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February 17, 2015

Dear Shareholder:

Having just completed a very important licensing and joint venture agreement to more rapidly move our ophthalmic drug candidate forward in the U.S., we would like to take this time to report on the status of RegeneRx and the exciting prospects for both the short term and long term future of our company. This letter is intended to be a top-line synopsis, rather than a comprehensive analysis, of the various partnerships in which we are engaged as well as our operations and future direction. We will also identify key clinical milestones and inflection points from now through 2016. We reserve the right to modify our goals and expectations from time to time in accordance with clinical development, partnering activities, access to capital markets, and the general climate in the pharmaceutical industry.

For the past several years, RegeneRx has been implementing a strategy to leverage our clinical assets by engaging in product development and commercial partnerships, given our limited access to capital. During this period, we continued to support research and development with Thymosin beta 4 (Tβ4) by working with more than 50 leading academic and medical institutions in the U.S. and Europe to conduct research intended to supplement and/or expand our clinical efforts. As a result, our clinical progress and partnering activities have progressed in a manner that now enables us to move expeditiously toward product commercialization.

PRODUCT DEVELOPMENT AND COMMERCIALIZATION DEALS

In an effort to expedite product development, while mitigating risk, in 2012 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, as well as in the U.S.

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, the right to 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; therefore, we believe RegeneRx has an opportunity for value enhancement without capital risk to RegeneRx or 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 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 affect large urban populations in China. Lee's is awaiting regulatory approval to begin the study, which they expect to receive soon.

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, totaling $2,350,000. 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. G-tree has assembled an impressive team with strong product development expertise in the pharmaceutical industry in Korea.

It is important to recognize the complexity of development activities in moving a drug candidate from Phase II to Phase III, whether in Asia or in the U.S., including optimizing 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. I'm pleased to report that G-tree has been vigorously, and successfully, performing this work in preparation for clinical trials in Korea. Moreover, this effort will now be very important for development of RGN-259 in the U.S., as discussed below. In December 2014, G-tree filed an IND for a Phase IIb/III clinical trial for RGN-259 in Korea and is expected to enroll patients later this year.

In January of 2015, we created a joint venture with G-tree (ReGenTree LLC) to develop RGN-259 in the U.S. for dry eye syndrome (DES) and neurotrophic keratopathy (NK), an orphan condition of the cornea. 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 in Korea. Moreover, much of the manufacturing work discussed above is directly applicable to commercialization of RGN-259 in the U.S. so many of the tasks are completed and will not have to be replicated, saving a significant amount of time and money.

We believe the joint venture is a uniquely appropriate structure within which to develop RGN-259. RegeneRx will own a significant portion of the equity of ReGenTree while G-tree will earn additional equity based on achievements of critical developmental milestones. We will receive an up-front payment of $1 million, payable in two tranches: (i) within forty-five business days after closing and (ii) within forty-five business days after enrollment of the first patient in an ophthalmic trial in the U.S. 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 our royalty rights, will result in a share of the eventual commercial value of the joint venture of 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 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, and there is no sale of RegeneRx equity associated with this partnership. Moreover, RegeneRx has significant control over major decisions within ReGenTree, such as commercialization strategy, mergers, acquisitions, etc. Given that the value of the dry eye market in the U.S. is approaching a billion dollars per year, 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.

CRITICAL CLINICAL MILESTONES

During the next 24 months we and our partners expect to reach numerous clinical milestones in countries throughout the world, all of which we believe should add significant value to RegeneRx.

- In China, we expect initiation of Lee's Phase II clinical trial in dry eye before Q3 of this year with results in late 2015 or early 2016;
- In Korea, we expect initiation of G-tree's Phase IIb/III trial in dry eye this year with results in 2016;
- In the U.S., we expect initiation of ReGenTree's Phase III trial in neurotrophic keratopathy this year with results in late 2015 or early 2016;
- In the U.S., we expect initiation of ReGenTree's Phase II trial in dry eye later this year with results in 2016.

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

The current worldwide dry eye market is estimated at $1.9 billion per year, expanding to $2.8 billion by 2017. To date, only one pharmaceutical product has been approved in the U.S. for dry eye syndrome and commands annual sales exceeding $700 million. Patients often experience burning and stinging from use of the drug, which commonly takes six months of use 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.

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 in its urban areas and to a rapidly expanding incidence of dry eye symptomology among its 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 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, the NK 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. On December 31, 2013 the FDA granted orphan status for Tβ4 for the treatment of NK in the U.S.

OPERATIONS AND FUTURE PLANS

Currently, RegeneRx has active partnerships in three major territories: the U.S., China and Pan Asia. Our partners have been moving forward and making significant progress in each territory and are prepared to initiate their clinical trials programs this year. 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 data should be forthcoming in months, not years, after patients begin enrollment. We, therefore, should be able to maintain our existing operations at the current level while we await results from these trials and continue to seek additional partnership opportunities.

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. Our goal is to wait until the results are obtained from the current ophthalmic clinical trials before moving into the EU with RGN-259. If successful, this should allow us to obtain a higher value for the asset at that time. However, we intend to continue to develop RGN-352, either by obtaining grants to fund a Phase IIa clinical trial in the cardiovascular or central nervous system fields or finding a suitable partner with the resources and capabilities to develop it as we have with RGN-259.

Our current cash, together with the payments we expect to receive under our recent joint venture total approximately $1.7 million. Based on our preliminary operating budget, we believe we have funds to last well into 2016. This estimate does not include receipt of any funds from grants, new partnerships or the raising of additional capital if the market climate warrants.

INVESTOR RELATIONS

Now that we have partners with significant ongoing efforts and resources in the U.S., China and Pan Asia and important clinical milestones on the near-term horizon, we intend to spend additional effort on investor relations in order to present our story to a broader retail market, as well as to institutional investors and analysts. It is our belief that the market valuation of RegeneRx at $15-$20 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 in advanced clinical trials for both large markets and orphan disorders, with near term clinical milestones and little financial risk to RegeneRx, we would 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 late stage clinical development worldwide for medical disorders with unmet needs that offer the potential for significant revenue generation in a relatively short period of time. Starting this year, and over the next twenty-four months, RGN-259 should be reaching important milestones starting with the initiation of a Phase III trial in the U.S. for the orphan eye disease, NK, a Phase IIb/III trial in Korea for dry eye, and a Phase II dose response trial in China also for dry eye, all of which should be completed and producing patient data within months of enrollment of the first patients. We believe each trial will generate attention and enthusiasm among patients, physicians, and investors and, upon success, help 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 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 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, 2013, 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.