



Issuer Free Writing Prospectus  
Filed Pursuant to Rule 433  
Registration no. 333-260029  
Relating to Preliminary Prospectus dated October 25, 2021



# Issuer Free Writing Prospectus, Cautionary Statement Concerning

## Forward-looking Statements

**CAUTIONARY STATEMENT CONCERNING FORWARD LOOKING STATEMENTS** This document contains forward-looking statements. In addition, from time to time, we or our representatives may make forward-looking statements orally or in writing. We base these forward-looking statements on our expectations and projections about future events, which we derive from the information currently available to us. Such forward-looking statements relate to future events or our future performance, including: our financial performance and projections; our growth in revenue and earnings; and our business prospects and opportunities. You can identify forward-looking statements by those that are not historical in nature, particularly those that use terminology such as “may,” “should,” “expects,” “anticipates,” “contemplates,” “estimates,” “believes,” “plans,” “projected,” “predicts,” “potential,” or “hopes” or the negative of these or similar terms. In evaluating these forward-looking statements, you should consider various factors, including: our ability to obtain additional funding to develop our product candidates; our ability to satisfy any requirements imposed by the FDA (or its foreign equivalents); the impact of COVID-19 on our clinical trials, preclinical activities and our ability to raise future financing; our ability to continue our relationship with Toray; the need to obtain and retain regulatory approval of our products, both in the United States and in countries deemed necessary for future trials; our ability to complete our clinical trials in a timely fashion and within our expected budget and resources; compliance with obligations under intellectual property licenses with third parties; our ability to commercialize our product candidates; market acceptance of our products; and our dependency on third-party manufacturers to successfully, and timely, supply or manufacture our products. These and other factors may cause our actual results to differ materially from any forward-looking statement. Forward-looking statements are only predictions. The forward-looking events discussed in this document and other statements made from time to time by us or our representatives, may not occur, and actual events and results may differ materially and are subject to risks, uncertainties and assumptions about us. We are not obligated to publicly update or revise any forward-looking statement, whether as a result of uncertainties and assumptions, the forward-looking events discussed in this document and other statements made from time to time by us or our representatives might not occur.

## Statement About Free Writing Prospectus

This free writing prospectus relates to the proposed initial public offering of common stock of Bluejay Diagnostics, Inc., which are being registered on a registration statement on Form S-1 (File No. 333-260029) (the "Registration Statement"). This free writing prospectus should be read together with the preliminary prospectus dated October 25, 2021 included in the Registration Statement (the "Preliminary Prospectus"), which can be accessed through the following link: [https://www.sec.gov/Archives/edgar/data/0001704287/000121390021054486/fs12021a1\\_bluejay.htm](https://www.sec.gov/Archives/edgar/data/0001704287/000121390021054486/fs12021a1_bluejay.htm)

We have filed a Registration Statement, including the Preliminary Prospectus, with the SEC with respect to the offering of our securities to which this communication relates. The Registration Statement has not yet become effective. Before you invest, you should read the Preliminary Prospectus (including the risk factors described therein) and, when available, the final prospectus relating to the offering, and the other documents filed with the SEC, for more complete information about us and the offering. You may obtain these documents, including the Preliminary Prospectus, for free by visiting EDGAR on the SEC website at <http://www.sec.gov>. Alternatively, the company or the underwriter for the offering will arrange to send you the Preliminary Prospectus and, when available, the final prospectus and/or any supplements thereto, if you contact Dawson James Securities, Inc. at 101NFederalHwy,Suite600,BocaRaton,FL,33432 by e-mail at [investmentbanking@dawsonjames.com](mailto:investmentbanking@dawsonjames.com) or by telephone at (561)391-5555.



**Bluejay Diagnostics is focused on improving patient outcomes in critical care settings using Symphony:**

Delivering a cost efficient, rapid, near-patient product for triage and treatment guidance



**The Symphony System**

# Bluejay is Focused on Improving Patient Outcomes in Hospital/LTAC\* Settings

Using Symphony, a cost efficient, rapid, near-patient product for triage, diagnosis and monitoring of disease progression

## Key Investment Highlights

Physicians need high-sensitivity near-patient testing for triage/treatment guidance in critical care settings

Symphony System has the potential to enable physicians to make better treatment decisions

IL-6 Test for Sepsis Triage leads a pipeline targeting a potential multi-billion-dollar market opportunity

Marketed in Japan for 3years by collaborator Toray\*\* as "Research Use Only" product

FDA 510(k) application for the IL-6 Test for Sepsis Triage planned for late Q3:22

Plan to expand the testing menu to include other well-validated critical care biomarkers

Developed by Toray\*\* through an extensive 12-year program & Bluejay has exclusive ex-Japan global rights

Attractive recurring revenue model and a focused marketing plan to support the launch

Led by a Team of healthcare and diagnostics veterans

IPO proceeds to support development and marketing of IL-6 for Sepsis Triage



\*LTAC = Long Term Acute Care

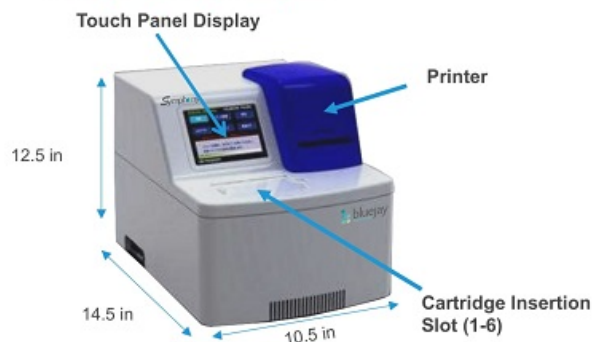
\*\*Toray Industries, Inc.

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# The Symphony System : Technology Platform

Analyzer and Cartridge basics

## The Symphony Analyzer



- Same operational matrix irrespective of the test performed
- Same detection method
- 6 different samples or 6 different tests, simultaneously

## Symphony Cartridge

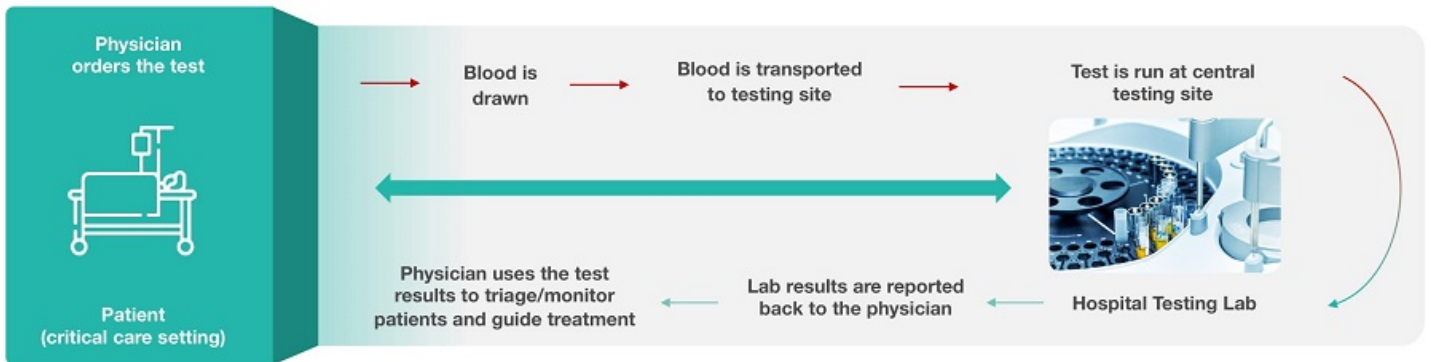


- No additional chemicals
- No pre-processing of the sample
- ELISA = Enzyme-Linked Immunosorbent Assay

The Symphony platform will be leveraged by developing tests for other indications

# Lengthy Testing Time Reduces Utility for Triage/Treatment Guidance

For use in hospital/long-term acute care (LTAC\*\*) settings to provide triage/treatment guidance



## Current Testing Methods:

- Testing systems are very large, so they need to be run in a central lab setting
- The whole process, from blood draw to results, takes 8-48hr – this is a long time in a critical care setting
- Systems require highly trained, expensive laboratory technicians to operate and maintain them



# Symphony Transforms Care Through Rapid, Near-Patient Testing

Enables Physicians to make better treatment decisions for patients with life-threatening illnesses



## Symphony's Differentiated Features:

- The System can test whole blood samples (without the need for any pre-test processing)
- Symphony is a desk-top system, so tests can be run in critical care settings, near the patient's bedside
- Results are provided quickly to make triage/treatment decisions (time to results ~24 minutes)



## Symphony System Potential Advantages\*

Uses well-accepted ELISA\*\* chemistry plus unique microfluidics/nanotechnology platform

Potential Advantages	Bluejay's Symphony	Major Diagnostic Manufacturers
Testing Location	Near patient	Central lab
Test System Size	Desk Top	Very Large
Sample type	Whole blood	Plasma/Serum
Sample Pre-process	No	Yes
Time from test to result	~24 minutes	8-48hr
Staffing	No dedicated personnel (phlebotomist, Med Tech)	Requires a Phlebotomist, Med Tech
System Cost	\$	\$\$\$
Cost per Test*	\$80	\$275
Revenue Model	Reagent Rental	System Purchase



\*Source: Bluejay Diagnostics market research

\*\*ELISA = Enzyme-Linked Immunosorbent Assay

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## Symphony Product Pipeline Targets Multi-Billion Dollar Markets\*

Plan to expand the testing menu to include other well-validated critical care biomarkers

Product Pipeline Commercial Rights	Research	Development	Clinical Testing	Regulatory	Estimated Market Opportunity*
<b>Symphony™ IL-6 Sepsis Triage</b> Bluejay Diagnostics					Hospitals: \$925M + LTAC: \$2-3B
<b>Symphony™ hsTNT/I Triage</b> Bluejay Diagnostics and Toray Industries					Hospitals: \$3.6B
<b>Symphony™ NT-proBNP Triage</b> Bluejay Diagnostics and Toray Industries					

Ongoing investment in Symphony System to improve user interface and support user adoption

**New Tests Will Follow the IL-6 Development Pathway**



\*Source: Bluejay Diagnostics market research

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## First Product: IL-6 for Sepsis Triage

Measuring IL-6 could help medical professionals make earlier and better triage/treatment decisions

### Interleukin-6 (IL-6) is a Principal Inflammatory Cytokine Released During Trauma or Infection

- IL-6 is an **established marker** of immune system activation
- Elevated in response to infection such as COVID-19 and sepsis
- Also important in autoimmune disorders, such as rheumatoid arthritis (RA), cardiovascular diseases and all cancers

### IL-6 needs to be measured quickly and reliably

- It appears early on as a “first responder” during infection or inflammation
- Reliably measuring IL-6 levels could help medical professionals triage, diagnose and monitor disease progression


### Current tests have received Emergency Use Authorization (EUA) for use in COVID-19 sepsis/RUO\* for arthritis

- Beckman-Coulter, Roche and Siemens (EUA: COVID-sepsis) and Toray (RUO: arthritis)
- Tests are run in a central lab setting
- Estimated time from blood draw to results: 8-48hr
- IL-6 stability and turn-around time has limited adoption and utilization

## IL-6 is Following Well Established Clinical Testing Pathway

Studies will document Symphony performance versus standard of care

**Elements of Clinical Testing Program: Will be Completed by Q3:22 (using ~250 subjects):**

Testing Program	Testing Sites
Reference Range Study Cut-Off Value Study Cut-Off Validation Study Analytical Testing	<div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p>UT Southwestern Medical Center®</p> <p>Zale Lipshy Pavilion Hospital</p> </div> <div style="text-align: center;"> <p>William P. Clements Jr. University Hospital</p>  </div> </div>

### Regulatory Plan

Milestone	Target Timing
Initial Testing Program at UT Southwestern	Underway
UT Southwestern Testing Program results form the basis of FDA Pre-submission application	January 2022
Conduct an expanded Testing Program	Q1-Q3:2022
File an FDA 510(K)* application for the use of IL-6 in sepsis	Q3: 2022



\*including Regulatory pathways (510(K) or de novo), to be determined with FDA, or any other alternative paths including EUA = Emergency Use Authorization, RUO = Research Use Only, LDT = Lab Developed Test

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# Market Entry: Symphony IL-6

Staged approach

Deployment as we progress through our clinical trials



## STAGE I

### Laboratory Developed Tests

- Selected deployment
- Clinical labs and ICUs who would perform internal validation



## STAGE II\*

### EUA (COVID-19 Sepsis)

- ICUs
- COVID centers/labs
- Clinical labs



## STAGE III

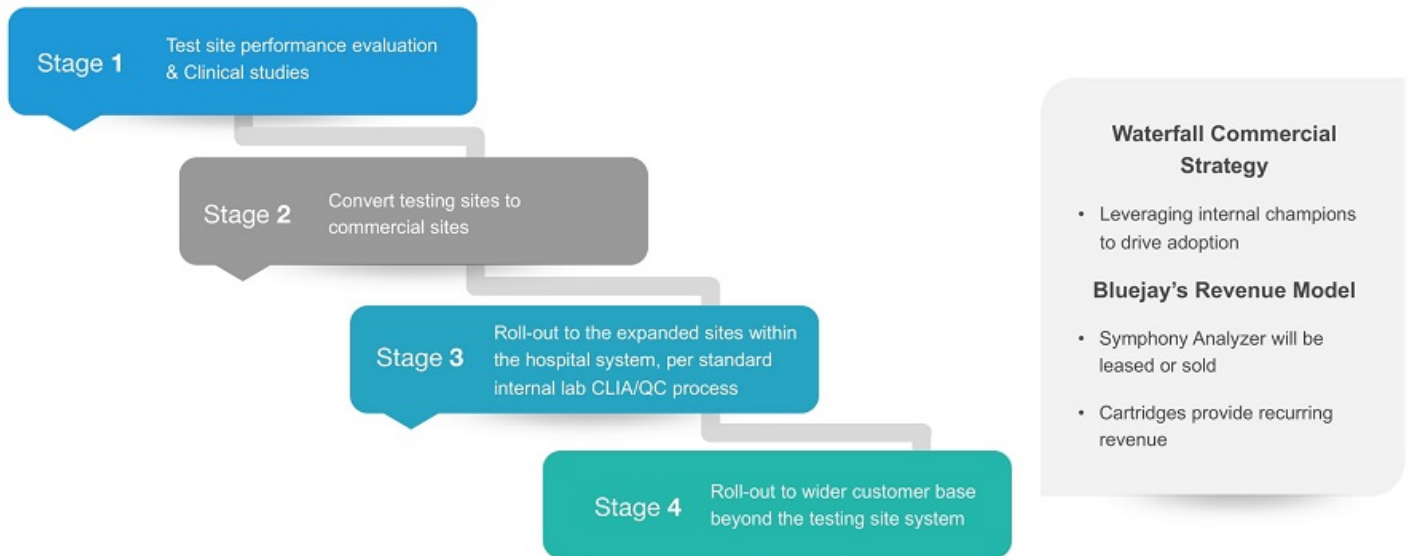
### 510(k) Sepsis triage

- Emergency Rooms
- Sepsis centers
- Cancer Centers

\*Stage II remains an option

# Launch Plan Starts by Converting Bluejay's Test Sites to Commercial Sites

Existing multi-location healthcare testing sites are built-in initial commercial customers



## Manufacturing Overview

Contract Manufacturing Agreements in Place with Toray and Sanyoseiko



- Multinational company with 96+ years of manufacturing experience
- Toray will manufacture cartridges for 3 years



- More than 50 years of global experience in medical devices manufacturing
- Manufacturing the Symphony Analyzer
- Manufacturing cartridges alongside Toray starting 2023



# Management

Bluejay is led by a team of industry veterans with years of diagnostic and product launch experience

<b>Indranil "Neil" Dey</b> CEO and Co-founder	<ul style="list-style-type: none"><li>• Involved in introducing Her2neu test for Herceptin (&gt;\$1.2 billion revenue) and introduction of Erbitux (&gt;\$1.15 billion revenue)</li><li>• Head of business development - Western U.S. for MPATH, a \$300 million business unit with 65 direct reports</li><li>• Ph.D. in Biochemistry (UNESCO fellow) from BRC, Hungary, MBA (Fulbright Scholar) from Cambridge University, UK</li></ul>
<b>Gordon Kinder</b> CFO	<ul style="list-style-type: none"><li>• More than 15 years of experience in corporate finance. Started at Ernst &amp; Young LLP in 2005</li><li>• Founded Capella Financial Services in 2008 and has served as senior finance executive for variety of companies</li><li>• BA in History from Kenyon College and MBA and MS in Accounting degrees from Northeastern University</li></ul>
<b>Jason Cook</b> CTO	<ul style="list-style-type: none"><li>• Responsible for Bluejay's product development and manufacturing</li><li>• 15+ years of experience in the field of POC and diagnostics product development</li><li>• Ph.D. in Biomedical Engineering from University of Texas at Austin</li></ul>
<b>Kevin Vance</b> Chief Commercial Officer	<ul style="list-style-type: none"><li>• In charge of Bluejay's worldwide direct sales and strategic partnerships</li><li>• Before joining Bluejay, served as Chief Business Development Executive for Vibra Healthcare</li><li>• BS, Industrial Engineering &amp; Operations Research from U. of Mass Amherst; MBA, Western New England University</li></ul>



## Board of Directors\*

<p><b>Douglas C. Wurth</b> Chairman</p>	<ul style="list-style-type: none"> <li>• 20 year career at J.P. Morgan Chase, including CEO of the International Private Bank and CEO of the Alternative Investments division of Asset Management</li> <li>• General Counsel to Senator Robert Dole's 1996 Presidential Campaign, practiced law at Skadden, Arps, Meagher and Flom</li> <li>• B.A Notre Dame University; J.D. University of Virginia School of Law</li> </ul>
<p><b>Indranil "Neil" Dey</b> CEO</p>	<ul style="list-style-type: none"> <li>• 25+ years in healthcare industry (pharma &amp; diagnostics)</li> <li>• Involved in introducing Her2neu test for Herceptin (&gt;\$1.2 billion revenue) and introduction of Erbitux (&gt;\$1.15 billion revenue)</li> <li>• Ph.D. in Biochemistry (UNESCO fellow) from BRC, Hungary and MBA (Fulbright Scholar) from Cambridge University, UK</li> </ul>
<p><b>Svetlana Dey</b></p>	<ul style="list-style-type: none"> <li>• More than 15 years of management experience in healthcare industry</li> <li>• Co-founder of Bluejay, President &amp; CEO of LMBRI LLC, Board Member of Laminar Pharma, Inc.</li> <li>• Masters Degree in Mathematics from the State University of Mari El Republic, Russia</li> </ul>
<p><b>Donald R. Chase</b></p>	<ul style="list-style-type: none"> <li>• 35 years, President &amp; CEO West Bank Corporation, Multi State Community Bank, Mass</li> <li>• Chairman , NUVO Bank, DeNovo Bank, Springfield, Mass, Merchants Bank, Director Millyard Bank, N.H.</li> <li>• Bachelor of Science Degree, Accounting, Western New England University, Springfield, Mass,</li> </ul>
<p><b>Fred S. Zeidman</b></p>	<ul style="list-style-type: none"> <li>• 50+ years of corporate advisory experience</li> <li>• Chairman Emeritus Gordian Group, Chairman Emeritus University of Texas Health Science System</li> <li>• Bachelor's degree from Washington University in St. Louis and a Master's in Business Administration from New York University</li> </ul>

J.P.Morgan

Skadden

IMPATH

Imbri

LAMINAR PHARMA

merchants BANCSHARES INC.

westbank




THE HOUSTON MUSEUM

bluejay

\*Gary Gemignani has agreed to join the Board upon the completion of the IPO

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## Finance Overview

Invested Capital and Use of Proceeds\*

### Total Invested Capital

- \$9 MM including equity and convertible debentures

### Offering

- Raising \$18MM (excluding the over-allotment)

### Use of Proceeds\*

- To support development and marketing of IL-6 for Sepsis Triage



\*See the S-1 document for a full set of financial information

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# Offering Overview

Issuer	BlueJay Diagnostics, Inc.
Ticker/Exchange	BJDX / Nasdaq Capital Market
Capital Raise	\$18,000,000 + 15% over-allotment option
Terms	<p>The public offering price per unit is \$10.00. Each Unit Consists of:</p> <ol style="list-style-type: none"> <li>a) One share of our common stock</li> <li>b) one Class A warrant (the "Class A Warrants") to purchase one share of our common stock at an exercise price equal to \$5.00 per share (or 50% of the unit offering price), exercisable until the fifth anniversary of the issuance date</li> <li>c) one Class B warrant (the "Class B Warrants," and together with the Class A Warrants, the "Warrants") to purchase one share of our common stock at an exercise price equal to \$10.00 per share (or 100% of the unit offering price), exercisable until the fifth anniversary of the issuance date.</li> <li>d) Holders of Class B Warrants may exercise such warrants on a "cashless" basis upon the earlier of (i) 10 trading days from the issuance date of such warrant or (ii) the time when \$10.0 million of volume is traded in our common stock, if the volume weighted average price ("VWAP") of our common stock on any trading day on or after the date of issuance fails to exceed the exercise price of the Class B Warrant.</li> </ol>
Use of Proceeds	<ul style="list-style-type: none"> <li>• To obtain our initial 510(k) regulatory approval in the United States for our sepsis product candidate</li> <li>• To market the Sepsis test and Symphony system and establish a distribution network across the United States; and</li> <li>• The remainder for working capital and general corporate purposes.</li> </ul>
Joint Book-running Managers	Dawson James Securities, Inc. & I-Bankers Direct, LLC



## Bluejay is Focused on Improving Patient Outcomes in Hospital/LTAC\* Settings

Using Symphony, a cost efficient, rapid, near-patient product candidate for triage, diagnosis and monitoring of disease progression

### Key Investment Highlights

Advancing a novel & proprietary point of care diagnostic platform – the *Symphony System* – for near term market availability

- Same proprietary instrument can be used for multiple clinical diagnostic tests and offers numerous competitive advantages
- Development path has been de-risked through 12+ years of development and 3+ years of clinical evaluation led by Toray

Lead Symphony test is for IL-6 measurement for sepsis triage/monitoring

- Well established and diverse diagnostic market for all sepsis situations
- Existing IL-6 test options are reimbursed for a multi-billion dollar U.S. market
- A strong pipeline of new Symphony test applications in development will follow

Strong near term value milestones targeted

Experienced, successful leadership team well matched for commercial development of this product line



\*LTAC - Long Term Acute Care

\*Toray Industries, Inc.

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Delivering a cost efficient, rapid, near-patient product for triage and treatment guidance



**The Symphony System**

# Contact



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