15245 Shady Grove Road
Suite 470
Rockville, MD 20850
301.208.9191

December 21, 2020

Dear Stockholder:

As the end of the year approaches, we would like to take this opportunity to briefly update you on the status of our ophthalmic clinical trials for neurotrophic keratitis (NK) (SEER-1) and dry eye syndrome (ARISE-3), and on our near-term operating strategy. As always, we reserve the right to modify our goals and expectations from time to time in accordance with clinical development of our product candidates, access to capital markets, and the general climate in the pharmaceutical industry.

NK AND ARISE-3 PHASE 3 CLINICAL TRIALS

In our Letter to Stockholders in January of this year we stated that, "we believe 2020 will likely be the most important year in our Company's history," primarily due to the NK and the ARISE-3 phase 3 clinical trials studying RGN-259 sterile eye drops.

Top line results for the NK trial (SEER-1) were reported in May 2020. The trial recruited, treated and analyzed 18 patients. Six out of 10 patients in the RGN-259 treated group and 1 out of 8 patients in the placebo treated group achieved complete corneal healing in 4 weeks. In terms of the primary endpoint, "ratio of corneal wound healed patients after four weeks' administration", the statistical difference was slightly over 0.05 ($p = 0.0656$, Fisher's exact test), due to the limited number of patients in each group. This strong trend likely would have reached a statistically significant p value of <0.05 had more patients been entered into the trial. When another statistical analysis was used to analyze the same primary endpoint (Chi square test), there was statistical significance, $p = 0.0400$, even with the limited number of patients.

In addition, in a pre-specified secondary endpoint evaluating corneal epithelial healing at day 43 (two weeks post-treatment) and the durability of RGN-259 treatment, we also confirmed a clear statistical difference using the Fisher's exact test, $p = 0.0359$. Several other efficacy parameters were either highly significant or strongly trending toward statistical significance in the RGN-259 group indicating the depth of patient response to RGN-259. These results demonstrated the efficacy of RGN-259 in NK, despite the small number of patients. As expected, it was well tolerated and there were no safety issues associated with our drug.

We also mentioned that during the past several years, ReGenTree LLC, our U.S. joint venture with GtreeBNT to develop RGN-259 in North America, began creating a modified eye drop formulation that it believes will enhance the efficacy of thymosin beta 4 for NK, improve the patient experience, and allow a proprietary-valued orphan product price for this rare disease. ReGenTree has completed a preliminary formulation for NK patients that will be considered for use in future clinical study, which will be determined after we see the results of the ARISE-3 trial.

As GtreeBNT previously announced, due to the Corona virus pandemic, top line results for ARISE-3 have been pushed out to early 2021. ARISE-3 remains a major inflection point for RegeneRx and will have a huge bearing on the future of the Company and its operating strategy. We continue to have high hopes for this trial.

For those of you unfamiliar with dry eye syndrome, the worldwide dry eye syndrome (DES) market is estimated at well over $4 billion per year and expanding rapidly. To date, three pharmaceutical products have been approved in the U.S. that are used to treat dry eye syndrome, although not optimal in their treatment of the disorder. As mentioned in previous communications, Novartis purchased the dry eye drug, Xiidra®, from Takeda for up to $5.3 billion. Xiidra® had 2018 U.S. sales of approximately $400 million. We believe this transaction reflects the market value of approved dry eye drugs and is a benchmark for the potential value of RGN-259. We also believe RGN-259 is significantly differentiated from Xiidra® and Restasis®, approved for increasing tear production, as RGN-259 has shown no significant toxicities or patient discomfort in over 1,700 patients treated to date and acts more rapidly in alleviating the signs and symptoms of dry eye.

A third product was recently approved for DES. Eysuvis® (loteprednol etabonate ophthalmic suspension 0.25%) is the first ocular corticosteroid approved by the FDA for the actual treatment of dry eye disease. Kala is planning to launch it in the U.S. in the near future. Since Eysuvis® is a steroid it is approved for use for only for up to 2 weeks of treatment as steroids can have significant and long-lasting side effects. We believe RGN-259, if approved, offers advantages over any steroidal eye drop formulation.

OPERATIONS

We have stated in previous press releases, stockholder letters, and SEC filings that RegeneRx has limited capital and will be deploying its capital to maintain existing operations through the reporting of ARISE-3 results. This is unequivocally our primary goal. We have periodically raised incremental amounts of capital over several years through investments by management, the board of directors, and certain affiliates to fund the Company's operations through phase 3 clinical results of RGN-259 but we have not had access to enough capital at reasonable cost to pursue some of our other product development objectives. Moreover, we believe clinical success with RGN-259 will validate Tβ4's therapeutic properties and open up valuable partnering opportunities for both RGN-259 and RGN-352. Our hope is that after the reporting of ARISE-3 data we will have a number of options to raise capital at a higher valuation, sell/license part or all of our RGN-259 asset to a major pharma company and, generally, be in a position to pursue other asset development, such as RGN-352. Another objective would be to move our listing to the NASDAQ market at the earliest practicable time.

RGN-352 has significant potential for the treatment of cardiovascular and neurovascular injuries, and most recently, it has been shown that it may have a role in the treatment of the symptoms of COVID-19 corona virus. A multi-institutional team of scientists from eight American research centers published a research paper on new therapeutic approaches for COVID-19 in which they propose that Tβ4, because of its ability to induce fibrinolysis, among its other activities, may be useful in treating patients with the COVID-19 virus. The researchers also found that COVID-19 elevates bradykinin levels in multiple tissues. This bradykinin-storm in COVID-19 patients induces leakage of fluid into the lungs and excessive release of hyaluronic acid

preventing oxygen uptake and carbon dioxide release in the lungs of severely affected COVID-19 patients and may be responsible for many of the more severe symptoms of COVID.

Importantly, the researchers also looked at differences in male/female morbidity and mortality and noted a number of interesting points linked with other studies. It is known that older age and a high number of co-morbidities are associated with increased severity and mortality in patients with COVID-19 and other similar infectious viruses such as SARS. While men and women have the same prevalence, men with COVID-19 are 2.4 times more at risk of death, independent of age.

That men with COVID-19 are 2.4 times more likely than women to die from the virus is extremely interesting because the gene for Thymosin beta 4 resides on the X chromosome. Women have two X chromosomes while men only have one. As the researchers suggested, this could explain the lower incidence of COVID-19 induced mortality in women because it is found on the X chromosome and escapes X-inactivation. Women, therefore, would have increased levels of Tβ4 compared to men; thus, the possible explanation why women have an improved chance of survival. If true, then administering pharmacological levels of Tβ4 to COVID-19 patients may significantly reduce morbidity and improve survival.

SUMMARY

To summarize, we are in a holding pattern while awaiting the results of ARISE-3 early in 2021. Upon success, we believe RegeneRx will have a number of viable options to pursue including potential monetization of RGN-259, access to operating capital at a higher valuation (less dilution) to pursue other asset development, including partnerships for RGN-352 development, and potential uplisting to the NASDAQ market without unacceptable dilution. While difficult, we and all of our stockholders need to remain patient until we learn the results of ARISE-3 in a matter of weeks.

We wish you Happy Holidays and that each of you and your families remain safe during these difficult times.

Best regards,

J.J. Finkelstein
President & CEO

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

Forward-Looking Statements

Any statements in this stockholder letter that are not historical facts are forward-looking statements made under the provisions of the Private Securities Litigation Reform Act of 1995. Any forward-looking statements involve risks and uncertainties that could cause actual results to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. Forward-looking statements in this stockholder letter include, but are not limited to, statements regarding our strategic and research partnerships, regulatory applications and approvals, the development and timing of our drug candidates, the use of our drug candidates to treat various conditions, operating strategies, and

our financial needs. The proposed clinical trials and costs to operate the Company during such trials, as well as the other forward-looking statements, are expectations and estimates based upon information obtained and calculated by the Company at this time and are subject to change. Moreover, there is no guarantee any of these trials will be successful or confirm previous clinical results. Please view these and other risks described in the Company's filings with the Securities and Exchange Commission ("SEC"), including those identified in the "Risk Factors" section of the annual report on Form 10-K for the year ended December 31, 2019, and subsequent quarterly reports filed on Form 10-Q, as well as other filings it makes with the SEC. Any forward-looking statements in this stockholder letter represent the Company's views only as of the date of this release and should not be relied upon as representing its views as of any subsequent date. The Company specifically disclaims any obligation to update this information, as a result of future events or otherwise, except as required by applicable law.