

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

Mail Stop 3030

April 15, 2010

Jon Faiz Kayyem, Ph.D. President and Chief Executive Officer GenMark Diagnostics, Inc. 757 S. Raymond Avenue Pasadena, California 91105

**Re:** GenMark Diagnostics, Inc.

**Registration Statement on Form S-1** 

Filed on March 19, 2010 File No. 333-165562

Dear Dr. Kayyem:

We have reviewed your filing and have the following comments. Where indicated, we think you should revise your document in response to these comments. If you disagree, we will consider your explanation as to why our comment is inapplicable or a revision is unnecessary. Please be as detailed as necessary in your explanation. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure. After reviewing this information, we may raise additional comments.

Please understand that the purpose of our review process is to assist you in your compliance with the applicable disclosure requirements and to enhance the overall disclosure in your filing. We look forward to working with you in these respects. We welcome any questions you may have about our comments or any other aspect of our review. Feel free to call us at the telephone numbers listed at the end of this letter.

#### General

1. Please confirm that any preliminary prospectus you circulate will include all non-Rule 430A information. This includes the price range and related information based on a bona fide estimate of the public offering price within that range, and other information that was left blank throughout the document. Please note that we may have additional comments after you file this information and missing exhibits.

#### Prospectus Cover

2. Please remove the "Sole Book-Running Manager" description from the cover page. You may continue to include the description on the back cover of the prospectus.

#### Table of Contents, page ii

3. We note your disclosure in the third paragraph under this table of contents. Since the registrant is responsible for the accuracy of disclosure included in its registration statement, remove language which implies that it is not.

#### Prospectus Summary, page 1

- 4. We refer to the second italicized paragraph in this section. Please revise the forepart of the prospectus to avoid the use of capitalized terms and words with definitions that are unique to this prospectus. Also, rather than cross referencing to the description of the reorganization, include a paragraph at the beginning of the prospectus to describe it for investors.
- 5. In the summary and throughout the forepart of your prospectus, reduce the use of technical or industry terms that are likely to be unfamiliar to an investor first learning of your business and industry from this prospectus, and define those terms you believe are essential at the time the term is first used. For example, we note your disclosure in the first paragraph that you are a molecular diagnostics company, but you do not define that term until the bottom of page 2; we also note as an example your disclosure on page 4.
- 6. Please provide us independent, objective support for your statements regarding the accuracy and efficacy of your technology and convenience of your system to target customers. Please also provide us the basis for your belief that your technology will "improve patient care and be economically attractive to third-party payors," as discussed on page 1, and that your system may increase your target user base to over 5,000 laboratories and hospitals, as disclosed on page 5.
- 7. In an appropriate location under the caption "Our Company," explain the source of your revenues to date.

## Market Opportunity and Limitations of Current Technologies, page 2

- 8. Please provide us with support for the market opportunity data and industry statistics that you have included throughout your prospectus. Clearly mark the relevant sections that support the data and statistics, and note the applicable page number in the registration statement where the disclosure is located. Please also tell us:
  - how you confirmed that the information reflects the most recent available information:
  - whether all of the information is publicly available;

- whether you paid for the compilation of any of the data;
- whether any market information was prepared for your use in the registration statement or by an affiliated party; and
- whether the authors of the industry information consented to your use of such data in the registration statement.

#### Reorganization, page 5

9. Please revise to clarify, if true, that your business and operations will be conducted through your operating subsidiary upon completion of the offering.

# We are reliant on the commercial success of our XT-8 System..., page 8

10. Please revise to clarify that you have not had significant sales of your XT-8 instrument and that you currently rent the instruments at no charge, as discussed at the bottom of page 9.

# Providing XT-8 instruments to our customers..., page 9

- 11. Please expand to state whether you currently sell enough test cartridges to offset your expenses associated with the reagent rental agreements.
- 12. Please reconcile your disclosure that you offer XT-8 instruments for sale and that you have not had significant sales of the instrument with your disclosure on page 43 that your product sales "consisted solely of test cartridge sales."

#### Risks Related to our Common Stock and This Offering, page 24

13. Please tell us whether and when you plan to register a class of your securities under the Exchange Act. If you do not intend to so register a class of securities, please disclose the risks related to discontinuance of periodic disclosure due to the automatic reporting suspension under section 15(d) of the Exchange Act; also explain the effect of the inapplicability of the proxy rules and section 16 of the Exchange Act.

## Provisions of our certificate of incorporation, our bylaws..., page 27

14. Please expand your disclosure to describe the potential dilutive and anti-takeover effects that exist specifically in light of the large amount of your authorized but unissued common stock.

## Reorganization of Osmetech plc, page 30

- 15. Expand to explain why the registrant was originally registered in England and Wales since it appears that business operations are located in the United States. Also disclose where the registrant's assets are located and the value of assets located outside the United States.
- 16. Please provide us with a legal analysis as to how you have determined that the transaction in which shares of GenMark Diagnostics common shares will be issued to shareholders of Osmetech plc do not need to be registered under the Securities Act.
- 17. Please file as exhibits the scheme of arrangement and the agreement in which Osmetech plc and GenMark Diagnostics, Inc. have agreed to be bound by the scheme of arrangement.

#### Capitalization, page 33

- 18. Please revise to remove the caption relating to cash and cash equivalents from your presentation of capitalization.
- 19. Please revise to include detailed footnote disclosure quantifying and identifying each pro forma adjustment recorded along with an explanation of how each pro forma adjustment was calculated and determined for both the GenMark Pro Forma and the Pro Forma as Adjusted columns. As part of your revised disclosure, please include all relevant assumption used in such calculations, including the conversion terms of the Osmetech common shares. In this regard, we note that the Pro Forma as Adjusted disclosures are not yet complete. Please note we may have further comments once this information is included.

# Management's Discussion and Analysis of Results of Operations..., page 39

#### Revenue, page 40

20. Please reconcile your disclosure in the first paragraph under this section with your disclosure at the top of page 18, which indicates that you have not generated significant revenue from your Warfarin Sensitivity Test. Also reconcile the last sentence of the first paragraph with your disclosure on page 43, which indicates that you did not have any product sales of your XT-8 instrument.

#### Cost of Sales, page 40

21. Please file as an exhibit your contractual agreement with your manufacturer.

Critical Accounting Policies and Significant Judgments and Estimates, page 42

#### Share-Based Compensation, page 42

- 22. We note from your disclosure on page F-16 that during the year ended December 31, 2009, Osmetech granted options to employees to purchase a total of 262,398,130 shares of common stock and warrants to purchase 50,782,043 shares of common stock. In light of the disclosure on page 25 that there is only a limited volume of trading of Osmetech's ordinary shares, please tell us whether, at the date of grant, you obtained a contemporaneous or retrospective valuation of your underlying common stock and whether it was performed by an unrelated valuation specialist. In addition, please revise the filing to disclose the following information related to issuances of equity instruments:
  - Discuss the significant factors considered, assumptions, and methodologies used in determining the fair value of the underlying common stock at each date on which equity instruments were granted. These additional disclosures should include quantitative information regarding your assumptions and the weighting of the valuation methods. You should also address why you believe that the methods and assumptions used were appropriate under the circumstances and how you concluded that the fair value of your common shares was appropriately represented by the limited volume of trading of your common shares. In addition, discuss the consideration given to any alternative factors, methodologies and assumptions; and
  - Discuss each significant factor contributing to any differences between the estimated IPO price and the fair value determined on each underlying common stock, either contemporaneously or retrospectively, as of the date of each grant and equity-related issuance. Describe significant intervening events within the company and changes in assumptions as well as weighting and selection of valuation methodologies employed that explain the changes in the fair value of your ordinary shares up to the filing of the registration statement.

#### Product Sales, page 43

23. Please expand your disclosure to clarify whether your product sales of test cartridges result solely from your reagent rental agreements, or whether other avenues are available for customers to purchase the cartridges.

#### Sales and Marketing, page 44

24. Please revise to clarify how the one-time market research study conducted in 2009 was associated with your "new strategy."

#### Liquidity and Capital Resources, page 46

- 25. Please advise as to how your \$14.6 million in working capital can "include" \$16.5 million in cash and cash equivalents.
- 26. Please disclose the minimum cash ratios to which you are subject under the loan and security agreement with Square 1 Bank, as well as your proximity to such ratios.

#### Our Products, page 55

27. Please revise to clarify the extent to which your products have contributed to your revenues to date, and quantify the percentage of revenues attributable to each.

#### Manufacturing, page 63

28. Please define the term "ISO-certified."

## Sales and Marketing, page 63

- 29. Please revise to quantify the amount of your systems that are acquired by customers through the reagent rental agreement compared to outright purchases.
- 30. Please provide all disclosure required by Regulation S-K Item 101(c)(vii), including the names of your three largest customers.

## License Agreements, page 65

31. Please file any material license agreements that are described here and have not been filed. Also, expand the disclosure to describe the material terms of these agreements.

#### Executive Compensation, page 77

32. We note that you have not included any disclosure in response to Item 402(s) of Regulation S-K. Please advise us of the basis for your conclusion that disclosure is not necessary and describe the process you undertook to reach that conclusion.

## Market Compensation Data, page 78

33. Please clarify the extent to which compensation decisions are derived from utilizing comparative information when implementing your compensation policies or making specific compensation awards. Identify the component companies of the benchmark study and discuss how each element of compensation relates to the data you analyzed. For example, it appears from your compensation discussion and analysis that you use comparative information only in setting base salary. If true, please revise your

disclosure to clarify that is the case. Please also revise your disclosure at the top of page 79 to clarify whether a specific target for base salary was sought or whether adjustments were made after reviewing the comparative information.

## Base Salary, page 79

34. We note that the compensation committee considered "success in achieving our corporate goals during 2009 [and] individual performance and contribution of the executive during fiscal year 2009..." We also note that most of the executive officers listed were hired near the end of 2009. Please reconcile.

#### Stock-Based Incentive Awards, page 80

35. Expand the second paragraph to explain in more detail how the compensation committee determined the number of stock option awards to grant at initial hire.

#### Principal Stockholders, page 91

36. Please identify the natural persons who have or share voting and/or dispositive power with respect to the entities listed in the table on page 91.

#### <u>Indemnification Agreements, page 93</u>

37. Please describe in greater detail the indemnification provisions that you intend to include in the agreements.

#### Lock-Up Agreements, page 100

38. Please identify the parties and disclose the number of shares subject to the lock-up agreements. Please also quantify the number of restricted shares held by non-affiliates that will be eligible for sale under Rule 144(k) after the expiration of the lock-up period and the number of restricted shares held by affiliates that will be subject to the volume and other restrictions of Rule 144 after that date.

#### <u>Index to Financial Statements, page F-1</u>

39. Consideration should be given on an ongoing basis to the updating requirements of Rule 3-12 of Regulation S-X. An updated accountant's consent should also be included with any amendment to the filing.

## Osmetech plc Consolidated Statements of Operations, page F-7

40. We see that you have presented a loss from discontinued operations and a gain on sale of discontinued operations during the year ended December 31, 2007. Please

revise the filing to present the basic and diluted per-share amounts for your fiscal 2007 discontinued operations in accordance with FASB ASC 260-10-45-3.

# Osmetech, plc Notes to Consolidated Financial Statements, page F-10

#### Note 1. Organization and basis of presentation, page F-10

41. We see that immediately prior to the completion of this initial public offering Osmetech will undergo a reorganization whereby GenMark Diagnostics will acquire all of the outstanding ordinary shares of Osmetech. We also see in connection with the reorganization all of the issued shares of Osmetech will be cancelled in consideration of (i) the issuance of 1 share of common stock of GenMark to the former shareholders of Osmetech for each 230 ordinary shares of Osmetech and (ii) the issuance of new shares in Osmetech to GenMark. Please tell us how you intend to present and account for the reorganization of GenMark Diagnostics and Osmetech. Cite the applicable authoritative accounting literature you believe supports your conclusions. Clarify why Osmetech will issue shares to GenMark in connection with the reorganization and how such issuance impacts your accounting requirements for the reorganization. Please revise the registration statement as necessary to include the significant information outlined in your response.

# Note 2. Summary of Significant Accounting Policies, page F-11

## Revenue Recognition, page F-12

42. We see on page 63 that as part of the "reagent rental" agreements, customers agree to purchase a minimum volume of test cartridges intended to allow for you to recover the cost of the instruments. Please tell and revise the filing to disclose the material terms of these agreements, including any cancellation or repurchase rights, and how the commitment to purchase test cartridges impacts your recognition of revenue under the arrangement. Please also tell us how you assess the instruments for impairment when the minimum volume of purchases is not met or when you otherwise determine the instruments may be impaired.

## Item 15. Recent Sales of Unregistered Securities, page II-2

## <u>Issuances of Ordinary Shares and Warrants by Osmetech, page II-2</u>

43. Please expand your disclosure to more completely address the requirements of Regulation S-K Item 701, including disclosure of the identity of the persons or class of persons to whom the securities were sold.

## Item 16. Exhibits and Financial Statement Schedules, page II-4

44. We note that you have requested confidential treatment for portions of exhibits to your registration statement. We will review and provide any comments on your request separately. Please resolve all comments regarding your request prior to requesting effectiveness of this registration statement.

\* \* \*

As appropriate, please amend your registration statement in response to these comments. You may wish to provide us with marked copies of the amendment to expedite our review. Please furnish a cover letter with your amendment that keys your responses to our comments and provides any requested information. Detailed cover letters greatly facilitate our review. Please understand that we may have additional comments after reviewing your amendment and responses to our comments.

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 all information required under the Securities Act of 1933 and that they have provided all information investors require for an informed investment decision. 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.

Notwithstanding our comments, in the event the company requests acceleration of the effective date of the pending registration statement, it should furnish a letter, at the time of such request, acknowledging that:

- should the Commission or the staff, acting pursuant to delegated authority, declare the filing effective, it does not foreclose the Commission from taking any action with respect to the filing;
- the action of the Commission or the staff, acting pursuant to delegated authority, in declaring the filing effective, does not relieve the company from its full responsibility for the adequacy and accuracy of the disclosure in the filing; and
- the company may not assert staff comments and the declaration of effectiveness as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

In addition, please be advised that the Division of Enforcement has access to all information you provide to the staff of the Division of Corporation Finance in connection with our review of your filing or in response to our comments on your filing.

We will consider a written request for acceleration of the effective date of the registration statement as confirmation of the fact that those requesting acceleration are aware of their respective responsibilities under the Securities Act of 1933 and the Securities Exchange Act of 1934 as they relate to the proposed public offering of the securities specified in the above registration statement.

We direct your attention to Rules 460 and 461 regarding requesting acceleration of a registration statement. Please allow adequate time after the filing of any amendment for further review before submitting a request for acceleration. Please provide this request at least two business days in advance of the requested effective date.

You may contact Kevin Kuhar at (202) 551-3662 or Jay Webb, Accounting Reviewer, at (202) 551-3603 if you have questions regarding comments on the financial statements and related matters. Please contact Celia Soehner at (202) 551-3463 or me at (202) 551-3800 with any other questions.

Sincerely,

Peggy Fisher Assistant Director

cc (via facsimile): Michael S. Kagnoff, Esq. — DLA Piper LLP