. Given the volume of information discussed this quarter, we have issued this release in advance of our conference call to allow investors additional time to review.

"The third quarter represents a potential turning point for our company, as we are approaching our clinical trial enrollment goals for our partnered foundation product NRX-101, while opening new clinical initiatives in chronic pain, urinary tract infection, and NRX-100 for suicidal depression," said Stephen Willard, J.D., Chief Executive Officer and Director of NRx Pharmaceuticals. "We have four upcoming milestones: in our core clinical trial of NRX-101, in the Department of Defense (DOD) -funded clinical trial of DCS for chronic pain, in our program to open an IND and secure QIDP classification for NRX-101 in cUTI, and in our program to seek New Drug Approval for NRX-100 (intravenous ketamine) and establish that drug in a freshly-capitalized company. Achieving any one of those milestones has the potential to unlock substantial shareholder value, while success on more than one front has the potential to unlock exponential growth.

"I am incredibly proud of our team, our collaborators & partners, and most of all the patients who have made such important contributions to these efforts. All of us at NRx are deeply grateful to the many shareholders who have reached out to us, encouraged us, and supported us during a period of immense challenge in the biotechnology market. Together, we are pursuing NRx's goal of bringing hope to life on a daily basis."

Third Quarter Clinical, Regulatory and Corporate Highlights

Development of NRX-101 for Treatment-Resistant Bipolar Depression (TRBD)

The Company announces today that it is near completion of enrollment of the originally-targeted 70 participants in the Phase 2b/3 trial of NRX-101 in TRBD; enrollment will continue through November to increase study power. We expect top-line data from this cohort of patients shortly after the last patient visit. The target population is based on the Company's January 2023 meeting with the FDA in which the Company 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.

Based on the guidance of the 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 data integrity standard identified last quarter (95% agreement between site raters and central raters) has been achieved across the newly-enrolled cohort of patients.

In April 2023, the Company contracted with 1nHealth to initiate a recruitment campaign that may cover up to 45 states in the U.S. to recruit sufficient participants for this enlarged trial. The Company has similarly broadened its 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 "The Mighty," a voice-of-the-patient organization with national reach to publicize the clinical trial to the 800,000+ subscribers who have indicated a focus on bipolar depression and suicidality.

The Company has completed manufacture of all clinical supplies required for its ongoing clinical trials. This initiative is expected to yield stability data sufficient to support a shelf life in excess of two years at time of potential drug launch (should the clinical trials be successful). The completion of this manufacturing milestone may allow the Company to decrease ongoing expenditure associated with manufacturing and development of chemical manufacturing controls. Product stability work has continued to support the targeted two-year shelf life at potential drug launch.

During Q3, the Company has solidified its working relationship with Alvogen and begun working in unison to plan the final development and commercialization of NRX-101. As previously announced, a successful readout from this trial and FDA interaction will trigger a $10 million milestone payment from Alvogen together with transfer of future development costs to our partner.

Based on milestones achieved during this quarter, the NRX-101 project is on track for completion of a pivotal trial in coordination with a commercial stage partner in less than two years from its re-initiation in March 2022 at the tail of the COVID pandemic to its projected readout. This includes the time required to complete transfer of manufacturing to the US and to validate a full chemistry, manufacturing and controls (CMC) and stability program with the FDA.

NRX-101 for Treatment of Chronic Pain:

The Company has previously detailed the scientific basis for treatment of chronic pain with DCS as outlined in a 2016 scientific paper published by Schnitzer, et. al. and in the White Paper posted by the Company's Scientific Leadership (Sappko, et. al.). In the second quarter, the Company licensed US Patent 8,653,120 for the use of DCS in chronic pain and filed a now-accepted Investigational New Drug (IND) application with the FDA to initiate commercial drug development of NRX-101 in chronic pain.

Chronic pain affects more than 50 million American adults, compared to the approximately 3 million who report thoughts of suicide on an annual basis. There has been no new non-opioid class of drugs to treat nociceptive pain in the past two decades and NRX-101 has the potential to be the first N-methyl-D-aspartate (NMDA)-antagonist drug to seek approval for this indication. Today, ketamine is used off label to treat nociceptive pain, despite its clear limitations (addiction, neurotoxicity, hallucination, and the need for IV administration.)

The Company awaits results of a 200-person randomized prospective trial funded by the US DOD (NCT 03535688) in which patients with chronic pain were randomly assigned to DCS 400mg/day vs. placebo. The investigators have identified primary completion of this trial as occurring in November 2023, with top-line results. Should these results support efficacy of DCS in the treatment of chronic low back pain, they are expected to provide a Breakthrough Therapy path towards treatment of chronic pain with DCS and DCS-containing medicines.

Today, the Company is announcing that it has submitted NRX-101 for consideration by the multibillion dollar HEAL initiative (HEAL) and its national consortium of clinical trial sites (EPPICNET). This initiative was funded by the US Congress to test innovative non-opioid medicines for Chronic Pain. We believe that NRX-101 represents the first NMDA-targeted non-addictive medicine to be presented to this program. Should the DOD-funded trial yield encouraging data, the Company anticipates that non-dilutive sources of capital will be available, given the national focus on the opioid crisis. Progress in treating chronic pain with NRX-101 may open a far larger market for NRX-101 than the originally-targeted psychiatry indications.

Progress on NRX-100 (ketamine) for treating acute suicidality.

When NRx met with the FDA in January 2023, the agency strongly encouraged the Company to develop NRX-100 (ketamine) as a labeled drug, rather than rely on prior stabilization of suicidality and depression achieved via the common clinical practice of infusing generic ketamine compounded in licensed pharmacies. Shortly thereafter, the FDA issued the first of two advisory letters warning physicians against using compounded forms of ketamine and began a program of rigorous inspections of such pharmacies. Although there was once an expectation that intranasal administration of ketamine would be effective in treating suicidality, the attempts to demonstrate the clinical efficacy of nasal racemic ketamine for acute suicidality have not succeeded.

Accordingly, in Q3 the Company finalized a scientific collaboration with Prof. Marion Leboyer of Paris, France and Prof. Mocrane Abbar of Lyon, France in order to incorporate the results of a 156-person inpatient trial of intravenous ketamine vs. placebo for the stabilization of patients admitted for acute suicidality (the KETIS trial). The findings of the trial demonstrate a statistically significant reduction in both suicidality (the primary endpoint) and depression (the secondary endpoint) among patients treated with intravenous ketamine compared to those treated with placebo. (Link)

The patient-level deidentified data have now been received by the Company and are being assembled in the electronic format

required by the FDA. The Company is now in the process of negotiating access to similar patient-level data from an National Institutes of Health (NIH)-funded US-based clinical trial the findings of which confirm the KETIS trial. The Company believes that these multicenter, randomized prospective trials encompassing more than 240 participants, combined with randomized, prospective data on more than 200 US patients when submitted for review at a patient level could be sufficient to demonstrate preliminary safety and efficacy of intravenous ketamine in acutely suicidal patients. Data are expected to be transmitted to FDA by the end of 4Q23.

Submission of an NDA for the use of IV Ketamine is dependent upon submission of a manufacturing file documenting the manufacture of a presentation of ketamine suitable for single-patient use in the treatment of suicidal depression. In November 2023, the Company announced the signing of a development and manufacturing agreement with Nephron Pharmaceuticals, Inc. (West Columbia, SC) to develop a single patient presentation of ketamine. This formulation is expected to overcome some of the formulation deficiencies of existing forms of ketamine (developed for anesthesia) and is expected to have diversion-resistant and tamper-resistant features. The Company believes that this latter aspect is important because of the well-known uses of ketamine as a drug of abuse and as a vehicle for date rape. DOJ Date Rape Drugs

The Company's current timeline projects submission of a New Drug Application for ketamine in the first quarter of 2024 with a targeted PDUFA date in Q4 2024. Nephron has considerable experience in the manufacture of ketamine products and, therefore, the Company anticipates that two-year shelf stability at launch may be achieved with six months of real-time accelerated stability.

Establishment of a ketamine-focused spinoff company

The Company does not anticipate funding this initiative with its core NRx assets and today advised investors of its plan to establish a ketamine-focused spinoff company that would potentially provide current and new investors with both capital appreciation and a royalty stream. A term sheet for up to $30 million in anchor financing for a new public entity has been presented to management by a capable investor and a structure whereby a portion of the equity in the ketamine asset will be allocated to existing shareholders. This proposal will be discussed at the upcoming annual meeting of shareholders.

There is an acute public health need for a safely manufactured, divergent-resistant form of ketamine, particularly in light of drug shortages caused by newly (and appropriately) rigorous FDA manufacturing standards. NRx anticipates a near-term potential address this public health need by year end 2024.

Treatment of Urinary Tract Infection (UTI) and Urosepsis:

Although treatment of UTI is quite different from use of NRX-101 to treat Central Nervous System disorders, D-cycloserine was originally developed as an antibiotic because of its role in disrupting the cell wall of certain pathogens. This is true of a number of drugs used in psychiatry today. D-cycloserine fell out of favor as an antibiotic in the 1970s because of the CNS effects caused by its NMDA-blocking properties and because of the widespread availability of effective first and second-generation antibiotics.

However, DCS is unique in its near-100% excretion in the urine and the ability to achieve high urinary tract levels of DCS with oral administration. The Company's clinical experience in psychiatry suggests that the lurasidone component of NRX-101 blocks unwanted CNS effects and unlocks the potential to treat antibiotic-resistant urinary tract infections with decreased propensity to cause unwanted CNS effects.

In recent years, increased antibiotic resistance to common pathogens that cause urinary tract infections and urosepsis (i.e., sepsis originating in the urinary tract) has resulted in a marked increase in cUTI, hospitalization, and death from urosepsis. The US Center for Disease Control and Prevention reports that more than 1.7 million Americans contract sepsis each year, of whom at least 350,000 die during their hospitalization or are discharged to hospice (CDC Sepsis Ref.). In 2015 DCS was demonstrated to be effective against pathogens that are increasingly resistant to first- and second-line antibiotics. During Q3 2023, NRx tested NRX-101 and its components against resistant pathogens that appear on the Congressionally-mandated Qualified Infectious Disease Product (QIDP) list and proved in vitro effectiveness against antibiotic-resistant *E. coli, Pseudomonas, and Acinetobacter* – thereby appearing to meet the requirements of the QIDP program.

Qualification for QIDP affords a sponsor five years of additional market exclusivity from FDA, regardless of patent status, together with Fast Track Designation and Priority Review. The Company believes that NRX-101 as an oral medication has the potential to demonstrate benefit in patients who would otherwise require intravenous third and fourth generation antibiotics. There are approximately 3 million patients per year who contract cUTI in the US annually (Lodise, et. al.). Additionally, should NRX-101 succeed in clinical trials, the Company will consider developing a follow-on product that is anticipated to achieve another 20 years of patent exclusivity.

Based on the in vitro study performed at CRL, the Company has submitted an Investigational New Drug application, requesting QIDP, Fast Track, and Priority Review designation. FDA approval of this IND is expected by year-end 2023.

As with the NRX-100 development project, the Company does not anticipate funding this initiative with core NRx assets and is exploring structures for a new entity that would provide current and new investors with both capital appreciation and a royalty stream. Should the Company succeed in serving 10% of the cUTI market, the Company believes that the revenue from NRX-101 has the potential to hundreds of million annually, based on 3 million cases per year (Lodise, et. al.) in the US and potential pricing of over $3,500/course of therapy.

Cash runway and financing

The Company continues to believe cash on hand is sufficient to fund operations through potential delivery of the upcoming milestones described herein. As discussed, funding of ketamine-related and UTI-related initiatives is anticipated under new entities with alternative financing. Additional financing plans to be discussed at the upcoming meeting of shareholders.

Share price suppression associated with Naked Shorting

Shareholders and others have repeatedly noted that the Company's share price appears to be adversely affected by short sales of stock that frequently accompany positive news. While covered short sales (i.e. those sales that are accompanied by borrowing of an existing share of stock) is legal, "naked" shorting, without an underlying borrowed share, is not. A recent Federal Court decision holds brokerages liable for damages to companies associated with persistent naked short positions.

In Q3, the Company contracted with ShareIntel, Inc. to examine disparities between NRx stock positions as reported by brokerages and NRx shares reported by DTC, the electronic clearinghouse for the Nasdaq exchange. The Company is today announcing that persistent disparities of approximately 1 million to 1.5 million shares were identified. The Company's has now instructed its counsel to initiate outreach to the compliance departments of the identified brokerages, demanding that all uncovered short positions in the Company's stock be closed via a forced delivery of shares. The Company has been advised by counsel that this action has resulted in share appreciation when implemented by other issuers of Nasdaq stock.

Financial Results for the Second Quarter Ended September 30, 2023

For the three months ended September 30, 2023, NRx Pharmaceuticals recorded $3.3 million of research and development expenses compared to $4.1 million for the three months ended September 30, 2022. The decrease of $0.8 million is related primarily to a decrease of $0.5 million in clinical trials and development expenses related to the NRX-101 program for Suicidal Treatment-Resistant Bipolar Depression partially offset by a increase in various other costs.

For the nine months ended September 30, 2023, NRx Pharmaceuticals recorded $10.8 million of research and development expenses compared to $12.6 million for the nine months ended September 30, 2022. The decrease of $1.8 is related primarily to a decrease of $1.0 million in clinical trials and development expenses, $0.9 million related to fees paid to regulatory and process development consultants, $0.2 million in stock-based compensation, partially offset by an increase in various other costs.

For the three months ended September 30, 2023, NRx Pharmaceuticals recorded $2.5 million of general and administrative expenses compared to $5.0 million for the three months ended September 30, 2022. The decrease related primarily of a decrease of $1.3 million in insurance expenses, $0.9 million in employee expenses, $0.2 million in stock-based compensation expense, $0.3 million in legal, professional and accounting fees partially offset by an increase in various other costs.

For the nine months ended September 30, 2023, NRx Pharmaceuticals recorded $12.3 million of general and administrative expenses compared to $21.9 million for the nine months ended September 30, 2022. The decrease of $9.5 million is related primarily to a decrease of $4.9 million in legal, professional and accounting fees, $2.8 million in insurance expenses, $1.1 million in stock-based compensation expense, $0.5 million in consultant fees, $0.4 million in employee expenses, partially offset by an increase in various other costs.

For the three months and ended September 30, 2023, NRx Pharmaceuticals recorded $6.1 million in net loss compared to $9.1 million for the quarter ended September 30, 2022. For the nine months and ended September 30, 2023, NRx Pharmaceuticals recorded $25.8 million in net loss compared to $29.5 million for the quarter ended September 30, 2022.

As of September 30, 2023, we had $8.9 million in cash and cash equivalents. The company continues to believe cash on hand is sufficient to fund operations through potential delivery of the upcoming milestones described herein. Additionally, we are evaluating operational efficiencies to extend this runway.

Conference Call and Webcast Details

A live webcast of the conference call will be available on the Company's website tomorrow at 4:30 p.m. ET, at https://ir.nrxpharma.com/events. 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

NRX-101, a fixed dose combination of D-cycloserine and lurasidone, has been granted Fast Track Designation, Breakthrough Therapy Designation, a Special Protocol Agreement, and a Biomarker Letter of Support from the FDA for Bipolar Depression with Suicidality. NRX-101 is further being developed for chronic pain and PTSD.

Up to 50% of individuals with bipolar disorder attempt suicide over their lifetime, and estimates indicate that up to 20% may die by suicide. The only FDA-approved treatment for patients with 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 the STABIL-B trial, NRX-101 received Breakthrough Therapy Designation from the FDA for the treatment of patients with severe bipolar depression and acute suicidality 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 chronic pain, PTSD and other indications.

About NRx Pharmaceuticals

NRx Pharmaceuticals is a clinical-stage biopharmaceutical company developing therapeutics based on its NMDA platform for the treatment of central nervous system disorders, specifically suicidal bipolar depression, chronic pain and PTSD. The Company is developing NRX-101, an FDA-designated investigational Breakthrough Therapy for suicidal treatment-resistant bipolar depression and chronic pain. NRx has partnered with Alvogen Pharmaceuticals around the development and marketing of NRX-101 for the treatment of suicidal bipolar depression. NRX-101 additionally has potential to act as a non-opioid treatment for chronic pain.

NRx has recently announced plans to submit a New Drug Application for ketamine in the treatment of suicidal depression, based on results of well-controlled clinical trials conducted under the auspices of the US National Institutes of Health and newly obtained data from French health authorities, licensed under a data sharing agreement. NRx was awarded Fast Track Designation for development of ketamine (NRX-100) by the US FDA as part of a protocol to treat patients with acute suicidality.

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)

	September 30, 2023	December 31, 2022
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 8,902	$ 20,054
Prepaid expenses and other current assets	4,187	5,741
Total current assets	13,089	25,795
Other assets	21	21

Total assets	$ 13,110	$ 25,816
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable	$ 3,631	$ 2,076
Accrued and other current liabilities	4,728	4,855
Accrued clinical site costs	575	914
Convertible note payable and accrued interest – short term	10,069	7,703
D&O insurance payable	314	—
Warrant liabilities	10	37
Total current liabilities	19,327	15,585
Convertible note payable and accrued interest – long term	—	2,822
Total liabilities	$ 19,327	$ 18,407
Preferred stock, $0.001 par value, 50,000,000 shares authorized;	—	—
Series A convertible preferred stock, $0.001 par value, 12,000,000 shares authorized; 3,000,000 and 0 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	3	—
Common stock, $0.001 par value, 500,000,000 shares authorized; 83,919,554 and 66,442,989 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	84	67
Additional paid-in capital	242,533	230,339
Accumulated other comprehensive loss	(22)	—
Accumulated deficit	(248,815)	(222,997)
Total stockholders' (deficit) equity	(6,217)	7,409
Total liabilities and stockholders' (deficit) equity	$ 13,110	$ 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 September 30,		Nine months ended September 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 3,314	$ 4,129	$ 10,837	$ 12,571
General and administrative	2,494	5,012	12,344	21,876
Settlement expense	—	—	250	—
Total operating expenses	5,808	9,141	23,431	34,447
Loss from operations	(5,808)	(9,141)	(23,431)	(34,447)
Other (income) expenses:				
Interest income	(119)	(95)	(420)	(119)
Interest expense	40	—	40	3
Change in fair value of convertible note payable	359	—	2,794	—
Change in fair value of warrant liabilities	(26)	37	(27)	(236)
Change in fair value of Earnout Cash liability	—	—	—	(4,582)
Total other (income) expenses	254	(58)	2,387	(4,934)
Net loss	$ (6,062)	$ (9,083)	$ (25,818)	$ (29,513)
Change in fair value of convertible note attributed to credit risk	—	—	22	—
Other comprehensive loss	—	—	22	—

Comprehensive loss	$ (6,062)	$ (9,083)	$ (25,840)	$ (29,513)
Net loss per share:				
Basic and diluted	$ (0.07)	$ (0.14)	$ (0.35)	$ (0.45)
Weighted average common shares outstanding:				
Basic and diluted	81,946,957	66,449,593	74,114,180	65,532,409

SOURCE NRx Pharma