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IN RE: 82 Fed. Reg. 36809 (August 7, 2017), "Prospective Grant of Exclusive Patent License: MicroRNA therapeutics for treating squamous cell carcinomas" to miRecule, Inc.

Dear Mr. Love:

Thank you for providing us with your comments regarding the Federal Register notice of the proposed license the National Institutes of Health (NIH) intends to grant to miRecule, Inc.

Prior to posting notices for a proposed grant of an exclusive license, the NIH determines that the criteria set forth in 37 CFR 404.7(a)(1)(ii-iii) have been satisfied and that the company is qualified both technically and financially to be granted an exclusive license to the Government's intellectual property in the fields of use as specified. The notice period provides an opportunity for public comment and possible objection to the proposed license. We consider all comments prior to negotiating the proposed license and have considered your comments.

With regards to this case in particular, we are aware that miRecule is a start-up company currently incubated within BioHealth Innovations, Inc. (BHI). BHI is a highly visible Maryland non-profit organization with the mission of supporting start-up life science companies with business, scientific and legal matters. We are intimately aware of the risks associated with start-up ventures and especially those that undertake early stage technology that require extensive research, development and clinical validation. As your organization knows and has itself articulated in its comment letter, these ventures are inherently risky and plagued with uncertainty. MicroRNA therapeutics in particular has had a difficult naissance. As such, many of the suggestions and comments you proposed in your letter are routinely contemplated both in our review of companies' applications for license and incorporated in the draft terms of our agreements. Specifically, exclusive agreements would not be executed without a company agreeing to scientific, clinical and financial benchmarks and milestones for advancing the therapeutic. Moreover, a company's failure to adhere to those benchmarks and milestones could lead to the NIH terminating the agreement or partially retracting the license grant and issuing additional licenses to other companies. Note that other than miRecule's application no other company approached the NIH with an interest in licensing this patent estate for commercialization.

With regards to the company founder being a former NIH investigator and co-inventor of the patent estate his start-up company seeks to license, we have already addressed all questions of potential conflict. Dr. Saleh terminated his employment at NIH prior to starting miRecule and he will take no part in direct negotiations of any license.

Dr. Saleh will have direct participation in the research under his company's Cooperative Research and Development Agreement (CRADA) with the National Institute on Deafness and Other Communication Disorders (NIDCD) in order to advance the technology since a positive research outcome under the CRADA is one step

closer to the development of a successful therapeutic to at least one squamous cell carcinoma. With respect to your request for various reports including CRADA documents, it is not consistent with our mission to create reports requested by the public and the proprietary content of the agreement governing the CRADA between the NIDCD is strictly confidential. In summary, the CRADA research plan sets forth a joint effort between miRecule and NIDCD to develop chemically modified mimic or mimetic microRNAs that are stable and less susceptible to nuclease degradation than previously identified microRNAs and that serve as therapeutics for cancer when delivered using tumor targeted nanoparticles. The CRADA will test these microRNAs in animal cancer models to evaluate their efficacy and the pharmaceutical properties of candidate formulations.

If your organization requests more documentation, such requests should be filed under the Freedom of Information Act. The webpage for the NIH FOIA Office provides more information on filing requests http://www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/freedom-information-act-office/submitting-foia-requests.

Sincerely,

Michael A. Shmilovich, Esq., CLP