



DIVISION OF
CORPORATION FINANCE

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

August 14, 2014

Via E-mail

Lawrence Mehren
President and Chief Executive Officer
Accelerate Diagnostics, Inc.
3950 South Country Club Road, Suite 470
Tucson, AZ 85714

**Re: Accelerate Diagnostics, Inc.
Form 10-K for Fiscal Year Ended December 31, 2013
Filed March 7, 2014
File No. 001-31822**

Dear Mr. Mehren:

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

Please respond to this letter within ten business days by amending your filing, by providing the requested information, or by advising us when you will provide the requested response. 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 any amendment to your filing and the information you provide in response to the comments we may have additional comments.

Item. 1 Business, page 5

Overview, page 5

1. We refer to your January 28, 2013 responses to prior comments 6 and 7 from our January 7, 2013 comment letter. Please tell us and revise your future filings to disclose the “new strategic direction” that your Board of Directors and management team established in 2012. Please also tell us and revise your future filings to disclose why you determined to pursue a new strategic direction, what steps management has taken to implement the new strategy and its impact on your business operations.
2. Your disclosure indicates that you are focused on developing and commercializing instrumentation for the identification and antibiotic susceptibility testing (AST) of “infectious pathogens.” Please tell us and revise your future filings to clarify which types of bacteria you intend to be testing with the instrumentation you are developing. Also, as it appears that some of your competitors in the molecular diagnostics market are seeking

separate FDA approval of their diagnostic tests for each species of bacteria, please tell us and revise your future filings to disclose how you intend to proceed with respect to regulatory approvals for your tests for different types of bacteria and for your AST diagnostics.

3. We note from the study available on your website entitled “Rapid simultaneous identification and quantitation of *Staphylococcus aureus* and *Pseudomonas aeruginosa* directly from bronchoalveolar lavage specimens using automated microscopy” that part of your image analysis relied upon progenitor cell growth into a clone of daughter cells. We also note that your system uses a “culture-free process.” Please tell us and in future filings disclose how you achieve cell growth without a culture. We note in this regard that your study indicates that certain of the bacteria being studied were subcultured on sheep’s blood agar.
4. We note your disclosure that your BACcel system utilizes a “proprietary” culture-free process with both genomic and phenotypic detection technologies. We also note your disclosure that your system includes a separate fluidic robot and high-speed scanning microscopes. Please tell us and in future filings disclose what portions of your system, including the robot and microscopes are proprietary to you and how your system uses genomic detection technologies.
5. Please tell us and revise future filings to clarify how you are generating revenue. If true, please disclose that to date you have not generated any revenue from your BACcel system.

Products.... page 6

6. We note your disclosure on page 6 that you anticipate initiating clinical trials for BACcel in the first half of 2015, CE mark registration in early 2015 and United States FDA approval in early 2016. Please tell us and revise your future filings to disclose the basis for your belief that you will achieve those milestones as of the currently disclosed dates. Please include in your response and disclose in future filings what steps you have taken to date to achieve those milestones and what steps remain to be taken in order to achieve those milestones including whether you will seek FDA registration and approval of your proposed clinical trials.
7. Please tell us and revise future filings to disclose what types of specimens you intend your system to be able to analyze. We note your disclosure under “Research and Development” that your DMRDP funding is for diagnosis of wound infections and other serious infections secondary to trauma and your disclosure that you have begun research on an instrument that will provide additional speed and workflow benefits for certain sample types, such as blood. Please ensure that your response and the disclosure in your future filings clearly indicate the scope of the products you are researching and developing and which products you intend to seek regulatory approval for prior to commercialization.

Research and Development, page 6

8. Your disclosure on page 7 indicates that three studies were conducted using the BACcel system. Please tell us who conducted these studies and whether these “joint” studies were independent. Please also tell us whether the referenced studies involved the pre-clinical instruments or the “proof of concept testing” that you reference on page 6. Please also tell us the findings and conclusions of the studies and whether the findings and conclusions were consistent with the internal lab data testing that you reference on page 6.
9. We note your disclosure that in 2008 you placed your systems in the research institutions identified in this section. Please tell us and disclose in future filings when the pilot clinical studies began and when they are expected to end. Please also clarify in your response and in future filings what benefits you expect to receive from the collaborations described in this section and if there are agreements in place specifying the rights and obligations of each party to the collaboration. Please file any of these agreements as an exhibit to your filing as required by Regulation S-K Item 601(b)(10).
10. Your disclosure in this section refers to pilot clinical studies. Please tell us and disclose in future filings how these pilot clinical studies advance your FDA approval process.
11. If the three studies mentioned in this section are not posted on your website, please provide us with a copy of those studies.
12. We note from the study available on your website entitled “Rapid simultaneous identification and quantitation of *Staphylococcus aureus* and *Pseudomonas aeruginosa* directly from bronchoalveolar lavage specimens using automated microscopy” that it appears that your system demonstrated identification using “growth rates, cell morphology, and clone growth morphology to distinguish bright cocci growing in clusters (staphylococci) and thin, dim, slowly growing rod bacilli...” and from that basis your system was able to distinguish between *Staphylococcus aureus* (a bacteria whose cellular morphology is staphylococci) and *Pseudomonas aeruginosa* (a bacteria whose cellular morphology is cocobacillus). Please tell us and revise future filings to disclose how your system would distinguish between different types of bacteria that have staphylococci, bacillus or cocobacillus colony morphologies. For example, if your microscope detected bacteria with a staphylococci colony morphology, please tell us and disclose in future filings how your system would distinguish *Staphylococcus aureus* from the various other species within the *Staphylococcus* genus.
13. We also note from the study referenced in the prior comment that it appears that it takes several steps to prepare the bacterial samples before they are introduced into your microarrays. Please tell us and revise future filings to disclose the steps necessary to be taken prior to the automated microscopy, the amount of time necessary to perform those steps and whether you intend to automate those steps.

14. We note from the study on your website entitled “Rapid Ertapenem Susceptibility Testing and *Klebsiella pneumoniae* Carbapenemase (KPC) Phenotype Detection in *Klebsiella pneumoniae* Using Automated Microscopy of Immobilized Live Bacterial Cells” that it appears that your system was able to identify the ertapenem resistant *K. pneumoniae* when it was known that the pathogen was *K. pneumoniae*. Similarly, we note from the study on your website entitled “Rapid antibiotic susceptibility phenotypic characterization of *Staphylococcus aureus* using automated microscopy of small number of cells” that your system was able to detect which strains of *S. aureus* were susceptible to various antibiotics when it was known that the pathogen was *S. aureus*. From your “Overview” section, it appears that the clinical dilemma is that the physician must start therapy without knowing the “organism or its drug susceptibility.” Please tell us and in future filings disclose how your system would add useful information in a clinical setting where the identity of the pathogen is not known.

Sales, Licensing and Alliance, page 7

15. Please tell us and revise future filings to disclose how you intend to market the BACcel system. In this regard, please identify your target market and discuss how you will sell the product to your customers. Will you build a salesforce, utilize distributors, and/or sell in a different manner? Also, please indicate whether your customers will rely on governmental and/or insurance reimbursement to pay for your system and the tests that it performs.

Intellectual Property, page 9

16. Please tell us and revise future filings to disclose the importance, duration and effect of your patents. Refer to Regulation S-K Item 101(c)(1)(iv).

Capital Resources and Liquidity, page 20

17. We refer to your January 28, 2013 response to prior comment 1 representing that your future filings will provide investors with sufficient insight into the monies available to achieve development milestones. Your Form 10-K disclosure, however, does not appear to identify development milestones or discuss the amount of funding necessary to achieve those development milestones and commercialize the BACcel system. As such, it is not clear whether you have sufficient funds available to commercialize this new product. Accordingly, please provide us sample disclosure that identifies material milestones, discusses the costs associated with those milestones and addresses your ability to fund these costs and commercialize the product. Please confirm that you will provide similar disclosure, as applicable, in future filings.

We urge all persons who are responsible for the accuracy and adequacy of the disclosure in the filing to be certain that the filing includes the information the Securities Exchange Act of 1934 and all applicable Exchange Act rules require. Since the company and its management are

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in possession of all facts relating to a company's disclosure, they are responsible for the accuracy and adequacy of the disclosures they have made.

In responding to our comments, please provide a written statement from the company acknowledging that:

- the company is responsible for the adequacy and accuracy of the disclosure in the filing;
- staff comments or changes to disclosure in response to staff comments do not foreclose the Commission from taking any action with respect to the filing; and
- the company may not assert staff comments as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

Please contact Joseph McCann at (202) 551-6262 or Tim Buchmiller at (202) 551-3635 with any questions.

Sincerely,

/s/ Tim Buchmiller for

Amanda Ravitz
Assistant Director

cc (via e-mail): Daniel M. Mahoney
Snell & Wilmer LLP