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January 22, 2020

Dear Stockholder:

We would like to report on the status of RegeneRx and our goals for 2020. This letter is intended to be an overview of clinical trials, operations, and future direction, among other expectations in 2020. We reserve the right to modify our goals and expectations from time to time in accordance with clinical development of our product candidates, partnering activities, access to capital markets, and the general climate in the pharmaceutical industry.

PHASE 3 AND PHASE 2 CLINICAL TRIALS

We believe 2020 will likely be the most important year in our Company's history. We have two phase 3 clinical trials that are targeted for completion by our partner with data readouts during the year. The first should be the neurotrophic keratitis (NK) trial (SEER-1), which is testing our sterile, preservative-free eyedrop (RGN-259) to treat chronic NK, a serious, non-healing lesion in the cornea. Our US joint venture partner sponsoring the trial, ReGenTree, LLC, previously reported that 7 of 17 patients in the trial completely healed. The information was very encouraging, although it was not known at the time whether the healed patients were in the RGN-259 group, placebo group, or distributed among both. We expect ReGenTree to release topline results in the next few months.

A phase 3, 700-patient clinical trial in patients with moderate to severe dry eye syndrome (ARISE-3), utilizing a controlled adverse environment (CAE®) model, is also being sponsored by ReGenTree and is being conducted at 19 sites throughout the US. ReGenTree recently reported that patient accrual is on schedule and should be completed this summer with data read-out shortly thereafter. Under the trial protocol, the primary endpoints are improvement in fluorescein staining (a sign of dry eye) and reduction of ocular discomfort (a symptom of dry eye) from baseline to Day 15. These endpoints showed statistical significance in our ARISE-2 trial, which similarly utilized the CAE® model.

Our licensee, G-treeBNT, initiated a phase 2 open clinical trial in patients with epidermolysis bullosa (EB) in the US in December 2018. The phase 2 study is evaluating RGN-137, RegeneRx's dermal gel, to accelerate and improve epithelial wound healing in these patients. Recently, the FDA modified efficacy requirements in EB patients from complete wound closing to partial wound closing, as well as other efficacy parameters, which has had a positive impact on clinical trial design and on the prospects of potential new pharmaceutical products for treatment. Results of the trial will determine the path forward for phase 3. No date has been set for its completion.

PRODUCT MARKET DISCUSSION

DRY EYE SYNDROME

The current worldwide dry eye syndrome (DES) market is estimated at well over $4 billion per year and expanding rapidly. To date, two pharmaceutical products have been approved in the US for 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, which had 2018 US sales of approximately $400 million, for up to $5.3 billion. We believe this indicates the value of the market for approved dry eye drugs and is a benchmark for the potential future value of RGN-259. We also believe RGN-259 is significantly differentiated from Xiidra® and Restasis® as RGN-259 has shown no significant toxicities or patient discomfort in over 1,000 patients treated to date and acts more rapidly than the approved dry eye drugs to alleviate the signs and symptoms of dry eye.

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

NEUROTROPHIC KERATITIS

Neurotrophic keratitis is an orphan disorder characterized by corneal lesions, most often caused by the herpes virus, some of which become chronic and highly debilitating. Most sources, including the NIH, estimate that the prevalence of NK is below 5 people per every 10,000 in the general population or approximately 175,000 people in the US. While most patients eventually heal, a small percentage develop chronic NK, the target indication for RGN-259. RGN-259 has been designated an orphan drug in the US.

EPIDERMOLYSIS BULLOSA

EB is a rare hereditary disease where patients suffer from severe skin fragility and easily blister resulting in severe pain in both the skin and mucous membranes. It is estimated that there are approximately 500,000 patients worldwide, with U.S. and European countries having approximately 50,000 patients each. No specific treatment is currently available beyond supportive care, such as sterile dressing and antibiotics. RGN-137, the Company's Tβ4-based dermal gel, has been designated an orphan drug in the US and is targeted to be the first approved product for EB treatment based on its multiple wound healing activities.

FINANCIAL MANAGEMENT AND OPERATIONS

RegeneRx has leveraged its clinical assets by engaging in product development and commercial partnerships in the US, Asia, and the EU. We have 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 what we believe is the least possible cost to the Company and dilution to stockholders. In that regard, management, the board of directors, and our strategic partners and affiliates have invested their own capital and participated in numerous offerings over the past funding cycles.

Although raising capital in small tranches is time consuming and often requires as much time and effort as a larger raise, management has chosen to take this financial path because we believe doing so is in the best interests of our stockholders. Since we are currently traded on the OTCQB, most institutional investors are not able to invest in companies not traded on an "exchange" such as NASDAQ and NYSE. Uplisting to NASDAQ, for example, would require raising $8-10 million, which would be very dilutive for a ~$30 million market cap company, especially one awaiting read outs from two phase 3 clinical trials in the near future. We are pleased to remind you that RegeneRx has never had a reverse split, which is highly dilutive and often devastating to companies and their existing stockholders.

Recently, an unaffiliated outside investor exercised its final tranche of warrants resulting in approximately $240,000 of capital received by the Company. This sum, in addition to our existing operating capital, should provide funding to continue operations through the third quarter of 2020 and data read-outs from our two phase 3 clinical trials. We will need additional funds after that time. Accordingly, we continue to evaluate opportunities to raise additional capital and are exploring various alternatives, including, without limitation, a public or private placement of our securities, debt financing, corporate collaboration and licensing arrangements.

STRATEGIC PARTNERS

We have continued with our leverage strategy to out-license development and commercialization rights to some of our product candidates to partners that have the expertise and capital to develop our drug candidates. Currently, RegeneRx has active partnerships in four major territories: the US, Greater China, Pan Asia, and the EU. In each case, the cost of development is being borne by our partners with no financial obligation for RegeneRx. We have also retained certain territorial rights to our drug candidates currently under development in order to maximize their potential value after success is achieved.

G-treeBNT (G-tree), a Korean biopharmaceutical company, is our licensee for the rights to RGN-259 in Korea, Japan, Australia and several 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 US, Canada, Pan Asia and EU for Epidermolysis Bullosa (EB).

We created ReGenTree, LLC, a US joint venture with G-treeBNT, to develop RGN-259 in the US and Canada for dry eye syndrome, neurotrophic keratitis, 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 confirmed by their efforts to date. ReGenTree, through G-tree's financial and technical support, has made a significant investment in RGN-259 development. Its success in the US and Pan Asia should enhance RegeneRx's retained rights to RGN-259 in the EU and other Eastern European and Latin American 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 and 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 and has significant influence over major decisions within ReGenTree, such as commercialization strategy, mergers, acquisitions, etc., which require unanimous board approval.

ReGenTree and G-tree are currently sponsoring two phase 3 trials with RGN-259 and one phase 2 clinical trial with RGN-137 in the US.

Lee's Pharmaceuticals, a Hong Kong-based biopharmaceutical company with extensive operations in China, previously licensed the rights to develop and commercialize our Tβ4 products in Greater China (PRC, Hong Kong, Macau and Taiwan). Lee's recently indicated that it intends to accelerate development of RGN-259 (RegeneRx's preservative-free eye drop) through its ophthalmology-focused affiliate, Zhaoke Ophthalmology, which has completed a new ophthalmic formulation and manufacturing facility in China. We are pleased that Lee's Group has developed this capability and look forward to more progress in this area. We continue to have product development discussions with Lee's to expedite the development of RGN-259 in their licensed territory.

RESEARCH AND DEVELOPMENT

During this past year, we continued to support research and development with Thymosin beta 4 (Tβ4) by working with scientists at leading academic and medical institutions in the US, Asia and Europe to conduct research intended to supplement and/or expand our clinical and basic research efforts. These researchers typically work with Tβ4 under Material Transfer Agreements (MTAs). In several cases, new patents have been issued or approved and in other cases this R&D has expanded the body of information supporting our efforts. We currently have numerous MTAs in place around the world where research teams are spending millions of dollars, which we believe to be a very important yet undervalued component of our Company.

In October 2020, our Chairman, Dr. Allan Goldstein, will co-chair the 6th *International Thymosin Symposium* in Catania, Sicily. Scientists, physicians, members of the pharma industry, and RegeneRx partners from around the world will meet over a period of three days to present new data and discuss the newest research related to Thymosin beta 4.

At the *5th International Symposium*, in Washington, DC, we were informed of a possible 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. Although the correlation is not yet confirmed, research is continuing in this area at several major institutions around the US to see if Tβ4 might be useful in the early detection and/or treatment of sepsis.

Researchers also reported that Tβ4 appeared to be 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. 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. A paper was recently published and RegeneRx had previously initiated the patent process for this indication.

While we have retained significant and novel clinical assets to develop, primarily RGN-352 (injectable formulation of Tβ4 for cardiac, CNS and other systemic disorders) in the US, Pan Asia, and Europe, and

RGN-259 in the EU, we will await the outcome of the ARISE-3 and SEER-1 trials before seeking new strategic partners. After exploring various additional strategies for RGN-352 development over the past years, we believe that prospective strategic partners are unlikely to invest in such efforts until the results of the current clinical trials are completed. Basically, partners and funders are awaiting validation of Tβ4 in the current ophthalmic clinical trials prior to considering new partnership activities related to this technology. We believe this ultimately works to our advantage if our clinical trials are positive as it should significantly increase the value of our unlicensed product candidates.

INTELLECTUAL PROPERTY

We continue to maintain a robust patent portfolio and budget a significant percentage of our operating capital for this purpose. We closely monitor our patent applications in the United States, Europe and other countries with the advice of outside legal counsel to determine if they will continue to provide strategic benefits and value for future development and/or partnering opportunities.

Most recently, we filed patents for chronic granulomatous disease (CGA), a primary immunodeficiency disorder that results from the body's inability to effectively kill fungi and bacteria that can lead to severe and recurrent infections in numerous organs. Additionally, one of our collaborators received a patent in South Korea for the treatment of diabetic-induced vascular dysfunction. Other patent prosecutions related to our licensed products have been assumed by or shared with our partners.

NEW BOARD MEMBER

Last year 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. While at Sigma-Tau and now at Leadiant, he developed proprietary technologies and guided the company through development of orphan drug designations and registration of new medical products. In his few months as a Director of RegeneRx, Dr. Noseda has been of great value in helping us evaluate current product development by our licensees and we look forward to utilizing his expertise with respect to development of our potential orphan products.

INVESTOR AND INDUSTRY CONFERENCES

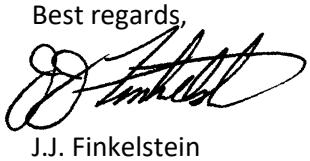
With partners sponsoring major clinical trials in the US, China and Pan Asia, and important clinical milestones on the near-term horizon, we continue to spend additional efforts on investor relations and industry meetings in order to present our story to a broader retail market and institutional investors and analysts. This effort provides an opportunity to meet with industry representatives who may be interested in new pharmaceutical products they can acquire and develop now or in the future. Over the past twelve months, we attended the *2019 Spring Investor Summit* in New York, and *The Fall Investor Summit* in New York. This year we expect to attend the *2020 Spring Investor Summit* in New York in March, the *2020 ARVO meeting* in Baltimore in May, and the 6th *International Thymosin Symposium* in Catania, Sicily, in October, which will be attended by researchers, RegeneRx partners and pharma industry representatives, and will

provide an opportunity to evaluate potential new and complementary developments with Tβ4. We will likely attend additional investor and industry meetings, as appropriate.

SUMMARY

We believe RegeneRx has a compelling combination of assets, partners, and products in 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. It continues to be our belief that the current market valuation of RegeneRx at ~$30 million is significantly below comparable companies with product candidates in much earlier stages of clinical development. Over the next few months, data read-outs from our two phase 3 ophthalmic clinical trials are expected to be announced and, if positive, we believe they will materially increase RegeneRx's market value, our ability to raise operating capital at lower cost, and our capability to further develop our other product candidates to position them for future partnership and/or licensing opportunities, all of which should benefit our stockholders.

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 and IP 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, 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.