



DIVISION OF  
CORPORATION FINANCE

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

September 3, 2013

Via E-mail

Thomas A. Nicolette  
Chief Executive Officer, President and Director  
Akers Biosciences, Inc.  
201 Grove Road  
Thorofare, New Jersey 08086

**Re: Akers Biosciences, Inc.  
Registration Statement on Form S-1  
Filed August 7, 2013  
File No. 333-190456**

Dear Mr. Nicolette:

We have reviewed your 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 amending your registration statement and providing the requested information. 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 registration statement and the information you provide in response to these comments, we may have additional comments.

Summary  
General

1. Please note that when you file a pre-effective amendment containing pricing-related information, we may have additional comments. As you are likely aware, you must file this amendment prior to circulating the prospectus. Please note that when you file a pre-effective amendment that includes your price range, it must be bona fide. We interpret this to mean that your range may not exceed \$2 if you price up to \$10 and 20% if you price above \$10.
2. Please confirm that the images included in your registration statement are all of the graphic, visual or photographic information you will be including. If you intend to use any additional images, please provide us proofs of such materials. Please note that we may have comments regarding this material.

3. Please revise your prospectus to remove your statement on page 1 that you have not independently verified market and industry data from third-party sources and prepared by management. It is not appropriate to directly or indirectly disclaim liability for information in the registration statement.
4. Please include in this part of your disclosure a brief description of your platform technologies, as well as both your marketed products and your pipeline products.
5. Please revise your disclosure to provide a summary of the material risks concerning your company and your proposed offering, including but not necessarily limited to the following:
  - Your history of operating losses, including your large accumulated deficit, and your inability to date to achieve profitability;
  - Your reliance on a small number of customers for the vast majority of your revenues;
  - Your need for additional capital to support your operations and the possibility that you may not be able to obtain such capital;
  - Your limited marketing resources and sales capabilities and your resulting dependence on distributors; and
  - The disproportionate share ownership by your directors, executive officers and affiliates and the lack of influence your shareholders will have over corporate affairs.

Market Overview, page 3

6. Please identify your products that have received FDA clearance for over-the-counter use and your other products that do not fall within the oversight of regulatory authorities in this section and elsewhere, as necessary, throughout your registration statement.

Risk Factors

Risks Related to the Company and Our Business

“We have a history of operating losses and we cannot guarantee that we can ever achieve sustained profitability,” page 7

7. In this risk factor, you state that your net loss for the six months ended June 30, 2013 was \$200,962, which is also reflected in your financial statements. However, your summary financial data on page 6 indicates that your net loss during this period was over \$3.6 million. Please reconcile this discrepancy.

“Due to our dependence on a limited number of customers and the loss of any such customer would have a material adverse effect....,” page 7

8. Please indicate whether you have entered into any agreement with Cardinal Health or Fisher Healthcare with respect to the distribution of your PIFA Heparin/PF4 Rapid Assays. If so, please describe the material terms of any such agreement and file the agreement as an exhibit to your registration statement or provide an analysis as to why your business is not substantially dependent on any such agreement.

“If we fail to obtain regulatory approval in foreign jurisdictions....,” page 10

9. Please identify the specific foreign jurisdictions in which you plan to market your products.

“We may be unable to market our products outside the United States if our products cannot meet certain requirements of the Federal Food, Drug and Cosmetic Act requirements for exporting medical devices,” page 10

10. The final two paragraphs in this risk factor relate to meeting certain regulatory requirements outside of the Federal Food, Drug and Cosmetic Act. Please include these two paragraphs under a separate risk factor heading discussing risks stemming from a failure to meet the regulatory requirements in foreign markets. You should also list here and wherever else appropriate the six products for which you have received CE marks.

“Clinical trials that may be required to support regulatory submissions in the United States and in international markets are expensive . . .,” page 11

11. Please include in this risk factor the amount that you estimate you will spend on R&D over the next fiscal year.

“The results of our clinical trials may not support either further clinical development of the commercialization of our product candidates,” page 12

12. Please explain in this risk factor that each medical device marketed in the United States must receive a 510(k) clearance from the Food and Drug Administration.

“Modification to our devices may require additional FDA approval which could force us to cease marketing and/or recall the modified device until we obtain new approvals,” page 12

13. Please briefly explain the term “PMA approval” in this risk factor.

“We may not have sufficient resources to effectively introduce and market our products, which could materially harm our operating results,” page 13

14. The last two sentences of this risk factor appear to have been included in error. Please revise your risk factor accordingly.

15. Please consider combining this risk factor with the final risk factor on this page as both risk factors appear to relate to the same issue. Also, in relation to your limited sales capabilities, please revise your risk factor to note that you reduced your account executive sales force by 40% during the six month period ended June 30, 2013, discuss the reasons for this decision, and highlight any resulting impact on your sales efforts.

“We may incur substantial costs as a result of litigation or other proceedings relating to patent or other intellectual property rights . . .,” page 19

16. Please include in this risk factor examples of such litigation that has been filed against you or any of your founders, executive officers, and/or directors, if any.

“We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employees,” page 20

17. Please include in this risk factor examples of such claims made against your employees, if any.

“If we deliver products with defects, we may be subject to product recalls or negative publicity...,”page 21

18. Please disclose the amount of product liability insurance you have obtained.

“There can be no assurance that our shares will be listed on the NASDAQ Capital Market . . .,” page 23

19. Please note in this risk factor that you may not yet qualify for listing on NASDAQ and that you will need to take certain measures to do so, including effecting a reverse split of your common shares.

“We will incur significant costs as a result of being a publicly traded company . . .,” page 27

20. Please include in this risk factor, to the extent practicable, an estimate of the annual costs associated with being a public company.

“A sale of a substantial number of shares of the common stock...” page 27

21. Please revise your risk factor heading to note that investors in the offering may experience immediate dilution of their ownership following completion of the offering.

Dilution, page 30

22. You state on page 70 that the holder of the preferred stock has agreed to convert such shares into 50,000,000 shares of common stock immediately prior to the consummation of this offering. Please revise the presentation to separately disclose the effect of the conversion of preferred stock to common stock.

Management’s Discussion and Analysis of Financial Condition and Results of Operations, page 32

23. Please describe the equity financing you have relied upon over the last two years.

General and Administrative Expenses, page 34

24. Please disclose why you wrote-off the long-term note receivable of \$151,569 from ChubeWorkx in June 2012. In addition, you state on page F-14 that accounts receivable of \$1,041,388 was due from ChubeWorkx at June 30, 2013. Please clarify why you believe that amount is collectible.
25. Please explain why you recorded bad debt expense of only \$9,047 in 2012, given bad debt expense of \$1,650,185 in 2011. Revise your disclosure accordingly.

Research and Development Expenses, page 34

26. Please provide a breakdown of research and development expense by major project for each period presented.

Other Income and Expenses, page 35

27. Please explain how you determined the \$99,710 gain on the transaction, involving the sale of (en) 10 in exchange for the expansion of the ChubeWorkx marketing rights and its commitment to purchase 80 million shares of your common stock. Revise your disclosure accordingly.
28. Please explain how you determined the \$91,286 gain on the demutualization of your insurer. Revise your disclosure accordingly.
29. Please explain your accounting treatment for the re-acquisition of technology from Pulse and the forgiveness of its obligations to you, as disclosed on page F-28, and quantify the related impact on your operating results for 2011. Revise your disclosure accordingly.

Critical Accounting Policies, page 38

30. We note that you have elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(1) of the JOBS Act. Please include a statement in your critical accounting policy disclosures which explains that this election allows you to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. Please also state that your financial statements may not be comparable to companies that comply with public company effective dates.

Revenue Recognition, page 39

31. Please disclose in the notes to the financial statements your accounting policy for estimates of items that reduce gross revenue such as product returns, chargebacks, customer rebates and other discounts and allowances. In addition, please provide us proposed disclosure to address the following:
- Nature and amount of each accrual at the balance sheet date;
  - The factors that you consider in estimating each accrual such as historical return of products, levels of inventory in the distribution channel, etc.;
  - To the extent that information you consider in the preceding bullet is quantifiable, disclose both quantitative and qualitative information and to what extent information is from external sources (e.g., end-customer prescription demand, third-party market research data comparing wholesaler inventory levels to end-customer demand). For example, in discussing your estimate of product that may be returned, consider disclosing and discussing, preferably by product and in tabular format, the total amount of product (in sales dollars) that could be potentially be returned as of the balance sheet date;
  - Include a roll forward of the liability for each estimate for each period presented showing the following:
    - Beginning balance,
    - Current provision related to sales made in current period,
    - Current provision related to sales made in prior periods,
    - Actual returns or credits in current period related to sales made in current period,
    - Actual returns or credits in current period related to sales made in prior periods, and
    - Ending balance; and
  - In your discussion of results of operations for the period to period revenue comparisons, discuss the amount of and reason for fluctuations for each type of

reduction of gross revenue (i.e. product returns, chargebacks, customer rebates and other discounts and allowances) including the effect that changes in your estimates of these items had on your revenues and operations.

Business

Product Portfolio, page 43

32. Please indicate which of your marketed or pipeline products, if any, are required or are expected to require clinical trials to support your 510(K) submission. Please provide disclosure that describes these trials, if applicable.
33. Please indicate whether the products marketed under the PIFA platform have received FDA 510(k) approval. If any have not, please describe the exemption you relied upon.

Distribution, page 48

34. Please amend your disclosure to identify the material terms of your License and Supply Agreement with Chubeworkx Guernsey Limited, including the following:
- continuing obligations of both parties under the agreement;
  - payment obligations (including applicable any royalties to be paid on product sales);
  - duration of the agreement; and,
  - any termination provisions.

In addition, we note that you filed an amendment to your License and Supply Agreement with Chubeworkx as Exhibit 10.4 to the registration statement but that you have not filed the original agreement between the parties. Please amend your registration statement to also include your original agreement with Chubeworkx as an exhibit.

Intellectual Property, page 49

35. In this disclosure, please list all of your material patents, the products to which they relate, their expiration dates, and their jurisdictions. Please also consider indicating the type of protection you have under each patent, e.g. composition of matter, use or process.

Principal Stockholders, page 67

36. Please include footnote disclosure indicating the individual(s) who have voting and/or investment power over the common shares held by Chubeworkx Guernsey Limited and Legal & General Group plc.

Shares Eligible for Future Sale  
Lock-Up Arrangements, page 72

37. Please file a copy of the form lock-agreement as an exhibit to your registration statement. If it is to be filed as an exhibit to your underwriting agreement, please confirm this for us.

Financial Statements  
General

38. Please revise to disclose all related party transactions on the face of the financial statements and/or notes, as required by Rule 4-08(k) of Regulation S-X and ASC 850-10-50.

Condensed Consolidated Financial Statements for the Six Months Ended June 30, 2013 and 2012  
Notes to Condensed Consolidated Financial Statements  
Note 4-Note Receivable, page F-9

39. Please clarify here and on page F-26 that this note was repaid in cash and that it was from a related party.

Note 11-Share-Based Payments, page F-10

40. You disclose on page 61 that 7,000,000 warrants were cancelled in 2013. Please revise to clarify how this cancellation is reflected in the table or clarify in the notes to the financial statements that these warrants were cancelled subsequent to the balance sheet date.

Note 18-Other Income, page F-14

41. Please clarify that \$91,286 of the miscellaneous income represents the gain from the demutualization of your insurer as stated on page 35. In addition, clarify the nature of this gain and the accounting treatment thereof.

Note 19-Subsequent Events, page F-14

42. Please disclose any equity issuances made subsequent to the balance sheet date, such as common stock, preferred stock, options, warrants, etc. Provide us an analysis of how you determined the fair value of the common stock and your intended accounting treatment for any transactions. Disclose the reasons for any differences between the fair value used for the equity issuances and your anticipated IPO price.



Consolidated Financial Statements for Years Ended December 31, 2012 and 2011

Notes to Consolidated Financial Statements

Note 3-Significant Accounting Policies

(i) Revenue Recognition, page F-24

43. You state that revenue is allocated to the separate elements based on the relative fair value. Please clarify in the note how your policy complies with ASU 2009-13, which states that arrangement consideration shall be allocated at the inception of the arrangement to all deliverables on the basis of their relative selling price.

Note 12-Equity, page F-31

44. Please explain your planned accounting treatment for the \$500,000 one-time payment to be received upon conversion of the preferred stock.
45. Please clarify why you believe the 30,000,000 common stock and 10,000,000 preferred stock issued to Thomas Knox on September 14, 2012 have been recorded at fair value. In addition, please tell us what consideration was given to recording a beneficial conversion feature for the convertible preferred stock. Your disclosure on page 66 indicates that the conversion rate is equivalent to .0145 per common share. Refer to ASC 470-20-30.

Note 16-Commitments, page F-35

46. Please disclose the information required by ASC 450-20-50. Also, include an explanation of the legal settlement payable, described on page F-29.

Note 18-Subsequent Events, page F-36

47. You disclose that on June 13, 2013, simultaneous with entering into the Amended License and Supply Agreement, the Company and Chubeworkx entered into a purchase agreement, pursuant to which Chubeworkx purchased 80,000,000 shares of the Company's common shares for an aggregate purchase price of \$1,600,000. You also state on page 33 that on June 13, 2013, ABI announced that the Company had extended Chubeworkx' exclusive territory in return for selling its equity ownership of (en) 10 to Chubeworkx for \$100,000. As these transactions appear to be done simultaneously, it appears you should consider all of these transactions together when determining how to record the revenue. Please revise to clarify the accounting treatment. Refer to ASC 605-25-3. Provide the required disclosures under ASC 605-25-50. If you believe any of the deliverables have standalone value, please clarify the basis for your conclusions.
48. The purchase price of the 80,000,000 shares, issued in June 2013, appears to equate to \$0.02 per share. Please tell us how the \$0.02 per share price compares to the fair value of your common stock on the date of this transaction. Provide additional disclosure in the

filing to explain the difference between \$0.02 and your anticipated IPO price. We may have further comments once the IPO price has been set.

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 Act of 1933 and all applicable Securities 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.

Notwithstanding our comments, in the event you request acceleration of the effective date of the pending registration statement please provide a written statement from the company 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.

Please refer to Rules 460 and 461 regarding requests for acceleration. 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. Please allow adequate time for us to review any amendment prior to the requested effective date of the registration statement.

Thomas A. Nicolette  
Akers Biosciences, Inc.  
September 3, 2013  
Page 11

You may contact Frank Wyman at (202) 551-3660 or Mary Mast at (202) 551-3613 if you have questions regarding comments on the financial statements and related matters. Please contact Scot Foley at (202) 551-3383, Bryan Pitko at (202) 551-3203 or me at (202) 551-3715 with any other questions.

Sincerely,

/s/ Bryan J. Pitko for

Jeffrey P. Riedler  
Assistant Director

cc: Joseph Lucosky, Esq.  
Lucosky Brookman LLP  
101 Wood Avenue South, 5<sup>th</sup> Floor  
Woodbridge, NJ 08830