



DIVISION OF  
CORPORATION FINANCE

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

January 27, 2012

Via E-mail

Dr. Antonius Schuh, Ph.D.  
Chief Executive Officer  
TrovaGene, Inc.  
11055 Flintkote Avenue, Suite B  
San Diego, CA 92121

**Re: TrovaGene, Inc.  
Amendment No. 1 to Registration Statement on Form 10-12G/A  
Filed December 30, 2011  
File No. 000-54556**

Dear Dr. Schuh:

We have reviewed your filing 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 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 these comments, we may have additional comments.

General

1. As you are aware, your Form 10 goes effective by lapse of time within 60 days of the date filed pursuant to Exchange Act Section 12(g)(1). Please note that the effectiveness of your Form 10 will commence your periodic reporting obligations under the Exchange Act even if all of our comments have not yet been resolved.
2. Please note that where we provide examples to illustrate what we mean by our comments, they are examples and not exhaustive lists. If our comments are applicable to portions of the filing that we have not cited as examples, please make the appropriate changes in accordance with our comments.

Item 1. Business, page 3

3. To the extent material, please expand the Business section to discuss the sources and availability of the raw materials used in your research and development, and the names of principal suppliers. Please refer to Item 101(h)(4)(v) of Regulation S-K.

Background, page 3

4. It is unclear from your filing whether and when you intend to seek FDA approval for your product. Pages 4, 8, 10, and 15 suggest you intend to seek FDA approval, yet on page 16 you state your expectation that your product candidates will be “an LDT and not a diagnostic kit,” and therefore not subject to FDA regulation. Please revise your filing to clearly explain your intention. If you intend to seek FDA approval for your product, please clearly so state on page 3 when you discuss your planned pursuit of a CE Mark, and revise the risk factor on pages 15-16 entitled “If the FDA were to begin regulating genomic tests . . .” accordingly. Please also expand your filing to disclose when you intend to pursue regulatory approval.
5. On page 3, you state that you in-licensed a new DNA-based biomarker specific for a subtype of AML. Since 2006, you have executed out-license agreements incorporating this biomarker with Ipsogen S.A. and Asuragen, Inc., which has resulted in royalty and license fee revenues. In addition, you have also signed license agreements with various labs including LabCorp, Invivoscribe, Skyline Diagnostics, MLL Munich Leukemia and Warnex, each of which entitles you to various payments under certain circumstances. Please revise your disclosure in the Business section to describe the material terms of each agreement. In this respect, the descriptions on pages F-37 and F-38 must also be expanded as necessary. Your disclosure in the Business section should include the following information:
  - The name of each party to each material license agreement;
  - The material obligations of each party, including any financial obligations;
  - A description of the royalty rates payable under the agreement, expressed within a ten percent range (for example, “single digits,” “teens,” “twenties,” etc);
  - The potential aggregate milestones payable, if any;
  - The amounts paid to date;
  - The term of the agreement; and
  - The termination provisions of the agreement.

In addition, please file all identified license agreements as exhibits to your Form 10, or provide us with a legal analysis as to why these agreements need not be filed pursuant to Item 601(b)(10)(2)(ii) of Regulation S-K.

6. Please define the abbreviation “CLIA” in the first instance you use this term.

Our Technologies, page 4

7. On page 4, you describe clinical trials that you conducted in India. Please clearly indicate in your filing, wherever you discuss these clinical trials, that these clinical trials have not been sanctioned by the FDA nor conducted under the guidance of the FDA, and that the results of these clinical trials are irrelevant to your ability to receive regulatory approval.
8. Please expand your discussion on page 4 to provide more detail regarding the clinical trials conducted in India. Your description should include the following information:
  - When the clinical study was held;
  - How long the clinical study was active;
  - How you targeted patients to enroll;
  - Whether you conducted this study with any other parties; and
  - The steps taken to ensure the accuracy of the results.

The Market, page 5

9. Please provide sources for all quantified information on pages 5-8 of this section.
10. Please define the abbreviations “RA” on page 6, “EGFR” on page 7, and “OEM” on page 8.

Our Business Strategy, page 8

11. Please expand your disclosure to describe the significance of a CLIA lab, the term “home brew,” and how these relate to the FDA approval process.

Research and Development, page 9

12. On page 9, you state that you have a “small group of dedicated scientists.” Please quantify the number of scientists that are located in your San Diego office.
13. You indicate that it is your “goal” to have at least two self-funded development projects ongoing at all times. Please estimate when you anticipate meeting this goal.

Manufacturing and Distribution, page 10

14. You indicate that you plan to introduce assays into the marketplace through ASR or LDTs in CLIA licensed laboratories. Please estimate when you anticipate meeting this goal.

Government Regulation, page 10

15. You state on page 3 of your filing that you will pursue a CE mark for marketing approval. However, the process for receiving a CE mark is not described in this subsection. Please revise your filing accordingly.

Item 1A. Risk Factors

“Our independent registered public accounting firm has expressed doubt . . .,” page 11

16. The title of this risk factor indicates that there is a risk to your company that your questionable ability to continue as a going concern may hinder your ability to obtain future financing. However, this risk is not discussed in the risk factor text. Please revise accordingly.

“We will need to raise substantial additional capital to commercialize . . .,” page 11

17. Please quantify your working capital as of the latest practicable date.
18. You disclose in this risk factor that your existing capital resources will not be sufficient to fund your operations for the next 12 months. Please disclose how long your existing resources will fund your operations. Please also approximate how much additional capital you will need to sustain operations for 12 months.
19. To the extent practicable, please quantify the additional capital you will need to advance your current product candidates to market.
20. On page 12 in this risk factor, you indicate that “if” your capital resources are insufficient to meet future requirements you will have to raise additional funds to continue the development and commercialization of your technology. However, on page 11 you indicate that you do not have existing capital resources to fund your operations for the next 12 months. Please revise this risk factor on page 12 to clearly indicate that your capital resources are insufficient to meet future requirements.

“Reimbursement may not be available for products based upon . . .,” page 13

21. This risk factor appears to discuss a risk that is substantially similar to the risk discussed on page 12 entitled “Our ability to successfully commercialize our technology will depend largely upon the extent to which third-party payors reimburse our tests.” Please revise your filing to combine these risk factors.

“If our potential medical diagnostic tests are unable to compete effectively . . .,” page 13

22. This risk factor appears to discuss a risk that is substantially similar to the risk immediately prior to it on page 13 entitled “Many of our competitors have financial, marketing and human resource assets greater than ours . . . .” Please revise your filing to combine these risk factors.

“Our failure to convince medical practitioners to order tests using . . .,” page 14

23. This risk factor appears to discuss a risk that is substantially similar to the risk discussed on page 13 entitled “The commercial success of our product candidates will depend upon the degree of market acceptance of these products among physicians, patients, health care payors and the medical community.” Please revise your filing to combine these risk factors.

“Our failure to obtain human urine samples from medical institutions . . .,” page 14

24. The last three sentences of this risk factor appear to discuss a risk that is not described in the heading of this risk factor, and appear to be more appropriate to the discussion of the risk described in the risk factor on page 13 entitled “The commercial success of our product candidates will depend upon the degree of market acceptance . . . .” Please revise your filing to incorporate the discussion of your need for the support of thought leaders into the earlier risk factor.

“We depend upon our officers, and if we are not able to retain them . . .,” page 14

25. Please identify your key employees.
26. If you have had difficulty attracting personnel in the past, please so disclose.

“If we do not receive regulatory approvals, we will not be able to develop . . .,” page 15

27. You indicate on page 3 that one of your corporate priorities is to pursue and receive a CE Mark for your HPV urine-based test. However, you do not mention the risk of not receiving a CE Mark in this risk factor. Please revise accordingly.

“If the FDA were to begin regulating genomic tests, we could be forced . . .,” page 15

28. Please expand this risk factor to briefly describe the FDA regulations Quality System Regulation and Medical Device Reporting.

“We may incur substantial costs as a result of litigation or other proceedings . . .,” page 17

29. If third parties have previously challenged the validity of your patents, please so disclose to describe the circumstances.

“We have not paid dividends on our common stock in the past . . .,” page 19

30. Please clearly state in this risk factor that readers should not rely on an investment in your company if they require dividend income.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations

Critical Accounting Policies

Royalty and License Revenues, page 21

31. Please include a description of your collaborative agreements to identify the products or product candidates that are the subject of your research. Disclose each party’s rights and obligations under the agreement and termination provisions. To the extent that the agreement grants licenses to any of the parties, the terms of the license(s) should be described.

Allowance for Doubtful Accounts, page 21

32. Please disclose the nature of your accounts receivable. Also disclose any significant debtor concentration. Clarify why accounts receivable increased significantly during the periods presented.

Research and Development, page 22

33. Please provide quantitative and qualitative disclosure about the amount of costs, both internal and external, incurred during each period presented and incurred to date on each of your major research and development projects. To the extent that you cannot attribute costs to a project, please explain why management does not maintain and evaluate those costs by project.

Convertible Debentures, page 23

34. Please tell us what authoritative literature you used to account for the Forbearance Agreement entered into during 2009 and for the subsequent modifications and the eventual extinguishment of your convertible debentures.

Results of Operations, page 23

35. Please provide a more robust discussion explaining the change in revenues during the three months ended September 30, 2011 and 2010; and the nine months ended September 30, 2011 and 2010.

Item 3. Properties, page 25

36. Please file your lease as an exhibit to your Form 10 pursuant to Item 601(b)(10)(2)(iv) of Regulation S-K.

Item 5. Directors and Executive Officers, page 26

37. Please expand the biographical information of Ms. Cerrone to describe her business experience from January 2005 to July 2008. Please refer to Item 401(e)(1) of Regulation S-K.

Director Independence, page 28

38. You state that a majority of the board consists of members that are currently “independent,” as that term is defined under NASDAQ listing standards. Please identify all independent directors. Please refer to Item 407(a) of Regulation S-K.

Item 6. Executive Compensation, page 29

Summary Compensation Table, page 29

39. Please update this table, and the compensation tables on page 30, with compensation information for the fiscal year ended December 31, 2011.

Item 9. Market Price of and Dividends on the Registrant’s Common Equity and Related Stockholder Matters, page 33

40. Please update the Equity Compensation Plan Information table on page 34 to provide information for the fiscal year ended December 31, 2011.
41. We note your disclosure regarding equity compensation plans not approved by stockholders. Please briefly describe the material features of these plans. Please refer to Item 201(d)(3) of Regulation S-K.

Item 10. Recent Sales of Unregistered Securities, page 34

42. Regarding each instance of private placement financings, please name the persons or identify the class of persons to whom the securities were sold. Please refer to Item 701(b) of Regulation S-K.

Consolidated Financial Statements  
Consolidated Statements of Operations, page F-4

43. Tell us why you do not present revenues from royalties separately from revenues attributable to license fees on the face of your consolidated statements of operations.

Notes to Consolidated Financial Statements  
3. Summary of Significant Accounting Policies  
Royalty and License Revenues, page F-15

44. It is unclear from your current policy note disclosure how your policy is applied to each of your revenue streams. For example, typically consideration allocated to license fees is recognized when earned if the license has stand-alone value. Revenue on substantive milestone payments is recognized in the period in which the milestone is achieved. Royalty revenue is generally recorded in the same period as the sales that generate the royalty payment. Please revise your policy note here and in the MD&A to discuss your revenue recognition policy separately for each of your revenue streams. Please refer to ASC 605-25 as necessary in your response.

Consolidated Financial Statements at September 30, 2011, unaudited

45. Please revise your interim financial statement disclosures based on the preceding comments, as applicable.

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 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



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- 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.

You may contact Ibolya Ignat at (202) 551-3656 or Lisa Vanjoske at (202) 551-3614 if you have questions regarding comments on the financial statements and related matters. Please contact Rose Zukin at (202) 551-3239, Dan Greenspan at (202) 551-3623 or me at (202) 551-3710 with any other questions.

Sincerely,

/s/ Daniel S. Greenspan for

Jeffrey P. Riedler  
Assistant Director

cc: Jeffrey J. Fessler  
Sichenzia Ross Friedman Ference LLP  
61 Broadway, 32nd Floor  
New York, NY 10006