

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

DIVISION OF CORPORATION FINANCE

April 9, 2014

<u>Via E-mail</u> Paul Lammers, M.D., M.Sc. President and Chief Executive Officer Mirna Therapeutics, Inc. 2150 Woodward Street, Suite 100 Austin, TX 78744

> Re: Mirna Therapeutics, Inc. Confidential Draft Registration Statement on Form S-1 Submitted March 12, 2014 CIK No. 0001527599

Dear Dr. Lammers:

We have reviewed your confidential draft 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 providing the requested information and either submitting an amended confidential draft registration statement or publicly filing your registration statement on EDGAR. 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 the information you provide in response to these comments and your amended confidential draft registration statement or filed registration statement, we may have additional comments.

General

- 1. Please submit all outstanding exhibits as soon as practicable. We may have further comments upon examination of these exhibits.
- 2. Please provide us proofs of all graphic, visual or photographic information you will provide in the printed prospectus prior to its use, for example in a preliminary prospectus. Please note that we may have comments regarding this material.
- 3. Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications. Similarly, please

supplementally provide us with any research reports about you that are published or distributed in reliance upon Section 2(a)(3) of the Securities Act of 1933 added by Section 105(a) of the Jumpstart Our Business Startups Act by any broker or dealer that is participating or will participate in your offering.

Prospectus Summary, page 1

- 4. We note your statement here and throughout the registration statement that you are a "leading clinical stage biopharmaceutical company developing a broad pipeline of microRNA-based oncology therapeutics." In light of the early-stage development of your product candidates and the fact that you have only one product candidate in clinical trials, please revise your disclosure to delete reference to being a "leading" clinical stage biopharmaceutical company.
- 5. Please revise your disclosure to identify the other scientists and leading academic institutions who have reached conclusions about the key role that microRNAs play in tumor suppression.
- 6. Please define the term "transient transfection" at your first reference on page 4.
- 7. We note your inclusion of a pipeline chart on this page and on pages 82 and 95 and, in particular, your inclusion of certain early development programs which rely on undisclosed microRNA. Please revise your pipeline chart to identify the applicable microRNA or microRNA mimic for each program and disclose the relevant potential indication(s) that will be pursued for each program, if known. In the alternative, please remove reference to such programs in light of their very early stage of development and the lack of information with respect to the microRNA relied upon for these programs.

Risk Factors

"We have incurred significant losses since inception...," page 10

8. Please revise your risk factor disclosure to include your total accumulated deficit to date.

"We are highly dependent on the services of our President and Chief Executive Officer, Paul Lammers, M.D., M.Sc., and other key executives and scientists...," page 32

9. Please identify the other key executive and scientists upon which you are highly dependent.

"If we are unable to obtain and maintain sufficient patent protection for our technology and product candidates...," page 37

10. Please revise your risk factor discussion to include a brief discussion of your most material patents, the product candidates or technology to which they relate, the

jurisdiction in which they were granted, and the expected expiration date of the patent protection.

"If we breach any of the agreements under which we license the use, development and commercialization rights to our product candidates...," page 43

11. Please revise your risk factor disclosure to provide a brief description of the license agreements upon which you are principally reliant including the product candidates and/or technology covered and the material terms and obligations under such agreements.

"If approved, MRX34 or any future products may cause or contribute to adverse medical events...," page 50

- 12. We note your disclosure that some participants in your Phase 1 clinical trial of MRX34 have reported adverse effects after being treated with MRX34. Please revise your risk factor disclosure to provide the following information:
 - the number of patients who have experienced an adverse event;
 - the specific adverse events experienced;
 - whether any such events were characterized as severe;
 - whether such adverse events were determined to be related to the administration of MRX34; and
 - whether, and if so, how, such events impact your assessment of the safety profile for MRX34.

Please also include this information with respect to adverse events in the other locations of the prospectus in which you discuss the Phase 1 clinical trial of MRX34.

"We may be subject to claims challenging the inventorship or ownership of our patents...," page 44

13. Please revise your risk factor to discuss the extent to which your financial obligations to Yale are related to your leading product candidates and, if so, please include a description of any such financial obligations.

Use of Proceeds, page 62

14. We note that you intend to use a specific amount of proceeds from the offering to fund clinical development expenses for MRX34. Please expand your disclosure to indicate whether you expect the proceeds from this offering together with existing cash and cash equivalents to enable you to complete the Phase 1 trial. If not, please disclose what the offering proceeds and your existing cash will allow you to accomplish as to the Phase 1 trial.

> 15. Pursuant to the requirements of Item 504 of Regulation S-K, where you have identified the specific purposes for which you intend to use the offering proceeds, you must disclose the approximate amount of proceeds intended to be used for each such purpose. In this regard, please provide an estimate of the amount of proceeds that you intend to use for the development of each of your product candidates in preclinical development. Please make any necessary conforming changes to your Prospectus Summary as well.

Managements' Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Estimates Stock-based Compensation, page 74

16. Please note that we are deferring final evaluation of stock compensation and related costs until an amendment including your estimated offering price has been filed. Advise us of any new option grants or other equity issuances and include the date of grant or issuance, the exercise price, the fair value of the equity instrument at the date of grant and how you determined the fair value. Please provide us with a quantitative and qualitative analysis explaining the difference between the estimated offering price and the fair value of most recent equity issuance.

<u>Results of Operations</u> Research and Development Expenses, pages 75 and 77

17. To help us better understand your research and development expenses for each of the three years and your explanations of the year over year changes, please provide us a schedule for each year that provides a break-down of research and development expenses showing at a minimum the following categories: salaries and personnel-related costs, consulting fees, fees paid for contract research services, the costs of laboratory equipment and facilities, license fees and other external costs. For each category, show the amount of government grant reimbursement. Reconcile each year to total research and development expenses shown in your statements of operations.

<u>Business</u> Overview, page 81

- 18. We note your disclosure that MRX34 has shown a manageable safety profile through the first 45 weeks of your Phase 1 clinical trial. Please revise your disclosure to explain what constitutes a "manageable" safety profile. Please also discuss the specific experiences of your subjects which led you to reach this conclusion. In this regard, please provide a full discussion of the adverse events experienced by patients in your Phase 1 trial, to date. Such discussion should include all information highlighted in our comment above with respect to your risk factor at page 50.
- 19. We note your reference to the published reports from microRNA scientists at numerous research institutions with respect to the key role miR-34 plays in controlling oncogene

expression. Please identify the scientists and institutions to which you are referring, the publications in which the reports were published, and whether such publications were peer-reviewed.

MRX34 Clinical Development Program, page 96

- 20. We note your reference to certain ongoing Phase 2 clinical trials for a product known as PNT2258 with respect to the delivery abilities of Smarticles. Please revise your disclosure to identify the company conducting such trials.
- 21. We note disclosure on page 76 indicating that an Investigational New Drug (IND) application for MRX34 was filed in 2013. Please disclose the date the application was filed, the identity of the filer, and the relevant indication(s). In particular, please specifically disclose whether you were required to file a separate IND for the hematological malignancies cohort added to your Phase 1 trial. If not, please explain why.
- 22. We note your disclosures throughout the prospectus, including on page 81, that you expect completed results in the Phase 1 trial in the liver-based cohort by the end of the first quarter of 2015 and completed results from the hematological malignancy cohort in mid-2015. Please disclose whether interim or preliminary data are expected to be available for either cohort and if so, when such data will become available.
- 23. You disclose on page 97 that the secondary objectives of the Phase 1 trial for MRX34 relate to pharmacokinetics, pharmacodynamics, and clinical activity. On page 4 of your prospectus summary, you disclose that safety is also an objective of this trial. Please disclose here whether you intend to assess safety of treatment with MRX34 as a secondary objective of this trial.

Combination Therapy for MRX34, pages 99-100

24. We note your disclosure that cell culture and animal liver cancer models have shown that MRX34 could be more effective when used in combination with sorafenib. Please disclose the observations from these earlier studies that you believe support this conclusion.

Manufacturing Drug Product, page 101

25. Please disclose all material terms of your manufacturing and supply agreement with Polymun. Please include a description of all material rights and obligations of the parties, as well as a discussion of the agreement's termination and duration provisions. Please additionally file the agreement as an exhibit to your registration statement pursuant to

Item 601(b)(10) of Regulation S-K. Alternatively, if you do not believe you are substantially dependent on the agreement, please advise us as to the basis of your beliefs.

Our Patent Portfolio, page 102

26. Please revise your disclosure to specify when the patents licensed from Yale with respect to the uses of let-7 microRNA are expected to expire.

Strategic Partnerships and Collaborations Yale University, page 115

- 27. Please disclose what patents are subject to the Yale license agreement and which of your product candidates are reliant on such patents. In particular, please clarify whether any of the underlying patent rights relate to your primary product candidate, MRX34, and confirm whether the specified royalty provisions are also applicable to net sales of MRX34.
- 28. Please revise your disclosure to discuss how the termination of your patent rights under the Yale license agreement impacts your corresponding patent rights under the Asuragen license agreement, and vice versa.

CPRIT, page 116

29. We note your disclosed obligation to pay CPRIT a portion of your revenue from sales of certain products. Please clarify whether your royalty obligations are applicable to sales of MRX34.

Director Compensation, page 126

30. Please file the January 2013 directors' compensation policy referenced on this page as an exhibit to your registration statement.

Terms and Conditions of Employee Arrangements with our NEOs, page 129

31. Please file the employment agreements with your NEOs as exhibits to your registration statement.

Shares Eligible for Future Sale Lock-up Agreements, page 152

32. Please file the form of lock-up agreement as an exhibit to your registration statement.

<u>Financial Statements</u> <u>Notes to Financial Statements</u> <u>3. Cancer Prevention and Research Institute of Texas Grant and Other Grants, page F-14</u>

33. Please refer to your disclosure that, under the terms of the award, the Company is required to pay to CPRIT a portion of its revenues from sales of certain products by the Company, or received from the Company's licensees or sublicensees, at a percentage in the low single digits until the aggregate amount of such payments equals a specified multiple of the grant amount, and thereafter at a rate of less than one percent, subject to the Company's right, under certain circumstances, to make a one-off payment in a specified amount to CPRIT to buy out such payment obligations. Disclose your accounting policy with respect to these terms.

9. Stock Option Plans, page F-19

34. Please include the disclosures required by ASC 718-10-50-2.d. and e.

If you intend to respond to these comments with an amended draft registration statement, please submit it and any associated correspondence in accordance with the guidance we provide in the Division's October 11, 2012 announcement on the SEC website at http://www.sec.gov/divisions/corpfin/cfannouncements/drsfilingprocedures101512.htm.

Please keep in mind that we may publicly post filing review correspondence in accordance with our December 1, 2011 policy (http://www.sec.gov/divisions/corpfin/cfannouncements/edgarcorrespondence.htm). If you intend to use Rule 83 (17 CFR 200.83) to request confidential treatment of information in the correspondence you submit on EDGAR, please properly mark that information in each of your confidential submissions to us so we do not repeat or refer to that information in our comment letters to you.

You may contact Ibolya Ignat at (202) 551-3656 or Jim Rosenberg at (202) 551-3679 if you have questions regarding comments on the financial statements and related matters. Please contact Austin Stephenson at (202) 551-3192, 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