Bluejay Diagnostics Appoints Edwin Rule as Vice President, Regulatory, Quality and Compliance

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ACTON, Mass., March 28, 2022 (GLOBE NEWSWIRE) -- Bluejay Diagnostics, Inc. (NASDAQ: BJDX) ("Bluejay", "the Company") a late-stage, pre-revenue diagnostics company focused on developing cost-effective, rapid, near-patient products for triage and monitoring of disease progression, today announced that Edwin "Ed" E. Rule, has joined the Company as Vice President Regulatory, Quality and Compliance. He will report to Neil Dey, Chief Executive Officer.

Mr. Rule is a highly credentialed regulatory, quality and compliance professional with more than 15 years of industry experience. He has extensive training and expertise in medical device regulations in the U.S. and numerous international markets. In addition, he brings vast experience in FDA medical device submissions, Quality/Regulatory requirements for documentation, records and process qualification and Quality System Auditing. Mr. Rule also brings a track record in developing and implementing quality systems, building bridges to effectively work with the FDA and other regulatory agencies and leading high-performance teams. Most recently, he was Director, Regulatory Affairs, Devices, for a well-known, respected medical device manufacturer. Mr. Rule will be responsible for Bluejay's Regulatory, Quality and Compliance functions and will provide support to the Symphony System product development team.

"I am very pleased to welcome Ed to Bluejay. This is a very important time for the Company, as we work to complete our product development program and submit a marketing application for our first product candidate, the Symphony IL-6 Test, to the FDA later this year. Ed's vast experience in regulatory affairs, quality and compliance will be instrumental to building highly effective, high-caliber systems to advance the Symphony IL-6 Test and upcoming programs in the pipeline through the regulatory process and preparation for commercial launch," said Neil Dey, Bluejay's Chief Executive Officer.

Edwin Rule, Vice President of Regulatory, Quality and Compliance of Bluejay Diagnostics, said, "I have dedicated my career to helping to bring important, new medical devices to patients by developing constructive regulatory strategies and quality systems to ensure the production of high quality, compliant products. I have done this by working closely with cross-functional teams and forging effective relationships with regulatory agencies. I am thrilled to join Bluejay because it is seeking to offer healthcare providers the opportunity to conduct important tests using whole blood for patients with life threatening conditions in a near-patient setting. Our commitment to advancing the Symphony System and the opportunity to work with such a talented team is very inspiring to me. I am looking forward to working with Neil and the Bluejay team to contribute to the Company's success."

Mr. Rule is an ASQ Six Sigma Green Belt and has training as an ISO 13485 Auditor. He has additional qualifications in Project and Program Management as well as FDA Clinical Trial oversight. Most recently, he was Director, Regulatory Affairs, Devices at Fresenius Medical Care's Renal Therapies Group. Prior to that, he provided medical device/pharmaceutical Quality Assurance and Regulatory Affairs consulting services to an international medical device manufacturer. Prior to that, Mr. Rule held various leadership roles in Quality/Quality Assurance at ProTom International Holding Corporation, Optos Inc., and Spire Biomedical Corporation. Mr. Rule graduated with a Master of Science in Marketing and Technological Innovation at Worcester Polytechnic Institute. He earned a Certificate of Professional Achievement in Administration and Management from Harvard University. And he graduated with a Bachelor of Science in Mechanical Engineering from Northeastern University.

***About the Symphony™System**:*
Bluejay's Symphony System (the Symphony System) is designed to address the need for simple, reliable, rapid near-patient testing. The Symphony System is designed to provide quantitative measurements of specific biomarkers to determine the need for additional patient care and monitoring, when used in combination with other test and laboratory measurements. The system does not require any sample prep and was shown in published clinical studies to deliver results in about 24 minutes.

This user-friendly system is expected to fit into ICU/near-patient settings without the need for dedicated staff to run a test. The system has been designed to measure test analytes using whole blood. Samples are collected and loaded into proprietary, test-specific cartridges.

The Symphony IL-6 Test is a development stage product candidate for investigational use only. It is limited by United States law to investigational use.

About Bluejay Diagnostics:

Bluejay Diagnostics, Inc. is a late-stage, pre-revenue diagnostics company focused on improving patient outcomes through the Symphony System, a more cost-effective, rapid, near-patient product candidate for triage and monitoring of disease progression in hospital and long-term acute care (LTAC) settings. Bluejay's first product candidate, an IL-6 Test for sepsis triage, is designed to provide accurate, reliable results in approximately 24 minutes from 'sample-to-result' to help medical professionals make earlier and better triage/treatment decisions. More information is available at www.bluejaydx.com.

Forward Looking Statements:

This press release contains statements that the Company believes are "forward-looking statements" within the meaning of the Private Litigation Reform Act. These statements include, but are not limited to, statements relating to the Company's product development program and submission of a marketing application for the Symphony IL-6 Test to the FDA later this year. Forward-looking statements are usually identified by the use of words such as "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "seeks," "should," "suggest", "will," and variations of such words or similar expressions or their negatives (as well as other words and expressions referencing future events, conditions, or circumstances). The Company has based these forward-looking statements on its current expectations and projections about future events, nevertheless, actual results or events could differ materially from the plans, intentions and expectations disclosed in, or implied by, the forward-looking statements the Company

makes. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors, including those discussed under item 1A. “Risk Factors” in our most recently filed Form 10-K filed with the Securities and Exchange Commission (“SEC”), as updated by the Company’s subsequent Quarterly Reports on Form 10- Q. You should not place undue reliance on these statements, as they are subject to risks and uncertainties, and actual results and performance in future periods may be materially different from any future results or performance suggested by the forward-looking statements in this release. This press release speaks as of the date indicated above. The Company undertakes no obligation to update any forward-looking statements, whether as a result of new information, future events, or otherwise. The Company expressly disclaims any obligation to update or revise any forward looking statements found herein to reflect any changes in the Company’s expectations of results or any change in events.

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