UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

DIVISION OF
CORPORATION FINANCE

August 20, 2021

Neil Dey
Chief Executive Officer and President
Bluejay Diagnostics, Inc.
360 Massachusetts Avenue, Suite 203
Acton, MA 01720

Re: Bluejay Diagnostics, Inc.
Draft Registration Statement on Form S-1
Submitted July 22, 2021
CIK No. 0001704287

Dear Mr. Dey:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

Draft Registration Statement on Form S-1

Industry and Market Data, page 0

1. Your statements that: (i) you have not independently verified the accuracy or completeness of third party data, (ii) your internal research has not been verified by any third party and (iii) investors are cautioned not to give undue weight to any such information, projections, and estimates may imply an inappropriate disclaimer of responsibility with respect to the third party information and internal research. Please either delete these statements or specifically state that you are liable for such information.

Prospectus Summary, page 1

2. We note your disclosure that your product may provide a market solution "if cleared, authorized, or approved by the U.S. Food and Drug Administration." Please revise to clearly disclose, if true, that you intend to label and distribute Symphony as an RUO product in the U.S. while you pursue 510(k) clearance from the FDA to use Symphony for in vitro diagnostic use.

3. Please revise your disclosure here and in the Business section to provide appropriate context for various conclusions and predictions as to the performance of your product candidates and revise and/or remove any statements that imply safety or efficacy as safety and efficacy determinations are solely within the authority of the FDA or similar foreign regulators. For example, we note statements that RUO use in Japan has resulted in "validation of the symphony platform," that results from your device "appear to be as accurate as those performed in a laboratory," that your diagnostic product "provide[s] results within 20 minutes," "reduces test result time from days to minutes" and your product candidate "will eliminate the number of operational ‘touch-points’ from ‘sample-to-result’ from six to two." Please revise this disclosure and similar statements throughout your prospectus to remove any suggestion that there is an expectation that your product candidate will be effective or will have improved performance. You may provide a summary of the data that you used to draw these conclusions but not the conclusions or predictions, and such discussion is more appropriate in the Business section where full and proper context can be provided.

4. We note your disclosure that you are "positioned now to complete the last regulatory stages of development needed to move to commercialization in the United States." Please revise to clarify where you currently are in the regulatory process and the material steps that you need to complete, including, if applicable, any clinical trials that must be conducted or regulatory applications that must be submitted.

5. We note your disclosure that Toray Industries is your development partner and investor. Please revise to explain the nature of Toray Industries' investment in your company. Based on your disclosure, it appears that Toray serves as a licensor and supplier only. Please also revise your summary to clearly state that you license the core technology used in your Symphony platform and test cartridge product candidates from Toray Industries.

6. Please revise the Prospectus Summary and Risk Factors to highlight the auditor's explanatory paragraph regarding your ability to continue as a going concern. Your disclosures should describe the potential consequences to your business if you are unable to raise additional financing.

Use of Proceeds, page 27

7. We note your disclosure that you intend to use approximately $5.0 million to obtain regulatory approvals. Please revise to disclose for which product candidates you intend to seek regulatory approval, in which jurisdictions and through which regulatory pathway using the proceeds from this offering.

Business

Our Symphony Platform, page 42

8. We note your disclosure that the Symphony platform is an innovative and proprietary technology platform that in clinical trials appears to provide rapid, highly sensitive, accurate, and simple measurements of key diagnostic biomarkers found in whole blood. Please revise to clarify if these clinical trials were conducted by the Company or a third party. Please also expand your disclosure to include a description of how the clinical trials were conducted and the results observed that would support the above statement.

Manufacturing, page 44

9. Please revise to highlight that pursuant to your agreement with Toray Industries, you are required to use Toray to manufacture test cartridges for a period of three years.

Regulatory Strategy, page 45

10. Please provide the basis for your statement that your Symphony IL-6 product candidate could also be used with confirmed COVID-19 illness. Please revise to disclose whether you have tested your product candidate for this indication and, if so, disclose the results of such testing.

11. We note your disclosure that your clinical studies are being conducted at The University of Texas, Southwestern Medical Center, Dallas, Texas and Parkland Clinic, Dallas, Texas. Please revise to disclose how many trials are being conducted and for each trial being conducted when the trial began, the current status of the trial and when you expect the trial to be completed.

12. With respect to your table on page 46 showing your expected timeline for your product candidates, it appears to be premature and speculative to provide the estimated time to market for your product candidates given that it appears that you have yet to complete material steps in order to commercialize your product candidates. Please revise this table to provide the status of FDA approval of your various product candidates, including clinical trials or studies you must complete, when you began clinical trials or studies and when you expect to complete them and whether you have submitted or when you intend to submit an application for approval to the FDA. Please also explain to us why you have not included Toray Industries next to your Symphony™ IL-6 product candidates. In this regard, we note that you license technology related to Symphony and the detection cartridges.

Intellectual Property, page 47

13. We note that you do not currently hold any patents directly but that you have an exclusive license with Toray to use their patents and know-how related to your Symphony platform and test cartridges. Please revise your intellectual property disclosure to clearly identify each material licensed patent or patent family, the type of patent protection granted for each technology such as composition of matter, use or process, the specific products or product candidates, product groups and technologies dependent on each patent, and the patent expiration dates and applicable jurisdictions, including any foreign jurisdictions.

License Agreement, page 47

14. We note that you intend to file as an exhibit a Lease and Supply Agreement with Toray Industries. If this is not the license agreement that you have with Toray Industries, please file the license agreement as an exhibit to your registration statement pursuant to Item 601(b)(10) of Regulation S-K.

15. We note your disclosure that you are required to pay a 15% royalty fee based on a percentage of “Net Sales” of products. Please revise to disclose the royalty term.

Description of Our Securities, page 72

16. We note that you refer shareholders to, in part, the applicable provisions of the Delaware General Corporation Law. It is not appropriate to qualify your disclosure by reference to information that is not included in the filing or filed as an exhibit. Please revise accordingly.

Recent Sales of Unregistered Securities., page II-2

17. Please revise your disclosure to name the persons or identify the class of persons to whom the securities were sold. Refer to Item 701(b) of Regulation S-K.

General

18. Please provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

You may contact Sasha Parikh at 202-551-3627 or Vanessa Robertson at 202-551-3649 if you have questions regarding comments on the financial statements and related matters. Please contact Deanna Virginio at 202-551-4530 or Ada D. Sarmento at 202-551-3798 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Cavas S. Pavri, Esq.