NRx Pharmaceuticals Reports Third-Quarter 2021 Business Update and Financial Results

November 16, 2021

RADNOR, Pa., Nov. 16, 2021 (GLOBE NEWSWIRE) -- NRx Pharmaceuticals (Nasdaq: NRXP) (NRx), a clinical-stage, biopharmaceutical company, today provided a business update and financial results for the quarter ended September 30, 2021. NRx will host a conference call Tuesday morning, November 16th, at 8:30 AM Eastern Time to discuss its business update and third-quarter financial results.

“In our second quarter as a public company, we have broadened our focus from safety and efficacy alone to establishing the manufacturing and scalability of the medicines in our pipeline. With the financial resources afforded by our investors, we have now established the operations required to commercialize our investigational medicines starting next year,” said Prof Jonathan Javitt, MD, MPH, Chairman and CEO of NRx Pharmaceuticals. “We look forward to restarting our NRX-101 psychiatry clinical trials and continuing to advance the research and development of ZYESAMI and the BriLife vaccine.”

Business Highlights in Q3, 2021

Overall

- This quarter reflects NRx’s second quarter of operations as a public company. NRx now has three-phase 3 investigational products, each of which has the potential for approval in 2022 or early 2023 and each of which represents a first-in-class medicine or vaccine for an unmet medical need. Those products are:
  - ZYESAMI® (aviptadil), an FDA Fast Track medicine for the treatment of Respiratory Failure in COVID-19, with application to other lethal diseases that affect the lung. ZYESAMI is the first medicine to specifically protect the alveolar type II cell that is essential for respiratory function.
  - BriLife™, a novel live virus vaccine that shows promise against COVID-19 and particularly against new variants of the SARS-CoV-2 virus, including the Delta variant.
  - NRX-101, an FDA Fast Track and Breakthrough Therapy-designated medicine to treat patients with suicidal bipolar depression, is the first NMDA-targeted antidepressant to be awarded a composition of matter patent by the U.S. Patent and Trademark Office.
- NRx aims to report meaningful revenues from sales within two years based on Emergency Use Authorization or approval of one or more products.



ZYESAMI® Update

- Dr. Francis Collins, Director of the NIH, identified ZYESAMI as one of a small number of remaining candidates still being considered by the NIH to treat COVID-19 from a starting field of 600 or more candidate medicines. Dr. Collins stressed that medicines were selected based both on their potential for efficacy and their demonstrated potential for manufacturability. During the quarter, Dr. Anthony Fauci gave briefings that included ZYESAMI at the White House and Congress.
- NIH has funded the ACTIV-3b TESICO trial, an FDA Phase 3 trial that has now enrolled more than half of its targeted 660 patients. The trial randomizes patients with COVID-19 respiratory failure to ZYESAMI vs. Veklury® (remdesivir) and placebo in a factorial design trial (NCT04843761). The independent Data Safety Monitoring Board met to assess safety and futility at the enrollment midpoint of more than 300 enrolled patients and reported no drug-related Serious Adverse Events. The trial was cleared for continued enrollment.
- During the quarter, NRx developed and validated a patentable formulation, manufacturing method, and container closure system that enables NRx to produce ZYESAMI (aviptadil) at a commercial scale in lot sizes of up to 100,000 doses with shelf stability of 150 days or more. Based on this development:
  - NRx updated Module 3 of its FDA IND, providing the documentation necessary to show the full manufacturing capability of NRx to provide ZYESAMI upon potential regulatory approval. FDA reviewed the Module 3 and identified no “clinical hold” items.
  - NRx established an EU/UK compliant manufacturing facility and, in October, passed the qualified person (Q.P.) audit required to release medicine in the European Union and the United Kingdom.
- Based on the above manufacturing developments, commercial-scale ZYESAMI will now be incorporated into the NIH ACTIV-3b trial in the U.S., U.K., E.U., and Brazil.
- Based on the above manufacturing developments, NRx is preparing a New Drug Application for ZYESAMI to be submitted under the Accelerated Approval (biomarker) pathway with the FDA.
- NIH has introduced ZYESAMI to E.U. and U.K. regulators via the ACTIV-3b trial, and NRx has retained regulatory counsel to submit emergency use and drug approval requests in those regulatory jurisdictions.
- NRx continues funding the development and providing of ZYESAMI in two additional clinical trials that evaluate the potential of ZYESAMI for inhaled use: a phase 2b/3 trial sponsored by NRx in the U.S. and the BARDA-funded I-SPY trial.
- In 2022 NRx anticipates launching a clinical trial of ZYESAMI for the treatment of sepsis-related ARDS for which Stony Brook University was previously awarded an FDA Orphan Drug Designation. NRx is actively exploring the initiation of clinical trials for ZYESAMI in other lethal diseases that affect the lung, for which effective treatments are currently lacking.
- NRx has partnered with the PolyPeptide Group to develop a proprietary large-scale manufacturing process for aviptadil drug substance (API), capable of yielding 5 million doses per manufacturing batch. Prior to this development, aviptadil was only manufactured in a high-cost process yielding 100,000 doses per batch. This historic process was discontinued by its sponsor as no longer environmentally sustainable. During the quarter, NRx received the first million dose batch of aviptadil drug substance and has secured delivery of 7 million doses of aviptadil drug substance through Q2 2022.
- NRx has entered into a collaboration with IQVIA™ (NYSE:IQV), a leading global provider of advanced analytics, technology solutions and clinical research services to the life sciences industry to lead the pharmacovigilance services and medical information in preparation for potential regulatory actions regarding ZYESAMI.
- NRx has partnered with MannKind Corporation (Nasdaq:MNKD) to develop a ZYESAMI inhaler for respiratory conditions.
- NRx announced that it has signed an agreement with Cardinal Health (NYSE: CAH) to provide third-party logistics and distribution of ZYESAMI upon regulatory approval.

BriLife™ Update

- NRx was awarded worldwide development and commercialization rights to Israel’s BriLife™ vaccine by Israel’s Ministry of Defense on behalf of the

Israel Institute for Biological Research.

- The BriLife vaccine shows unique promise in providing immunity against the Delta variant that is currently causing a surge in the global COVID-19 pandemic. Moreover, the vaccine has been demonstrated to evolve in the same manner as the SARS-CoV-2 virus evolves, thus potentially generating immunity against future variants.
- During the quarter, Israel completed the vaccination of 240 patients with the BriLife vaccine at the final strength 108 dose. The immunologic response was such that vaccinated patients were given “green passports” and not required to be vaccinated with mRNA vaccines. Serologic testing of a sample of those patients demonstrated neutralizing antibody levels against the Delta variant that were comparable to the neutralizing antibody levels generated against the wild-type virus.
- NRx has obtained advice from the World Health Organization, and the European Medicines Agency (EMA) in designing a Phase 2b/3 registration trial targeted to commence in December 2021. The trial will enroll patients in Israel, the Nation of Georgia, Ukraine, and two E.U. countries with the support of the National Governments, Health Ministries, and Cromos, LLC
- NRx established a subsidiary company at the invitation of the Luxembourg Ministry of Economy and has initiated the manufacturing scale-up process for the BriLife vaccine in partnership with a contract manufacturing partner in the Brussels region. The Company aims to manufacture the first GMP batch of BriLife at a million-dose scale by June 2022.
- NRx is in discussions with BNP Paribas Luxembourg, led by the bank’s Head of Global Trade Solutions, to establish a € 150 million financing arrangement to support the BriLife vaccine.
- NRx is in discussions with the Government of Luxembourg to establish a BriLife manufacturing facility.

NRX-101 Update

- NRx is preparing to restart the Phase 3 trial of NRX-101 under FDA Breakthrough Therapy Designation and a Special Protocol Agreement to treat patients with suicidal bipolar depression and expects the trial to resume in early 2022.
- In preparation for that registration trial, NRx is manufacturing phase 3 GMP drug supplies in preparation for submitting a manufacturing module in partnership with Alcami, Inc., as part of the rolling review process.

Financing Update

NRx completed a $30 million private placement in August through the sale of 2,727,273 shares of common stock and Preferred Investment Options.

Relief Therapeutics Litigation

- NRx continues to invest in ZYESAMI and fund all R&D costs associated with its development following Relief Therapeutics’ decision to cease funding in early 2021.
- In October 2021, Relief Therapeutics filed a lawsuit alleging breach of contract and other causes of action against NRx and its Chairman, as detailed in the 10-Q.
- NRx has agreed to defer its answer and counterclaims pending mediation efforts to resolve ongoing points of contention with Relief Therapeutics. Mediation is due to begin in early January 2022, with the intention of ensuring an allocation of proceeds that reflects the contributions made by each party.

Third Quarter 2021 Financial Results

- Research and development expenses for the three months ended September 30, 2021, totaled $6.3 million, compared to $4.3 million for the three months ended September 30, 2020. The increase was primarily driven by an increase in clinical trials and development expenses related to ZYESAMI.
- General and administrative expenses for the three months ended September 30, 2021, totaled $13.8 million, of which $9.3 million were non-cash stock-based compensation and consulting fees. General and administrative expenses for the three months ended September 30, 2020, totaled $3.8 million, of which $2.8 million was non-cash stock-based compensation, consulting fees, and warrant expense. The increase was primarily due to the increase in non-cash stock-based expenses and an increase in insurance expenses.
- Reimbursements from Relief Therapeutics were zero for the three months ended September 30, 2021, compared to $2.9 million for the three months ended September 30, 2020.
- Other expenses for the three months ended September 30, 2021, were $0.7 million, compared to zero for the three months ended September 30, 2020. The increase was primarily due to increases in the Earnout cash liability and warrant liability.
- Net loss for the three months ended September 30, 2021, was $20.8 million, or $0.40 per share, compared with a net loss of $5.2 million, or $0.15 per share, for the three months ended September 30, 2020.

Nine Months Ended September 30, 2021, Financial Results

- Research and development expenses for the nine months ended September 30, 2021, totaled $13.8 million, compared to $6.3 million for the nine months ended September 30, 2020. The increase was primarily driven by an increase in clinical trials and development expenses related to ZYESAMI.
- General and administrative expenses for the nine months ended September 30, 2021, totaled $28.4 million, of which $18.6 million were non-cash stock-based compensation and consulting fees. General and administrative expenses for the nine months ended September 30, 2020, totaled $4.9 million, of which $2.9 million was non-cash stock-based compensation, consulting fees, and warrant expense. The increase was primarily due to the increase in non-cash stock-based compensation expenses, consulting fees, and an increase in insurance expenses.
- Settlement expense for the nine months ended September 30, 2021, was $21.4 million compared to zero for the nine months ended September 30, 2020. Settlement expense is a non-cash expense.
- Reimbursements from Relief Therapeutics were $0.8 million for the nine months ended September 30, 2021, compared to $5.0 million for the nine months ended September 30, 2020.
- Other income for the nine months ended September 30, 2021, was $0.6 million, driven by a $1.2 million decrease in warrant liability partially offset by a $0.8 million increase in the Earnout cash liability. Other expenses for the nine months ended September 30, 2020, were $0.4 million primarily due to a loss on conversion of convertible notes payable.
- Net loss for the nine months ended September 30, 2021, was $62.3 million, or $1.44 per share, compared with a net loss of $6.6 million, or $0.20 per share for the nine months ended September 30, 2020.
- As of September 30, 2021, cash was $38.9 million, compared to $1.9 million as of December 31, 2020. NRx believes it has sufficient cash to support operations through the next 12 months. Clinical trial operations for ACTIV-3b and I-SPY are primarily funded by the U.S. Government.

Financial Charts

NRX PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three months ended	Nine months ended

	September 30, 2021	2020	September 30, 2021	2020
Operating expenses:				
Research and development	$ 6,275,911	$ 4,331,709	$ 13,843,895	$ 6,326,416
General and administrative	13,823,240	3,753,704	28,382,177	4,895,092
Settlement expense	—	—	21,365,641	—
Reimbursement of expenses from Relief Therapeutics	—	(2,936,214)	(771,244)	(4,957,145)
Total operating expenses	20,099,151	5,149,199	62,820,469	6,264,363
Loss from operations	(20,099,151)	(5,149,199)	(62,820,469)	(6,264,363)
Other (income) expenses:				
Gain on extinguishment of debt	—	—	(120,810)	—
Interest expense	5,368	12,513	15,656	51,317
Change in fair value of warrant liability	260,238	—	(1,208,412)	—
Change in fair value of Earnout Cash liability	408,342	—	763,043	—
Change in fair value of embedded put	—	—	—	27,160
Loss on conversion of convertible notes payable	—	—	—	306,641
Total other (income) expenses	673,948	12,513	(550.523)	385,118
Loss before tax	(20,773,099)	(5,161,712)	(62,269,946)	(6,649,481)
Provision for income taxes	—	—	—	—
Net loss	(20,773,099)	(5,161,712)	(62,269,946)	(6,649,481)
Deemed dividend – warrants	—	—	(2,691,799)	—
Deemed dividend - Earnout Shares	—	—	(253,130,272)	—
Net loss attributable to common stockholders	$ (20,773,099)	$ (5,161,712)	$ (318,092,017)	$ (6,649,481)
Net loss per share:				
Basic and diluted	$ (0.40)	$ (0.15)	$ (1.44)	$ (0.20)
Net loss per share attributable to common stockholders:				
Basic and diluted	$ (0.40)	$ (0.15)	$ (7.35)	$ (0.20)
Weighted average common shares outstanding:				
Basic and diluted	51,739,452	34,139,672	43,290,675	33,799,503

NRX PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2021 (Unaudited)	December 31, 2020
ASSETS		
Current assets:		
Cash	$ 38,883,569	$ 1,858,513
Account receivable, net of allowance of $257,463 as of December 31, 2020	—	831,390
Prepaid expenses and other current assets	6,350,889	240,352
Total current assets	45,234,458	2,930,255
Other assets	15,921	10,914
Total assets	$ 45,250,379	$ 2,941,169
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 5,559,412	$ 3,153,310
Accrued and other current liabilities	1,995,961	1,728,483
Accrued clinical site costs	1,154,042	1,547,432
Earnout Cash liability	26,283,238	—
Warrant liabilities	775,263	—
Notes payable and accrued interest	515,059	248,861
Accrued settlement expense	—	39,486,139
Total current liabilities	36,282,975	46,164,225
Notes payable and accrued interest	—	547,827
Total liabilities	$ 36,282,975	$ 46,712,052
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value, 50,000,000 shares authorized; 0 shares issued and outstanding at September 30, 2021 and December 31, 2020	—	—
Common stock, $0.001 par value, 500,000,000 shares authorized; 54,810,338 and 42,973,462 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	54,810	42,974
Additional paid-in capital	161,362,260	46,365,863
Accumulated deficit	(152,449,666)	(90,179,720)

Total stockholders' equity (deficit)	8,967,404	(43,770,883)
Total liabilities and stockholders' equity	$ 45,250,379	$ 2,941,169

About NRx Pharmaceuticals

NRx Pharmaceuticals (www.nrxpharma.com) (NRx) draws upon more than 300 years of collective, scientific, and drug-development experience to bring improved health to patients. Its investigational product, ZYESAMI® (aviptadil) for patients with COVID-19, has been granted Fast Track designation by the U.S. Food and Drug Administration (FDA) and is currently undergoing phase 3 trials funded by the U.S. National Institutes of Health, the Biomedical Advanced Research and Development Authority part of the U.S. Department of Health and Human Services, and the Medical Countermeasures program, part of the U.S. Department of Defense. The FDA has additionally granted Breakthrough Therapy Designation, a Special Protocol Agreement, and a Biomarker Letter of Support to NRx for NRX-101, an investigational medicine to treat suicidal bipolar depression. NRX-101 is currently in Phase 3 trials, with readouts expected in 2022. In July 2021, the Government of Israel awarded NRx the exclusive worldwide right to develop and market the BriLife™ COVID vaccine developed by the Israel Institute for Biological Research.

NRx is led by executives who have held senior roles at Allergan, J&J, Lilly, Novartis, Pfizer, and the US FDA. NRx is chaired by Prof Jonathan Javitt, MD, MPH, who has held leadership roles in six biotechnology startup companies with public exits and been appointed to advisory roles in four U.S. Presidential Administrations. The NRx board includes Dr. Sherry Glied, former U.S. Assistant Secretary for Health (ASPE), Daniel E. Troy, J.D., former Chief Counsel of the US FDA, Chaim Hurvitz, former director of Teva and President of the Teva International Group, and General H.R. McMaster, Ph.D. (U.S. Army, Ret.) the 26th United States National Security Advisor.

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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Slide taken from a presentation given by Dr. Francis Collins, Director of the National Institutes of Health in September 2021:
https://www.globenewswire.com/NewsRoom/AttachmentNg/0b0de2d6-065d-4028-aa19-602157bdbe87

SLIDE TAKEN FROM A PRESENTATION GIVEN BY DR. FRANCIS COLLINS, DIRECTOR OF THE NATIONAL INSTITUTES OF HEALTH IN SEPTEMBER 2021

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Source: NRx Pharmaceuticals, Inc.