

DIVISION OF CORPORATION FINANCE UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

November 10, 2011

<u>Via E-mail</u> Seth Lederman President, Chief Executive Officer and Chairman Tonix Pharmaceuticals Holding Corp. 509 Madison Avenue, Suite 306 New York, New York 10022

# Re: Tonix Pharmaceuticals Holding Corp. Current Report on Form 8-K Filed October 14, 2011 File No. 333-150149

Dear Mr. Lederman:

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 an amendment to your filing and the information you provide in response to these comments, we may have additional comments.

#### Description of our Business, page 4

- 1. Your business description should address the general development of your business for the past three years. For example, your corporate overview should clearly explain your relationship to each of the persons and entities referenced in that description. Also, expand your disclosure in this section to describe clearly the activities you have undertaken to develop your products since inception, including, for example, the research and development activities described on pages 37 and 38, and why, for example, you do not appear to have undertaken further studies on TNX-102 since the Phase 2a study in 2001.
- 2. Please revise to clarify if and how the development studies, research and other necessary activities you describe are being conducted by your employees, L&L Technologies,

Lederman & Co, Pharmanet Canada or others. Please describe any arrangements to share responsibilities or designate certain tasks as the responsibility of one or a number of the participating groups of persons.

- 3. We note the statement on your subsidiary's website that "[d]ue to the competitive nature of this business, Krele is not disclosing the assets it is developing or is considering adding to its portfolio." With a view to clarifying disclosure, advise us of any such assets.
- 4. Please clarify when you intend to undertake the proposed studies you outline in this section, and disclose in approximate quantitative terms the material costs, if any, associated with each of those studies.
- 5. Please revise to provide an overview, in quantitative and qualitative terms, summarizing the approximate amount of time to reach commercialization for each of your principal product candidates taking into account material factors such as research and regulatory approval. Also, given the state of development of your products, revise your disclosure that appears to suggest you already create marketable products, such as your disclosure that "We create new dose formulations" on page 4.
- 6. Please clarify the purpose of the licenses disclosed at the bottom of the second paragraph in this section.
- 7. Please tell us why your business description does not appear to address the rights relating to isometheptene mucate that you acquired from Lederman & Co. LLC pursuant to Exhibit 10.7.
- 8. Please revise to reconcile the statement on page six that "the therapeutic uses we target are new uses for these active ingredients" with the disclosure that cyclobenzaprine is widely used off-label to treat FM.
- 9. We note the statement on page seven that "TNX-102, our most advanced product candidate, is a bedtime pill." Your disclosure suggests that you currently have a manufactured pill. Please revise to clarify. Also, it is unclear what you mean by "advanced" and in what way TNX-102 is closer to commercialization than TNX-105.

# Emerging Market Opportunity, page 10

- 10. Please revise to further clarify the nature of the studies and findings you identify in the two bullet points on page 10. For example, it is unclear what material elements made up the study conducted by Caliper Life Sciences and when it was undertaken. It is also unclear what your basis is for the "findings" in the first bullet point. Please disclose what activities were undertaken, the nature of any analyses conducted on those results, and the background of the individuals who conducted the activities and analyses.
- 11. Similarly, we note the statement that "[o]ther compounds that bind this receptor have been shown to have effects in treating PTSD." It is unclear why you do not describe

what effects the compound had and what studies or institutions were the source of the observations that "have been shown." Please revise accordingly.

#### Drug Delivery Technology, page 11

- 12. Please describe the material terms of your agreement with Lipocine, Inc. referenced in the first paragraph. Also, describe the reformulation work being undertaken by Lipocine on your behalf.
- 13. Please provide an expanded description of the study referenced in the second paragraph, including the extent of the study, how the results were measured and when it was undertaken.

#### Intellectual Property, page 14

14. With a view to disclosure, please tell us which intellectual property disclosed on page 14 relates to TNX-201 that you disclose on page 37 was received from Lederman & Co. in exchange for \$295,500. Please disclose the duration of material patents. Also, given your disclosure in the fourth paragraph on page 23 regarding licenses, please describe your material patent licenses and file material license agreements as exhibits.

#### Risk Factors, page 20

- 15. Please revise page 29 or where appropriate to further address "potential side effects." We note, for example, the reference to adverse effects of cyclobenzaprine on slide 42 of Exhibit 99.02.
- 16. Consider revising here or where appropriate to address any material risk related to the assumption that there will be a significant market-wide increase in the use of all muscle relaxants for the treatment of FM. We note slide 23 of Exhibit 99.02.

#### Risks related to our Stock, page 32

17. Please reconcile your disclosure that there has been a limited trading market here and in the third risk factor on page 34 for your common stock with your disclosure in the first paragraph on page 50.

#### Management's Discussion and Analysis..., page 36

Results of Operations, page 37

18. Please quantify your research and development expenses that relate to analysis of Phase 2a clinical studies for TNX-102 and receptor binding studies and address whether these costs increased or decreased relative to the prior fiscal period.

19. Please revise the discussion of your period to period changes in research and development and general and administrative expenses to clarify when the significant activities were conducted by persons or entities other than you, such as a contractor or third party clinic.

## Research and Development Expenses, page 38

20. Please clarify the nature of your sleep study as referenced in this section. For example, it is unclear what individuals and facilities were involved.

#### Certain Relationships and Related Transactions, page 39

21. Please expand your disclosure in this section to disclose the material terms of each of your agreements with related parties. We note, for example, the transactions referenced on page F-16 or the Technology Transfer and Assignment Agreement, dated as of June 4, 2010, by and between Krele Pharmaceuticals, Inc. and Lederman & Co., LLC.

#### Financial Statements and Exhibits, page 55

- 22. Please tell us where you have filed as an exhibit the agreement regarding your lease of property entered into on September 28, 2010.
- 23. We note that you indicate that confidential treatment is requested for portions of Exhibits 10.09 and 10.10; however, it appears no request for confidential treatment has been submitted. Please advise.
- 24. We note the reference on page four to "a study conducted by Frost & Sullivan on behalf of Tonix." We also note the reference on page 10 to "studies conducted by a third party that we engaged, Caliper Life Sciences." Please confirm, if true, that the Frost & Sullivan study you reference is the only such study cited in your Form 8-K and that it is filed as Exhibit 99.02. Also, please provide a copy of the Caliper Life Sciences study and advise us of your understanding with respect to the applicability of Rule 436 to these studies in the event you file a registration statement.

#### Financial Statements as of and for the Fiscal Years Ended December 31, 2010 and 2009

#### Consolidated Statements of Operations, page F-3

- 25. Please revise to present basic and diluted per-share amounts on the face of the statements of operations for each period presented. Refer to ASC 260-10-45-2.
- We note the undeclared cumulative dividends on Preferred Stock of \$148,735 (page F-26), \$78,211 (page F-13) and \$32,000 (page F-13) at June 30, 2011, December 31, 2010 and December 31, 2009, respectively. Please tell us if the loss applicable to common stock is materially different in quantitative terms from the reported net loss

for each period presented and, if so, tell us how you considered the requirements of SAB Topic 6.B.

## Notes to Consolidated Financial Statements, page F-6

27. Please revise to include a reconciliation of the numerators and the denominators of the basic and diluted per-share computations. Also revise to disclose the securities that could potentially dilute basic EPS in the future that were not in included in the computation of diluted EPS because to do so would have been antidilutive for the periods presented. Refer to ASC 260-10-50-1.

Note H – Income Taxes, page F-11

28. Please revise to provide the unrecognized tax benefit disclosures required by ASC 740-10-50-15.

Note L – Subsequent Events, page F-16

29. Please disclose the date through which you have evaluated subsequent events for the annual and interim financial statements presented, and whether that date is either the date the financial statements were issued or available to be issued. Refer to ASC 855-10-50-1.

Unaudited Pro Forma Condensed Combined Financial Statements, page F-31

Unaudited Pro Forma Condensed Combined Statements of Operations for the Year Ended December 31, 2010, page F-33

- 30. Please revise to also present the historical loss per share data for both Tonix and Tamandare for the year ended December 31, 2010 and six months ended June 30, 2010.
- 31. We note the weighted average shares of 11,319,780 (page F-33) and 19,362,452 (page F-34) that were used in the computation of basic and diluted net loss per share for the year ended December 31, 2010 and six months ended June 30, 2011, respectively. Please supplementally provide us with your calculation to arrive at the pro forma weighted average shares outstanding for each period. Also tell us how you considered the possible dilution of the pro forma per share data resulting from the issuance of \$1,625,000 of convertible debentures concurrent with the Share Exchange. Refer to Rule 11-02(b)(7) of Regulation S-X.
- 32. We note in footnote (D) that you reflect the accelerated vesting of 1,737,000 shares of restricted stock as an adjustment to your pro forma balance sheet on page F-32. We further note in footnote (G) that you did not give effect to the accelerated vesting

of the 1,737,000 shares of restricted stock in your calculation of pro forma basic and diluted loss per common share. Please revise to reflect the accelerated vesting of the 1,737,000 shares in your calculation of pro forma basic and diluted loss per common share, or explain to us why you believe that such pro forma effect is not required. Refer to Rule 11-02(b)(7) of Regulation S-X.

## 1. Share Exchange, page F-35

33. We note that Tonix Shareholders received in exchange for all of their shares of Tonix Common and Preferred Stock, an aggregate of 22,666,667 shares of Tamandare's Common Stock in the October 7, 2011 Share Exchange. We further note on page F-26 the undeclared cumulative dividends on Preferred Stock of \$148,735 at June 30, 2011. Please tell us and revise to disclose how the undeclared cumulative dividends were affected in the exchange. To the extent that these will remain undeclared cumulative dividends after the exchange, clearly disclose this in the pro forma information.

#### Note 2. Pro Forma Adjustments, page F-35

34. We note in footnote (C) that you reflect the issuance of \$1,625,000 of debentures concurrent with the Share Exchange, including the \$500,000 of debentures which were exchanged for the Tonix debentures and the \$40,000 deferred financing costs, as adjustments to your pro forma balance sheet. We further note in footnote (H) that "the debentures were not assumed to have been issued on January 1, 2010 and, accordingly, no pro forma interest expense is reflected in the accompanying pro forma statements of operations." Please tell us how you considered Rule 11-02(b)(6) of Regulation S-X to arrive at your conclusion to not reflect the interest expense and amortization of deferred financing costs related to the debentures as adjustments to your pro forma statements of operations.

#### Form 10-K for the Fiscal Year Ended December 31, 2010

#### Item 9A. Controls and Procedures, page 18

35. We note that you did not disclose management's conclusion on the effectiveness of disclosure controls and procedures ("DC&P") as of December 31, 2010. Please confirm to us that you will disclose management's conclusion on the effectiveness DC&P in all future filings on Form 10-K, based on the evaluation of these controls and procedures required by paragraph (b) of Rule 13a-15 or Rule 15d-15 under the Exchange Act. Refer to Item 307 of Regulation S-K, and the instructions to Item 9A of Form 10-K.

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
- 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 Joanna Lam, Staff Accountant, at (202) 551-3476 or John Archfield, Senior Staff Accountant, at (202) 551-3315 if you have questions regarding comments on the financial statements and related matters. Please contact Ruairi Regan, Staff Attorney, at (202) 551-3269 or James Lopez, Branch Chief, at (202) 551-3536 with any other questions.

Sincerely,

/s/ James Lopez (for)

John Reynolds Assistant Director

cc: (via e-mail) Harvey Kesner, Esq. Sichenzia Ross Friedman Ference Anslow LLP