



Bluejay Diagnostics Provides Mid-Year Business and Corporate Update

June 3, 2025

ACTON, Mass., June 03, 2025 (GLOBE NEWSWIRE) -- Bluejay Diagnostics, Inc. (NASDAQ: BJDJ) ("Bluejay" or the "Company"), a medical diagnostics company developing rapid near-patient testing solutions for critical care, today provided a 2025 mid-year business and corporate update.

Recent Business Highlights and Developments:

- **SYMON Clinical Program Update:** The Company has initiated its pivotal SYMON-II clinical study, following the successful completion of the SYMON-I pilot study, for which a primary analysis highlighted that IL-6 levels within 24 hours of ICU admission may predict sepsis patient mortality out to 28 days. Currently, the Company is collecting, freezing and biobanking samples, with plans to subsequently measure IL-6 concentrations in the bio banked samples near the end of patient enrollment or after the patient enrollment has completed, and later analyze the IL-6 data with the patient outcomes to see if the established IL-6 cutoff value has been validated for 28-day all-cause mortality. Patient enrollment started during the fourth quarter of 2024 and is continuing. The Company's goal is to use the Symphony IL-6 test to complete the testing in the SYMON-II clinical trial, following completion of the Company's redevelopment of the cartridges used in the Symphony system.
- **Regulatory Pathway:** Based on previous interactions with the U.S. Food and Drug Administration (FDA), the Company continues to plan for a 510(k) submission for its Symphony IL-6 test, with a goal of submitting a 510(k) regulatory application to the FDA in the fourth quarter of 2027 and an objective of achieving FDA approval as early as the third quarter of 2028.
- **Manufacturing Progress:** Bluejay continues its collaboration with SanyoSeiko for manufacturing of the Symphony analyzer. The Company is also beginning the process of redeveloping aspects of the Symphony cartridges to address several technical challenges to bring Symphony to a level consistent with necessary performance and quality requirements. While the Company continues to explore the potential for conducting cartridge redevelopment at an in-house facility, it is now actively exploring other alternative pathways for how to pursue such redevelopment, including by outsourcing this work to a third-party contract manufacturing organization that would oversee this process and provide cartridge supply to the Company.
- **Recent Financial Results:** As of April 30, 2025, the Company possessed cash and cash equivalents of approximately \$ 5.7 million, while having current liabilities of approximately \$1.0 million. The Company incurred losses of approximately \$7.7 million for the fiscal year ended December 31, 2024, and \$1.9 million for the fiscal quarter ended March 31, 2025.
- **April 2025 Private Placement:** In April 2025, the Company raised gross proceeds of approximately \$3.8 million via inducement agreements related to Class C warrant exercises and the issuance of new Class E warrants, strengthening the near-term balance sheet. The Company continues to seek further financing, with a goal of raising at least \$30 million in the aggregate through the end of the 2027 fiscal year.
- **Downsizing of Organization:** To preserve cash resources and seek to extend its cash runway, the Company has recently implemented a series of recent cost savings measures in its product development operations and has reduced its overall Company-wide full-time employee headcount to 5 persons following the recent departure of its Chief Technology Officer.

Upcoming 2025 Annual Meeting of Stockholders: The Company's 2025 annual meeting of stockholders (the "2025 Annual Meeting") is scheduled to be held at 1:00 p.m. Eastern Time on June 18, 2025. The Company's Board of Directors will be reduced from six to five seats as of the 2025 Annual Meeting, and the Board has nominated five currently serving directors to stand for re-election, three of whom are independent, non-employee directors. The Company has proposed the consideration of two reverse stock split proposals at the 2025 Annual Meeting, which are intended, if ultimately approved and implemented, to increase the price of the Company's common stock to assist the Company in continuing to meet the Nasdaq Stock Market's minimum price per share criteria for continued listing on that exchange. "We continue to make focused progress despite a constrained capital environment," said Neil Dey, Bluejay's President and Chief Executive Officer. "Our SYMON-I clinical data underscored IL-6's potential to transform sepsis risk stratification and we look forward to the future completion of our SYMON-II clinical trial. We are actively engaged in identifying funding and strategic opportunities to advance Symphony's regulatory and commercial roadmap."

For additional information, please refer to Bluejay's filings with the Securities and Exchange Commission (the "SEC"), including its quarterly report on Form 10-Q for the period ended March 31, 2025, filed with the SEC on May 13, 2025 and available [here](#).

About the Symphony IL-6 Test:

The Symphony Test platform is designed to determine patient acuity for triage and monitoring based on the measurement of a specific biomarker. The Symphony IL-6 Test to determine patient acuity for sepsis triage and monitoring ("Symphony IL-6 Test") is currently Bluejay's lead product candidate.

About the SYMON Clinical Study Program:

The SYMON Clinical Study Program includes SYMON-I I (clinicaltrials.gov ID NCT06181604) and SYMON-II (NCT06654895). SYMON-I is a pilot study to determine IL-6 levels associated with various endpoints, including, but not limited to 28-day all-cause mortality and in-hospital mortality. The SYMON-II study is the pivotal study to validate the outcomes of the SYMON-I study, which the Company plans to use to support a 510(k) application to the FDA.

About Bluejay Diagnostics: Bluejay Diagnostics, Inc. is a medical diagnostics company focused on improving patient outcomes using its Symphony System, a cost-effective, rapid, near-patient testing system for sepsis triage and monitoring of disease progression. Bluejay's first product candidate, an IL-6 Test for sepsis, is designed to provide accurate, reliable results in approximately 20 minutes from 'sample-to-result' to help medical professionals make earlier and better triage/treatment decisions. More information is available at www.bluejaydx.com.

Symphony is a registered trademark of Bluejay Diagnostics, Inc.

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. Forward-looking statements in this press release include, without limitation, statements about the ongoing SYMON-II clinical trial, plans to redevelop the cartridges used in the Company's Symphony system, including the potential for working with a third-party contract manufacturing organization in connection with such redevelopment, the expected nature and timing of the Company's planned FDA submission and related plans for clinical study completion, whether the Company's cash position will be sufficient to fund operations needed to achieve regulatory approval and initial commercialization of the Symphony IL-6 Test, whether such regulatory approval will actually occur, the Company's plans for future fundraising, the continuation of the Company as a going concern, the Company's plans to hold its 2025 Annual Meeting on June 18, 2025 and request stockholder approval of two reverse stock split proposals and the re-election of five continuing directors, and the Company's ability to continue to have its common stock listed on the Nasdaq Capital Market in the future. Forward-looking statements may be identified by words such as "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "seeks," "should," "suggest," "will," and similar expressions. 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 market and other conditions and those discussed under [Part I, Item 1A, "Risk Factors"](#) in its Annual Report on Form 10-K for the fiscal year ended December 31, 2024, filed with the SEC on March 31, 2025, and in [Part II, Item 1A, "Risk Factors"](#) in its Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2025, filed with the SEC on May 13, 2025. You should not place undue reliance on these forward-looking statements, as they are subject to risks and uncertainties, and actual results and performance in future periods may not occur or 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, except as required by law. The Company expressly disclaims any obligation to update or revise any forward-looking statements found herein to reflect any future changes in the Company's expectations of results or any future change in events, except as required by law.

Additional Information about the 2025 Annual Meeting and Where to Find It:

In connection with the 2025 Annual Meeting, Bluejay filed a [Definitive Proxy Statement](#) with the SEC on May 16, 2025. Only Bluejay stockholders of record at the close of business on May 15, 2025 are entitled to vote at the 2025 Annual Meeting or any adjournment or postponement thereof. The Definitive Proxy Statement and proxy card were mailed to Bluejay stockholders on or about May 22, 2025. BEFORE MAKING ANY VOTING DECISION, BLUEJAY STOCKHOLDERS ARE URGED TO READ IN THEIR ENTIRETY THE DEFINITIVE PROXY STATEMENT (INCLUDING ANY FUTURE AMENDMENTS OR SUPPLEMENTS THERETO) AND ANY OTHER DOCUMENTS FILED WITH THE SEC IN CONNECTION WITH THE 2025 ANNUAL MEETING OR INCORPORATED BY REFERENCE IN THE PROXY STATEMENT BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSALS BEING VOTED ON AT THE 2025 ANNUAL MEETING.

Investors and security holders may obtain free copies of the Definitive Proxy Statement, definitive additional materials and such other documents containing important information about the 2025 Annual Meeting at the SEC's web site at www.sec.gov, and on Bluejay's website at www.bluejaydx.com by clicking on the "Investors" link and then reviewing the "SEC Filings" feed. Electronic Copies of the Definitive Proxy Statement and the Company's 2024 Annual Report on Form 10-K are also available at www.cstproxy.com/bluejaydx/2025. The contents of the websites referenced above are not deemed to be incorporated by reference into the Definitive Proxy Statement.

Participants in the 2025 Annual Meeting Solicitation:

Bluejay and its directors and executive officers may be deemed participants in the solicitation of proxies from Bluejay stockholders in connection with the 2025 Annual Meeting. Security holders may obtain information regarding Bluejay's directors and executive officers in the Definitive Proxy Statement referred to above (filed with the SEC on May 16, 2025), and in subsequent filings on Form 8-K.

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