Zacks Small-Cap Research

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RegeneRx Biopharma, Inc. (RGRX-OTC)

UPDATE

RGRX: Dry Eye Drug RGN-259 Looks Interesting, But RegeneRx Needs Cash…

Current Recommendation	**Neutral**
Prior Recommendation	N/A
Date of Last Change	04/24/2011
Current Price (11/16/11)	$0.17
Target Price	**$0.50**

Earlier this month, RegeneRx release top-line data from the companies phase 2 trial testing RGN-259 for the treatment of signs and symptoms of dry eye syndrome. Management has interpreted the results as positive, believe that clinically meaningful endpoints were met and proof-of-concept was demonstrated to the point that warrants a discussion with the U.S. FDA. The market, however, remains skeptical of the data because some key primary endpoints did not achieve statistical significance. As such, we continue to believe that more data is necessary before RegeneRx shares can breakout. We note that potential partners for RGN-259 are most likely less concerned with statistical significance than investors. But until a deal is done, the stock remains fully in "Show Me" mode. Our rating is 'Neutral'.

SUMMARY DATA

52-Week High	**$0.32**
52-Week Low	**$0.17**
One-Year Return (%)	**-25.53**
Beta	**1.18**
Average Daily Volume (sh)	**133,037**
Shares Outstanding (mil)	**80**
Market Capitalization ($mil)	**$14**
Short Interest Ratio (days)	**0.08**
Institutional Ownership (%)	**0**
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**

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	0.0 A	0.1 E	1.3 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	-$0.03 A	-$0.02 E	-$0.08 E
2012					-$0.08 E
2013					-$0.10 E

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WHAT'S NEW

Third Quarter Financials

On November 14, 2011, RegeneRx filed its Form-10Q for the third quarter 2011. The company reported revenues of $0.03 million in sponsored research revenue during the quarter. Operating expenses in the quarter were $2.0 million, of which $1.4 million was research and development costs, primarily driven by the company's phase 2 dry eye program with RGN-259. Net loss for the quarter was $2.0 million, or $0.03 per share. This was in-line with our expectations. RegeneRx exited the third quarter ended September 30, 2011 with $0.5 million in cash and investments. We believe the company is in dire need of cash, as the current balance is enough to fund operations only until the end of the year.

INVESTMENT THESIS

Phase 2 Data Met With Mixed Response

On November 4, 2011, RegeneRx reported results from the company's phase 2 clinical trial with RGN-259 (0.1% preservative-free eye drop formulation of Tβ4) for the treatment of signs and symptoms of dry eye syndrome. The trial enrolled a total of 72 patients and tested subjects in a Controlled Adverse Environment (CAE) model over a period of 30 days. The trial was conducted by ORA, Inc., an ophthalmic contract research organization that specializes in dry eye research and clinical trials.

Results from the study show that RGN-259 was safe and well-tolerated. However, results did not meet the two prespecified primary outcome measures to statistical significance. These two endpoints were inferior corneal fluorescein staining and decrease ocular discomfort on day 29. These were the two endpoints chosen by management to identify a reduction in signs (inferior corneal fluorescein staining) and symptoms (ocular discomfort) of dry eye syndrome.

While the study did not meet the two primary outcome measures above, three statistically significant secondary outcome measures attributable to RGN-259 were identified. These include:

- ✓ A 325% reduction from baseline in central corneal fluorescein staining compared to placebo at the 24 hour recovery period ($p = 0.0075$). → This is indicative of a reduction in ocular surface damage of the central cornea, a key sign of dry eye syndrome.

- ✓ A 257% reduction from baseline in exacerbation of superior corneal fluorescein staining in the chamber as compared to the placebo ($p = 0.0210$). → This is indicative of a reduction in ocular surface damage of the superior cornea, a key sign of dry eye syndrome.

- ✓ A 27% reduced exacerbation of ocular discomfort at day 28 during a 75-minute challenge in a controlled adverse environment (CAE) compared to the placebo group ($p = 0.0244$). → This indicates that RGN-259 can potentially slow exacerbation of ocular symptoms in patients with dry eye syndrome. We note the primary endpoint tested ocular discomfort at day 29, missing statistical significance only slightly.

Other CAE-related findings, such as superior corneal staining reduction and peripheral (combination of the average of superior and inferior) corneal staining reduction, were observed having statistical significance, while others had positive trends after treatment with RGN-259.

We note these observations are in line with the known biological properties and mechanisms of action of RGN-259 reported in previous studies. With respect to inferior corneal fluorescein staining (one of the two primary endpoints), management did see a statistical trend at day 28 during exposure to adverse conditions in the CAE chamber in patients receiving RGN-259, rather than at day 29. Although this improvement was not deemed to be statistically significant it did exhibit a trend ($p=0.0968$).

Despite just missing significance on the two primary endpoints, management believes the data is encouraging, and should be enough to hold a post phase 2 meeting with the U.S. FDA. We remind investors that this trial was a small exploratory program looking at the first human clinical responses to RGN-259. The goal was to show proof-of-concept, gain clinical experience, and identify potential outcomes that could serve as approvable endpoints in a larger phase 2b trial or pivotal phase 3 registration program.
RegeneRx has previously completed a small pilot study in patients with diabetic vitrectomy. Results showed 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.

…Where Do We Go From Here…

In our view, for RGN-259 to be a commercially viable product, it must be differentiated meaningfully from Allergan's Restasis (TTM sales of $676 million worldwide). Restasis is indicated to help patients "natural tear production" that may be suppressed by inflammation due to chronic dry eyes. The Restasis label says nothing about reducing the signs and symptoms of dry eyes. Sign and symptom improvements are clinically relevant endpoints that we believe are necessary for future pivotal trials.

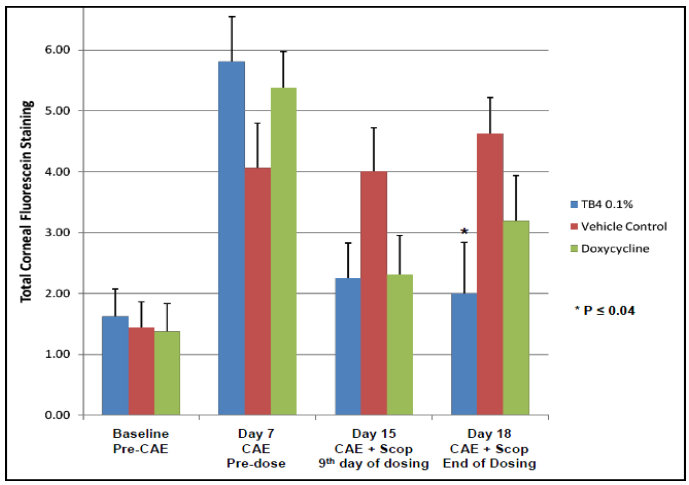
Investors often focus too greatly on statistical significance in a phase 2 trial. Missing the primary endpoints causes a negative knee-jerk reaction. But investors – as they often do – forget that the purpose of an exploratory phase 2 program is to show proof-of-concept and explore endpoints and study parameters which will be used in the pivotal phase 3 registration program. Management believes all the data discussed above is clinically meaningful. It's not a "Home Run", but they certainly didn't strike out either. We see above that both primary endpoints would have been statistically significant at day 28 instead of day 29. We also believe that results may have been statistically significant had the sample population been larger than 72 patients.

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. Restasis should post sales near $700 million in 2011. Management estimates the total market for dry eye therapeutics will hit $2.8 billion by 2017. One item worth noting, pharmaceutical companies fully understand the goal here – to move into phase 3. Partners are less concerned with statistical significance in a phase 2 exploratory program than investors. If RegeneRx was in partnership discussions before today, nothing from today's release should end those discussions.

…Background on RGN-259…

RegeneRx's is developing RGN-259, a sterile, non-steroidal, preservative-free, topical eye drop formulation of Thymosin beta 4 (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, which includes injectable formulations (RGN-352) for myocardial infarction and multiple sclerosis and topical formulations (RGN-137) for epidermolysis Bullosa.

RegeneRx has generated significant preclinical data suggestive of utility for use in dry eyes. The chart to the right 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.

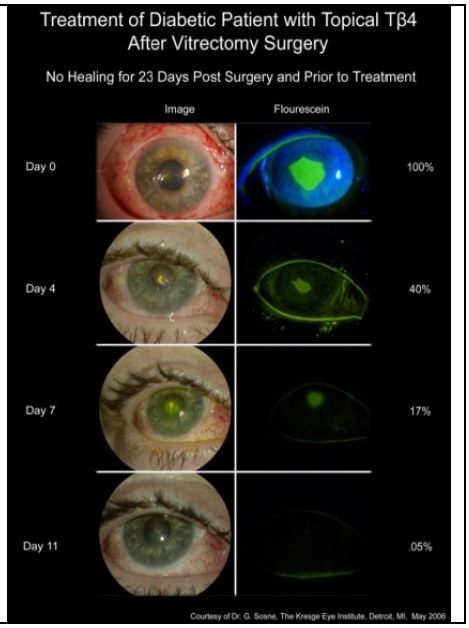
…Compassionate Use…

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.

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.



RGN-352 Remains On Hold

RGN-352 is an injectable formulation of Tβ4 for systemic administration. The company has initially targeted patients who have suffered an acute myocardial infarction (AMI). Preclinical research published in 2007 in *Nature* (Jan 11;445(7124):177-82), show 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. Additional preclinical data suggest 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. Data was published in *Circulation* (29;117(17):2232-40) in 2008 demonstrates Tβ4 is an essential paracrine factor of embryonic endothelial progenitor cell-mediated cardioprotection.

During 2009, RegeneRx completed a phase 1 clinical trial evaluating the safety of RGN-352 in 60 healthy subjects. Based on these results and extensive preclinical efficacy data discussed above, management pushed RNG-325 into a phase 2 trial seeking to evaluate RGN-352 in patients who have suffered an acute myocardial infarction. Unfortunately, in March 2011, RegeneRx was notified by the FDA that the trial was placed on clinical hold as a result of our contract manufacturer's alleged failure to comply with Good Manufacturing Practices (GMP).

Management recently disclosed that the manufacturer intends to close its manufacturing facility. The FDA has prohibited the RegeneRx from using any of the active drug or placebo manufactured by the manufacturer in human trials, meaning that management will have to find new material to commence the phase 2 trial. Due to the time required for revalidation of processes and assays and financial constraints, all clinical activity with RGN-352 has been placed on hold.

This includes testing RGN-352 in neurological indications. Preclinical data on RGN-352 is suggestive of significant biological activity in neuroprotection and remyelination. Preclinical research published in the scientific journals *Neuroscience and the Journal of Neurosurgery* indicates that RGN-352 may also prove useful for patients with multiple sclerosis (MS), as well as stroke and traumatic brain injury. In these studies, the administration of Tß4 resulted in regeneration of neuronal tissue and improvement of neurological function. Future studies here are contingent on funding and manufacturing supply of RGN-352.

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. These include programs in pressure ulcers, venous stasis ulcers, and Epidermolysis Bullosa (EB).

...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, so management recently completed enrollment at 30 patients. 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.

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.

PIPELINE



Source: RegeneRx, Inc.

INVESTMENT THESIS

...Intrigued By Tβ4…

Earlier this year we 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. Phase 2 data from a dry eye study offered mixed results in November 2011. However, we believe that RGN-259 may still 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. 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. More data is clearly necessary though before a move into phase 3 and a commercial partnership can be formed.

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.

PROJECTED FINANCIALS

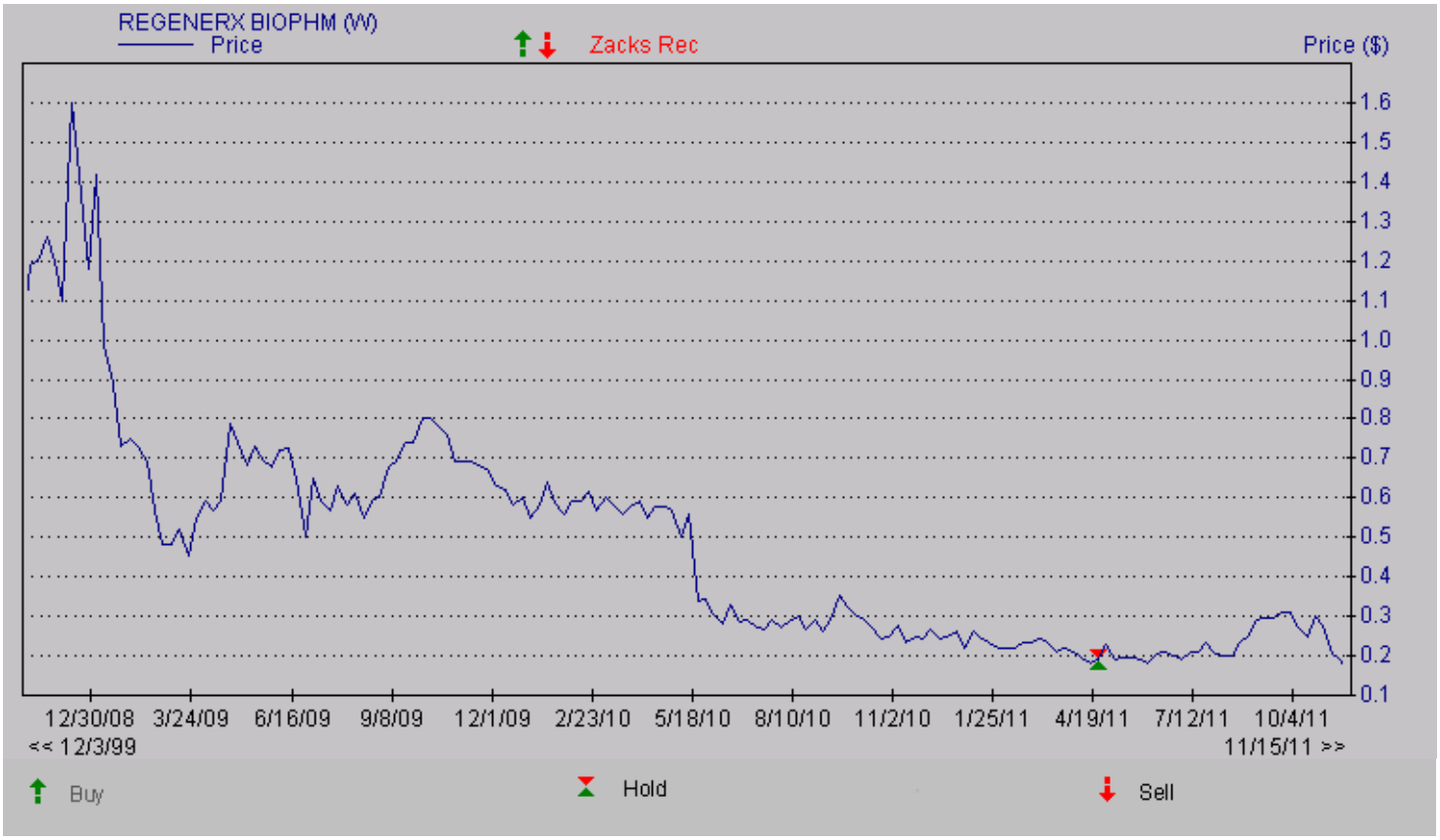
RegeneRx Bio, Inc.
Income Statement

RegeneRx Biopharma	2009 A	2010 E	Q1 A	Q2 A	Q3 A	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**	**$0.0**	**$0.1**	**$1.3**	**$1.5**	**$0.0**	**$0.0**
YOY Growth	-	-	-	-	-	-	*100.0%*	-	-	-
Total Revenues	**$0**	**$0.8**	**$0.6**	**$0.6**	**$0.0**	**$0.1**	**$1.3**	**$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	$1.4	$1.0	$5.4	$5.5	$6.0	$7.0
% R&D	-	-	-	-	-	-	-	-	-	-
SG&A	$2.8	$3.2	$0.7	$0.7	$0.7	$0.7	$2.7	$3.0	$3.2	$3.5
% SG&A	-	-	-	-	-	-	-	-	-	-
Operating Income	($6.5)	($5.0)	($1.6)	($1.5)	($2.0)	($1.6)	($6.7)	($7.0)	($9.2)	($10.5)
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)	($2.0)	($1.6)	($6.7)	($7.0)	($9.2)	($10.5)
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)	($2.0)	($1.6)	($6.8)	($7.0)	($9.2)	($10.5)
Net Margin	*0%*	*0.0%*	-	-	-	-	-	-	-	-
Reported EPS	**($0.12)**	**($0.07)**	**($0.02)**	**($0.02)**	**($0.03)**	**($0.02)**	**($0.08)**	**($0.08)**	**($0.10)**	**($0.11)**
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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