

DIVISION OF

corporation finance Mail Stop 3030

April 21, 2017

<u>Via E-mail</u> Dwight H. Egan President and Chief Executive Officer Co-Diagnostics, Inc. 4049 S. Highland Drive Salt Lake City, Utah 84124

> Re: Co-Diagnostics, Inc. Amendment No. 1 to Draft Registration Statement on Form S-1 Submitted March 31, 2017 CIK No. 0001692415

Dear Mr. Egan:

We have reviewed your amended 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.

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

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. Unless we note otherwise, our references to prior comments are to comments in our February 8, 2017 letter.

### Explanatory Note, page 3

- 1. We note your response to prior comment 1. If you choose to use 2 separate prospectuses, please continue to revise throughout to ensure that each prospectus clearly and thoroughly highlights the concurrent offering and related impacts. At a minimum, your revisions should address:
  - how the concurrent offerings could impact factors such as price, demand, and liquidity, and

• the requirement in paragraph 16 of Schedule A and Item 501(b)(3) of Regulation S- K that an issuer include a fixed price or bona fide price range where there is no public market for that issuer's securities. We note in this regard that the selling shareholder prospectus must disclose a bona fide price at which the selling shareholders will sell the offered shares until a market develops for your shares and thereafter at prevailing market prices or privately negotiated prices.

## Prospectus Summary, page 8

- 2. Please revise further here and throughout to clearly identify what you intend to sell, in what part of the world and to whom. Importantly, your present disclosure focuses heavily on the scientific explanation of a unique algorithm underlying your proposed tests, but it is still unclear whether you have developed or will develop the actual test, or just sell the algorithm or a license. For example, under "The Company" you indicate that you intend to "manufacture and market molecular diagnostic tests that are designed ... to provide better tests." It is unclear from this whether you intend to sell a diagnostic test or a product that allows other companies to develop better tests. Also, clarify whether your menu of tests, described as "Current" in the bullet points under "Product Offering" are actually available to purchase.
- 3. In addition, you indicate that you intend to focus your sales efforts outside of the United States and Europe in the near term, but given your references to FDA, CE mark and CLIA, please ensure that you have highlighted your expectations in terms of regulatory pathways, including timelines and capital outlays, for any US or European sales. Any such disclosure should be clearly identified as subject to significant uncertainty. Further, provide more detail around your conclusions regarding FDA regulation for lab developed tests, as well as whether you expect that your "field validation" will permit faster CE mark approval.
- 4. Explain what "field validation" entails and clarify, if true, that it does not relate to any present pending or anticipated FDA submission. Also, clarify that you have not taken any steps or made any preparations in furtherance of achieving a CE mark or FDA clearance.
- 5. We note your response to prior comment 4. Given that you have not yet derived any revenue from sales of your products, please clarify your reference to "maintaining" your profit margin in the first paragraph under the heading "The Company."
- 6. Please expand your response to prior comment 5 to disclose what material steps you must complete in order to achieve your timeline of making initial sales in India within six months of the closing of this offering and your anticipated capital needs to complete each step.

### Recent Developments, page 10

7. We note your added disclosure regarding the license agreement and stock purchase agreement with Watermark Group, Inc. and the January 31, 2017 lawsuit filed by P&G Holdings. Please tell us what consideration you have given to added risk factor disclosure regarding any potential liability you may have for terminating the license agreement, rescinding the stock purchase agreement, and pursuant to the lawsuit filed by P&G Holdings. Please also disclose the material terms of the rescission and cancelation agreement, and file as exhibits the stock purchase agreement, the rescission and cancelation agreement, and the \$445,000 Watermark note.

# The Offering, page 12

8. Revise to make clear that you have not yet applied for or received your Nasdaq listing or ticker symbol.

## Risk Factors, page 13

9. Please reconcile your response to prior comment 10 with your disclosure in the last paragraph on pages 8 and 44 indicating that you may derive revenue from HMOs.

### Use of Proceeds, page 31

10. We note your response to prior comment 12. Please reconcile your disclosure here regarding \$10 million with the proposed maximum aggregate offering price disclosed in your fee table and ensure that your fee table covers the maximum amount of all securities being registered by both prospectuses.

### Capitalization, page 32

11. We refer to prior comment 14. Please revise the table to present total capitalization equal to the sum of total debt, including both current and non-current portions, and total stockholders' deficit. Please also revise to show both historical capitalization as of the most recent balance sheet date presented in the filing and pro forma capitalization adjusted for the proceeds of the offering and any other material changes in capitalization expected to occur in connection with your offering.

### Management's Discussion and Analysis, page 34

### Executive Overview, page 37

12. We note your response to prior comment 15. Please ensure that your exhibit index includes all exhibits that will be filed with your registration statement.

13. In the second paragraph on page 39, please clarify whether the conversion price is the greater or lesser of the two alternatives.

### Net Loss, page 41

14. It appears from your disclosure that your net loss decreased for the year ended December 31, 2016 as compared to the year ended December 31, 2015. Accordingly, please revise your disclosure regarding an increase in net loss or advise.

### Business, page 43

### Product Offering, page 45

15. We note your response to prior comment 18; however, you continue to include disclosure here and on page 9 about your current offerings in international markets. Please revise.

## CDI Reagents and Software, page 45

16. We note your response to prior comment 19. We may have further comments pending our receipt and review of the supplemental materials.

### Revenue Model, page 46

- 17. We note your response to prior comment 21. Please disclose the material terms of your agreement with Synbiotics Limited, including the material obligations of the parties, duration of the agreement, and any termination provisions, and file the agreement as an exhibit.
- 18. Please expand your revisions made in response to prior comment 22 to describe the regulatory process in India and in the disclosed Caribbean nations and the steps you will need to complete to achieve your anticipated regulatory approval timeframe. Please also explain what you mean by "successfully marked" in the last paragraph on page 46.

### Principal Stockholders, page 56

19. Please advise how you determined not to (1) aggregate the holdings of Dwight and Seth Egan or (2) include the selling security holders in this table.

### Certain Relationships and Related Party Transactions, page 57

20. We note your response to prior comment 28. Please reconcile your disclosure in the fifth paragraph of this section with your disclosure in the last paragraph on page F-18 regarding the oral modification to the license agreement, and tell us whether you have

any written documentation of this oral modification. Please also file as an exhibit the March 1, 2017 amendment to the April 18, 2014 license agreement.

21. Please file as exhibits the revolving loan agreements with the entities associated with your CFO.

## Description of our Capital Stock, page 58

22. Please respond to that portion of prior comment 29 that asked you to provide the disclosure required by Regulation S-K Item 201(a)(2).

Consolidated Financial Statements, page F-1

## Note 1. Description of Business, page F-7

- 23. We note that you entered into an agreement with Synbiotics Limited to construct and jointly own and operate a manufacturing facility in India. Please expand the notes to financial statements to describe the significant terms of the arrangement, including a description of your rights and obligations and the related accounting applied.
- 24. The first paragraph of the revenue disclosure on page F-10 describes general revenue policies for equipment and services. However, disclosure on page 45 of your filing suggests that your planned products include reagents and software. Please either revise the disclosure to be specific to your planned product offering or consider whether it is appropriate and useful to disclose a prospective revenue policy at this time.
- 25. As a related matter, tell us why you should not present disclosure about the pending adoption of ASC 606, Revenue from Contracts with Customers.

### Note 2. Notes Payable, page F-11

- 26. The descriptions for some of your notes payable appear to have conversion terms that were contingent on filing a registration statement by December 31, 2016. Since that event did not occur by the specified date, please expand your disclosure to clarify the impact on the terms of the notes.
- 27. The descriptions for some of your notes payable have conversion terms that reference an anticipated bridge financing. Please revise to clarify whether you are referring to the December 2016 bridge notes or some other anticipated financing.
- 28. With respect to the December 2016 Bridge notes payable, please reconcile the disclosure on page F-14 about the conversion terms with disclosure about the conversion terms appearing on pages 39, 65 and 74 of your filing. Please ensure that the notes to financial

statements fully describe the conversion terms and potential penalties in the event of non-performance. Refer to ASC 470-10-50-5.

- 29. As a related matter, please ensure that the notes to financial statements fully explain all material rights and privileges of the Bridge notes. For instance, based on the underlying agreements, the notes appear to include registration rights, restrict your ability to restructure other debt and provide for significant penalties in the event of default or other non-performance. Refer to ASC 470-10-50-5.
- 30. With respect to the warrants issued with the Bridge notes, the description of the floating exercise price does not appear to be as described in the underlying agreement filed in Exhibit 10.7. Please revise or advise. Further, based on the underlying agreement, it appears that there are circumstances where you could be required to issue additional warrants. Please ensure that the notes to financial statements describe all material terms of the warrants. Refer to ASC 505-10-50-3.
- 31. Based on the underlying agreements, the bridge notes and related warrants appear to include a down-round feature for subsequent sales of equity. Please expand the notes to financial statements to describe this feature and to describe the potential impact of the registration and public listing of your shares on the accounting for the conversion feature and warrants. Refer to ASC 815-40. Similar considerations appear applicable to your other convertible debt instruments.

### Note 3. Stock-based Compensation, page F-16

32. Tell us why you believe it is appropriate to estimate expected volatility based on volatility of one comparable company. Similarly, for warrants, tell us how you determined "historical and market-based implied volatility" for your privately held shares.

### Alternate pages for Selling Stockholder Prospectus

33. We note that that the notes are convertible at a rate that depends upon the price in the underwritten portion of this offering. Please confirm, however, that you will complete the volume of shares offered prior to requesting effectiveness. This also applies to the form of primary offering prospectus.

### Recent Sales of Unregistered Securities, page 72

34. Please provide the Regulation S-K Item 701 disclosure for the November and December convertible promissory notes disclosed on page 58.

You may contact Andri Carpenter at (202) 551-3645 or Gary Todd, Senior Accountant, at (202) 551-3605 if you have questions regarding comments on the financial statements and related matters. Please contact me at (202) 551-3528 with any other questions.

Sincerely,

/s/ Amanda Ravitz

Amanda Ravitz Assistant Director Office of Electronics and Machinery

cc: Peter DiChiara, Esq. Carmel, Milazzo & DiChiara LLP