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): **April 14, 2020**

Eagle Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-36306**	**20-8179278**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

50 Tice Boulevard, Suite 315 **Woodcliff Lake, NJ**	**07677**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(201) 326-5300**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

☐ 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**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	EGRX	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 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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.

On April 16, 2020, Eagle Pharmaceuticals, Inc., or the Company, issued a press release announcing that on April 14, 2020 the Company submitted an Investigational New Drug, or IND, application to the U.S. Food and Drug Administration, or the FDA, for a Phase 2 clinical trial in partnership with Hackensack University Medical Center to evaluate the efficacy of RYANODEX® (dantrolene sodium) in patients infected with SARS-CoV-2, the virus causing the COVID-19 pandemic. The press release also announced that the Company has been in contact with the FDA's Coronavirus Treatment Acceleration Program (CTAP), to request potential expedited review of the IND application with the aim of beginning the clinical trial as soon as possible.

On April 16, 2020, the Company also posted on its website at https://www.eagleus.com/eagle-pharmaceuticals-corporate-website-statement/ a corporate statement providing an update on the Company's efforts with respect to the COVID-19 pandemic, or the COVID-19 Update.

A copy of the press release and the COVID-19 Update are furnished as Exhibit 99.1 and Exhibit 99.2, respectively, to this Current Report on Form 8-K. The information in this Item 7.01 and Exhibit 99.1 and Exhibit 99.2 attached hereto 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, or the 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, regardless of any general incorporation language in such filings, unless expressly incorporated by specific reference in such filing.

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Report 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "plan," "anticipate," "estimate," "intend" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on the Company's expectations and assumptions as of the date of this Current Report. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from these forward-looking statements. Forward-looking statements contained in this Current Report include, but are not limited to, the potential benefits, antiviral activity and efficacy of RYANODEX including the potential for RYANODEX to be a possible therapeutic option for COVID-19; the success of the Company's collaboration with Hackensack University Medical Center; and expectations for regulatory submissions and approvals. Other factors that may cause the Company's actual results to differ from those expressed or implied in the forward-looking statements in this Current Report are discussed in the Company's filings with the U.S. Securities and Exchange Commission, including the "Risk Factors" sections contained therein. Except as required by law, the Company assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated April 16, 2020.
99.2	Corporate Statement Providing COVID-19 Update dated April 16, 2020.
104	Cover Page Interactive Data File (formatted as inline XBRL).

SIGNATURES

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.

Eagle Pharmaceuticals, Inc.

Dated: April 16, 2020

By: /s/ Scott Tarriff
Scott Tarriff
Chief Executive Officer

Exhibit 99.1

Eagle Pharmaceuticals Announces Laboratory Test Results Demonstrating *In Vitro* Antiviral Activity of RYANODEX® (dantrolene sodium) Against Coronavirus SARS-CoV-2

IND Submitted to FDA for Planned Clinical Study at Hackensack University Medical Center to Evaluate RYANODEX for Treatment of COVID-19 Patients

WOODCLIFF LAKE, N.J.—April 16, 2020—Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle"), a New Jersey-based pharmaceutical company, today announced that its product RYANODEX® (dantrolene sodium) for injectable suspension inhibited the growth of SARS-CoV-2, the virus causing the COVID-19 pandemic, in a controlled *in vitro* laboratory test. On Tuesday, April 14, Eagle submitted its Investigational New Drug ("IND") application to the U.S. Food and Drug Administration ("FDA") for a Phase 2 clinical trial in partnership with Hackensack University Medical Center to evaluate the efficacy of RYANODEX in patients infected with SARS-CoV-2. Eagle has been in contact with the FDA's Coronavirus Treatment Acceleration Program ("CTAP") to request potential expedited review of the IND application and aims to begin the clinical trial as soon as possible.

Eagle is working to increase production of RYANODEX in advance of clinical results and to potentially shorten the supply chain lead time if necessary. To that end, Eagle is forming a partnership for strategic manufacturing support with Amneal Pharmaceuticals, Inc. (NYSE: AMRX) based in Bridgewater, N.J., one of the largest U.S.-based pharmaceutical manufacturers. Eagle is also working with its existing manufacturing partner, Durham, N.C.-based Alcami Corporation, a leading provider of contract manufacturing services for pharmaceutical and biotechnology clients around the globe to increase its production.

RYANODEX is approved by the FDA for the treatment of patients with malignant hyperthermia ("MH") in conjunction with appropriate supportive measures, and for the prevention of MH in patients at high risk. MH is a life-threatening condition experienced by susceptible individuals exposed to certain medications. MH is characterized by high body temperature, muscle hyperactivity, rapid heart rate and other symptoms.

RYANODEX acts by modulating free intracellular calcium levels to restore calcium homeostatic balance inside cells. Eagle has worked for many years to understand how RYANODEX impacts calcium regulation in cells. This work has served as the basis for Eagle to study a number of different diseases and disorders in which intracellular calcium dysregulation may be an important factor.

Eagle is now exploring the relationship between viral infection and the regulation of calcium levels inside cells. Viruses can exploit host cells to replicate by creating dysfunction in the intracellular environment. Depending on the virus type, an altered intracellular calcium balance may enhance virus entry, replication and release. As a result, intracellular calcium levels may be an important factor in viral-host interactions and viral infections. Dysregulation of the intracellular calcium homeostasis may benefit the virus lifecycle leading to cell death and worsening of the disease.

“The results of Eagle Pharmaceuticals’ virus neutralization assay demonstrated a lack of viral growth in RYANODEX-treated cells compared to those not treated with RYANODEX. This outcome suggests that RYANODEX may have antiviral activity against SARS-CoV-2, which we believe represents a novel approach to impeding the virus lifecycle by modulating free intracellular calcium levels of host cells,” said Adrian Hepner, M.D., Ph.D., Chief Medical Officer of Eagle Pharmaceuticals. “We now plan to conduct a clinical trial in partnership with Hackensack University Medical Center to evaluate the efficacy and safety of RYANODEX as a potential treatment for patients hospitalized with COVID-19.”

“Effective treatments for patients with COVID-19 are needed urgently,” said Scott Tarriff, Chief Executive Officer of Eagle Pharmaceuticals. “Our years of research have resulted in a deep knowledge of how RYANODEX works and insights into the potential of RYANODEX to address unmet needs for multiple diseases in which calcium dysregulation plays a significant role. We believe the antiviral effect observed in the laboratory suggests RYANODEX may be useful in combating the COVID-19 public health crisis our world now faces.”

***In Vitro* Laboratory Viral Neutralization Assay Results**

The viral neutralization assay demonstrated the *in vitro* antiviral activity and lack of cytotoxicity of RYANODEX at concentrations observed in humans after administration of recommended doses.

The assay was performed using Vero E6 cells, which are susceptible to SARS-CoV-2 infection. After determining the median tissue culture infection dose of the SARS-CoV-2 isolate, a standardized viral dose was added to cells preincubated with different concentrations of RYANODEX, ranging between 5 to 100 micromolar (“µM”). After removal of the virus-RYANODEX mixtures, the cells were incubated further and evaluated for viral effects by observation under a phase-contrast inverted microscope for the presence or absence of SARS-CoV-2 cytopathic effects (“CPE”) in the cells.

The assay had several controls, including cells infected with the same virus that did not receive any RYANODEX treatment, and cells exposed to RYANODEX without viral infection. The cells were then analyzed over six days for CPE as evidence of viral growth.

Specifically, on day 2 post-infection, no CPE (indicating no virus growth) was observed in any of the infected cell cultures containing RYANODEX. On day 4 and day 6 post-infection, no CPE was observed in cells incubated with 20 to 40 µM of RYANODEX. Based on this experiment, it was concluded that the minimum concentration of RYANODEX needed to inhibit SARS-CoV-2 infection in incubated cell cultures is 20 µM.

No CPE was observed with the 20 and 40 µM RYANODEX concentrations at all time points. Toxic effects on the cells only were observed at the two highest RYANODEX concentrations (100 and 50 µM), both in infected and uninfected cell cultures. In contrast, at the lower RYANODEX dilutions (less than 50 µM), both infected and uninfected cell cultures showed good cell viability. Further, the control cells without RYANODEX all had CPE, evidencing viral growth causing marked cytotoxicity and cell death.

Clinical Trial of RYANODEX for the Treatment of COVID-19

Eagle is partnering with Hackensack University Medical Center to conduct a controlled Phase 2 clinical trial in patients with COVID-19, which will evaluate the effectiveness and safety of RYANODEX for the treatment of COVID-19 as adjunctive treatment to current standard of care. The World Health Organization Ordinal Scale of Severity, the Sequential Organ Failure Assessment ("SOFA") and other relevant clinical measurements will be used as efficacy endpoints. The trial will enroll approximately 60 adult COVID-19 patients with confirmed SARS-CoV-2 infection.

"Hackensack Meridian *Health*, the largest provider of patient services in New Jersey, is committed to helping address the COVID-19 pandemic. Not only are we providing patient care but our collaboration with Eagle Pharmaceuticals addresses our mission to help establish the scientific basis for therapies that might alleviate symptoms or address the root cause of the disease," said Ihor S. Sawczuk, M.D., FACS, Regional President and Chief Research Officer, Hackensack Meridian *Health*, which owns Hackensack University Medical Center.

Pending FDA authorization of Eagle's IND application, the trial will begin enrolling participants at Hackensack University Medical Center with initial results anticipated in May 2020.

"As partners with Eagle Pharmaceuticals, we look forward to conducting this clinical trial to determine if the *in vitro* evidence of antiviral activity seen in the lab can be replicated in patients with COVID-19. We believe the data generated will add to our understanding of how best to address COVID-19 disease," said David S. Perlin, Ph.D., Chief Scientific Officer and Senior Vice President of the Center for Discovery and Innovation, Hackensack Meridian *Health*.

About RYANODEX

RYANODEX® (dantrolene sodium) for injectable suspension is indicated for the treatment of malignant hyperthermia in conjunction with appropriate supportive measures, and for the prevention of malignant hyperthermia in patients at high risk.

Eagle's RYANODEX is a proprietary formulation of dantrolene sodium that is reconstituted within 10 seconds with sterile water for a single injection and administered as IV push in less than one minute. In most cases, a single dose of RYANODEX requires a single vial. RYANODEX therefore requires significantly less preparation and administration time compared to other dantrolene sodium formulations, which require multiple vials and larger infusion volume to deliver a single dose.

This news release discusses investigational uses for an FDA-approved product. The information is not intended to convey conclusions about the efficacy or safety of investigational use. RYANODEX has not been demonstrated to be safe or effective for the treatment of COVID-19. There is no guarantee that any investigational uses of RYANODEX will gain FDA approval.

Important Safety Information

RYANODEX® is not a substitute for appropriate supportive measures in the treatment of malignant hyperthermia, including:

Discontinuing triggering anesthetic agents

Increasing oxygen

Managing the metabolic acidosis

Instituting cooling when necessary

Administering diuretics to prevent late kidney injury due to myoglobinuria (the amount of mannitol in RYANODEX® is insufficient to maintain diuresis).

Precautions should be taken when administering RYANODEX® preoperatively for the prevention of malignant hyperthermia, including monitoring vital signs, avoiding known triggering agents, and monitoring for early clinical and metabolic signs of malignant hyperthermia that may indicate additional treatment is needed.

The administration of dantrolene sodium is associated with loss of grip strength and weakness in the legs, as well as drowsiness, dizziness, dysphagia, dyspnea, and decreased inspiratory capacity. Patients should not be permitted to ambulate without assistance until they have normal strength and balance. Care must be taken to prevent extravasation of RYANODEX® into the surrounding tissue due to the high pH of the reconstituted RYANODEX® suspension and potential for tissue necrosis.

RYANODEX® full Prescribing Information can be found at www.RYANODEX.com.

About Eagle Pharmaceuticals, Inc.

Eagle is a fully integrated pharmaceutical company with research and development, clinical, manufacturing, and commercial expertise. Eagle is committed to developing innovative medicines that result in meaningful improvements in patients' lives. Eagle's commercialized products include RYANODEX®, BENDEKA®, BELRAPZO™, and its oncology and CNS/metabolic critical care pipeline includes product candidates with the potential to address underserved therapeutic areas across multiple disease states. Additional information is available on the Eagle's website at www.eagleus.com.

About Hackensack Meridian *Health* Hackensack University Medical Center
Hackensack Meridian *Health* Hackensack University Medical Center, a 781-bed nonprofit teaching and research hospital located in Bergen County, NJ, is the largest provider of inpatient and outpatient services in the state. Founded in 1888 as the county's first hospital, it is now part of one of the largest networks in the state comprised of 34,100 team members and more than 6,500 physicians. Hackensack University Medical Center was listed as one of the top two hospitals in New Jersey in *U.S. News & World Report*'s 2018-19 Best Hospital rankings. It was also named one of the top five New York Metro Area hospitals. Hackensack University Medical Center is one of only five major academic medical centers in the nation to receive Healthgrades America's 50 Best Hospitals Award for five or more years in a row. Becker's Hospital Review recognized Hackensack University Medical Center as one of the 100 Great Hospitals in America 2018. The medical center is one of the top 25 green hospitals in the country according to Practice Greenhealth, and received 25 Gold Seals of Approval™ by The Joint Commission – more than any other hospital in the country. It was the first hospital in New Jersey and second in the nation to become a Magnet® recognized hospital for nursing excellence; receiving its fifth consecutive designation in 2014. Hackensack University Medical Center has created an entire campus of award-winning care, including: the John Theurer Cancer Center; the Heart & Vascular Hospital; and the Sarkis and Siran Gabrellian Women's and Children's Pavilion, which houses the Joseph M. Sanzari Children's Hospital and Donna A. Sanzari Women's Hospital, which was designed with The Deirdre Imus Environmental Health Center® and listed on the Green Guide's list of Top 10 Green Hospitals in the U.S. Hackensack University Medical Center is the Hometown Hospital of the New York Giants and the New York Red Bulls and is Official Medical Services Provider to THE NORTHERN TRUST PGA Golf Tournament. It remains committed to its community through fundraising and community events especially the Tackle Kids Cancer Campaign providing much needed research at the Children's Cancer Institute housed at the Joseph M. Sanzari Children's Hospital. To learn more, visit www.HackensackUMC.org.

About Amneal
Amneal Pharmaceuticals, Inc. (NYSE: AMRX) headquartered in Bridgewater, NJ, is a fully-integrated pharmaceutical company focused on the development, manufacturing and distribution of generic and specialty drug products. The Company has manufacturing operations in North America, Asia, and Europe, working together to bring high-quality medicines to patients primarily within the United States.

Amneal has an extensive portfolio of more than 225 marketed commercial products and is expanding its portfolio to include complex dosage forms, including biosimilars, in a broad range of therapeutic areas. The Company also markets a portfolio of branded pharmaceutical products through its Specialty segment focused principally on central nervous system and endocrine disorders. For more information, visit www.amneal.com.

About Alcami
Alcami is a world-class fully-integrated contract development and manufacturing organization ("CDMO") headquartered in North Carolina, with executive offices in Durham and Wilmington. With approximately 900 employees, Alcami helps biologics and pharmaceutical companies of all sizes navigate the complex road of delivering breakthrough therapies to patients faster, from concept to commercialization. Alcami connects its global clients with customizable and innovative solutions for API development and manufacturing, solid state chemistry, formulation development, analytical development and testing services, clinical and commercial finished dosage form manufacturing (oral solid dose and parenteral), packaging, and stability services. www.alcaminow.com.

Forward-Looking Statements

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 including, but not limited to, the potential benefits, antiviral activity and efficacy of RYANODEX including the potential for RYANODEX to be a possible therapeutic option for COVID-19; the success of the Company’s collaboration with Hackensack University Medical Center; the Company’s ability to establish and maintain successful manufacturing and distribution collaborations including with Amneal Pharmaceuticals, Inc., and Alcami Corporation; the Company’s expectations regarding its ability to manufacture sufficient quantities of RYANODEX to supply its Phase 2 clinical trial in patients with COVID-19 and supply chain management; the progress and development of RYANODEX in a clinical trial in patients with COVID-19, including the ability to enroll patients in the trial, timing for completion and reporting of results; and expectations for regulatory submissions and approvals; and the Company’s expectations regarding the medical need for RYANODEX. All statements that are not statements of historical facts are forward-looking statements. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including, without limitation, risks that results from *in vitro* laboratory tests of RYANODEX are not necessarily predictive of future clinical trial and *in vivo* results; the Company may not fully enroll the clinical trial of RYANODEX or it will take longer than expected; uncertainty of success in the development and potential commercialization of RYANODEX as a therapy for COVID-19; unexpected concerns that may arise from additional data, analysis or results obtained during the clinical trial; regulatory authorities may require additional information or further studies, or may fail or refuse to approve or may delay approval of RYANODEX as a therapy for COVID-19; the occurrence of adverse safety events; risks of unexpected costs or delays; the risks of other unexpected hurdles; regulatory authorities may require additional information or further studies; product liability claims; third party collaboration risks; and the impact related to the effect of COVID-19 or other public health epidemics on the Company’s sales and operations, including employees. Forward-looking statements in this press release should be evaluated together with the many risks and uncertainties that affect the Company’s business, particularly those identified in the “Risk Factors” section of the Company’s Annual Report on Form 10-K for the year ended December 31, 2019 filed with the Securities and Exchange Commission on March 2, 2020 and its other subsequent filings with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Except to the extent required by law, the Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Investor Relations for Eagle Pharmaceuticals, Inc.:
Lisa M. Wilson
In-Site Communications, Inc.
T: 212-452-2793
E: lwilson@insitecony.com

Public Relations for Eagle Pharmaceuticals, Inc.:
Rose Ramseth
WE Communications
T: 212-551-4841
E: rramseth@we-worldwide.com

Public Affairs for Eagle Pharmaceuticals, Inc.:
Nikki Ritchie
SVC
T: 212-687-8080
E: Eagle-SVC@sardverb.com

Exhibit 99.2

A Statement from our Founder,
CEO and Director Scott Tarriff
April 16, 2020

Eagle has always been deeply committed to developing innovative medicines that meaningfully improve patients' lives, and this mission remains as important as ever during the global pandemic. Although we are a relatively small company with a dedicated employee base of just over 100 professionals, Eagle is proud to join the effort to identify effective treatments for COVID-19 patients and address the impact of the SARS-CoV-2 virus.

Eagle has worked for many years to understand how RYANODEX® (dantrolene sodium) for injectable suspension impacts the complex process of calcium regulation in cells. This work has served as the basis for Eagle to study a number of different diseases and disorders in which intracellular calcium dysregulation may be an important factor.

We believe that an altered intracellular calcium balance may enhance virus replication. Because of this, intracellular calcium levels may be an important factor in some viral infections. Based on novel insights derived from its earlier work using RYANODEX®, Eagle recently conducted controlled *in vitro* laboratory tests, in which RYANODEX® inhibited the growth of SARS-CoV-2 (the virus causing the COVID-19 pandemic). Based on these promising results, Eagle intends to initiate a clinical trial this month in partnership with Hackensack University Medical Center to evaluate the efficacy and safety of RYANODEX® in COVID-19 patients.[1] To read more about the latest news on this effort, please click here.

Since the beginning of the COVID-19 outbreak, Eagle has been committed to the safety of our employees and to the patients and health care providers who rely on our products. Accordingly, we have taken precautions to help ensure the safety and well-being of our team members, and we have implemented processes and technologies to minimize disruption to our business. Eagle continues to actively monitor this rapidly evolving situation so that we can take additional steps as needed.

We salute the health care providers working on the front lines to help those affected by the COVID-19 and the many workers across our country providing essential services. We are all in this together, and we are grateful to be a part of the effort to address this public health crisis.

Scott Tarriff
Chief Executive Officer of Eagle Pharmaceuticals

Cautionary Note Regarding Forward-Looking Statements

This letter contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 including, but not limited to, statements by Eagle Pharmaceuticals, Inc. ("Eagle") regarding its development of RYANODEX® as a possible therapeutic option for COVID-19 including the potential benefits, antiviral activity and efficacy of RYANODEX®; Eagle's ability to replicate in vitro laboratory tests of RYANODEX® in future clinical trial and in vivo results; the initiation, progress and development of RYANODEX® in a clinical trial of patients with COVID-19; and the ability to protect employee safety and minimize business disruption in light of the COVID-19 pandemic. All statements that are not statements of historical facts are forward-looking statements. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including, without limitation, risks that results from in vitro laboratory tests of RYANODEX® are not necessarily predictive of future clinical trial and in vivo results; Eagle may not fully enroll the clinical trial of RYANODEX® or it will take longer than expected; uncertainty of success in the development and potential commercialization of RYANODEX® as a therapy for COVID-19; unexpected concerns that may arise from additional data, analysis or results obtained during the clinical trial; regulatory authorities may require additional information or further studies, or may fail or refuse to approve or may delay approval of RYANODEX® as a therapy for COVID-19; the occurrence of adverse safety events; risks of unexpected costs or delays; the risks of other unexpected hurdles; product liability claims; third party collaboration risks; and the impact related to the effect of COVID-19 or other public health epidemics on Eagle's sales and operations, including employees. Forward-looking statements in this letter should be evaluated together with the many risks and uncertainties that affect Eagle's business, particularly those identified in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the year ended December 31, 2019 filed with the Securities and Exchange Commission on March 2, 2020 and its other subsequent filings with the Securities and Exchange Commission. All forward-looking statements contained in this letter speak only as of the date on which they were made. Except to the extent required by law, Eagle undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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[1] RYANODEX® (dantrolene sodium) for injectable suspension is an investigational drug not yet approved by the United States Food and Drug Administration for the treatment of patients with COVID-19. RYANODEX® is currently approved for the treatment of malignant hyperthermia in conjunction with appropriate supportive measures, and for the prevention of malignant hyperthermia in patients at high risk. For more information about RYANODEX®, please visit: www.ryanodex.com