Bluejay Diagnostics Provides Second Quarter Business and Corporate Update

August 7, 2025

ACTON, Mass., Aug. 07, 2025 (GLOBE NEWSWIRE) -- *Bluejay Diagnostics, Inc.* (NASDAQ: BJDX) ("Bluejay" or the "Company"), a medical diagnostics company developing near-patient solutions for critical care, today announced financial results for the quarter ended June 30, 2025, and provided an update on its Symphony IL-6 test program and key operational milestones.

Second Quarter 2025 and Recent Corporate Highlights

- **SYMON-II Pivotal Clinical Study Underway**: Bluejay has initiated patient enrollment in the SYMON-II pivotal clinical trial, designed to validate findings from the successful SYMON-I pilot study. Early indicators show continued clinical momentum. The trial aims to assess the predictive performance of IL-6 levels in ICU patients for 28-day all-cause mortality.
- **Symphony IL-6 Development and Regulatory Pathway**: Bluejay remains on track to complete SYMON-II sample testing by the end of 2026, with a target 510(k) submission to the FDA in 2027.
- **Strategic Manufacturing Alignment with SanyoSeiko**: Bluejay continues to work closely with SanyoSeiko Co., Ltd. as its contract manufacturing organization (CMO) for the Symphony analyzer. In parallel, the Company is advancing plans to secure cartridge redevelopment and validation manufacturing through a qualified FDA-registered CMO. These steps aim to ensure regulatory-grade supply chain readiness for clinical validation and commercialization.
- **Amended License & Supply Agreement with Toray Industries**: On July 23, 2025, Bluejay entered into an amendment with Toray Industries, extending the timeline to establish alternate cartridge manufacturing to October 2026. The amendment also confirms completion of Toray's know-how transfer and final supply obligations—strengthening Bluejay's independence in future manufacturing.
- **Financing Progress and Outlook**: In April 2025, Bluejay raised gross proceeds of $3.85 million through a warrant inducement financing. The Company anticipates requiring additional capital through 2027 to support manufacturing readiness, clinical trials, and regulatory activities. The Company is actively exploring strategic and institutional financing avenues to meet these milestones.

Upcoming Catalysts

- Manufacturing Site Selection and Onboarding for Cartridge Redevelopment
- Completion of Cartridge Redevelopment Specifications and Validation Readiness
- Patient Enrollment Acceleration and Interim Data Review from SYMON-II
- Initiation of Analytical Validation Studies
- Ongoing Partnership and Financing Discussions to Support Regulatory Strategy

"We continue to make focused progress on multiple fronts—clinically, operationally, and financially. Our continued and timely progress of SYMON-II clinical studies marks a major step toward demonstrating Symphony IL-6's predictive value in sepsis care," said Neil Dey, Chief Executive Officer of Bluejay Diagnostics. "With updated licensing terms from Toray and manufacturing alignment through SanyoSeiko, we are positioning the Symphony platform for scalable development. We are actively engaging with strategic partners and capital providers to support this mission."

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, and the continuation of the Company as a going concern. 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, and in its Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2025, filed with the SEC on August7th , 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.

Investor Contact:
Investor Relations
Bluejay Diagnostics, Inc.
ir@bluejaydx.com
Website: www.bluejaydx.com

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