

Bluejay Diagnostics, Inc.

(BJDX: NASDAQ)

BJDX: FDA Meeting Confirms Pathway

We employ a discounted cash flow (DCF) model and a 15% discount rate in our valuation of Bluejay Diagnostics. Our methodology applies a 50% probability of commercial success to Bluejay's Symphony Platform.

Current Price (8/25/2023) **\$6.29**
 Valuation **\$32.00**

SUMMARY DATA

52-Week High **21.60**
 52-Week Low **3.80**
 One-Year Return (%) **-70.0**
 Beta **1.2**
 Average Daily Volume (sh) **621,909**

Shares Outstanding (mil) **1.02**
 Market Capitalization (\$mil) **7.8**
 Short Interest Ratio (days) **1.1**
 Institutional Ownership (%) **0.7**
 Insider Ownership (%) **44.4**

Annual Cash Dividend **\$0.00**
 Dividend Yield (%) **0.00**

5-Yr. Historical Growth Rates
 Sales (%) **N/A**
 Earnings Per Share (%) **N/A**
 Dividend (%) **N/A**

P/E using TTM EPS **N/A**
 P/E using 2023 Estimate **N/A**
 P/E using 2024 Estimate **N/A**

Zacks Rank **N/A**

OUTLOOK

Bluejay Diagnostics is developing the Symphony diagnostic testing system which is able to rapidly detect IL-6 in whole blood for patient triage. IL-6 is an important early detection marker for sepsis, cancer progression, rheumatoid arthritis, COVID and other severe conditions. It is a clinically established biomarker for assessment of severity of infection and inflammation across many disease indications.

The device was evaluated in a 2016 study. It found a high positive correlation between Symphony results and the CLEIA standard supporting its use in identifying RA patients in need of emergent treatment. A 2021 study found it comparable with an EUA cleared product for COVID triage.

Bluejay is now investigating the test in the clinic for sepsis triage and monitoring. Other earlier stage programs for hsTNT/I and NT-proBNP for MI and heart failure are also proposed on the Symphony platform.

The NIH estimates ~1.7 million US cases of sepsis per year and 270,000 related deaths. Other indications with higher prevalence could also benefit from rapid IL-6 detection.

If Bluejay obtains regulatory approval for IL-6 sepsis triage and monitoring, it will pursue additional diagnostic tests for MI, CHF, neutropenic sepsis in cancer & other disease indications.

Risk Level Above Average
Type of Stock Small-Growth
Industry Med-Biomed/Gene

ZACKS ESTIMATES

Revenue

(In millions of USD)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	\$0.0 A	\$0.2 A	\$0.0 A	\$0.0 A	\$0.2 E
2023	\$0.0 A	\$0.0 A	\$0.0 E	\$0.0 E	\$0.0 E
2024					\$0.0 E
2025					\$1.6 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2022	-\$2.00 A	-\$1.92 A	-\$2.94 A	-\$2.36 A	-\$9.22 A
2023	-\$2.49 A	-\$2.75 A	-\$0.84 E	-\$0.85 E	-\$5.62 E
2024					-\$3.34 E
2025					-\$3.28 E

WHAT'S NEW

2Q:23 Financial and Operational Results

Since our May initiation of Bluejay Diagnostics, Inc. (NASDAQ: BJDY), the company has regained compliance with the NASDAQ minimum bid price requirement following a reverse share split on July 24th. Bluejay is preparing to complete its pivotal trial and pursue a 510(k) FDA regulatory submission. The company prepared the new study design for evaluating the Symphony diagnostic in IL-6 detection and participated in a pre-submission meeting in mid-August where the pursuit of a 510(k) approval was confirmed. This report further reviews Bluejay's second quarter financial performance and recent accomplishments. Following the second quarter report, a \$1.6 million registered direct offering was **priced** at \$7.37 per share which is expected to close on August 28th.

Highlights for 2023 include:

- **Collaboration** agreement with Blood Centers of America – February
- Regulatory strategy **refinement** – May 2023
- FDA pre-submission meeting – August 2023
- Bluejay **regains** compliance with NASDAQ minimum bid requirement – August

Bluejay generated no revenues during 2Q:23 and reported a net loss of (\$2.8) million, or (\$2.75) per share. For the quarter ending June 30, 2023 and versus the same period in the prior year:

- Revenues of \$0 compared to \$249,000 as the sale of five Symphony analyzers to Toray took place in the prior year period;
- Research & Development expense totaled \$1.7 million, up 122% from \$0.8 million. The increase was attributable to personnel costs and product development expenses;
- General & Administrative expenses were \$1.1 million, down 10% from \$1.2 million primarily due to a focus on cost containment while preparing to begin the pivotal study;
- Sales and Marketing costs were \$154,000 vs. \$81,000, up 90% due to increased personnel costs;
- Net loss was (\$2.8) million or (\$2.75) per share compared with net loss of (\$1.9) million or (\$1.92) per share, respectively.¹

At quarter's end, marketable securities, cash and equivalents totaled \$5.1 million. Cash burn for 2Q:23 was (\$1.7) million. Financing cash flows were minimal and represented 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. We anticipate that following the August 25th capital raise, Bluejay will need just under \$14 million to support R&D and operations to obtain FDA clearance of the Symphony test which is expected at the end of 2024. Capital is expected to be raised in several tranches to support the pivotal trial and regulatory submission for the Symphony diagnostic measuring IL-6.

Returning to Compliance with NASDAQ Minimum Bid Price Requirements

On October 25, 2022, Bluejay received notification from the NASDAQ that the company's shares had closed below \$1.00 for the previous 30 consecutive business days. The letter required the shares to trade above \$1.00 for ten business days in order to regain compliance. NASDAQ provided 180 days to regain compliance then extended the period by another 180 days which changed the required compliance date to October 23, 2023.

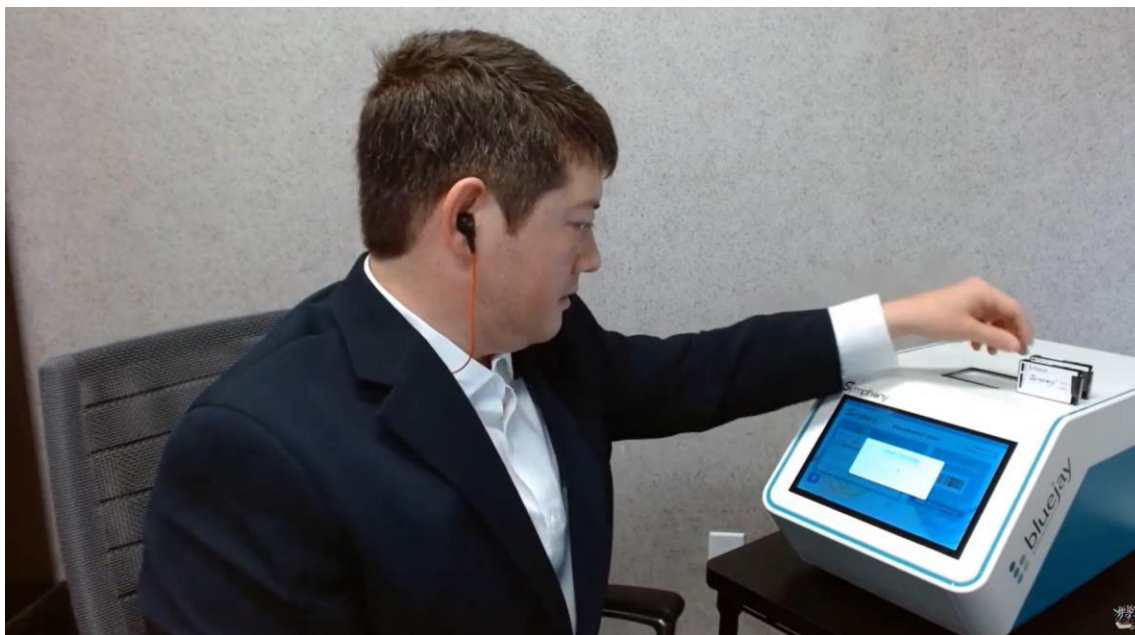
On July 24th Bluejay **executed** a 1:20 reverse stock split reducing the shares outstanding from approximately 20 million to approximately 1 million. Following the reverse split, on August 8th, NASDAQ notified Bluejay that it had **re-gained** compliance with minimum bid requirements.

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

Chief Technology Officer Interviews

Bluejay Chief Technology Officer Dr. Jason Cook participated in a series of interviews that discussed Bluejay's Symphony diagnostic, its competitive advantage and the development program for the device. The discussion went further to look at what comes after a successful IL-6 test, the competitive environment and broader themes addressing diagnostic testing legislation, impacts of COVID and volatility in the small cap life sciences space.

Exhibit I – Dr. Jason Cook and Symphony Diagnostic²



- [Symphony Diagnostic Demonstration](#)
- [The Competitive Environment in Rapid Turnaround Diagnostics](#)
- [What is Bluejay's Symphony System?](#)
- [What are Symphony's Competitive Advantages?](#)
- [Status of Bluejay's Pivotal Trial](#)
- [What's Next for Bluejay Diagnostics?](#)
- [Bluejay Diagnostics Symphony System](#)
- [Fireside Chat with Bluejay's Chief Technology Officer, Dr. Jason Cook](#)

Upcoming Milestones

- Capital raise – 2H:23
- Resumption of IL-6 Symphony diagnostic pivotal trial – 4Q:23
- Completion of IL-6 Symphony diagnostic pivotal trial – 2024
- Submission of 510(k) application – 2H:24
- FDA response to 510(k) submission – 2025

Valuation

We update our valuation to reflect future capital needs, the reverse share split and latest share count as provided in the second quarter Form 10-Q filing and updated for the August 2023 capital raise. We foresee the clinical trial beginning in 4Q:23 with direct costs estimated between \$3.5 and \$4.0 million with 16 sites supporting enrollment. Our valuation stands at \$32 per share.

² Screen shot from interview with Dr. Jason Cook, Bluejay Diagnostic Chief Technology Officer

Summary

Bluejay Diagnostics has identified a niche in the diagnostic testing market that calls for low-volume, high accuracy tests for critical diseases. While Bluejay's first foray into point of care testing is in sepsis, there are many other opportunities for rapid turnaround tests and a severe unmet need for diagnostic results to inform medical decision making.

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.

Bluejay's Symphony diagnostic is able to accept a small whole blood sample in the available cartridges and run the test in the analyzer with up to six cartridges to produce a result in less than 20 minutes. The diagnostic cartridge and machine are inexpensive enough to justify at any emergent care facility and even in the field for remote operations or military hospitals as the immuno-analyzer has its own power supply. If Bluejay is successful, it may offer many diagnostics that can be rapidly deployed anywhere in the future. With a full suite of tests, the device becomes even more valuable and could carve out an important niche in diagnostic testing where accurate and rapid results are critical to patient care. Other indications in the pipeline to be pursued after the sepsis triage test is granted marketing clearance include chest pain diagnostics hs-TnT and NT-proBNP.

Clinical trials are now underway in the United States and Bluejay has recently identified the proper primary endpoint and regulatory pathway for its pivotal study. The initial endpoint was the use of mechanical assisted ventilation; however, since there are now fewer incidents of severe respiratory distress, the company has settled on the use of 28-day mortality and risk stratification of hospitalized sepsis patients. Our estimates call for the trial to be completed in 2024, followed shortly after by a regulatory submission using the 510(k) pathway. 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 sell the devices and cartridges.

While we see a modest level of risk as Bluejay works out the details of the clinical trial and raises additional capital, we also see substantial opportunity in a market that lacks the type of testing necessary to make important medical decisions, especially in low volume, time sensitive situations where accuracy is paramount.

Key reasons to own Bluejay Diagnostics shares:

- **Symphony system offers several advantages over traditional systems**
 - **Ease of use**
 - **Cost, time and space savings**
 - **Versatile platform able to support a broad test menu**
 - **Throughput and multiple testing capability**
 - **Immediate test of analyte, avoiding degradation during queue wait time**
- **Bluejay holds global license (ex-Japan) for manufacturing, marketing and sale of Symphony system**
 - **Domestic commercialization using small sales force and distributors**
 - **Ex-US commercialization using partners and distributors**
- **Further expansion into additional low volume, quick turnaround tests**
 - **Chest pain markers**
 - **Autoimmune disease**
 - **Inflammatory diseases**

PROJECTED FINANCIALS

Bluejay Diagnostics, Inc. - Income Statement

Bluejay Diagnostics, Inc.	2022 A	Q1 A	Q2 A	Q3 E	Q4 E	2023 E	2024 E	2025 E
Total Revenues (\$US '000)	\$249	\$0	\$0	\$0	\$0	\$0	\$0	\$1,636
<i>YOY Growth</i>								
Cost of Goods Sold	\$200	\$0	\$0	\$0	\$0	\$0	\$0	\$736
Product Gross Margin	20%	0%	0%	0%	0%	0%	0%	55%
Research & Development	\$4,152	\$1,355	\$1,676	\$600	\$500	\$4,131	\$2,000	\$2,200
General & Administrative	\$4,763	\$1,177	\$1,073	\$1,125	\$1,265	\$4,640	\$4,900	\$5,350
Sales & Marketing	\$451	\$148	\$154	\$121	\$114	\$537	\$500	\$1,800
Income from operations	(\$9,318)	(\$2,680)	(\$2,904)	(\$1,846)	(\$1,879)	(\$9,308)	(\$7,400)	(\$8,450)
<i>Operating Margin</i>								
Other Expense	\$21	\$140	\$90	\$0	\$0	\$230	\$0	\$0
Pre-Tax Income	(\$9,297)	(\$2,540)	(\$2,813)	(\$1,846)	(\$1,879)	(\$9,078)	(\$7,400)	(\$8,450)
Provision for Income Tax	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>Tax Rate</i>								
Net Income	(\$9,297)	(\$2,540)	(\$2,813)	(\$1,846)	(\$1,879)	(\$9,078)	(\$7,400)	(\$8,450)
<i>Net Margin</i>								
Reported EPS	(\$9.22)	(\$2.49)	(\$2.75)	(\$0.84)	(\$0.85)	(\$5.62)	(\$3.34)	(\$3.28)
<i>YOY Growth</i>								
Basic Shares Outstanding	1,008	1,019	1,023	2,203	2,220	1,616	2,217	2,577

Source: Company Filing // Zacks Investment Research, Inc. Estimates

HISTORICAL STOCK PRICE

Bluejay Diagnostics, Inc. – Share Price Chart



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