SECURITIES & EXCHANGE COMMISSION EDGAR FILING

Big Rock Partners Acquisition Corp.

Form: 8-K

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): February 23, 2021

BIG ROCK PARTNERS ACQUISITION CORP.
(Exact Name of Registrant as Specified in Charter)

Delaware	001-38302	82-2844431
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

2645 N. Federal Highway, Suite 230 Delray Beach, FL	33483
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: (310) 734-2300

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☒ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Units, each consisting of one share of Common Stock, one Right and one-half of one Warrant	BRPAU	The Nasdaq Stock Market LLC
Common Stock, par value $0.001 per share	BRPA	The Nasdaq Stock Market LLC
Rights, exchangeable into one-tenth of one share of Common Stock	BRPAR	The Nasdaq Stock Market LLC
Warrants, each whole warrant exercisable for one share of Common Stock at an exercise price of $11.50	BRPAW	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

As previously announced, Big Rock Partners Acquisition Corp. a Delaware corporation ("BRPA"), NeuroRx, Inc., a Delaware corporation ("NeuroRx"), and Big Rock Merger Corp., a Delaware corporation and wholly-owned subsidiary of BRPA ("Merger Sub"), entered into an Agreement and Plan of Merger providing for the merger of Merger Sub will merge with and into NeuroRx, with NeuroRx surviving the merger and becoming a wholly-owned subsidiary of BRPA, with the stockholders of NeuroRx becoming stockholders of BRPA.

On February 23, 2021, NeuroRx announced that its Phase 2b/3 trial of ZYESAMI™ (aviptadil) for the treatment of patients with respiratory failure due to critical COVID-19, which was performed in collaboration with Relief Therapeutics Holdings, AG, has demonstrated 10-day accelerated recovery from respiratory failure in critically ill patients with COVID-19 treated with high flow nasal oxygen at the day 28 interim endpoint, and that NeuroRx intends to file for Emergency Use Authorization if positive results continue to be demonstrated at the day 60 endpoint in line with new guidance from the Food and Drug Administration. The press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information set forth under this Item 7.01 is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended ("Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended ("Securities Act") or the Exchange Act, except as expressly set forth by specific reference in such filing.

Cautionary Note Regarding Forward Looking Statements

This Current Report on Form 8-K and the exhibits filed or furnished herewith include "forward-looking statements" within the meaning of the federal securities laws with respect to the proposed transaction between NeuroRx and BRPA, including statements regarding the drugs under development by NeuroRx. Actual results may differ from BRPA's and NeuroRx's expectations and consequently, you should not rely on these forward-looking statements as predictions of future events. These forward-looking statements generally are identified by the words "aspire," "expect," "estimate," "project," "budget," "forecast," "anticipate," "intend," "plan," "may," "will," "will be," "will continue," "will likely result," "could," "should," "believe(s)," "predicts," "potential," "continue," "future," "opportunity," "strategy," and similar expressions are intended to identify such forward-looking statements. These forward-looking statements involve significant risks and uncertainties that could cause the actual results to differ materially from the expected results. Most of these factors are outside BRPA's and NeuroRx's control and are difficult to predict. Factors that may cause such differences include, but are not limited to: (1) the approvals, timing, and ability to complete the proposed business combination, which may adversely affect the trading price of BRPA's securities; (2) BRPA's ability to remain listed on the Nasdaq Capital Market prior to the closing of the proposed business combination; (3) the combined company's continued listing on the Nasdaq Capital Market after closing of the proposed business combination; (4) the benefits of the proposed business combination, including future financial and operating results of the combined company; (5) the inherent uncertainty associated with the FDA approval process; (6) the risk that the proposed transaction disrupts current plans and operations of NeuroRx as a result of the announcement and consummation of the transaction described therein and herein; (7) costs related to the proposed business combination; (8) changes in applicable laws or regulations; (9) the possibility that the combined company may be adversely affected by other economic, business, and/or competitive factors; (10) the impact of COVID-19 or other adverse public health developments; and (11) other risks and uncertainties that are detailed in the proxy statement/consent solicitation statement/prospectus and registration statement filed on Form S-4 with the Securities and Exchange Commission ("SEC") and as indicated from time to time in BRPA's filings with the SEC. These filings identify and address other important risks and uncertainties that could cause actual events and results to differ materially from those contained in the forward-looking statements.

Additional Information and Where to Find It

This document does not constitute an offer to sell or exchange, or the solicitation of an offer to buy or exchange, any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, sale or exchange would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. BRPA has filed a registration statement on Form S-4 ("Registration Statement"), which includes a preliminary proxy statement for the solicitation of the approval of BRPA's stockholders, a preliminary prospectus for the offer and sale of BRPA's securities in the transaction and a preliminary consent solicitation statement of NeuroRx, and other relevant documents with the SEC. The definitive proxy statement/prospectus/consent solicitation statement will be mailed to stockholders of BRPA and NeuroRx as of a record date to be established for voting on the proposed business combination. INVESTORS AND SECURITY HOLDERS OF BRPA AND NEURORX ARE URGED TO READ THE REGISTRATION STATEMENT, PROXY STATEMENT/PROSPECTUS/CONSENT SOLICITATION STATEMENT AND OTHER RELEVANT DOCUMENTS THAT WILL BE FILED WITH THE SEC CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTIONS. Investors and security holders will be able to obtain free copies of the registration statement, proxy statement, prospectus and other documents containing important information about BRPA and NeuroRx once such documents are filed with the SEC, through the website maintained by the SEC at http://www.sec.gov. In addition, copies of the documents filed with the SEC by BRPA can be obtained free of charge on BRPA's website at www.bigrockpartners.com or by directing a written request to BRPA at 2645 N. Federal Highway, Suite 230 Delray Beach, FL 33483.

Participants in the Solicitation

BRPA, NeuroRx and their respective directors and executive officers, under SEC rules, may be deemed to be participants in the solicitation of proxies of BRPA's stockholders in connection with the proposed business combination. Investors and securityholders may obtain more detailed information regarding the names and interests in the proposed business combination of BRPA's directors and officers in BRPA's filings with the SEC, including the proxy statement/prospectus/consent solicitation statement. You may obtain a free copy of these documents as described in the preceding paragraph.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits:

Exhibit	Description
99.1	Press release, dated February 23, 2021.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

BIG ROCK PARTNERS ACQUISITION CORP.

Dated: February 23, 2021

By: /s/ Richard Ackerman
Name: Richard Ackerman
Title: Chairman, President and Chief Executive Officer

NeuroRx Announces that ZYESAMI™ (Aviptadil) has Successfully Demonstrated 10-Day Accelerated Recovery from Respiratory Failure in Critically Ill Patients with Covid-19 Treated with High Flow Nasal Oxygen at 28 Day Interim Endpoint

NeuroRx to File for Emergency Use Authorization in This Patient Population if Positive Results Continue to be Demonstrated at Day-60 Endpoint in Line with FDA's New Guidance

RADNOR, Pa., Feb. 23, 2021 – NeuroRx, Inc. announced today that the Phase 2b/3 trial[1] of ZYESAMI™ (aviptadil, previously RLF-100™) for the treatment of Respiratory Failure in critically ill patients with Covid-19 has demonstrated multidimensional benefit around its prespecified primary endpoint of Recovery from Respiratory Failure with discharge from hospital and ICU (without relapse) by day 28 in patients with critical Covid-19 who were treated with High Flow Nasal Oxygen. Although not envisioned at the start of the clinical trial, High Flow Nasal Oxygen has become the predominant form of treatment in Covid-19 respiratory failure, with mechanical ventilation reserved for those whose blood oxygen levels cannot be maintained on this less invasive modality. The trial was conducted at 10 U.S. hospitals under the direction of NeuroRx in collaboration with RELIEF THERAPEUTICS Holding AG (SIX: RLF;OTCQB: RLFTF). NeuroRx has signed an agreement to complete a business combination with Big Rock Partners Acquisition Corporation (NASDAQ: BRPA).

The clinical trial was originally approved as a 28 day study at FDA's direction. In December, NeuroRx added a 60 day endpoint based on the recognition that the traditional 28-day endpoint adopted in the 1990s for trials in Acute Respiratory Distress Syndrome is not appropriate for critically ill patients with Covid-19, who are frequently maintained in the ICU with advanced technologies well beyond this time point. NeuroRx and other clinical trial sponsors alerted FDA to this trend and yesterday the FDA published formal guidance [2] changing the required time for measuring the prespecified endpoint of "alive and free of respiratory failure" in critically ill patients to 60 days. Interim data are being reported because they were unblinded as per the original protocol and the last patient in the trial reached day 60 yesterday. Therefore, study conduct cannot be adversely influenced by release of these interim findings.

At 28 days, patients treated with ZYESAMI™ demonstrate 35% higher likelihood of recovery from respiratory failure with continued survival compared to patients treated with placebo (Hazard Ratio 1.53; P=.08). In tertiary care hospitals, ZYESAMI-treated patients were 46% more likely to recover and return home before day 28 (Hazard Ratio controlling for age and severity 1.84; P=.058). Should these trends continue through day 60, they have the potential to reach statistical significance. At day 28, a highly significant 10-day difference in median time to recovery and hospital discharge has emerged in ZYESAMI-treated patients compared to those treated with placebo (P<.006).

Should the above trends continue through day 60, NeuroRx anticipates filing a request for Emergency Use Authorization in this population of critically-ill patients (i.e. those on High Flow Nasal Oxygen) who have exhausted all currently approved treatments. FDA decisions implement a benefit/risk framework. NeuroRx previously announced the high degree of safety observed with use of ZYESAMI. This safety has continued to be documented in the more than 300 additional patients treated under the Expanded Access Protocol and in patients who have filed requests under the federal Right to Try act.

Yesterday's guidance emphasizes the importance of analyzing patient outcomes by treatment subgroup and, in this case, the study did not recruit enough patients treated with mechanical ventilation to confirm the benefit seen in open-label studies. In the seven months that have elapsed since the trial began, mechanical ventilation has gone from first line therapy to treatment of last resort for patients with Covid-19. Recognizing this, NeuroRx signed clinical trial agreements with the I-SPY clinical trial platform and the National Institutes of Health under which ZYESAMI will continue to be evaluated in patients who require mechanical ventilation.

The study's principal investigators, Dushyantha Jayaweera, M.D., FACP (University of Miami), Professors J. Georges Youssef, M.D. (Houston Methodist Hospital), and Richard Lee, M.D. (University of California, Irvine) commented, *"We are excited to report that ZYESAMI demonstrates a highly significant reduction in time to recovery compared to patients treated with placebo in those treated with High Flow Nasal Oxygen, together with increased likelihood of recovery and excellent safety. We look forward to learning whether this benefit can also be shown for patients treated with other stages of C*ovid-*19 with inhaled forms of ZYESAMI. We look forward to working with the sponsor to secure emergency use authorization for ZYESAMI in this population of patients."*

Jonathan C. Javitt, M.D., M.P.H., CEO of NeuroRx, added, "*We look forward to reporting the final 60 day efficacy data shortly. We are indebted to the researchers, patients, and families who have helped us demonstrate this meaningful clinical benefit for ZYESAMI. We are honored to name the drug in honor of the late Prof. Sami Said who discovered its active ingredient, VIP. Additional efficacy data on patients who require mechanical ventilation will be obtained from ongoing research supported by BARDA and the National Institutes of Health, in addition to our newly initiated study of inhaled use ZYESAMI in hospitalized patients who have not yet developed respiratory failure"*

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1 (www.clinicaltrials.gov NCT04311697)

2 COVID-19: Developing Drugs and Biological Products for Treatment or Prevention. https://www.fda.gov/media/137926/download

About VIP in COVID-19

Vasoactive Intestinal Polypeptide (VIP) was first discovered by the late Dr. Sami Said in 1970, for whom ZYESAMI™ is named. Although first identified in the intestinal tract, VIP is now known to be produced throughout the body and to be primarily concentrated in the lungs. VIP has been shown in more than 500 peer-reviewed studies to have potent anti-inflammatory/anti-cytokine activity in animal models of respiratory distress, acute lung injury, and inflammation. Most importantly, 70% of the VIP in the body is bound to a rare cell in the lung, the alveolar type II cell (ATII), that is critical in the production of lung surfactant that is essential to transmission of oxygen from the air to the blood by the pulmonary epithelial cells that line the air sacs (alveoli) of the lung. Initial radiographic changes in Covid 19 are suggestive of collapse of these alveoli.

Covid-19-related respiratory failure is caused by selective infection of the ATII cell by the SARS-CoV-2 virus. The ATII cells are vulnerable because of their (ACE2) surface receptors, which serve as the route of entry for the virus. These specialized cells manufacture surfactant that coats the lung and is essential for oxygen exchange. Loss of surfactant causes collapse of the air sacs (alveolae) in the lung and results in respiratory failure.

VIP is shown to block Coronavirus replication in the ATII cell, block cytokine synthesis, block viral-induced cell death (cytopathy), and upregulate surfactant production. To our knowledge, other than ZYESAMI™, no currently proposed treatments for Covid-19 specifically target these vulnerable Type II cells. Recent laboratory findings suggest that VIP directly interferes with the spike protein complex of the SARS-CoV-2 virus.

About NeuroRx, Inc.

NeuroRx draws upon more than 100 years of collective drug development experience from senior executives of AstraZeneca, Eli Lilly, Novartis, Pfizer, and PPD. In addition to its work on ZYESAMI™, NeuroRx has been awarded Breakthrough Therapy Designation and a Special Protocol Agreement to develop NRX-101 in suicidal bipolar depression and is currently in Phase 3 trials. Its executive team is led by Prof. Jonathan C. Javitt, M.D., M.P.H., who has served as a health advisor to four Presidential administrations and worked on paradigm-changing drug development projects for Merck, Allergan, Pharmacia, Pfizer, Novartis, and MannKind, together with Robert Besthof, MIM, who served as the Global Vice President (Commercial) for Pfizer's Neuroscience and Pain Division. NeuroRx recently announced a plan to complete a business combination with Big Rock Partners Acquisition Corp (NASDAQ: BRPA) ("BRPA"), and intends to apply for listing on the NASDAQ under the proposed symbol "NRXP". For more information, visit www.neurorxpharma.com.

About RELIEF THERAPEUTICS Holding AG

Relief focuses primarily on clinical-stage programs based on molecules of natural origin (peptides and proteins) with a history of clinical testing and use in human patients or a strong scientific rationale. Currently, Relief is concentrating its efforts on developing new treatments for respiratory disease indications. Its lead drug candidate RLF-100™ (aviptadil) is being investigated in two placebo-controlled U.S. late-stage clinical trials in respiratory deficiency due to COVID-19. Relief holds a patent issued in the United States and various other countries covering potential formulations of RLF-100™.

RELIEF THERAPEUTICS Holding AG is listed on the SIX Swiss Exchange under the symbol RLF and quoted in the U.S. on OTCQB under the symbol RLFTF. www.reliefTherapeutics.com Follow us on LinkedIn

CORPORATE CONTACTS

NeuroRx, Inc.
Jonathan C. Javitt, M.D., MPH
Chairman and Chief Executive Officer
ceo@neurorxpharma.com

INVESTOR RELATIONS

NeuroRx (United States)
Brian Korb
Solebury Trout
bkorb@troutgroup.com
917-653-5122

MEDIA CONTACT

NeuroRx (United States):
David Schull
Russo Partners, LLC
david.schull@russopartnersllc.com
858-717-2310

Disclaimer - Relief:

This communication expressly or implicitly contains certain forward-looking statements concerning RELIEF THERAPEUTICS Holding AG. The results reported herein may or may not be indicative of the results of future and larger clinical trials for the treatment of respiratory failure from COVID-19 or other respiratory diseases. Such statements involve certain known and unknown risks, uncertainties and other factors, which could cause the actual results, financial condition, performance or achievements of RELIEF THERAPEUTICS Holding AG to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Such forward-looking statements do not constitute guarantees of future performance and are subject to a variety of risks and uncertainties, including whether the results described herein will be sufficient to gain any regulatory approvals for RLF-100™. RELIEF THERAPEUTICS Holding AG is providing this communication as of this date and do not undertake to update any forward-looking statements contained herein as a result of new information, future events or otherwise.

Cautionary Note Regarding Forward Looking Statements – NeuroRx:

Statements contained in this press release that are not historical facts may be forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements generally relate to future events or NeuroRx's future financial or operating performance. In some cases, you can identify forward-looking statements because they contain words such as "may," "will," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these words or other similar terms or expressions that concern NeuroRx's expectations, strategy, plans or intentions. Such forward-looking statements may relate to, among other things, the outcome of any discussions or applications for the future use of ZYESAMI, the approvals, timing, and ability to complete the proposed business combination with BRPA, and the combined company's ability to continue listing on Nasdaq after closing the proposed business combination. Such forward-looking statements do not constitute guarantees of future performance and are subject to a variety of risks and uncertainties. NeuroRx does not undertake any obligation to update forward-looking statements as a result of new information, future events or developments or otherwise.

Additional Information and Where to Find It

This press release relates to a proposed business combination and related transactions (the "Transactions") between NeuroRx and BRPA. This press release does not constitute an offer to sell or exchange, or the solicitation of an offer to buy or exchange, any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, sale or exchange would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. BRPA has filed a registration statement on Form S-4 ("Registration Statement"), which includes a preliminary proxy statement for the solicitation of the approval of BRPA's stockholders, a preliminary prospectus for the offer and sale of BRPA's securities in the Transactions and a preliminary consent solicitation statement of NeuroRx, and other relevant documents with the SEC. The proxy statement/prospectus/consent solicitation statement will be mailed to stockholders of NeuroRx and BRPA as of a record date to be established for voting on the proposed business combination. INVESTORS AND SECURITY HOLDERS OF NEURORX AND BRPA ARE URGED TO READ THE REGISTRATION STATEMENT, PROXY STATEMENT/PROSPECTUS/CONSENT SOLICITATION STATEMENT AND OTHER RELEVANT DOCUMENTS THAT WILL BE FILED WITH THE SEC CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTIONS. Investors and security holders will be able to obtain free copies of the registration statement, proxy statement, prospectus and other documents containing important information about NeuroRx and BRPA once such documents are filed with the SEC, through the website maintained by the SEC at http://www.sec.gov. In addition, copies of the documents filed with the SEC by BRPA can be obtained free of charge on BRPA's website at www.bigrockpartners.com or by directing a written request to BRPA at 2645 N. Federal Highway, Suite 230 Delray Beach, FL 33483.

Participants in the Solicitation

NeuroRx, BRPA and their respective directors and executive officers, under SEC rules, may be deemed to be participants in the solicitation of proxies of BRPA's stockholders in connection with the proposed Transactions. Investors and securityholders may obtain more detailed information regarding the names and interests in the proposed Transactions of NeuroRx's and BRPA's respective directors and officers in BRPA's filings with the SEC, including the proxy statement/consent solicitation statement/prospectus statement. You may obtain a free copy of these documents as described in the preceding paragraph.