15245 Shady Grove Road
Suite 470
Rockville, MD 20850
301.208.9191

April 22, 2019

Dear Stockholder:

We would like to report on the status of RegeneRx and our expectations for the next 12 to 18 months. This letter is intended to be an overview of clinical trials, operations, and future direction. We reserve the right to modify our goals and expectations from time to time in accordance with clinical development of our product candidates by our partners, additional partnering activities, access to capital markets, and the general climate in the pharmaceutical industry.

RegeneRx has continued its strategy of leveraging its clinical assets by engaging in product development and commercial partnerships. We obtained funding as needed to manage our intellectual property, maintain our status as a public company, and continue other critical and important facets of our operations at the least possible cost to the Company. In that regard, management, the board of directors, and strategic partners and affiliates participated in the recent $1.3 million convertible debt issue, which was 50% completed in February with the remaining 50% due upon the first visit of the first patient in ARISE-3 Phase 3 dry eye clinical trial, expected during the second quarter of 2019. During this past year, we continued to support research and development with Thymosin beta 4 (Tβ4) by working with leading academic and medical institutions in the U.S., Asia and Europe to conduct research intended to supplement and/or expand our clinical and basic research efforts.

Previously, our Chairman, Dr. Allan Goldstein, presided over the *5th International Thymosin Symposium* in Washington, DC. Of the numerous papers and presentations made at the meeting, two stood out as particularly interesting by scientists working with Tβ4 under Material Transfer Agreements (MTAs) with us.

The first was of the possible inverse relationship between Tβ4 and f-actin in patients with sepsis that can rapidly develop into septic shock, which kills 25%-40% of those who develop this disease. If this relationship is confirmed, it could lead to a new rapid diagnostic test and potential treatment with RGN-352, our injectable formulation of Tβ4. We expect to hear from the researchers later this year.

The second was that Tβ4 is active in reducing chronic granulomatous disease (CGD) by promoting autophagy (the normal clearance of damaged or redundant cellular components within the body) and reducing inflammation. CGD can affect patients of any age, but it is most commonly diagnosed in young children under the age of 5. It is a primary immunodeficiency disorder that results from the body's inability to effectively kill fungi and bacteria, which can lead to severe and recurrent infections in numerous organs. It is estimated that under 2,000 patients in the U.S. have CGD, thus, it is an

ultra-orphan disease. A paper has been submitted for review to a major scientific journal and we look forward to its publication.

PRODUCT DEVELOPMENT

We have continued with our strategy to out-license rights to our product candidates in markets that would be difficult or impossible for us to develop internally. We have also retained certain territorial rights to drug candidates currently under development in order to maximize their potential value after success is achieved.

Lee's Pharmaceuticals, a successful and fast-growing Chinese biopharmaceuticals company, previously licensed the rights to develop and commercialize our Tβ4 products in China, Hong Kong, Macau and Taiwan. Lee's recently indicated that it intends to accelerate its development of RGN-259 (RegeneRx's preservative-free eye drop) now that it has completed a state-of-the-art ophthalmic formulation and manufacturing facility in China. We are very pleased that Lee's has developed this capability and look forward to more progress in this area in China.

G-treeBNT (G-tree), a Korean biopharmaceutical company, is our licensee for the rights to RGN-259 in Korea, Japan, Australia and a number of other countries in Asia that we refer to as the Pan Asian rights. We also licensed G-tree the rights to develop RGN-137 (RegeneRx's dermal wound healing product), in the U.S. Pan Asia and EU for Epidermolysis Bullosa (EB), an inherited orphan indication causing fragility and blistering of the skin. G-tree initiated a 15-patient pilot study in EB patients in December 2018 that, if successful, will encourage moving into Phase 3.

As many of you know, we created a U.S. joint venture with G-tree (ReGenTree LLC) to develop RGN-259 in the U.S. for dry eye syndrome (DES), neurotrophic keratopathy (NK), an orphan condition of the cornea, and other potential cornea-related ophthalmic disorders. We chose to enter this relationship for several reasons, including demonstration by G-tree of technical and product development competency and a willingness to put forth the necessary time, effort, and capital, as indicated by their efforts to date. ReGenTree is in position to capitalize on these efforts pursuant to its dedicated and significant investment in RGN-259 development. Its success in the U.S. and Pan Asia should enhance RegeneRx's retained rights to RGN-259 in the EU and most other Eastern European countries.

We believe the joint venture is an appropriate structure within which to develop RGN-259 as RegeneRx will retain a significant portion of the equity of ReGenTree while G-tree will earn additional equity based on achievements of critical developmental milestones. RegeneRx will also receive a single to double-digit royalty on any commercial sales by ReGenTree or a sublicensee. We estimate RegeneRx's equity ownership in ReGenTree, along with RegeneRx's royalty rights, will result in a share of the eventual commercial value of the joint venture of approximately 40% (or higher depending on whether and when RGN-259 is licensed or sold to a third party), or if it is commercialized internally through the joint venture. We structured the joint venture so that RegeneRx has no financial obligations for the entire development process through NDA approval.

Moreover, RegeneRx has significant influence over major decisions within ReGenTree, such as commercialization strategy, mergers, acquisitions, etc., which require unanimous board approval. Given that the value of the worldwide dry eye market is well over $4 billion per year, and growing rapidly, we believe this is an opportunity to effectively develop RGN-259 in the U.S. with a partner that has the interest, expertise and financial capabilities to achieve timely success, without financial obligation or risk to RegeneRx.

It is important to recognize the complexity of development activities in moving a drug candidate from Phase 2 to Phase 3, whether in Asia or in the U.S., including large and expensive clinical trials, optimization of product packaging, stability and sterilization, and other related tasks required for commercial manufacturing. This requires significant capital, time, and expertise and must be performed within strict regulatory guidelines called Good Manufacturing Practices, which G-tree has successfully completed to date. We believe Lee's Pharma will be able to do so as well.

Critical Clinical Milestones

During the next 12-18 months we and our partners expect to reach numerous clinical milestones, all of which, we believe, should add significant value to RegeneRx.

- ReGenTree has initiated ARISE-3, its 700-patient Phase 3 dry eye trial in the U.S. with results expected in 2020. ReGenTree intends to meet with FDA after ARISE-3 trial results;
- ReGenTree will likely close SEER-1, its U.S. Phase 3 trial in neurotrophic keratopathy this year and report results in patients accrued to date during the second half of 2019;
- In the U.S., G-treeBNT initiated a pilot study in December 2018 in patients with EB adopting wound-healing endpoints as recently modified by the FDA. If successful, we expect G-tree to move to Phase 3 in this serious and debilitating orphan indication:

Market for RGN-259 in the U.S. and China

The current worldwide dry eye syndrome market is estimated at over $4 billion per year and expanding rapidly. To date, two pharmaceutical products have been approved in the U.S. for dry eye syndrome and command annual sales exceeding $1 billion, although not optimal in their treatment of the disorder. Patients often experience burning and stinging and it commonly takes six months of use until efficacy is seen, if at all, with one of the drugs. The package insert indicates that clinical trials demonstrated that the product is effective in only 15% of patients vs. 10% for placebo. The other approved product is also minimally effective with patients reporting some discomfort as well as dysgeusia, a foul metallic taste in the mouth, among other side effects.

Clinical data for RGN-259 to date shows that its effects are achieved within days, that there is no burning, stinging or foul taste and that it can significantly improve both the signs and symptoms of dry eye in patients with moderate to severe dry eye, which represent the current standards required by FDA for approval of new products for dry eye.

China's large population and quickly expanding industrial economy has led to severe pollution in its high-density urban areas and a rapidly expanding incidence of dry eye symptomology among its population. China is fast becoming the largest economic market for dry eye products. In an aggregation of market and medical reports, the prevalence of dry eye syndrome in China is believed to be over eight times greater than in the U.S. and over five times greater than in the five major countries of the EU and growing quickly.

NK is an orphan disease with a U.S. prevalence far below the statutory threshold of 200,000 diagnosed cases. We are not aware of point-prevalence epidemiology data for the U.S.; however, available incidence data from Europe – a population demographically similar to the U.S. – strongly support a low U.S. prevalence. Based on an average NK prevalence of 6% of all cases of herpetic keratitis, prevalence can be estimated as 0.89/10,000 or approximately 28,000 patients in the U.S. and a similar number in the EU, with a somewhat lower prevalence in patients with more severe Stage 2 and 3. On December 31, 2013 the FDA granted orphan status for Tβ4 for the treatment of NK in the U.S.

OPERATIONS, RESEARCH AND DEVELOPMENT AND FUTURE PLANS

Currently, RegeneRx has active partnerships in three major territories: the U.S., China and Pan Asia. In each case, the cost of development is being borne by our partners with no financial obligation for RegeneRx. Patient accrual, treatment, and follow-up for the ophthalmic trials are relatively fast, as opposed to most other clinical efforts, so we estimate data should be forthcoming over the next 12-18 months, although timing cannot be guaranteed. However, if additional financing is necessary prior to data readout, and/or if the financial markets are favorable, we will pursue another financing as appropriate.

We still have significant clinical assets to develop, primarily RGN-352 (injectable formulation of Tβ4 for cardiac, CNS and other systemic disorders) in the U.S., Pan Asia, and Europe, and RGN-259 in the EU. If emerging data in a study of blood levels of Tβ4 and f-actin in septic shock patients confirm preliminary data reported last year at the Thymosin meeting, we believe RGN-352 will be a very attractive opportunity for a multi-national strategic partner. Likewise, if the group of medical researchers with whom we are collaborating in Asia receives a proposed grant to study RGN-352 in a porcine model of myocardial infarction, and it replicates previously reported results, we believe it will also attract a global partner. Both of these development projects would be complex and take a significant amount of expertise and capital to undertake.

In that regard, we announced the appointment of Alessandro Noseda M.D. to the Company's Board of Directors, effective April 1, 2019. He is the sixth member of the Company's Board. Dr. Noseda is the Chief Scientific Officer of Leadiant Biosciences S.p.A. and has extensive scientific and medical experience in the global development of new medical technologies and drug products. He has held numerous managerial positions with the R&D and marketing organizations of multinational pharmaceutical companies during his career. Previously, Dr. Noseda was the Director of Scientific

Office and Strategic Alliances with Sigma-Tau, where he managed key R&D projects and was involved in creating partnerships with Novartis and Debiopharm, among others. He has also been Chief Executive Officer of Leadiant Biosciences SA (formerly Sigma-tau Research Switzerland) from 2007 to 2017. While at Sigma-Tau and Leadiant, he developed proprietary technologies and guided the company through development of orphan drug designations and registration of new medical products. Dr. Noseda has served on the Board of Directors of numerous private biotech companies. We believe Dr. Noseda will be of tremendous value to RegeneRx in helping us assess future product and partnership opportunities and especially with respect to potential orphan products.

With respect to research and development, we believe RegeneRx has built an effective model that encourages independent researchers throughout the world to work with our products by entering into Material Transfer Agreements (MTAs). MTAs allow us to supply Tβ4, along with our expertise, for research use and, in return, receive rights to license in new intellectual property. The research teams may freely publish their results, which we encourage. This model effectively leverages our assets and continually supplements the growing body of data underlying our drug candidates, while sometimes producing new intellectual property. As we currently have approximately twenty MTAs in place around the world where research teams are spending millions of dollars, we believe this to be a very undervalued component of our Company.

Our current cash, together with the additional financing proceeds from our recent convertible debt financing to be received after the first patient is enrolled in ARISE-3, should last into Q2 of 2020 based on our current operating budget. This estimate does not include receipt of any funds from grants, new partnerships or the raising of additional capital if the market climate warrants nor any significant unexpected expenses.

INVESTOR RELATIONS

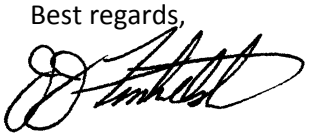
With partners sponsoring significant clinical trials in the U.S., China and Pan Asia and important clinical milestones on the near-term horizon, we intend to spend additional efforts on investor relations in order to present our story to a broader retail market, as well as to institutional investors and analysts. We recently attended the *2019 Spring Investor Summit* in New York in April and intend to attend other targeted meetings to meet with investors interested in companies like RegeneRx. It continues to be our belief that the market valuation of RegeneRx at $25-$30 million is significantly below comparable companies with product candidates in much earlier stages of clinical development. We also believe that if we can effectively present RegeneRx as a company that has worldwide product opportunities in advanced clinical trials for both large markets and orphan disorders, with near term clinical milestones and little financial risk to RegeneRx, we should appeal to a broad spectrum of investors in the biopharmaceutical space.

CONCLUSION

We believe RegeneRx has a compelling combination of assets, partners, and products in worldwide late-stage clinical development for medical disorders with unmet needs that offer the potential for

significant revenue generation in a relatively short period of time. Over the next 12-18 months, RGN-259 should reach important milestones including the first patient enrollment and completion of the Phase 3, 700-patient ARISE-3 dry eye trial in the U.S., the finalization and reporting of the Phase 3 U.S. neurotrophic keratopathy trial in patients accrued to date, and the completion of the 15-patient U.S. EB pilot study, all with data read-outs expected during this period. We strongly believe that, upon success, enthusiasm among patients, physicians, and investors will increase the value of our company to a level we believe is consistent with the clinical stage and potential of our product portfolio. We are very appreciative of the support and patience of you, our stockholders, and hope to share great results with you in the near future.

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, future royalty and milestone payments, regulatory applications and approvals, the development and timing of our drug candidates, the use of our drug candidates to treat various conditions, our growth strategy, 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, 2018, 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.