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Dear Shareholder:

We would like to take this time to briefly update on RegeneRx's partnerships, the ARISE-2 phase 3 dry eye clinical trial, and our business activities of this past year and looking ahead. We believe we have a compelling combination of assets, partnerships, and product candidates worldwide that are in late-stage clinical development for medical disorders with unmet needs and offer the potential for significant financial returns.

As always, we reserve the right to modify our goals and expectations from time to time in accordance with clinical developments, partnering activities, access to capital markets, and the general climate in the pharmaceutical industry.

Consistent with our long-standing goals, RegeneRx has employed a strategy of leveraging clinical assets by engaging in product development through commercial partnerships. Over the past year, we have also continued to support innovative research for development of Thymosin beta 4 ("Tβ4") by working with leading academic and medical institutions in the U.S. and around the world where research exploring potential new uses of Tβ4 in various diseases and disorders is being performed.

In November, the George Washington University hosted the 5th International Symposium on Thymosins in Health and Disease. Tβ4 was the focus of much of the two-day meeting and several new and exciting targets were identified by several of our collaborators and supported with strong early data, which may offer new product opportunities for large and orphan disease populations. Patents have been recently filed for these uses while the body of data related to Tβ4 has grown significantly over the past two years and we are evaluating expanding clinical efforts into these areas via new partnerships.

EXPANSION OF STRATEGIC PARTNERSHIPS

As noted in previous letters to stockholders, we embarked on a strategy to out-license rights our product candidates in markets that would be difficult or impossible for us to develop internally. This led to the out-licensing of certain product candidates in China, Korea, Japan, Australia, and other Asian countries, among others.

With GtreeBNT Co., Ltd. ("Gtree"), a Korean pharmaceutical company, we expanded the licensing rights for RGN-137, our dermal gel product to include Canada, Europe, Japan and Australia, in addition to the U.S. Gtree is responsible for all clinical development and commercialization activities in its territories and has certain development milestones necessary to retain the license. This transaction provided

working capital to RegeneRx that was non-dilutive and designed to provide capital significantly beyond the release of results of the ARISE-2 clinical trial.

Our second partnership is with ReGenTree, the U.S. joint venture we entered into with Gtree in 2015, which licensed RGN-259 in the U.S. for the treatment of dry eye syndrome ("DES") and chronic neurotrophic keratopathy ("NK"), an orphan condition of the cornea. In 2016 we added Canada to the license agreement held by the U.S. joint venture and received a six figure sum, which was non-dilutive. No other material terms of the license agreement were modified.

For a full description of our strategic partnerships please see our most recent 10-k and 10-Q filings with the SEC.

ARISE-2 DRY EYE CLINICAL TRIAL

In October 2017 we announced top line results of our second phase 3 dry eye clinical trial, ARISE-2. Through our ReGenTree joint venture agreement, we are restricted to confidentiality on items not disclosed by ReGenTree or Gtree with respect to detailed information about the trial. However, we did report the following results provided to us by management of ReGenTree: "The ARISE-2 study, which was conducted together with Ora, Inc., demonstrated a number of statistically significant improvements in both signs and symptoms of dry eye syndrome with 0.1% RGN-259 versus placebo, while showing excellent safety, comfort, and tolerability profiles. The ocular discomfort symptom showed a statistically significant reduction in the RGN-259-treated group at day 15 as compared to placebo (p=0.0149) in the change from baseline. For sign, RGN-259 also improved the dry eye patient's ability to withstand an exacerbated condition in a patient subgroup with both compromised corneal fluorescein staining and Schirmer's test at baseline. In this population, RGN-259 showed superiority over placebo in reducing corneal fluorescein staining in the change from baseline at days 15 and 29 (p=0.0207 and 0.0254, respectively). RGN-259 confirmed its global effects on dry eye syndrome and fast onset in multiple sign and symptom efficacies with no safety issues in the ARISE-1 and ARISE-2 studies as well as in the pooled data, although ARISE-2 was not successful in duplicating the results of ARISE-1 where the study population was limited and less diversified."

What this means is that with ARISE-2 and ARISE-1, as well as our first phase 2 clinical trial, totaling approximately 1,000 patients, there is a broad and rapid onset of clinically relevant sign and symptom efficacy with no adverse effects. We believe that quick benefit of a topical dry eye drug that is well tolerated with no side effects would offer clear superiority compared to approved products and would be very welcomed in this patient population.

DES is a difficult disease to effectively treat and only one drug has been approved to treat dry eye syndrome. Meeting the historical approval standard of treating both a sign and symptom of DES and exactly repeating this outcome in successive clinical trials is a high hurdle, which, we believe is due to the multiple causes and diverse patient populations affected by dry eye syndrome. As stated by the president and CEO of ReGenTree, "we have built a strong foundation demonstrating the strengths of RGN-259 with rapid global efficacy characteristics of the drug candidate and an excellent safety, tolerability and comfort profile." Further data analysis is ongoing.

ReGenTree will meet with the FDA early in 2018 and determine the next regulatory step. Only one other pharma company has received NDA approval for a dry eye drug that treats both the signs and symptoms of dry eye and that NDA was granted by combining the clinical results from several trials to determine that there was clinically relevant efficacy.

ReGenTree continues discussions with big pharma companies interested in RGN-259. Clearly, the optimal timing for any transaction must be determined by all parties involved and affects the value of any subsequent transaction.

SEER-1 NK Clinical Trial

Through ReGenTree, we also are sponsoring a phase 3 clinical trial for NK, an orphan disease in the U.S. and EU meeting the statutory threshold of fewer than 200,000 diagnosed cases in each territory. As an orphan drug, RGN-259 would be eligible for a number of benefits including expanded exclusivity, premium pricing, and certain tax benefits. On December 31, 2013, the FDA granted orphan status for Tβ4 for the treatment of NK in the U.S. Although patients continue to be enrolled in the study, we have no current time line for completion of the phase 3 trial.

PATENTS

We have numerous patents throughout the world for our product candidates and we continue to develop our intellectual property portfolio as mentioned above. We recently received two patents in Israel and Canada for neuroprotection related to RGN-352 (injectable formulation of Tβ4 for cardiac and CNS disorders, among other possible systemic uses). We also received notification of a new U.S. patent that will be issued for the treatment of dry eye syndrome, and others have been submitted abroad. These will expand our portfolio of intellectual property related to this indication.

Our partners also have independently filed new or improved patent applications related to our product candidates, as was the case for RGN-259 this year. In these cases, the patent applications and future patents are designed to enhance our product exclusivity and/or protect other aspects of our technologies. RegeneRx retains the right to license such intellectual property for our own use in territories outside of a licensed territory, typically on a royalty-free basis, which is similar to our retained rights to any data generated by our licensees from their development of our product candidates. This, of course, could be of substantial benefit to our Company in the future.

OPERATIONS, CAPITAL 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 material financial obligation for RegeneRx.

We retain significant clinical assets to develop, primarily RGN-352 (injectable formulation of Tβ4 for cardiac and CNS disorders, among others) in the U.S., Pan Asia, and Europe, and RGN-259 eye drops in the EU.

Regarding RGN-259, our goal is to continue to wait until the results are obtained from the current U.S. clinical program before seeking a partner for the EU, which could reasonably be expected to be in conjunction with a transaction by ReGenTree. If successful, this should allow us to obtain a higher value for the asset at that time and enhance our strategy to obtain partners in currently unlicensed territories. However, as more capital is required, we may determine that licensing out RGN-259 in part or all of the EU would be in the Company's best interests.

We expect the second tranche of capital for our expanded license to RGN-137 in the EU, Canada and Japan shortly, and expect the third and final tranche related to this transaction at the end of February 2018. Based on our estimated operating budget, with the funds on hand and to be received, we believe we can support operations into Q2 2018. This estimate does not include receipt of any funds from grants, new partnerships or the raising of additional capital if the market climate warrants. We continuously monitor our cash use as well as the clinical timelines. We will need to secure additional operating capital in 2018 and are evaluating various options including the licensing of certain additional rights to commercialize our clinical products, as well as raising capital through the capital markets, either privately or publicly.

INVESTOR RELATIONS

We have been investing additional resources on investor relations in order to present our story to a broader retail investor market, as well as to institutional investors and analysts. We have attended and spoken at investor and industry conferences and authorized our investor relations firm to initiate a social media program to expand our reach. We intend to expand this initiative in 2018

We continue to believe that the market valuation of RegeneRx is far below comparable companies as well as those with product candidates in much earlier stages of clinical development. We also believe that if we can move to a national exchange, we would be able to attract a much broader group of investors, thus increasing visibility and liquidity. Moving to an exchange will require significant additional capital and will be considered at the appropriate time.

CONCLUSION

We believe we have developed a compelling combination of assets, partnerships, and products worldwide that are in late-stage clinical development for medical disorders with unmet needs and offer the potential for significant financial returns. Each clinical trial has generated new and pertinent efficacy, tolerability and safety data and, we believe, has increased the value of our company, although not yet close to a level we believe is consistent with the clinical stage and potential value of our product portfolio. We are very appreciative of the continued support of our shareholders and will be pleased to share news with you as soon as it is available.

Best regards,

J.J. Finkelstein
President & CEO

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

Forward Looking Statements

Any statements in this shareholder 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 shareholder 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 of our drug candidates, the use of our drug candidates to treat various conditions, our growth strategy, and our financial needs. 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 the trials, regulatory communications, or capital raising efforts discussed herein will be successful. 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, 2016, 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 shareholder 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.