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Zacks Small-Cap Research (NOTE)

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Bluejay Diagnostics, Inc. (BJDX: NASDAQ)

BJDX: 2023 Financial Update

Research Note

Bluejay Diagnostics, Inc. (NASDAQ: BJDX) reports full year 2023 results capping a year that saw substantial interaction with the FDA determining a new trial design. The endpoint for Bluejay's previous trial sought to determine IL-6 concentration in patients with COVID and to predict the need for mechanical ventilation. With fewer COVID cases, the endpoint required revision. Winning FDA endorsement for a new design, Bluejay shifted the endpoint to 28-day mortality for sepsis patients, organized its SYMON study and initiated the trial in December 2023. The trial will have two parts, SYMON I and SYMON II, with the latter serving as a validation study. We anticipate updates in the second half of the year on trial progress. In the meantime, management has indicated that the trial is progressing well.

Highlights for 2023 and to date include:

- Collaboration agreement with Blood Centers of America – February 2023
- Regulatory strategy refinement – May 2023
- FDA pre-submission meeting – August 2023
- Initiation of SYMON study evaluating Symphony IL-6 in sepsis patients – December 2023
- Close of $3.5 million public offering – January 2024

Bluejay generated no revenues in 2023 and reported a net loss of ($10.0) million, or ($9.08) per share. For the year ending December 2023 and versus the same period in the prior year:

- Revenues of $0 compared to $249,000 with the sale of five Symphony analyzers to Toray which took place in 2022;
- Research & Development expense totaled $5.7 million, up 38% from $4.2 million. The increase was attributable to higher personnel costs, greater product development expenses related to bringing the Symphony analyzer and cartridges into compliance with FDA manufacturing standards and additional depreciation expense related to accelerated depreciation of R&D assets;
- General & Administrative expenses were $4.3 million, down 9% from $4.8 million primarily due to a focus on cost containment targeting personnel and insurance costs while preparing to begin the pivotal study;
- Sales and Marketing costs were $283,000 vs. $451,000, down 37% arising from a focus on reducing marketing costs;
- Other income rose on account of higher interest rates on cash balances contributing to interest income;
- Net loss was ($10.0) million or ($9.08) per share compared with net loss of ($9.3) million or ($9.22) per share, respectively.[1]

At year's end, marketable securities, cash and equivalents totaled $2.2 million. Cash burn for 2023 was ($9.0) million. Financing cash flows were $1.1 million and related to the proceeds from common stock issuance offset in part

[1] Prior year earnings per share are adjusted for the August 2023 reverse share split.

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by repayment of a finance lease and tax withholding on restricted stock grants. Bluejay holds insufficient cash and equivalents to fund operations for the next 12 months. Future capital is expected to be raised in several tranches to support the pivotal trial and regulatory submission for the Symphony diagnostic measuring IL-6.

SYMON Trial

In December, Bluejay launched the SYMON (Multicenter **Sy**mphony IL-6 **Mon**itoring Sepsis ICU Study) trial. The study has been listed on the clinicaltrials.gov website under the designator NCT06181604. The first subject was enrolled early in the new year and observations could be complete by the end of May.

Bluejay initially launched a trial that sought to effectively triage COVID patients using IL-6 as a marker and determine their need for mechanical assisted ventilation. However, due to the dramatic decline in severe COVID patients in 2022, the trial design needed to be changed. The primary endpoint is now 28-day mortality and risk stratification of hospitalized sepsis patients. Cutoff values that will be used for the study are now being determined. SYMON will be conducted in two parts. SYMON I, which is ongoing, and SYMON II which will serve as a validation study. SYMON II is expected to begin in July. SYMON will compare IL-6 levels measured with the Symphony diagnostic and compare them with mortality outcomes to determine a correlation. These results will support a cutoff threshold which will be used to triage patients.

Several clinical trial sites have been secured with Tier 1 hospitals. This includes Beth Israel Deaconess Medical Center, Washington University of St. Louis, New York Presbyterian Brooklyn Methodist Hospital, Wake Forest School of Medicine, The Ohio State University/Wexler Medical Center, Vanderbilt University Medical Center and Intermountain Healthcare.

The inclusion criteria for the new trial requires that enrollees have a diagnosis of sepsis or septic shock as determined by a physician. Subjects must also be adults admitted or intended to be admitted to the ICU and provide a plasma sample within 12 hours of the earliest diagnosis of sepsis or septic shock. The plasma sample will be evaluated by the Symphony diagnostic.

The first subject in the SYMON trial was enrolled early in the year and enrollment has been progressing well. An interim readout of the trial is expected in the second half of the year. Our estimates call for both parts of the trial to be completed in 2024, followed shortly after by a regulatory submission using the 510(k) pathway. While topline data should be available in 2H:24, Bluejay will work hard to present full data from the trial in conjunction with a presentation at a highly regarded scientific conference or in a distinguished journal. We further anticipate that a grant of marketing authorization will emerge in 2025, followed by commercialization. Bluejay has identified its market and plans to engage a small team of sales and marketing personnel in combination with partners and distributors to sell the devices and cartridges.

Sepsis is a leading cause of death in hospitals and physicians require accurate data on patient status before treatment. Existing testing approaches frequently require several time-consuming steps before a diagnostic can be run, consuming valuable time. Transportation, preparing the sample and waiting in queue for sufficient volume to justify a test requires a 24 – 48 hour wait to produce a result. However, physicians need answers immediately for critical care decisions. Due to the lack of rapid testing alternatives, we think Symphony could catalyze a substantial increase in IL-6 test volume, especially at the price point anticipated, to help guide physician decision-making in the emergent care setting.

SYMON Milestones:

- Launch SYMON – December 2023
- SYMON Interim Analyses – 2H:24
- SYMON II clinical trials website NCT listing – June 2024
- Launch of SYMON II Validation Trial – 3Q:24
- SYMON Topline – 2H:24
- SYMON Journal Publication - 2H:24/2025

Departure of CFO

In a April 2nd Form 8-K filing, Bluejay announced that it had terminated its agreement with DLA, LLC which is the staffing firm which provided the company's interim CFO, Frances Scally. As of March 29th, Ms. Scally ceased serving as an officer of the company. Her responsibilities were assumed by CEO Neil Dey, who will now serve as Bluejay's principal financial and accounting officer.

Symphony System

Symphony is an automated diagnostic system, consisting of a fluorescence immuno-analyzer which uses a single-use diagnostic test cartridge with reagents integrated into the cartridge. The system uses a 'sample-to-result' format, which means that once a specimen is taken from the patient, it is placed in the cartridge and then the cartridge is placed inside the analyzer where the test is run without further technician intervention or use of additional reagent. This reduces test complexity and eliminates the need for highly trained and expensive laboratory technicians to run the tests. The platform is designed to enable simple, rapid, and cost-effective analysis from a single clinical sample, which will allow long-term acute care facilities (LTACs), hospitals and clinics that have not been able to afford more expensive or complex diagnostic testing platforms access to this tier of analysis. The device can provide affordable patient testing in time sensitive, life-threatening situations. The system also allows for a faster turnaround as it is used in-house. This contrasts with the traditional use of an off-site laboratory. On-site testing may also help support the decision-making process and help avoid potential penalties often imposed on LTACs by insurance companies and government programs for failure to monitor sepsis. The time to result for the system is less than 20 minutes.

Sepsis

Sepsis is a potentially life-threatening complication of an infection that occurs when the body's immune system overreacts and damages its own tissues and organs. It is a leading cause of death in hospitals worldwide, estimated to affect 1.7 million adults in the United States[2] and 47 to 50 million around the globe[3] each year. Over 20% do not survive or are at greater risk of rehospitalization and death. Further, sepsis survivors suffer from persistent impairments such as cognitive deterioration, brain dysfunction, cardiovascular events and an increased chance of hospital readmission in the weeks to months after discharge. It is caused by a number of factors including viral or bacterial infection, pneumonia and blood poisoning among others.

Sepsis falls into two categories: sepsis and septic shock. Sepsis is both the general term for all stages and a systemic response to an infection, characterized by inflammation and organ dysfunction. Symptoms can include fever, increased heart rate, rapid breathing and decreased blood pressure. Septic shock presents a more advanced response that includes organ dysfunction and low blood pressure that requires vasopressor medications to maintain blood pressure. Both sepsis and septic shock are medical emergencies and require immediate attention. Septic shock can be fatal if not treated immediately. Septic shock is a severe circulatory, cellular and metabolic dysregulation that has higher mortality than sepsis.

Summary

Bluejay has launched its pivotal trial for the Symphony IL-6 diagnostic evaluating mortality and stratifying the risk of hospitalized sepsis patients. It has provided some milestones over the next year related to its SYMON trial and is on track for completing the trial by 2025. The first patient enrolled in early 2024 and the first part of the SYMON trial should be complete by May. SIMON II is slated to begin in the third quarter and should be complete before year end. While topline is expected in the second half, stakeholders will have to wait for a conference or journal publication to see the full data set for the trial. We expect to see updates from management as the year progresses.

[2] Centers for Disease Control and Prevention. What is Sepsis?
[3] Global Sepsis Alliance. Sepsis – A Global Health Crisis.

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