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Bluejay Diagnostics (NASDAQ: BJDJ) – Neutral Rated

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Reports 2nd Quarter – Post 1 for 20 Split: \$5M in Cash

Symphony Update: The company submitted a pre-submission application to the FDA presenting the new study design in May 2023 and participated in a pre-submission meeting on 11-Aug-23. At the meeting, the FDA provided feedback on the new study design, determined that the submission of a 510(k) is the appropriate premarket submission pathway, and requested that certain data be provided in the 510(k). Regulatory submission goal: 1H-24.

Second Quarter Results: The company spent \$2.9M in the second quarter and closed the period with \$5M in cash & equivalents.

Symphony Time-Line: Symphony IL-6 regulatory submission timeline of H1 of 2024. The company has targeted large, well-known medical and academic institutions for its study, which the company believes will help support initial commercialization and market penetration.

Symphony is Something New – “DeNovo”. It is an automated diagnostic system consisting of a fluorescence immuno-analyzer that uses a single-use diagnostic test cartridge with reagents integrated into the cartridge. Symphony utilizes a ‘sample-to-result’ format, which means that once a specimen is taken from the patient, it is placed in the cartridge. Then the cartridge is placed inside the analyzer, where the test is run in minutes without further technician intervention or additional reagent.

A Point of Care Rapid Test for IL-6: Bluejay’s IL-6 test for sepsis triage is intended to measure IL-6 levels in whole blood samples in near-patient settings. Interleukin-6 (IL-6) is an established biomarker of immune system activation. It is elevated in infection, inflammation, and cancer. IL-6 presents as an early “first responder” and needs to be measured quickly and reliably.

Valuation: As we are neutral rated, we do not publish our target. We do maintain a model including valuation. In that model we apply a conservative 10% success probability to our projected revenues in our Symphony product model in addition to our 30% risk rate applied in our Free Cash Flow to the Firm (FCFF), discounted EPS (dEPS), and Sum-of-the-Parts (SOP) models, which are then equal-weighted and averaged and rounded to the nearest whole number.

Risks to our thesis include: 1. Regulatory Approvals; 2. Clinical Science 3. Dependence on OEM suppliers; 4. Development of the target markets 5. Intellectual Capital 6. Dilution.



The Symphony System

Source: Bluejay

Stock Data			
52-Week Range	\$3.80	-	\$23.00
Shares Outstanding (mil.)	1.0		
Market Capitalization (mil.)	\$8		
Enterprise Value (mil.)	-\$9		
Debt to Capital	0%		
Book Value/Share	NA		
Price/Book	-		
Average Three Months Trading Volume (K)	NA		
Insider Ownership	44.4%		
Institutional Ownership	0.9%		
Short interest (mil.)	8.5%		
Dividend / Yield	\$0.00/0.0%		



Risks to our thesis include: (1) Regulatory Approvals; (2) Clinical Science (3) Dependence on OEM suppliers; (4) Development of the target markets (5) Intellectual Capital (6) Dilution Risks. In addition, the company details the following additional risks:

- The company is likely to incur losses for the foreseeable future until it is able to generate sufficient revenue from product sales.
- Losses from operations could raise doubts regarding the company's ability to continue as a going concern. The ability to continue as a going concern likely requires additional funding to finance the company's operations.
- The company's product candidates are dependent on its license agreement with Toray. The license agreement imposes significant obligations on the company, including the potential obligation to pay the minimum royalties upon regulatory approval. If the company's license agreement with Toray is terminated for any reason, the company may not be able to generate revenues, and its business could cease.
- The regulatory approval pathway the company must navigate may be expensive, time-consuming and uncertain, and may prevent the company from obtaining approval for the marketing of its product candidates.
- There can be no assurance that the company will successfully complete any clinical evaluation studies necessary to receive regulatory approvals.
- The company's success is highly dependent on its IL-6 product candidates, which are yet to be approved and, even if approved, may not be accepted by the marketplace.
- The company is dependent on third parties to manufacture its product candidates.
- If Toray is unable to successfully protect or enforce its intellectual property and proprietary rights or elects not to do so, the company's competitive position will be harmed.
- If others claim that the company or Toray are infringing on their intellectual property rights, the company may be subject to costly and time-consuming litigation.
- The company may face competition from companies that have greater resources creating a tough-to-compete environment.

Exhibit 1. Income Statement

BJDX, Inc. Income Statement (\$000)																		
YE Dec. 31	2021A	2022A	1Q23A	2Q23A	3Q23E	4Q23E	2023E	1Q24E	2Q24E	3Q24E	4Q24E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Revenue (\$000)																		
Symphony Revenues - IL6 (risk adjusted probability)	-	-	-	-	-	-	-	-	-	-	-	-	5,054	7,862	13,478	22,651	27,181	31,712
Symphony Revenues - Non- IL6															5,000	10,000	12,000	14,000
Total Revenues	-	249	-	-	-	-	-	-	-	-	-	-	5,054	7,862	18,478	32,651	39,181	45,712
Expenses																		
COGS	-	200	-	-	-	-	-	-	-	-	-	-	2,022	2,752	5,544	9,795	11,754	13,714
% COGS			50%	50%	50%	50%		50%	50%	50%	50%	#DIV/0!	40%	35%	30%	30%	30%	30%
Gross Profit	-	49	-	-	-	-	-	-	-	-	-	-	3,033	5,111	12,935	22,856	27,427	31,998
Research & Development	1,148	4,152	1,355	1,676	1,000	(31)	4,000	480	500	500	520	2,000	2,040	2,081	2,122	2,165	2,208	2,252
General & Administrative	1,792	4,763	1,177	1,073	1,215	1,394	4,858	1,189	1,239	1,239	1,288	4,956	5,055	5,156	5,259	5,364	5,471	5,581
Marketing & Business Development	290	451	148	154	156	166	625	480	500	500	520	2,000	4,000	6,000	6,120	6,242	6,367	6,495
Total expenses	3,230	9,366	2,680	2,904	2,371	1,529	9,483	2,149	2,239	2,239	2,328	8,956	11,095	13,237	13,501	13,771	14,047	14,328
Operating Profit	(3,230)	(9,318)	(2,680)	(2,904)	(2,371)	(1,529)	(9,483)	(2,149)	(2,239)	(2,239)	(2,328)	(8,956)	(8,062)	(8,126)	(566)	9,085	13,380	17,671
Oper Margin																		
Interest Income (expense)	(258)	258	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Income	-	(237)	140	90	-	-	230	-	-	-	-	-	-	-	-	-	-	-
Pre-tax income	(3,488)	(9,297)	(2,540)	(2,813)	(2,371)	(1,529)	(9,253)	(2,149)	(2,239)	(2,239)	(2,328)	(8,956)	(8,062)	(8,126)	(566)	9,085	13,380	17,671
Pretax Margin																		
Income Tax (Benefit)	-	-	-	-	-	-	-	-	-	-	-	-	-	(813)	(113)	2,725	5,352	7,068
Tax Rate		0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	10%	20%	30%	40%	40%
GAAP Net Income	(3,488)	(9,297)	(2,540)	(2,813)	(2,371)	(1,529)	(9,253)	(2,149)	(2,239)	(2,239)	(2,328)	(8,956)	(8,062)	(7,313)	(453)	6,359	8,028	10,602
GAAP-EPS	(0.41)	(0.46)	(0.12)	(2.75)	(0.79)	(0.51)	(4.17)	(0.72)	(0.09)	(0.09)	(0.09)	(0.99)	(0.32)	(0.29)	(0.02)	0.25	0.31	0.41
Non GAAP EPS (dil)	(0.41)	(0.46)	(0.12)	(2.75)	(0.79)	(0.51)	(4.17)	(0.72)	(0.09)	(0.09)	(0.09)	(0.99)	(0.32)	(0.29)	(0.02)	0.25	0.31	0.41
Wgtd Avg Shrs (Bas) - '000s	8,522	20,164	20,375	1,023	1,500	1,600	6,125	1,603	10,000	10,020	10,040	7,916	10,090	10,171	10,253	10,335	10,418	10,502
Wgtd Avg Shrs (Dil) - '000s	8,522	20,164	20,375	1,023	3,000	3,000	6,850	3,003	25,000	25,050	25,100	19,538	25,201	25,378	25,556	25,735	25,916	26,097

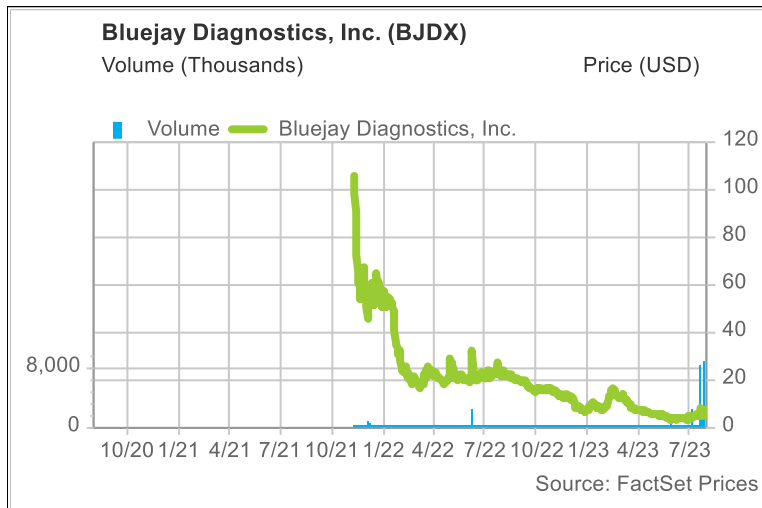
Source: Dawson James

Companies mentioned in this report:

Toray (Japan)

Important Disclosures:

Price Chart:



Price target and ratings changes over the past three years:

- Initiated – Buy – January 12, 2022 – Price Target \$10.0
- Update – Buy – January 14, 2022 – Price Target \$10.0
- Update – Buy – January 31, 2022 – Price Target \$10.0
- Update – Buy – March 10, 2022 – Price Target \$10.0
- Update – Buy – April 21, 2022 – Price Target Change \$10.0 to \$8.0
- Update – Buy – June 28, 2022 – Price Target \$8.0
- Update – Buy – July 6, 2022 – Price Target \$8.0
- Update – Buy – July 27, 2022 – Price Target \$8.0
- Update – Buy – August 26, 2022 – Price Target \$8.0
- Price Target Change – Buy – November 2, 2022 – Price Target \$4.0
- Update – Buy – November 9, 2022 – Price Target \$4.0
- Update – Buy – February 16, 2023 – Price Target \$4.0
- Update – Buy – March 21, 2023 – Price Target \$4.0
- Update – Buy – May 10, 2023 – Price Target \$4.0
- Rating Change – But to Neutral – August 1, 2023 – Price Target NA
- Update – Neutral – August 16, 2023 – Price Target NA

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- 1) **Buy:** The analyst believes the price of the stock will appreciate and produce a total return of at least 20% over the next 12-18 months.
- 2) **Neutral:** The analyst believes the price of the stock is fairly valued for the next 12-18 months.
- 3) **Sell:** The analyst believes the price of the stock will decline by at least 20% over the next 12-18 months and should be sold.

The following chart reflects the range of current research report ratings for all companies, followed by the analysts of the Firm. The chart also reflects the research report ratings relating to those companies for which the Firm has performed investment banking services.

Current as of 3-Aug-23

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	24	69%	3	8.60%
Market Perform (Neutral)	11	31%	3	8.60%
Market Underperform (Sell)	0	0%	0	0.00%
Total	35	100%	6	17.20%

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