Zacks Small-Cap Research

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RegeneRx Biopharma, Inc. (RGRX-OTC)

RGRX: Focusing Remains On Dry Eyes With TB4…

Current Recommendation	**Neutral**
Prior Recommendation	N/A
Date of Last Change	04/24/2011
Current Price (08/16/11)	$0.19
Target Price	**$0.50**

UPDATE

We recently initiated coverage of RegeneRx with a 'Neutral' rating. Despite the fact that we are intrigued by the potential to develop multiple therapeutic applications with Thymosin β4, we believe more data is necessary.

The lead development program is RGN-259 for dry eyes and neurotrophic keratitis (NK). Management initiated a phase 2 program in patients with dry eyes in late July 2011. Data from this trial should become available in October 2011. We expect management to seek to raise cash to support this trial in the near-term, and then strike a development partnership later in 2011 to push the candidate into phase 3.

Our target, based on DCF, is $0.50.

SUMMARY DATA

52-Week High	**$0.35**
52-Week Low	**$0.18**
One-Year Return (%)	**-33.31**
Beta	**1.57**
Average Daily Volume (sh)	**59,104**
Shares Outstanding (mil)	**80**
Market Capitalization ($mil)	**$16**
Short Interest Ratio (days)	**0.08**
Institutional Ownership (%)	**8**
Insider Ownership (%)	**5**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2011 Estimate	**N/A**
P/E using 2012 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	0 A	0 A	0 A	0.0 A	0.0 A
2011	0.6 A	0.6 A	0.2 E	0.2 E	1.6 E
2012					1.5 E
2013					0 E

Earnings per Share
(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	-$0.03 A	$0.00 A	-$0.01 A	-$0.00 E	-$0.03 E
2011	-$0.02 A	-$0.02 A	-$0.02 E	-$0.02 E	-$0.09 E
2012					-$0.09 E
2013					-$0.11 E

Zacks Projected EPS Growth Rate - Next 4 Years % **N/A**

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INVESTMENT THESIS

We recently initiated coverage of RegeneRx with a 'Neutral' rating at $0.50 price target. Despite the fact that we are intrigued by the potential to develop multiple therapeutic applications with Thymosin β4, we believe more data is necessary. The lead development program is RGN-259 for dry eyes and neurotrophic keratitis (NK). Preclinical animal data yielded some impressive results in NK and various forms of dry eyes. So much so, that the product was tested in compassionate use studies that demonstrated the ability of RGN-259 to repair and regenerate corneal tissue. We believe that RGN-259 may provide a novel approach to the treatment of patients with corneal defects. It offers a potential competing or complementary therapy to Allergan's Restasis (cyclosporine ophthalmic), an estimated $700 million drug in 2011. In fact, the drug has demonstrated statistical superiority to Restasis in earlier testing. Management initiated a phase 2 study with Ora, Inc., one of the world's leading ophthalmic research firms, in late July 2011. Preliminary data from this trial is expected in October 2011, followed up full data late 2011 or early 2012. This could allow management to strike a development partnership with a larger ophthalmic-focused pharmaceutical firm for phase 3. We note that RegeneRx presented encouraging preclinical data on RGN-259 at the 2011 Association for Research in Vision and Ophthalmology (ARVO) meeting in Ft. Lauderdale on May 3, 2011. Management used the ARVO meeting as a kick-off for partnership discussions with RGN-259.

…Waiting For Clinical Validation...

Research has demonstrated diverse biologic activity for Thymosin β4. Research shows the 43-amino acid peptide that plays a vital role in cell structure and motility and in the protection, regeneration, remodeling and healing of tissues. These effects have suggested a range of possible therapeutic applications, and several have been extended to animal models and human clinical trials. We believe the science and theory around Tβ4 is solid. Drug candidates developed around various formulations of Tβ4 have the potential to be disease modulators. For indications such as AMI, MS, dry eyes, and cystic fibrosis, this is enormously exciting, as most of the approved drugs for the aforementioned indications only target symptom relief. We believe proof-of-concept has been demonstrated by RegeneRx with RGN-352 in AMI, and with RGN-259 in neurotrophic keratitis and dry eyes. The potential is there for other Tβ4 formulations in epidermolysis bullosa (EB), multiple sclerosis (MS), and cystic fibrosis (CF) as well. What we need to see is pivotal data in large-scale, randomized, placebo-control trials that can be used for registration approval. We think the market will remains skeptical until this data has been presented.

Valuation

RegeneRx's stock looks vastly under-valued at today's price. The current market capitalization of only $15 million massively discounts the potential for drug such as RGN-352, RGN-259, and RGN-137. Indications such as dry eye, AMI, MS, CF are multi-hundred million dollar indications, even potential blockbuster indications depending on the success of the phase 3 trials. The market clearly does not see a blockbuster in RegeneRx' pipeline or else the stock would not be trading at $0.20 with a market capitalization of only $15 million. Instead, the market is skeptical, and sees only un-proven programs and a need to raise cash with committed equity financings later in 2011.

We see the dry eye program as the lead value generator right now. Animal model data on RGN-259 has been very encouraging, and dry eye represents a relatively low-cost, expedited route to market. We remind investors that Allergan's Restasis sold $621 million in 2010, and Restasis does little to correct the underlying cause of dry eye disease. Dry eye affects an estimated 20 to 30 million people in the U.S., and 25% of patients who visit ophthalmic clinics report symptoms of dry eye. It is one of the fastest growing segments of the pharmaceutical industry. We believe the dry eye and NK programs alone are worth more than the current market capitalization.

The AMI and MS programs with injectable RGN-352 are a bit of a wildcard. The clinical hold on the phase 2 AMI program due to manufacturing issues at the company's contract vendor have forced management to push RGN-352 to the back-burner. We expect it to stay there until additional funds are secured. Accordingly, the market is assigning little value to RGN-352 at this point. We believe if management can get this program back up and running at some point, it could provide meaningful upside to shareholders.

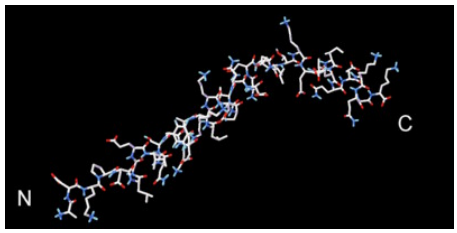
Our DCF model, which incorporates an aggressive discount rate and hearty skepticism on the pipeline, still show the shares as 200% under-valued. Our target is $0.50.

OVERVIEW

RegeneRx is a clinical-stage biopharmaceutical company engaged in the design, research and development of novel peptides targeted at diseases with unmet medical needs. RegeneRx's mission is to research and develop novel pharmaceuticals that protect, repair, and regenerate tissue and organ damage caused by disease, trauma or other pathology. RegeneRx acquired the rights to a novel peptide from the National Institutes of Health (NIH) in 1999. This intellectual property for Thymosin Beta 4 (Tβ4) allowed the company to direct its focus on tissue protection, repair, and regeneration in multiple disease indications. RegeneRx's management team is focused on moving three distinct Tβ4-based drug candidates through the clinic: RGN-137, RGN-259 and RGN-352. RegeneRx also holds over 150 issued patents and filed patent applications worldwide in order to enable and protect multiple indications and applications for its product candidates. In addition to Tβ4, RegeneRx is developing Tβ4 peptide fragments for cosmeceutical applications, separate and distinct from the pharmaceutical peptide and formulations. RegeneRx intends to pursue strategic business relationships to develop these smaller peptides for the cosmeceutical market.

Thymosin Beta 4 (Tβ4)

Thymosins are small unstructured polypeptides present in animal tissue with diverse biological activity. They were originally isolated from bovine thymus glands in the mid 1960s, but are found in many other types of tissue. Dr. Allan L. Goldstein, RegeneRx founder and current Chairman of the Board of Directors and the Chief Scientific Advisor, was integral in the discovery and characterization of thymosins, including Thymosin Alpha 1 (Tα1) and Thymosin Beta 4 (Tβ4).



Unstructured β-Thymosin

Tβ4 is a naturally occurring 43-amino acid peptide that plays a vital role in cell structure and motility and in the protection, regeneration, remodeling and healing of tissues. Research has demonstrated diverse biologic activities with intracellular concentrations that may reach as high as 0.5 mM. Tβ4 acts as the major G actin-sequestering molecule and shows a remarkable range of effects when added to the medium surrounding cells in culture. Preclinical data suggests that Tβ4 has a general role in tissue repair. This activity related to tissue repair may depend on interactions with intra- or extracellular receptors quite distinct from actin and possibly including receptors with extracellular recognition domains. These effects have suggested a range of possible therapeutic applications, and several have been extended to animal models and human clinical trials.

…A New Approach…

Although it is recognized that wound healing is a complex process, most companies working to develop new drugs in this area have focused primarily on the development of growth factors to stimulate healing and have, to date, met with only limited success. Unlike growth factors, numerous preclinical animal studies, published by independent researchers, have identified several important biological activities involving Tβ4 that we believe make it potentially useful as a wound healing, repair and tissue regenerating agent. These activities include:

- Progenitor (Stem) Cell Differentiation: Research published in the journal Nature in November 2006 featured the discovery that Tβ4 is the key signaling molecule that triggers adult epicardial progenitor cells, or EPCs, to differentiate into coronary blood vessels. EPCs are partially differentiated stem cells that can further differentiate into specific cell types when needed. Animal (both mice and pig) studies demonstrate the interaction of Tβ4 with EPCs results in the formation of cardiomyocytes that repair damaged myocardium.

Confirmatory research published in 2009 in the Journal of Molecular and Cellular Cardiology (MCC) concluded that Tβ4 is responsible for the initiation of the embryonic coronary developmental program and EPC differentiation in adult mice. These publications confirm that Tβ4's interaction with EPCs is necessary for the maintenance of a healthy adult animal heart, as well as normal fetal animal heart development. Similar research in the area of brain tissue was published in the journal Neuroscience in September 2009. This publication concluded that Tβ4 triggered the differentiation of oligodendrocyte progenitor cells to form myelin-producing oligodendrocytes, which led to the remyelination of axons in the brain of mice with experimental autoimmune encephalomyelitis (EAE).

- Actin Regulation: Tβ4 regulates actin, which comprises up to 10% of the protein of non-muscle cells in the body and plays a central role in cell structure and in the movement of cells. Research studies have indicated that Tβ4 stimulates the migration of human keratinocytes, or skin cells, human endothelial cells, and progenitor cells. Endothelial cells are the major cell type responsible for the formation of new blood vessels, a process known as angiogenesis. Certain of these studies conducted at the National Institutes of Health (NIH) were the first to suggest the role of Tβ4 in wound healing. We remind investors that RegeneRx in-licensed the rights to Tβ4 from the NIH in 2001.

- Reduction of Inflammation: Research has shown that Tβ4 is a potent anti-inflammatory agent in skin cells and in corneal epithelial cells in the eye. Tβ4 has also been shown to decrease the levels of inflammatory mediators and to significantly reduce the influx of inflammatory cells in the eye and re-perfused heart of animals. Preclinical research suggests that Tβ4 blocks activation of the NFκB pathway, which is involved in DNA activation of inflammatory mediators, thereby modulating inflammation in the body. This anti-inflammatory activity may explain, in part, the mechanism by which Tβ4 appears to improve functional outcome in the mouse model discussed above in which remyelination of axons in the brain of mice with EAE multiple sclerosis was observed. The mechanism suggests utility in additional therapeutic applications for inflammation-related diseases, such as cancer, osteoarthritis, rheumatic diseases, autoimmune diseases, pulmonary disease, and pancreatitis.

- Collagen and Laminin-5 Stimulation: Tβ4 possesses a number of additional biological activities shown to reduce inflammation, stimulate the formation and organization of collagen, and up-regulate at then gene level the expression of laminin-5, a subepithelial basement membrane protein. Basement proteins anchor down the epithelium to its loose connective tissue underneath through substrate adhesion molecules (SAMs). The basement membrane acts as a mechanical barrier, preventing malignant cells from invading the deeper tissues. These proteins are also essential for angiogenesis. Therefore, both collagen and laminin-5 are central to healthy tissue development and the prevention of disease.

- Apoptosis. Tβ4 has been shown to prevent apoptosis, or programmed cell death, in two animal models and in two tissue types. In the rodent model, corneal apoptosis, or loss of corneal epithelial cells leading to corneal epithelial thinning, was prevented through topical administration of Tβ4, and in the heart muscle of ischemic animal models, such as in mice and pigs, cell death was prevented by the systemic administration of Tβ4.

RegeneRx believes that the various biological activities of Tβ4 work together to play a vital role in the healing and repair of injured or damaged tissue. This suggests that Tβ4 is an essential component of the tissue protection and regeneration process that may lead to many potential medical applications. The company's clinical and preclinical pipeline is based on Tβ4, manufactured as a synthetic copy of the naturally occurring peptide and formulated for various routes of administration and applications.

…Intellectual Property…

RegeneRx holds approximately 150 issued patents and filed patent applications worldwide within 14 patent families. These patients cover peptide compositions, uses and formulations related to dermal and ophthalmic indications and other organ and tissue repair and regenerative medicine activities, as well as for cosmetic and consumer applications with Thymosin beta-4 and its related fragments. These include Tβ4 patents licensed from the NIH issued in the U.S., Europe, and Asia. These patents begin to expire in July 2019. The company has also licensed all rights to Tβ4 applications in respiratory distress syndrome and septic shock from The George Washington University (GWU), for which, if commercialized, RegeneRx will pay GWU a 4% royalty on sales in these areas. RegeneRx has filed numerous additional U.S. and international patent applications covering various compositions, uses, formulations and other components of Tβ4.

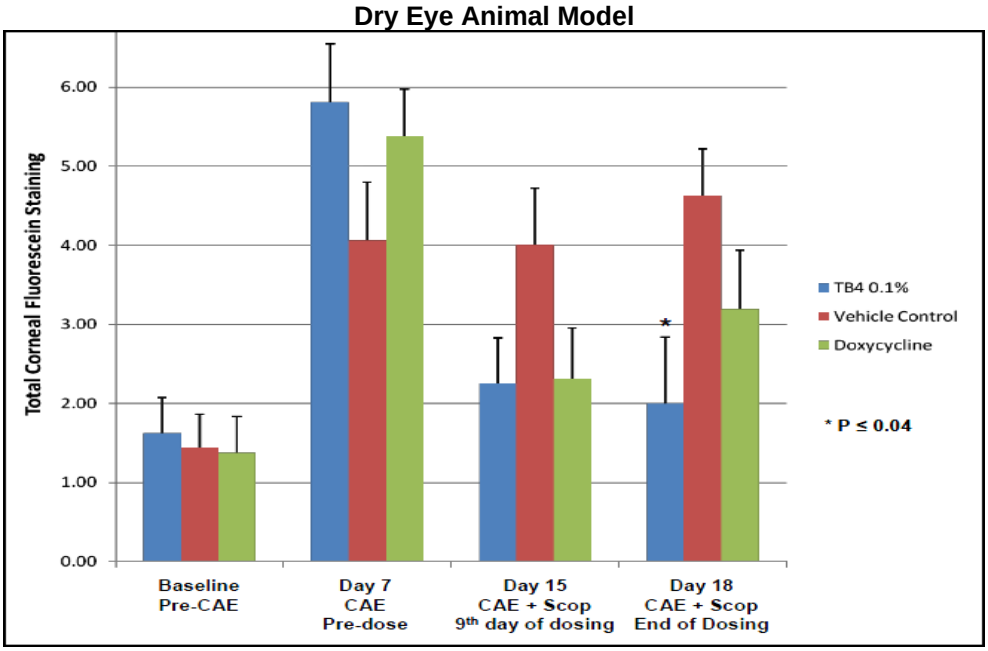
RGN-259 For Ophthalmic Indications



RegeneRx's is developing RGN-259, a sterile, non-steroidal, preservative-free, topical eye drop formulation of Tβ4 for ophthalmic indications such as neurotrophic keratitis (NK), a degenerative disease of the corneal epithelium and stroma, and various forms of dry eye syndrome. Tβ4 has already been studied successfully in compassionate use trials for NK. Additionally, preclinical studies in an animal model of dry eye have provided a scientific rationale to study RGN-259 in human clinical trials. RGN-259 offers potentially the lowest-cost / quickest path to market for the company's Tβ4 pipeline.

…Preclinical…

RegeneRx has generated significant preclinical data suggestive of utility for use in dry eyes. Given this data along with previous phase 1 safety work conducted with RGN-352 (injectable for systemic delivery) and RGN-137 (topical dermal formulation), the clinical programs with RGN-259 have the potential to move quickly by bypassing phase 1 studies. The chart below shows the ability of Tβ4 to maintain eye health in animals (mice) exposed to a controlled adverse environment (CAE) study. The data also suggests that eyes treated with Tβ4 are resistant to severe dry eyes, induced by scopolamine.



Animals were subjected to CAE for 18 days. Dosing of Tβ4, vehicle (negative control), and doxycycline (positive control) started on day 7. On days 15-18 animals were injected with scopolamine to induce severe dry eye. On day 15, Tβ4 reduced corneal staining back to baseline levels. On day 18, after induction of severe dry eye by scopolamine, eyes treated with Tβ4 maintained healthy (baseline) levels when compared to the vehicle and doxycycline ($p<0.04$). A second preclinical study conducted by Ora, Inc. confirmed these encouraging findings, and even compared RGN-259 to Allergan's Restatis (0.05% cyclosporine). We note that Allergan sold $621 million in Restasis in 2010. The data showed treatment with RGN-259 resulted in a statistically significant improvement in corneal healing at completion. Preclinical data from these studies was presented at the 2011 Association for Research in Vision and Ophthalmology (ARVO) meeting in Ft. Lauderdale on May 3, 2011.

Restasis is a used to increase the eyes' ability to produce tears, which may be deficient in patients with ocular inflammation. It effectively masks the symptoms of dry eyes, but does not go after the underlying cause of the disease. It's a step-up from OTC dry eye products like Refresh, but does not heal corneal surface defects such as ulcerations or neurotrophic keratitis (NK). Despite its limitations, for 2011, Allergan sees Restasis sales between $680 and $710 million. We think there is a significant unmet medical need for a product like RGN-259, a potential disease modifier, to treat dry eye patients where Restasis fails. At the very least, the RGN-259 my find use in combination with Restasis to improve tear production and corneal healing.

…Compassionate Use…

RegeneRx has conducted compassionate use studies in a total of ten patients that clearly demonstrated the ability of RGN-259 to repair and regenerate corneal tissue.

In the first compassionate use study, a middle-aged diabetic woman had undergone corneal epithelial debridement during surgery. The resultant corneal defect had not healed for 23 days prior to treatment with RGN-259. Typically, these wounds heal within a few days after surgery. Following treatment with RGN-259, the patient experienced reduced ocular irritation and the wound fully healed within 11 days (Figure-1).

In the second compassionate use (open label) study, a corneal specialist treated nine patients divided into two groups. All nine patients were treated with RGN-259 for periods of up to 49 days

- The first group consisted of six patients with a single non-healing eye ulcer resulting from neurotrophic keratitis (NK), a rare degenerative corneal disease commonly caused by the herpes zoster virus and induced by a nerve impairment resulting in painful corneal lesions that can lead to blindness. The NK patients evaluated had defects that had not healed for at least six weeks and in some cases for several years.

- The second group consisted of three patients with diffuse punctate erosions, corneal defects that appear as numerous small pinhole-sized lesions.

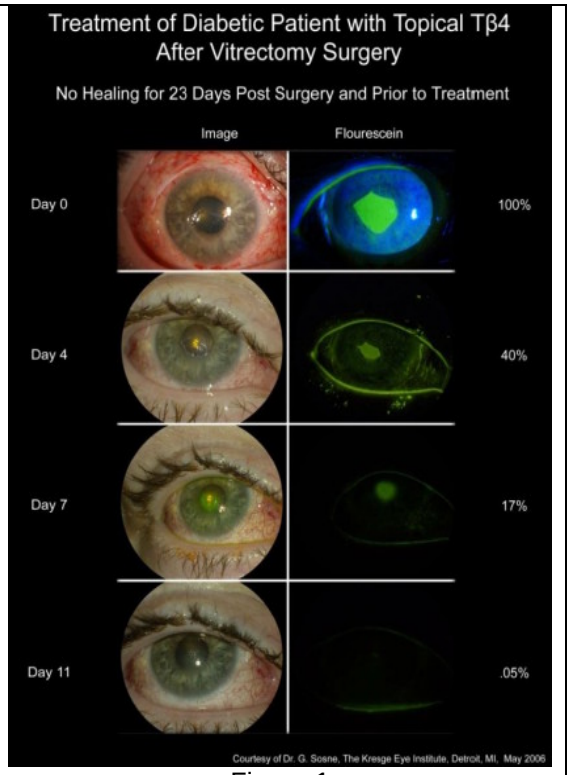


Figure-1

The six NK patients with single non-healing ulcers showed clinically significant improvement during the treatment with RGN-259 and the follow-up period, with four of the six patients healing completely. The completely healed ulcers remained healed during the follow-up period, and those that had demonstrated significant improvement continued to improve after completion of treatment with RGN-259. The three patients with diffuse punctate erosions demonstrated no significant improvement, although they did report reduced ocular irritation.

…Phase 2…

In a double blind, placebo-controlled, phase 2 clinical trial in patients with diabetic vitrectomy, RGN-259 was tested to see if it could accelerate post-surgical healing. Diabetic vitrectomy patients are a notoriously difficult to treat population. The trial was closed after enrollment of the low dose group because of slow patient accrual due to the fact that the procedure was being replaced by newer procedures not requiring removal of a cornea flap. Despite the study stopping early, management saw encouraging trends in the low-dose cohort: immediate reduction of irritation and inflammation along with thickening of corneas (cell and flare), all indicative of corneal re-epithelialization and wound healing and consistent with known properties of Tβ4.

The next step for the company is to conduct another phase 2 trial in patients with dry eyes. The trial will be a randomized, double-masked, placebo-control, “CAE” study designed to evaluate the safety and efficacy of RGN-259 to reduce inflammation and repaid corneal surface damage in patients with dry eyes. RegeneRx plans to conduct the study with Ora, Inc., one of the world’s largest ophthalmic clinical research firms. The trial initiated in July 2011. We expect it to take about 2 months to enroll the target number of 30 patients per arm. The primary assessments of the trial will be corneal staining, conjunctival staining, tear film breakup time, inflammation, eye irritation (burning / stinging), and blinking rate at the end of 28 days of treatment with RGN-259 or placebo. We expect top-line data to become available in October 2011. We view this as a relatively quick and low cost trial to run for RegeneRx. The total cost should be around $1.5 million. Following this proof-of-concept data, we would expect management to be able to secure a develop partnership with a larger firm focused on ophthalmology for phase 3.

We are optimistic on the potential for RGN-259. In all patients treated to date, RGN-259 has been well-tolerated, and there have been no drug-related adverse events. Based on preliminary findings, RegeneRx believes that RGN-259 may provide a novel approach to the treatment of patients with corneal defects and neurotrophic keratitis (NK). A product that provides disease modifying characteristics (epithelial healing / inflammation reduction) vs. just symptom masking could have significant market potential. RegeneRx is also collaborating with the U.S. military to evaluate the potential of RGN-259 to prevent or reduce eye damage caused by chemical warfare agents.

We expect RegeneRx to seek strategic partners with core-focuses on the ophthalmic market, as well as seek federal funding for expanded research with Tβ4 in this area. The global market for dry eye disorders was $1.9 billion in 2010. As noted above, Restasis posted sales of $621 million in 2010. Management estimates the market for dry eye therapeutics will hit $2.8 billion in size by 2017.

RGN-352 For Cardiovascular Indications

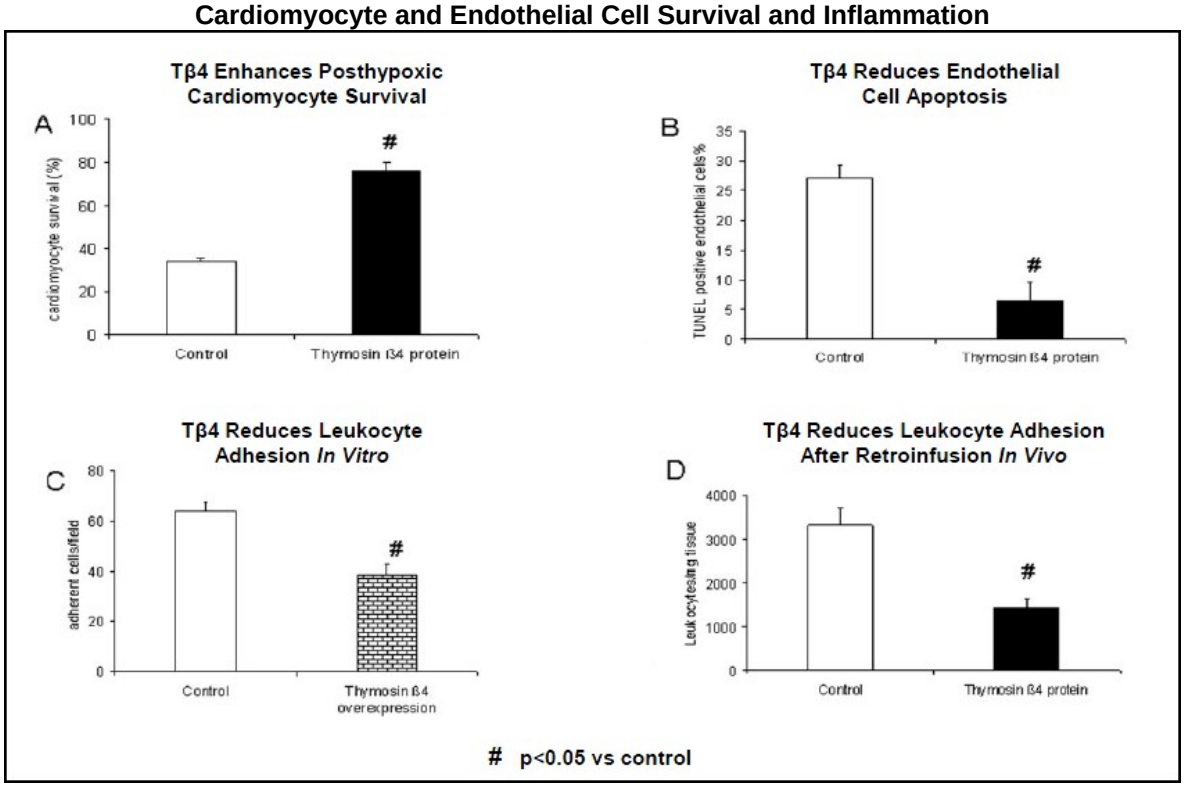


RegeneRx's lead product candidate, RGN-352, is an injectable formulation of Tβ4 for systemic administration. The company has initially targeted RGN-352 for patients who have suffered an acute myocardial infarction (AMI). Preclinical research published in 2007 in the scientific journal *Nature* (Jan 11;445(7124):177-82), showed that Thymosin β4 induces adult epicardial progenitor mobilization and neovascularization, and indicates that Tβ4 can guide specific types of stem cells from the outer layer of the heart to generate new myocardial blood vessels and tissue at injured sites.

…Preclinical Models…

RegeneRx has significant preclinical data suggestive of clinical efficacy for Tβ4 in humans. One study published in 2004 in *Nature* (Nov25:432(7016):466-72) demonstrated significantly improved ventricular function in mice. The data showed a 65% improvement in fractional shortening and a 100% improvement in ejection fraction at 4 weeks. The same study showed the ability of Tβ4 to reduce heart muscle damage after injury with a 53% reduction in scar volume. In April 2008, data was published in *Circulation* (29;117(17):2232-40) demonstrating Tβ4 is an essential paracrine factor of embryonic endothelial progenitor cell-mediated cardioprotection. The data is presented below:

Cardiomyocyte and Endothelial Cell Survival and Inflammation



Conclusions from the preclinical program on RGN-352 include:

- ✓ Tβ4-treated neonatal cardiomyocytes migrate further, beat more rhythmically, more rapidly and more vigorously, and survive for up to 28 days vs. 7-14 days compared to the controls.
- ✓ Tβ4 showed a statistically significant improvement in myocardial function and reduction in scar volume when administered immediately following coronary artery ligation in mouse models.
- ✓ Tβ4 improved survival post-AMI by 70% in mouse models.
- ✓ Tβ4 reduced infarct size, increased subendocardial shortening and dP/dTmax in an ischemia reperfusion pig model, and deemed responsible for all aspects of coronary vessel development in a cardiac-specific mouse Tβ4 knock-down model.
- ✓ Tβ4 shown to essentially replicate eEPC-mediated cardioprotection
- ✓ Tβ4 supports cardiac regeneration by inhibiting myocardial cell death after infarction, inducing vessel growth and myocardial progenitor mobilization and by organ-wise activation of the embryonic coronary development program in adult epicardium *in vivo*.

…Phase 1…

In 2009, management completed a phase 1 clinical trial evaluating the safety, tolerability and the pharmacokinetics of the intravenous administration of RGN-352. The trial was designed to explore the use of RGN-352 in other indications in which acute administration of Tβ4 may be warranted. The trial was conducted in two consecutive parts, referred to as phase 1a and phase 1b, both of which were double-blind, placebo-controlled, and dose-escalating over four doses. In total, the phase 1 program enrolled a total of 60 healthy subjects in the trial, consisting of 40 subjects in each phase, of which 20 subjects participated in both phases.

In the phase 1a trial, RegeneRx evaluated a single administration of RGN-352. Results of the phase 1a trial were reported in September 2008. The data show that a single intravenous injection of RGN-352 was well-tolerated at all four dose levels. In the phase 1b trial, RegeneRx evaluated a once daily administration for 14 consecutive days. These data were reported in December 2009. The data show that a once-daily intravenous injection of RGN-352 for 14 consecutive days was well-tolerated at all four (42mg, 140mg, 420mg, 1,260mg) dose levels. There were no reported dose-limiting adverse events in either part of the phase 1 trial.

In May 2010, RegeneRx was awarded a 3-year, $3.0 million grant from the NIH's Heart, Lung and Blood Institute to support the further development of RGN-352. The company booked $0.6 million in revenues in the first quarter 2011 from this grant. This includes preclinical works and manufacturing for the clinical trials.

…Phase 2…

RegeneRx has been planning to initiate a phase 2 trial with RGN-352 seeking to enroll 75-100 patients at approximately 20-25 clinical sites in the U.S., Israel and Russia. The trial is designed to show potential utility in the treatment of acute myocardial infarction (AMI), with endpoints looking at reduction in scar size, cardiac output parameters, and cardiovascular health biomarkers. The trial will test 2 doses of RGN-352 versus placebo. However, in March 2011, the company received a notice from the U.S. FDA indicating non-compliance with FDA's current Good Manufacturing Practice (cGMP) regulations by its contract manufacturer. We note this is the manufacturer for the finished drug product, not the Tβ4 API.

The clinical hold is limited to cGMP compliance issues at a specific contract manufacturing site and is not directed at the safety of RGN-352. Nevertheless, the phase 2 trial of RGN-352 has been placed on clinical hold by the FDA. Management is unable to estimate the length of time that the trial will be on clinical hold. This can be anything from a minor infraction, meaning the trial could begin enrollment in about three months, to requiring the re-manufacturer of the drug, which would take 9-12 months.

Given the uncertainty around the clinical hold and a lack of funds to complete the trial, RegeneRx has moved RGN-352 to the back-burner. Management has clearly shifted focus, and funds, to RGN-259. If the company can get RGN-352 back on track, the next steps would be a larger phase 2b trial, or a move into the first of most likely two pivotal phase 3 registration trials. The phase 3 trial will look at outcome endpoints, such as a reduction in major adverse cardiac events (MACE) and mortality. There are an estimated 650,000 patients in the U.S. in need of treatment for AMI. We estimate the market size is approximately $1 billion. An effective therapeutic could capture sizable share.

RGN-352 For Neurological Indications

As noted above, preclinical data on RGN-352 is suggestive of significant biological activity in neuroprotection and remyelination. Recent preclinical research published in the scientific journals Neuroscience and Journal of Neurosurgery indicate that RGN-352 may prove beneficial for patients with multiple sclerosis (MS), as well as stroke and traumatic brain injury.

…Preclinical Models…

RegeneRx has shown that Tβ4 increased oligodendrocyte progenitor cells (OPCs) and mature oligodendrocytes in the brain, reduces inflammatory infiltrates, and induces remyelination. Animal proof of principle data shows:

- ✓ OPC's increased by 200% in brain subventricular zone (SVZ) and >80% in white matter.
- ✓ Mature oligodendrocyte cells increased 90% in white matter.
- ✓ Neurological relative function recovery by 50% greater in Tβ4 treatment group.
- ✓ Oligodendrogenesis increased in brain approximately by 100%
- ✓ Inflammatory infiltrates adjacent to vessels in brain reduced by 30%.

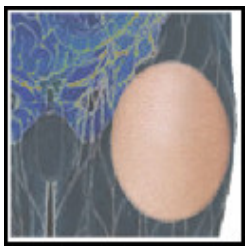
…Phase 1 / 2….

RegeneRx is facilitating a phase 1 / 2 program at the Henry Ford Hospital (HFH) in Detroit, Michigan. HFH is one of the nation's leading non-profit healthcare providers. HFH plans to initiate a physician sponsored investigational new drug application (IND) in order to evaluate the safety and therapeutic potential of RGN-352 in patients with MS. RegeneRx will produce drug and logistical support when necessary. We expect trial to commence in 2012, following funding though an NIH grant. There are roughly 300,000 potential patients in the U.S. that could use a product like RGN-352 if proven effective for MS.

…Other…

Given the mass of preclinical data suggestive of neuroprotection, management believes that RGN-352 could have potential in treatment patients with ischemic stroke and traumatic brain injury (TBI). Both offer distinctive 500,000+ patient populations in the U.S. alone. We have seen the U.S. military fund early-stage TBI programs in the past, so this is a potential route for management if they decide to push forward with RGN-352 in this indication.

RGN-137 For Topical Indications



RegeneRx is also developing a topical gel formulation of Tβ4 intended to promote dermal wound healing and tissue regeneration. Research has demonstrated that Tβ4 can accelerate dermal regeneration after a wound by reducing inflammation, stimulating angiogenesis, promoting the formation of collagen, inducing re-epithelialization, and up-regulating the expression of laminin-5. It's a unique mechanism that has potential to heal some difficult-to-treat wounds. Preclinical work indicates that Tβ4 can reduce scarring after injury in the skin and heart. Based on research conducted at the National Institutes of Health (NIH), RegeneRx has initiated clinical studies with RGN-137.

...Pressure Ulcers…

In late 2005, RegeneRx began enrolling patients in a phase 2 clinical trial designed to assess the safety and effectiveness of RGN-137 for the treatment of patients with chronic pressure ulcers, commonly known as bedsores. The trial was a randomized, double-blind, placebo-controlled, dose-response trial at 15 clinical sites in the U.S. that enrolled a total of 72 patients to evaluate the safety, tolerability, and wound healing effectiveness of three different concentrations of RGN-137 (0.01%, 0.03%, and 0.1%) compared to placebo. RGN-137 was applied topically to the ulcers, once-daily for up to 84 consecutive days. Patients in the trial were between 19 and 85 years old and had at least one stable Stage III or IV pressure ulcer with a surface area between 5 and 70 cm^2. Stage III and IV pressure ulcers are full thickness wounds that penetrate through the skin and muscle, sometimes completely to the bone. RegeneRx went after these most severe forms of pressure ulcers with limited treatment options available because they believe this would offer the best opportunity to see a difference between RGN-137 and the placebo.

In January 2009, management reported final data from this trial. RGN-137 was well-tolerated at all three dose levels studied, with no dose-limiting adverse events. Unfortunately, all Tβ4 doses performed similarly compared to placebo on the efficacy endpoint, with no statistically significant results. Patients treated with the middle dose showed a 17% rate of wound healing, which was the highest rate among the three active doses evaluated. The improvement in ulcer healing in this middle dose group following nine weeks of treatment was equal to the improvement in patients treated with placebo after 12 weeks of treatment.

...Venous Stasis…

In 2006, RegeneRx sponsored phase 2 trial designed to assess the safety and effectiveness of RGN-137 for the treatment of patients with venous stasis ulcers. Venous stasis ulcers are a common type of non-healing wound that develops on the ankle or lower leg in patients with chronic vascular disease. The trial was conducted and funded by Sigma-Tau. It was a randomized, double-blind dose-response trial at eight clinical sites in Italy and Poland, and enrolled a total of 73 patients to evaluate the safety, tolerability, and wound healing effectiveness of three different concentrations (0.01%, 0.03%, and 0.1%) of RGN-137 compared to placebo. RGN-137 was applied topically to the ulcers, once-daily for up to 84 consecutive days. Patients in the trial were between 18 to 79 years old and had at least one venous stasis ulcer with a surface area between 3 and 30 cm^2.

In March 2009, management reported final data from the trial. RGN-137 was well-tolerated at all three dose levels, with no dose-limiting adverse events. The data shows that 33% of the patients who received the middle dose of RGN-137 had their ulcers heal completely after the 12 weeks of treatment, compared to 24% of patients receiving the placebo, 16% of the patients receiving the lowest drug dose and 17% of patients receiving the highest drug dose. For the patients receiving the middle dose whose ulcers healed completely, the median time to complete healing was reduced by approximately 45%, relative to the placebo. Because of the small size of the trial, it was not adequately powered to achieve statistical significance. As a result, none of the differences observed was statistically significant. Nevertheless, we find the trends towards significance encouraging, and believe a larger, more adequately powered study, would show a benefit for RGN-137 over a control.

...Epidermolysis Bullosa…

In 2005, management began enrolling patients in a phase 2 trial designed to assess the safety and effectiveness of RGN-137 for the treatment of patients with dystrophic and junctional Epidermolysis Bullosa (EB). EB is a genetic defect (caused by a mutation in the keratin or collagen gene) that results in fragile skin and other epidermal tissues that can blister at the slightest trauma or friction, creating a wound that at times does not heal or heals poorly. EB can be severely debilitating and even lethal. Prevalence of EB in the U.S. is around 20,000 to 30,000 patients. The incidence rate is around 1 / 50,000, or around 6,000 people per year. Therefore, there is only a small population of EB patients eligible for inclusion in the company's phase 2 clinical trial. The phase 2 program is a randomized, double-blind, placebo-controlled, dose-response trial at nine U.S. clinical sites seeking to enroll a total of 36 patients. Enrollment has been proceeding slowly for the company because of the limited market size and difficulty finding EB patients that qualify for the trial.

As of mid-April 2011, 30 patients have been enrolled. We expect management to complete the trial, regardless of enrollment figures, by the end of 2011. The trial is designed to evaluate the safety, tolerability, and wound healing effectiveness of three different concentrations (0.01%, 0.03%, and 0.1%) of RGN-137 compared to placebo, dosed once-daily for 56 days. We expect data in the first quarter of 2012. EB has been designated as an "Orphan" indication by the FDA. RegeneRx received a grant of $681,000 from the FDA's Office of Orphan Products Development to partially fund this trial.

…Future Plans With RGN-137…

We are admittedly somewhat skeptical of the utility on RGN-137 in EB given the lack of statistical efficacy seen in pressure ulcers and venous stasis. That being said, management remains optimistic that RGN-137 can be effective in dermal wound healing. This is because each type of chronic ulcer has different etiologies and potentially different responses to therapy. Venous stasis ulcers differ from pressure ulcers as they result from venous insufficiency rather than from constant pressure or shearing factors. Likewise, patients with the more serious types of EB (dystrophic and junctional) have wounds that result from genetic factors, leading to a deficiency in collagen VII and an adhesive protein called laminin-5. Tβ4 has been shown to accelerate collagen deposition and promote laminin-5 expression in laboratory animal models.

This means that phase 2 EB trial may offers a better chance of success, and with Orphan designation, perhaps the best commercialization potential as well. We expect that RegeneRx will present data from the phase 2 EB trial in late 2011 or early 2012. Following the release of these data, we expect management to compile all the phase 2 data discussed above and meet with the U.S. FDA to discuss the next steps with RGN-137.

RGN-457 For Inhalation

RegeneRx previously conducted preclinical work on a new product candidate, RGN-457, based on Tβ4 formulated as an inhaled therapeutic agent. Management has completed a substantial amount of preclinical work necessary for an IND application, and is currently seeking a strategic partner to assist in the development of RGN-457 for the treatment of cystic fibrosis (CF) or other inflammatory lung diseases.

CF is a life-threatening, hereditary disease that impairs the patient's ability to breathe due to the accumulation of mucus secretions in the airways of the lungs. The predicted median age of survival for patients with cystic fibrosis is 37 years. There are estimated to be approximately 30,000 CF patients in the U.S. and 40,000 CF patients in Europe. This allows for a potential "Orphan" designation for RGN-457.

CF is caused by a genetic defect that results in defective or missing CF transmembrane conductance regulator (CFTR) proteins, which result in poor ion flow across cell membranes, including in the lungs, and the accumulation of abnormally thick, sticky mucus that leads to chronic lung infections and progressive lung damage. Current treatment options for CF include a highly purified solution of recombinant human deoxyribonuclease I (rhDNase) enzyme in Genentech's Pulmozyme (dornase alfa), and an inhaled version of the antibiotic tobramycin in Novartis' TOBI. Both products are designed to relieve symptoms, but do not cure the disease. Vertex Pharmaceuticals recently completed a positive phase 3 trial with VX-770, an oral CFTR potentiator designed to increase the function of defective CFTR proteins, which could be a disease modulator. Accordingly, we are not expecting RegeneRx to move RGN-457 into clinical development unless management believes it can effectively compete with Pulmozyme, TOBI, and potentially VX-770.

Cosmeceutical Peptides

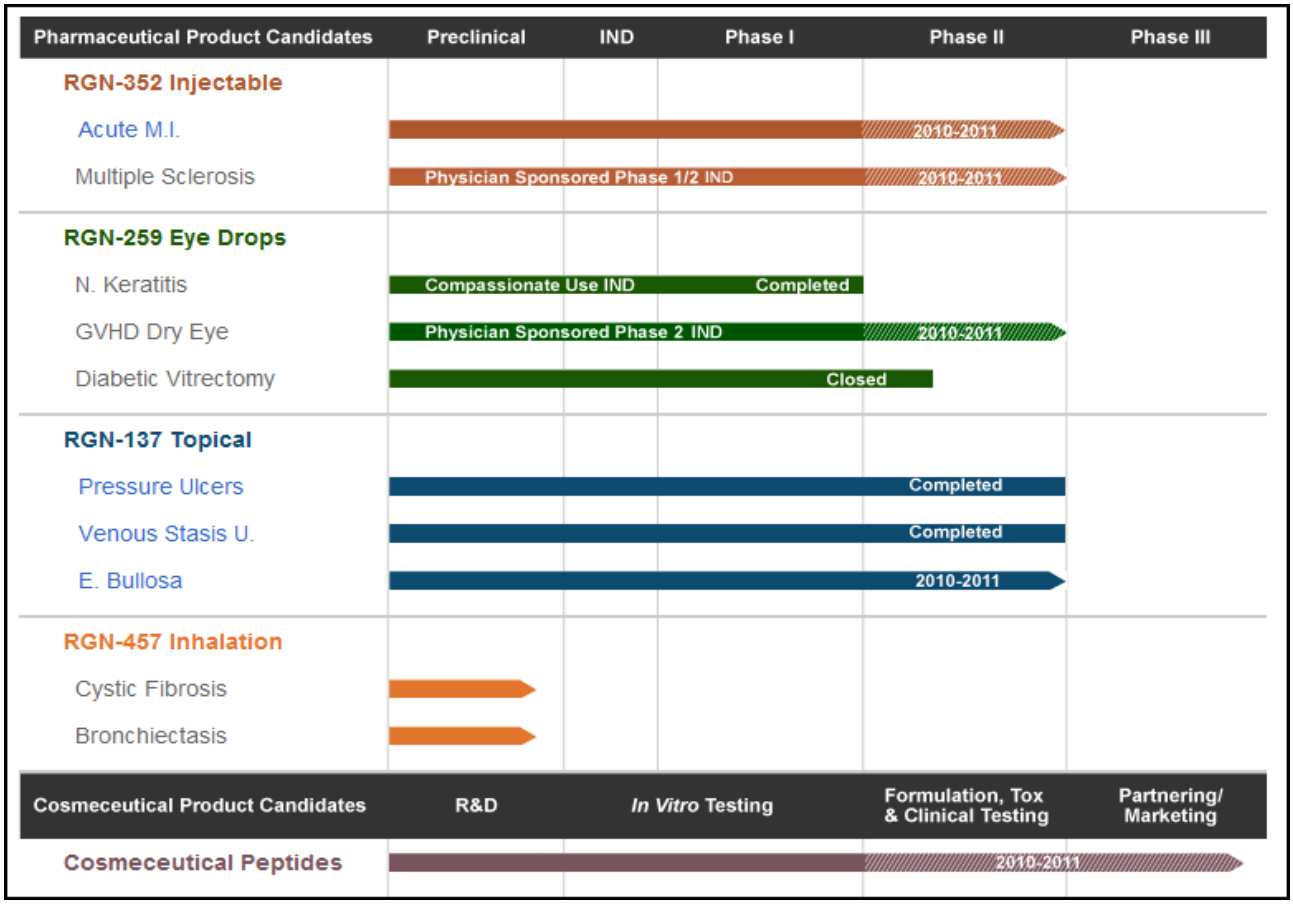
RegeneRx is seeking to identify and evaluate Tβ4 peptide fragments and derivatives that may be useful as novel components in cosmeceutical and consumer products. Management has identified several amino acid sequences, and variations thereof, within the Tβ4 molecule that have demonstrated *in vitro* activity in company preclinical research studies. RegeneRx has filed a number of patent applications related to this work.

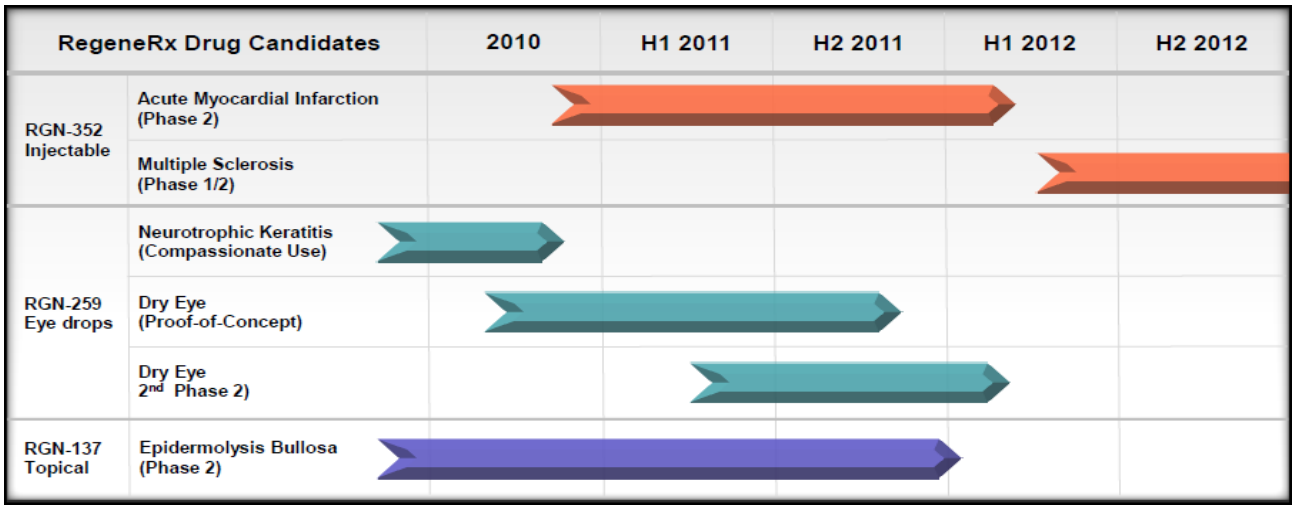
Biological activities of Tβ4 fragments may be useful, for example, in developing novel cosmeceutical products for the anti-aging market. To date, company research has suggested that these fragments suppress inflammation, accelerate the deposition of certain types of collagen, promote the production of elastin, and inhibit programmed cell death, among other activities. The development and commercialization strategy is to identify suitable commercial partners to license these novel fragments for various cosmeceutical applications. We expect the company to seek a strategic collaboration with cosmetics and consumer products companies to further develop and commercialize these fragments. Management has reported these discussions are ongoing.

Collaborations & Partnerships

RegeneRx has over 20 active research collaborations worldwide that support the company's clinical and preclinical research programs centered on Thymosin β4. The collaborations include U.S. and European universities, medical schools, hospitals, and government grants. Key relationships include the U.S. military evaluating the potential of RGN-259 to prevent or reduce eye damage caused by chemical warfare agents and a 3-year, $3 million grant from the NIH's Heart, Lung and Blood Institute to support the further development of RGN-352. We note the FDA has partially funded a clinical trial with Tβ4 in epidermolysis bullosa (EB). The company has received $4.5 million from the U.S. government so far, and RegeneRx has applied for additional grants ranging from $200,000 to $3 million to further support the advancement of Tβ4.

PIPELINE





Source: RegeneRx, Inc.

MANAGEMENT

J.J. Finkelstein, President and Chief Executive Officer:

Mr. Finkelstein has served as the President and Chief Executive Officer and a member of the Board of Directors since 2002. Mr. Finkelstein also served as Chief Executive Officer from 1984 to 1989 and as the Vice Chairman of the Board of Directors from 1989 to 1991. Mr. Finkelstein has worked as an executive officer and consultant in the bioscience industry for the past 29 years, including serving from 1989 to 1996 as chief executive officer of Cryomedical Sciences, Inc., a publicly-traded medical device company. Mr. Finkelstein has significant experience in developing early-stage companies. He has been responsible for the regulatory approval and marketing of several medical devices in the U.S. and abroad. In 2008, Mr. Finkelstein was appointed to the MdBio Foundation, where he serves as Chair. Mr. Finkelstein has served on the executive committee of the Board of Directors of the Technology Council of Maryland since 2006 and MdBio, Inc. since 1998, non-profit entities that support bioscience development and education in the State of Maryland. Mr. Finkelstein received a business degree in finance from the University of Texas.

David Crockford, Vice President of Clinical and Regulatory Affairs:

Mr. Crockford has served as the Vice President of Clinical and Regulatory Affairs, since March 2005 and was a consultant to the Company from 2000 until his appointment as Vice President. He has more than 25 years of experience in the biotechnology and pharmaceutical industries. During his career as a clinical and regulatory affairs professional, Mr. Crockford has established strategic plans, implemented and obtained marketing approval for 18 drug products, including one of the first human growth hormone preparations sold in the U.S., 17 in vitro diagnostic tests, and an intraoperative medical device to detect and treat cancer. Mr. Crockford's other clinical and regulatory achievements include the cost-effective and timely development of a number of innovative investigational drugs. Mr. Crockford is the author of a number of publications and is an inventor or co-inventor on more than a dozen patents.

C. Neil Lyons, Chief Financial Officer:

Mr. Lyons has served as the Chief Financial Officer and Treasurer since 2005. With more than 25 years of experience, Mr. Lyons has developed expertise related to operations, finance, SEC reporting and compliance, complex transactions, strategy, information systems and corporate governance. From 1979 to 1990, Mr. Lyons practiced with Deloitte, providing assurance and advisory services to several public companies in the Washington, D.C. metro area. Following that, Mr. Lyons served as a senior financial executive with HFS, Inc. (a major Department of Defense contractor) from 1990 to 1996, with Bell Atlantic from 1996 to 1998, with SkyBridge LP (an international satellite broadband start-up affiliated with Alcatel) from 1998 to 2003, and consulting with area businesses regarding the initial implementations of the Sarbanes-Oxley Act from 2003 to 2005. Mr. Lyons is a certified public accountant ("CPA") and received a Bachelor of Science degree in accounting, magna cum laude, from Florida Southern College.

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

Dr. Goldstein has served as the Chairman of the Board of Directors and the Chief Scientific Advisor since he founded the company in 1982. Dr. Goldstein has been a Professor of Biochemistry since 1978 and served as Chairman of the Department of Biochemistry and Molecular Biology at the George Washington University School of Medicine and Health Sciences until 2009. Dr. Goldstein is a recognized expert in the field of immunology and protein chemistry, having authored over 430 scientific articles in professional journals. He is also the inventor on over 25 issued U.S. patents (in the fields of biochemistry/molecular biology). Dr. Goldstein discovered several important compounds, including Tα1 and Tβ4, that are either in clinical trials or marketed worldwide. Dr. Goldstein has served on the Board of Trustees of the Sabin Vaccine Institute since 2000 and on the Board of Trustees of the Richard B. and Lynne V. Cheney Cardiovascular Institute since 2006. Dr. Goldstein has also done pioneering work in the area of medical education, developing distance learning programs offered through "Frontiers in Medicine," a medical education series that Dr. Goldstein developed.

VALUATION & RECOMMENDATION

Our Thesis

...Intrigued By Tβ4…

We recently initiated coverage of RegeneRx with a 'Neutral' rating. Despite the fact that we are intrigued by the potential to develop multiple therapeutic applications with Thymosin β4, we believe more data is necessary. The lead development program is RGN-259 for dry eyes and neurotrophic keratitis (NK). Preclinical animal data yielded some impressive results in NK and various forms of dry eyes. So much so, that the product was tested in compassionate use studies that demonstrated the ability of RGN-259 to repair and regenerate corneal tissue. We believe that RGN-259 may provide a novel approach to the treatment of patients with corneal defects. It offers a potential competing or complementary therapy to Allergan's Restasis (cyclosporine ophthalmic), an estimated $700 million drug in 2011. In fact, the drug has demonstrated statistical superiority to Restasis in earlier testing. Data from two preclinical programs was presented at the 2011 Association for Research in Vision and Ophthalmology (ARVO) meeting in Ft. Lauderdale on May 3, 2011. We are also intrigued by the fact that RegeneRx is collaborating with the U.S. military on RGN-259, seeking to evaluate the drug to prevent or reduce eye damage caused by chemical warfare agents.

RegeneRx is also developing RGN-352 in acute myocardial infarction (AMI). Preclinical data with RGN-352 demonstrates improvement in cardiomyocytes rhythmic beating and survival *in vitro*, as well as improvement in myocardial function and reduction in scar volume in animal models. Phase 1 data yielded encouraging safety and tolerability data. The ongoing phase 2 program is designed to show the type of utility in an acute population that would allow management to secure a develop partnership for a pivotal phase 3 program. Unfortunately, the phase 2 program has been placed on clinical hold due to non-compliance with FDA's current Good Manufacturing Practice (cGMP) regulations by RegeneRx's contract manufacturer. Once this program resumes, we think investor attention will return to the story. We are awaiting the company's next update on the status of reinitiating the trial. In May 2010, RegeneRx was awarded a 3-year, $3.0 million grant from the NIH's Heart, Lung and Blood Institute to support the further development of RGN-352.

Upside with RGN-352 could come from expanding the indication into multiple sclerosis (MS). Preclinical data shows that Tβ4 increases oligodendrocyte progenitor cells (OPCs) and mature oligodendrocytes in the brain, reduces inflammatory infiltrates, and induces remyelination. Animal proof-of-principle data show improvement in brain function recovery and a reduction in inflammatory infiltrates that cause lesions common with MS. RegeneRx is currently conducting a phase 1 / 2 trail with RGN-352 in MS.

The rest of the pipeline is admittedly early-stage. Despite the lack of statistical success of RGN-137 in two previous phase 2 trials for pressure ulcers and venous stasis, management is pushing forward with a third phase 2 trial in epidermolysis bullosa (EB). EB is an ultra rare genetic defect that results in fragile skin and chronic wounds, and given the small inflicted population, qualifies as an Orphan indication. Because the disease has a genetic component rather than an environmental affect, we believe RGN-137 has potential here to show efficacy. Tβ4 has been shown to accelerate collagen deposition and promote laminin-5 expression in laboratory animal models. During the two previous trials with RGN-137, there were clear signs of biological activity.

…Waiting For Clinical Validation...

Research has demonstrated diverse biologic activity for Thymosin β4. Research shows the 43-amino acid peptide that plays a vital role in cell structure and motility and in the protection, regeneration, remodeling and healing of tissues. These effects have suggested a range of possible therapeutic applications, and several have been extended to animal models and human clinical trials. We believe the science and theory around Tβ4 is solid. Drug candidates developed around various formulations of Tβ4 have the potential to be disease modulators. For indications such as AMI, MS, dry eyes, and cystic fibrosis, this is enormously exciting, as most of the approved drugs for the aforementioned indications only target symptom relief.

We believe proof-of-concept has been demonstrated by RegeneRx in AMI, neurotrophic keratitis and dry eyes. The potential is there in epidermolysis bullosa (EB), multiple sclerosis (MS), and cystic fibrosis (CF) as well. What we need to see is pivotal data in large-scale, randomized, placebo-control trials that can be used for registration approval. We think the market will remains skeptical until this data has been presented.

Valuation

RegeneRx's stock looks vastly under-valued at today's price. The current market capitalization of only $15 million massively discounts the potential for drug such as RGN-352, RGN-259, and RGN-137. Indications such as dry eye, AMI, MS, CF are multi-hundred million dollar indications, even potential blockbuster indications depending on the success of the phase 3 trials. The market clearly does not see a blockbuster in RegeneRx' pipeline or else the stock would not be trading at $0.19 with a market capitalization of only $15 million. Instead, the market is skeptical, and sees only un-proven programs and a need to raise cash with committed equity financings later in 2011.

…Heavily Discounted NPV…

We have taken a look at each potential indication for the various forms of Tβ4 under development at RegeneRx. We have forecasted peak sales opportunities given the potential label indication and the year of launch. We've heavily discounted these figures based on the stage of clinical development and the high historic failure rate of phase 1 and phase 2 drugs. We've also factored in a need for cash and development partnerships to achieve market approval for any one of the advancing candidates. Below is an NPV (net present value) calculation for each pipeline candidate using discounted cash flow (DCF) on each product candidate estimating peak sales, year of launch, and historic operating profits based on development partnerships and sales milestones and royalties.

	RGN-352		RGN-259		RGN-137	RGN-457
	Acute MI	Multiple Sclerosis	Neuro Keratitis	Dry Eye	Epiderm Bullsoa	Cystic Fibrosis
Total Market Size	~ 1 Million	~ 300,000	~ 4,000	~ 30 Million	~ 25,000	~75,000
State of Development	Phase 2	Phase 1 / 2	Phase 2	Phase 2	Phase 2	Preclinical
Est. Approval	2015	2016	2013	2013	2014	2018
Peak Sales	$500,000,000	$250,000,000	$25,000,000	$500,000,000	$25,000,000	$500,000,000
Probability Factor	15%	5%	50%	50%	20%	5%
Adjusted Peak Sales	$75,000,000	$12,500,000	$12,500,000	$250,000,000	$5,000,000	$25,000,000
NPV of Program	$6	$2	$4	$28	$1	$1
Pipeline Value	$41	Million				
Shares Outstanding	79	Million		*Target Price*	$0.51	

Source: Zacks Investment Research, Inc.

We see the dry eye program as the lead value generator right now. Animal model data on RGN-259 has been very encouraging, and dry eye represents a relatively low-cost, expedited route to market. We remind investors that Allergan's Restasis sold $621 million in 2010, and Restasis does little to correct the underlying cause of dry eye disease. Dry eye affects an estimated 20 to 30 million people in the U.S., and 25% of patients who visit ophthalmic clinics report symptoms of dry eye. It is one of the fastest growing segments of the pharmaceutical industry. RGN-259 has a different mechanism from Restasis, so it could be used as either an alternative or complementary therapy to the drug. We believe the dry eye and NK programs alone are worth more than the current market capitalization.

The AMI and MS programs with injectable RGN-352 are a bit of a wildcard. The clinical hold on the phase 2 AMI program due to manufacturing issues at the company's contract vendor have forced management to push RGN-352 to the back-burner. Accordingly, the market is assigning little value to RGN-352 at this point. We believe if management can get this program back up and running before the end of the year, it could provide meaningful upside to shareholders. The situation is similar with RGN-137 and RGN-457. Based on the failure of two previous trials with RGN-137, we are choosing to be very aggressive with our probability adjustment on the market potential here. For RGN-457, cystic fibrosis (CF) is a large market opportunity, but the success (and approval) of inhaled medications has been low, and competition is heating up. We note that Vertex is in late-stage development of a new oral drug candidate for CF that could dominate the market upon approval.

Yet, despite our aggressive discounting and hearty skepticism, we still see the shares as 200% under-valued. Our target calculated above is $0.51, which we've rounded down to $0.50 for simplicity.

…Committed Equity Financing…

The main reason for our 'Neutral' rating at the current time is the need for cash at some point in 2011. RegeneRx exited the second quarter 2011 $2.3 million in cash and investments. The company burned $1.6 million in the first quarter and $1.6 million in the second quarter. In January 2011, the company raised $1.45 million through two institutional investors. Existing shareholder, Sigma-Tau Group purchased $950,000 of common stock. New shareholder, Lincoln Park Capital Fund (LPC) purchased $500,000 of common stock. Both transactions took place at $0.27 per share, for a total of 5.37 million shares, which at the time was a 35% premium over the previous day's close. In addition, RegeneRx issued 2.15 million warrants to Sigma-Tau and LPC as part of the transaction. The warrants are exercisable at $0.38 per share over a five-year period.

In addition to the $1.45 million investment, RegeneRx entered into a separate purchase agreement where LPC has committed LPC to purchase up to $11 million of RegeneRx's common stock over a 30-month period. Under the terms of the agreement, LPC is obligated to make purchases as RegeneRx directs in accordance with the purchase agreement, which may be terminated by RegeneRx at any time, without cost or penalty. Sales of shares will be made in specified amounts and at prices that are based upon the market prices of the company's common stock preceding the sales to LPC, without any fixed discount.

We estimate the current cash balance of $2.3 million is enough to fund operations to October 2011. Therefore, in the near-term, we expect the company to begin offerings to LPC. Although we are pleased with the fact that the offerings will be at fair-market value, we believe the issuance of new shares and dilution will weight on the stock until the long-term funding position improves. This could come in the form of a developmental partnership on RGN-259 or RGN.352. We note that once management presents the data from the ongoing phase 2 trial with RGN-259, partnership interest in the candidate should increase.

Risks

The biggest risk we see is the potential clinical failure of RGN-259 or RGN-352. Safety and tolerability of these programs so far has been excellent. However, we have seen only preclinical and phase 1 data. We caution investors that candidates tend to react differently in large-scale human trials versus small preclinical animal models.

Other risks include funding, as noted above, and the FDA's clinical hold on RGN-352. At this point we are uncertain what the issue is at the finished goods manufacturer for RGN-359. All we know is that the FDA placed the phase 2 AMI trial on hold after a notice indicating non-compliance with FDA's current Good Manufacturing Practice (cGMP) regulations by its contract manufacturer.

Competition is another major concern. The company's clinical stage candidates are in early-to-mid stage development. Several pharmaceutical and biotech companies are working on candidates to treat acute myocardial infarction, multiple sclerosis, dry eye, chronic wounds, and cystic fibrosis. For example, RGN-457, an inhaled formulation of Tβ4, may be a viable candidate. But with Vertex recently presenting very solid phase 3 data on an oral CF drug, VX-770, RegeneRx may choose to discontinue the program due to a lack of funding or lack of interest from potential pharmaceutical partners.

PROJECTED FINANCIALS

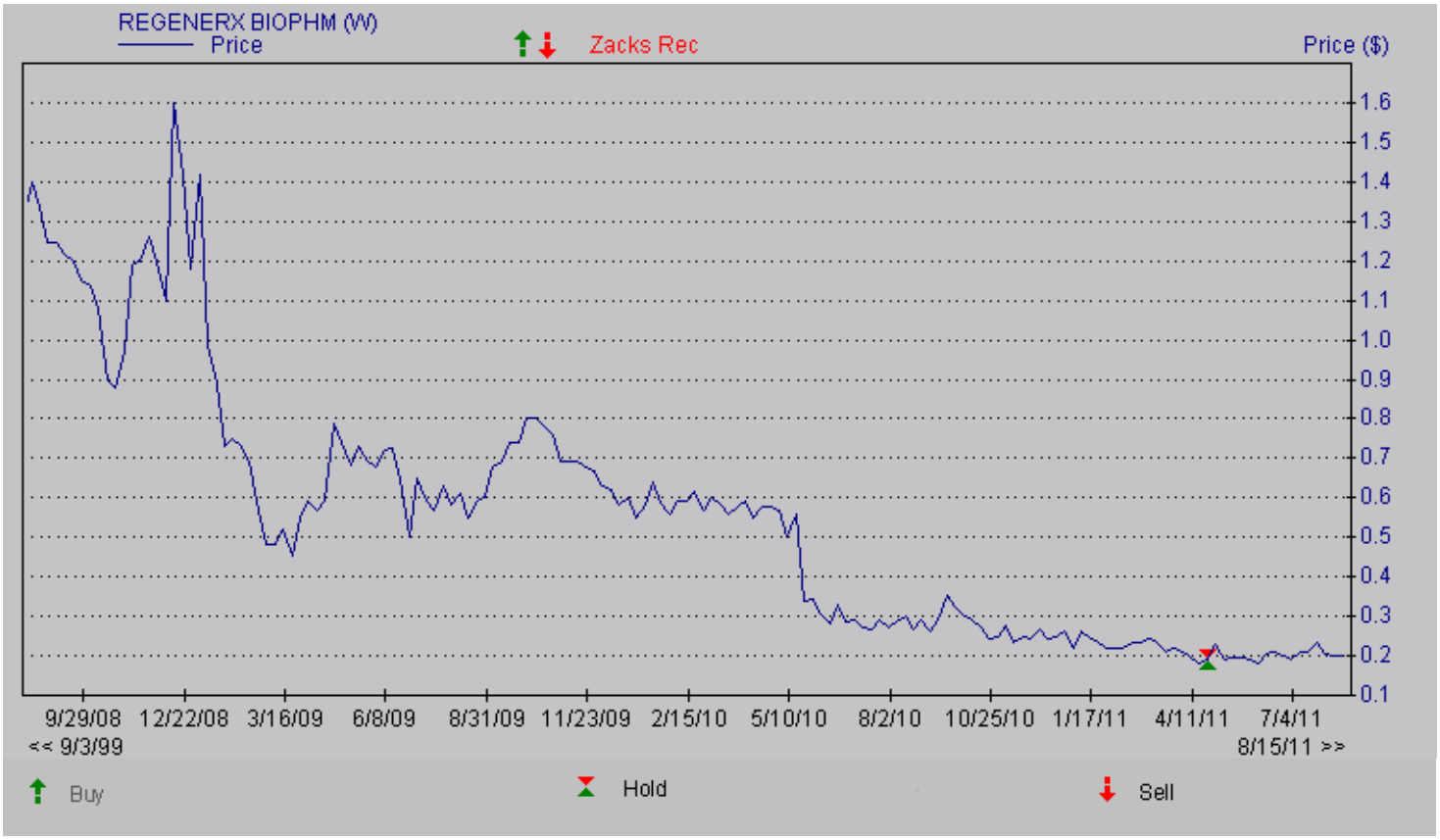
RegeneRx Bio, Inc.
Income Statement

RegeneRx Biopharma	2009 A	2010 E	Q1 A	Q2 A	Q3 E	Q4 E	2011 E	2012 E	2013 E	2014 E
Product Sales	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Sponsored Research	**$0**	**$0.8**	**$0.6**	**$0.6**	**$0.2**	**$0.2**	**$1.6**	**$1.5**	**$0.0**	**$0.0**
YOY Growth	-	-	-	-	-	-	*100.0%*	-	-	-
Total Revenues	**$0**	**$0.8**	**$0.6**	**$0.6**	**$0.2**	**$0.2**	**$1.6**	**$1.5**	**$0.0**	**$0.0**
YOY Growth	-	-	-	-	-	-	*100.0%*	-	-	-
CoGS	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	*0%*	*0.0%*	-	-	-	-	*0.0%*	*0%*	*0%*	*0%*
R&D	$3.7	$2.7	$1.5	$1.5	$1.2	$1.3	$5.5	$5.5	$6.0	$7.0
% R&D	-	-	-	-	-	-	-	-	-	-
SG&A	$2.8	$3.2	$0.7	$0.7	$0.9	$0.9	$3.1	$3.6	$3.8	$4.0
% SG&A	-	-	-	-	-	-	-	-	-	-
Operating Income	($6.5)	($5.0)	($1.6)	($1.5)	($1.9)	($2.0)	($7.0)	($7.6)	($9.8)	($11.0)
Operating Margin	*0%*	*0.0%*	-	-	-	-	-	-	-	-
Total Other Income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($6.5)	($5.0)	($1.6)	($1.5)	($1.9)	($2.0)	($7.0)	($7.6)	($9.8)	($11.0)
Taxes & Other	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($6.5)	($5.0)	($1.6)	($1.5)	($1.9)	($2.0)	($7.0)	($7.6)	($9.8)	($11.0)
Net Margin	*0%*	*0.0%*	-	-	-	-	-	-	-	-
Reported EPS	**($0.12)**	**($0.07)**	**($0.02)**	**($0.02)**	**($0.02)**	**($0.02)**	**($0.09)**	**($0.09)**	**($0.11)**	**($0.12)**
YOY Growth	-	*-37.1%*	-	-	-	-	-	-	-	-
Shares Outstanding	55.7	68.4	79.4	79.9	80.0	82.0	80.3	85.0	90.0	95.0

Source: Zacks Investment Research, Inc. *Jason Napodano, CFA*

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HISTORICAL ZACKS RECOMMENDATIONS



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