6106 Harvard Avenue
#713
Glen Echo, MD 20812
301.208.9191

August 12, 2024

Dear Stockholder:

The letter is to update you on important recent financial and strategic developments, as well as the status of our phase 3 neurotrophic keratitis (NK) clinical trials in the U.S. and EU (SEER-2 and SEER-3, respectively).

In May we met with our Korean partners from HLB Therapeutics (HLBT) regarding our mutual interests in modifying our ReGenTree joint venture to create an organization that would be both attractive and easy to be acquired by a multinational pharma company when our phase 3 trials are successfully completed. In that regard, we agreed that by HLBT contributing all licensed Asian rights to RGN-259 (except for Greater China, which are licensed to Zhaoke Ophthalmology) and by RegeneRx contributing its otherwise unencumbered worldwide rights to the JV, we would be in a better position to be a very attractive acquisition to big pharma in the future, assuming our phase 3 NK trials are successful. Rights contributions to the JV by both parties are subject to the same terms, conditions and royalties as currently exist in the license to the JV, subject to any future modifications, if appropriate. In return for its rights contribution, RegeneRx received a fee of $150,000 and return of 50% of the RegeneRx shares owned by HLBT (97,917 shares post-reverse split), which amounts to approximately 6.5% of the currently outstanding shares of RegeneRx stock.

HLBT has spent significantly more money than anticipated in developing RGN-259 for two ophthalmic indications, NK and dry eye disease, and financed the clinical trials and requisite regulatory requirements by loaning the JV the necessary capital, which, under the terms of the JV Operating Agreement, converts into equity capital in the JV at future milestones. Thus, to continue at the anticipated spend rate to complete the trials and to meet certain banking and accounting standards as a Korean public company, HLBT proposed that we accelerate their equity build-up from 61.5% of the JV to 70%, which results in the conversion to equity of all currently outstanding loans to the JV and facilitates additional loans to complete the ongoing clinical trials and subsequent regulatory activity. We agreed to do so as this still falls within our floor of a 25% equity position in the JV through FDA regulatory approval. We also agree that HLBT would receive the first $5 million from any third-party transaction as consideration for future expenditures on behalf of the JV.

I think both RegeneRx and HLBT are pleased with the outcome of these discussions and our ability to work together for the benefit of ReGenTree as well as our mutual interests.

Regarding the status of the phase 3 NK trials, ReGenTree continues to activate and add more clinical sites in the U.S. and EU each month. Patients are enrolling faster in the EU. As stated previously, topline data of SEER-3 70- patient trial being conducted in Europe is still expected to be available by the end of this year or early next year if everything goes as planned. As mentioned in our last letter, the U.S. accrual rate is slower due to one available drug for NK on the market that reduces the number of patients eligible to participate in the clinical trial for this orphan disease.

Recently, ReGenTree has engaged a pharmaceutical product valuation company to evaluate the commercial value of RGN-259 for the treatment of NK to help guide a potential licensing deal with big pharma when data is received from the NK trial in Europe. According to the draft report as reported by HLBT, the value of RGN-259 as an NK treatment is estimated to range from approximately US$800 million to US$2.2 billion, assuming success of the two phase 3 NK trials and potential market dominance expected upon approval of RGN-259.

The potential U.S. market value considers the only other pharmaceutical product approved for NK, Oxervate, which is sold by the Italian company, Dompé, has a treatment period of eight weeks, needs refrigerated storage by the patient, and has a complicated preparation process before its administration. The treatment cost is also approximately $100,000 for an eight-week treatment course. In contrast, RGN-259 treatment is four weeks, can be stored at room temperature by the patient, and is easy to administer using a traditional single-use squeeze vial. The pricing of RGN-259 has not yet been determined.

According to HLBT, the number of NK patients in the U.S. is estimated to be around 60,000. Oxervate's sales revenue in 2023 is estimated at over $800 million, and the market is growing rapidly, with a compound annual growth rate of 35% over the past five years. If RGN-259, which is more patient-friendly, is approved in the U.S. and followed by Europe, revenue from RGN-259 for NK treatment is expected to be substantial and expand faster.

An HLB Therapeutics official confirmed that multiple global big pharma companies are conducting due diligence on RGN-259 as an NK treatment, and we expect the negotiation process to accelerate if statistical significance is secured in a primary endpoint in the European phase 3 (SEER-3) study.

From a financial perspective at RegeneRx, we continue to operate at the lowest possible cash level and likely have enough capital to operate at this rate for the next 12-18 months, barring any unexpected developments. We do not believe we will need additional capital for the near future. Obviously, we will have more to say as we head toward the end of the year and see results from phase 3.

I would like to remind you that our goal is to preserve our stockholders' equity in the Company while we await results from the phase 3 NK clinical trials, which this latest transaction reflects. If the trials are successful, and depending on what ReGenTree decides to do in this case, we would determine an appropriate valuation for our asset and seek to raise capital to either "relist" the Company or sell the Company and declare a special dividend to distribute to our stockholders, among other possibilities.

Regarding any shares that are held by our stockholders that have not been exchanged pursuant to the 2023 reverse split, we recommend that you download the "2023 Reverse Split Letter of Transmittal" by clicking the following link, https://www.regenerx.com/download/2023+Reverse+Split+Letter+of+Transmittal.pdf, fill it out and send it to Equiniti Trust Company at the address on the Transmittal Letter. If you have any questions, you may call Equiniti's Shareholder Services at 877.248.6417.

Feel free to contact me at jjfnk@regenerx.com. Additionally, while stockholders can sign up on our email list on our website, it is a bit difficult to utilize so some of your questions may not have been answered. If you have any questions, please contact us at the email above and we will do our best to answer expeditiously.

We will continue to update you as appropriate and look forward to the results of the phase 3 trials as soon as possible.

Best regards,

J.J. Finkelstein
President & CEO

Allan L. Goldstein, Ph.D.
Chairman and Chief Scientific Advisor