Bluejay Diagnostics Provides First Quarter 2026 Corporate Update

May 7, 2026

ACTON, Mass., May 07, 2026 (GLOBE NEWSWIRE) -- Bluejay Diagnostics, Inc. (“Bluejay” or the “Company”), a medical diagnostics company focused on improving patient outcomes in critical care settings, today provided a corporate update highlighting progress achieved during the first quarter of 2026 and recent operational developments related to its Symphony™ near-patient diagnostic platform.

During the first quarter of 2026, Bluejay continued advancing the clinical, manufacturing, and regulatory activities supporting the development of its Symphony IL-6 test for sepsis patient monitoring and risk assessment in critical care settings.

Q1 2026 and Recent Highlights

• Continued enrollment progress in the ongoing SYMON-II pivotal clinical study evaluating the role of IL-6 in sepsis and septic shock patients. As of May 5, 2026, approximately 680 patients have been enrolled toward the target enrollment of 750 patients across participating clinical sites.

• Advanced manufacturing readiness activities for Symphony cartridges in collaboration with Sanyoseiko Co. Ltd., Bluejay’s contract manufacturing organization. The Company successfully resolved technical issues related to the Symphony cartridge manufacturing process and is progressing toward analytical and clinical validation activities intended to support future regulatory submission.

• Continued execution of Bluejay’s FDA-focused regulatory strategy for Symphony IL-6, with the Company maintaining its objective of preparing for a future 510(k) submission following completion of required analytical and clinical validation activities.

• Continued development activities related to Bluejay’s broader Symphony platform strategy, which includes future potential applications in additional critical care biomarkers and cardiovascular disease monitoring.

Neil Dey, President and Chief Executive Officer of Bluejay Diagnostics, commented, “We believe the first quarter of 2026 represented meaningful operational progress across several key areas of our Symphony program. Most importantly, we continued strong enrollment momentum in our SYMON-II pivotal study while also advancing manufacturing readiness activities intended to support future analytical and clinical validation. We are encouraged by the progress our team and partners have made in positioning Symphony toward the next phase of development.”

Mr. Dey continued, “We believe Symphony has the potential to address an important unmet need in critical care by enabling rapid, near-patient biomarker testing where time-sensitive clinical decisions are essential. As we continue executing our clinical and manufacturing roadmap, we remain focused on progressing toward regulatory readiness and future commercialization opportunities.”

Financial Highlights

As of March 31, 2026, Bluejay reported cash and cash equivalents of approximately $3.7 million. The Company reported a net loss of approximately $1.9 million for the first quarter of 2026, compared to approximately $1.9 million for the same period in 2025.

The Company believes it has continued to manage operating expenses with financial discipline while prioritizing critical clinical, manufacturing, and regulatory activities supporting the Symphony program.

About the Symphony IL-6 Test:

The Symphony^{TM} Test platform is designed to determine patient acuity for triage and monitoring based on the measurement of a specific biomarker. The Symphony^{TM} IL-6 Test to determine patient acuity for sepsis triage and monitoring (“Symphony ^{TM} IL-6 Test”) is currently Bluejay’s lead product candidate.

Note: Investigational device. Limited by United States law to investigational use.

About the SYMON Clinical Study Program:

The SYMON Clinical Study Program includes SYMON-I (clinicaltrials.gov ID NCT06181604), SYMON-II (NCT06654895), and SYMON-III (NCT07425587). 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. The SYMON-III study is a pilot study to determine IL-6 levels associated with patients presenting with increasing severity of infection in the emergency department and risk of developing sepsis.

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 does not yet have regulatory clearance for the Symphony System, and we will need to receive regulatory authorization from the U.S. Food and Drug Administration before Symphony can be marketed as a diagnostic product in the United States. 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.

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 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 item 1A. “Risk Factors” in the Company’s Annual Report on Form 10-K for the fiscal year ended December 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, 2026. 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.

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