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March 13, 2017

Dear Shareholder:

We would like to take this time to report on the business activities and accomplishments of RegeneRx in 2016 and the clinical milestones that we expect to reach in 2017. This letter will provide an update on our various partnerships, clinical trials, and operations. 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.

To continue our efficient use of capital, 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 with development of Thymosin beta 4 ("Tβ4") by working with leading academic and medical institutions in the U.S. and Europe where research intended to explore potential new uses of Tβ4 in various diseases and disorders is being performed.

PRODUCT DEVELOPMENT AND STRATEGIC PARTNERSHIPS

As noted in previous letters to stockholders, we embarked on a strategy to out-license rights to 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, and Australia, among other Asian countries. Two years ago we entered into a joint venture, ReGenTree LLC, to develop our ophthalmic assets in the U.S. Last year we expanded the joint venture territory to include Canada as further described below.

In 2012 we licensed to Lee's Pharmaceuticals, a successful and fast-growing Chinese pharmaceutical company, the rights to develop and commercialize our Tβ4 products in China, Hong Kong, Macau, and Taiwan. In return, we received an up-front licensing fee, and commercial milestone payments and a tiered royalty stream if Lee's is successful in bringing a product to market. Lee's is responsible for all clinical development and commercialization activities in their territory. We believe that the terms of this license provide RegeneRx with an opportunity for value enhancement without capital risk and dilution to stockholders. In the summer of 2014, after review of all of our FDA filings, preparation of a clinical dossier and manufacturing development, Lee's filed an IND with the Chinese FDA ("CFDA") to conduct a Phase II, dose-response study in mainland China in patients with dry eye syndrome. As many of you know, there is a growing and significant pollution problem that is often an underlying cause of dry eye and other related disorders that affects large urban populations in China. In 2015, the CFDA declined Lee's IND because the clinical trial drug product (RGN-259) was manufactured by RegeneRx outside of

China, which substantially affected the proposed start of the trial. During this past year, the CFDA reversed its ruling, which, we believe, positively affects the proposed Phase II trial. Lee's is in the process of preparing new documentation for the CFDA with the hope to initiate the clinical trial in patients with dry eye syndrome later this year.

In 2014, we licensed to G-treeBNT ("G-tree"), a Korean pharmaceutical company, the rights to develop and commercialize RGN-259 (RegeneRx's preservative-free eye drop) in Korea, Japan, Australia and a number of other countries in Asia that we refer to as the Pan Asian rights. These rights exclude China, Hong Kong, Macau, and Taiwan, which are held by Lee's. In return, we received an up-front licensing fee and G-tree purchased equity in RegeneRx equaling approximately 18% of our outstanding common stock. We also licensed G-tree the rights to develop RGN-137 (RegeneRx's dermal wound healing product) in the U.S. for epidermolysis bullosa ("EB"), an inherited orphan indication causing blistering of the skin. Most recently G-tree received the green-light from the FDA to begin a 200 patient, randomized, double-blind, placebo-controlled, Phase III trial of RGN-137 in the U.S. G-tree informed us that it plans to initiate this trial in Q3 of 2017.

G-tree has assembled an impressive team with strong product development expertise in the pharmaceutical industry in Korea and believes that if RGN-259 and/or RGN-137 are approved in the U.S., it will not have to conduct additional clinical trials in Korea and will be able to obtain Korean marketing approval based on the U.S. clinical data.

In January of 2015, we entered into a joint venture with G-tree ("ReGenTree LLC"), 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. We chose to enter this venture 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. In 2016 we added Canada to the U.S. joint venture for a sum of $250,000. No other terms of the JV were modified.

We believe the joint venture is a uniquely appropriate structure within which to develop RGN-259. RegeneRx currently owns 42% of the equity of ReGenTree while G-tree will earn additional equity based on achieving critical developmental milestones. In addition to the equity stake, RegeneRx will also receive a single to double digit royalty on commercial sales by ReGenTree. We estimate RegeneRx's equity ownership in ReGenTree, in addition to our royalty rights, will result in a share of the eventual commercial value of the joint venture of approximately 40% (if ReGenTree's rights to RGN-259 are licensed or sold to a third party or if it is commercialized internally through the joint venture). We estimate that the cost for development of RGN-259 for NK and dry eye syndrome in the U.S. is $25 - $30 million and we structured the joint venture so that RegeneRx has no financial obligations throughout the entire development process through receipt of NDA approval. Moreover, RegeneRx retains significant control over major decisions within ReGenTree, such as commercialization strategy, mergers, acquisitions, etc. Given the rapidly increasing value of the dry eye market in the U.S., we believe this is an excellent 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.

IMPORTANT CLINICAL MILESTONES ANTICIPATED IN 2017

During 2017 we and our partners expect to reach several clinical milestones that we believe should add significant value to RegeneRx.

- In the U.S., we expect the completion of ReGenTree's Phase III trials in dry eye syndrome and neurotrophic keratopathy, although NK may take longer due to the small pool of patients.
- In China, based on our discussions with Lee's Pharmaceuticals, we believe initiation of Lee's Phase II clinical trial in dry eye will happen this year;
- In the U.S., our partner, GtreeBNT, is planning a Phase III, 200-patient, randomized, placebo-controlled trial of RGN-137 in patients with EB in the third quarter of 2017.

MARKET FOR RGN-259 IN THE U.S. AND CHINA

The market to treat dry eye syndrome is large and growing. The current worldwide dry eye market is estimated to be well over $2 billion per year and continues to rapidly expand. To date, two pharmaceutical products have been approved in the U.S. for dry eye syndrome and the market is well over $1 billion.

With one of the approved drugs, patients often experience burning and stinging from its use, which commonly takes six months until efficacy is seen. The package insert indicates that clinical trials have demonstrated that the product is effective in 15% of patients vs. 10% for placebo.

With the other approved drug, the most common side effects are irritation, discomfort, dysgeusia (foul taste in mouth) and decreased visual acuity. The drug is to be used for twelve weeks.

In contrast, clinical data for RGN-259 shows that its effects are achieved within days, that there is no burning or stinging and that it can significantly improve both the signs and symptoms of dry eye, which represent the current standards required by FDA for approval of new products for dry eye.

In China, a quickly expanding economy has led to severe pollution and to a rapidly expanding incidence of dry eye symptomology among its urban population. It is believed that the market share for drugs for these indications is around 36% of China's ophthalmic drug market with an estimated market value of approximately $1.7 billion in 2012 and a projected growth rate of 12% annually through 2020.

NK is 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.

PATENTS

We have numerous patents throughout the world for our product candidates and we continue to develop our intellectual property portfolio. As we constantly monitor our portfolio, we sometimes pare

down any patents or patent applications that we do not feel are pertinent to our or our partners' product interests. In some cases, our partners have independently filed new or improved patent applications related to our product candidates, as has recently been the case for RGN-259. 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, FUND-RAISING 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.

We still have significant clinical assets to develop, primarily RGN-352 (injectable formulation of Tβ4 for cardiac and CNS disorders) in the U.S., Pan Asia, and Europe, and RGN-259 in the EU. We are also seeking to out-license RGN-137 in Asia and Europe. Our goal is to wait until the results are obtained from the current clinical trials before seeking a partner for the EU for RGN-259. 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.

On June 27, 2016, we entered into a Securities Purchase Agreement with an institutional investor pursuant to which we agreed to sell an aggregate of 5,147,059 shares of common stock and warrants to purchase 5,147,059 shares of common stock. We received approximately $1,520,000 in net proceeds from the 2016 offering. These funds have been used for general operating expenses including intellectual property development and maintenance, regulatory compliance, SEC and OTC filings, legal and accounting, and investor relations, among others.

As of September 30, 2016, we had approximately $1.1 million in cash. Based on our preliminary operating budget, we believe we have funds to last into approximately the beginning of Q4 2017. 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 2017 and are evaluating options including the licensing of certain additional rights to commercialize our clinical products, as well as raising capital through the capital markets. One possibility would be to file an S-1 registration statement to be prepared to sell shares to investors at an appropriate opportunity, ideally when our clinical trials are successfully completed.

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 continue to expand this initiative as we move closer to completion of our Phase III clinical trials.

It is our belief that the market valuation of RegeneRx at approximately $32 million 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 effectively present RegeneRx as a company that has worldwide product opportunities, is 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. 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 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 in a relatively short period of time. In 2017, RGN-259 should be reaching important milestones with the completion of our Phase III trials in the U.S. for patients with dry eye syndrome and the orphan eye disease, NK. We are encouraged that the positive changes in the Chinese FDA's regulations will allow our partner to initiate its Phase II trial for dry eye syndrome in China and are pleased that GtreeBNT has been given the permission from the U.S. FDA to begin the first Phase III trial of RGN-137 in patients with EB.

We believe each successful trial will generate attention and enthusiasm among patients, physicians, and investors and help increase the value of our company 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 are pleased to share our recent good news with you.

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. The proposed clinical trials and costs and resources to support 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 the trials discussed herein 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, 2015, 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.