

***REGENERx***

The Fall Investor Summit  
September 16-17, 2019

# Forward-Looking Statements

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This investor presentation contains certain forward-looking statements that 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. Examples of such forward-looking statements include statements concerning the target dates for completing the company's or its partners' ongoing clinical trials for ophthalmic and orphan indications, the potential size of addressable markets, including the market for eye drops and parenteral delivery products, the company's ability to enter into any collaborations with respect to the development or commercialization of its product candidates, and the therapeutic potential of Tβ4 for ophthalmic, cardiovascular and neurovascular disorders. Factors that may cause actual results to differ materially from any future results expressed or implied by any forward-looking statements include the risk that although Tβ4 has demonstrated potential therapeutic benefit for dermal, ophthalmic, cardiovascular and neurovascular disorders, the company's product candidates may not demonstrate safety and/or efficacy in clinical trials, the risk that encouraging results from early research, preclinical studies, compassionate use or clinical trials may not be confirmed upon further analysis of the detailed results, the risk that additional information relating to the safety, efficacy or tolerability of our product candidates may be required by regulatory agencies, the risk that the company or its licensees will not obtain approval to market the company's product candidates in the U.S. or abroad, the risks associated with reliance on outside financing to meet capital requirements, the risks associated with reliance on licensees for the funding or conduct of further development and commercialization activities relating to the company's product candidates, the risks that the company's patents will not be enforceable or expire prior to commercial marketing, and such other risks described in the company's 2018 Annual Report on Form 10-K, and other filings the company makes with the SEC. Any forward-looking statements are made pursuant to Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and, as such, speak only as of the date made. The Company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

RegeneRx (RGRX) is a clinical-stage, biopharmaceutical company engaged in the design, research and development of novel peptides targeted at diseases with unmet medical needs. The Company conducts its research and clinical trials through an outsourced partnership business model.

## Market Data

Ticker (OTCQB)	RGRX
Price (8/30/2019)	\$0.17
52 Week Range	\$0.09 - \$0.35
Market Cap	\$21.7 mil
Average Daily Trading (3 mos)	22,650
Common Shares Outstanding	131.5 mil
Insider/Affiliate Ownership	~49.1%

# Investment Highlights

- Thymosin beta 4 (T $\beta$ 4) is a novel therapeutic peptide for tissue and organ protection, repair, and regeneration.
  - 3 unique formulations for the treatment of ophthalmic, cardiac, CNS, PNS, and dermal disorders
  - Supported by over 800 scientific and medical publications and multiple clinical trials
- RGN-259 is a preservative-free eye drop formulation of T $\beta$ 4 in **late-stage** clinical development for dry eye syndrome and neurotrophic keratitis (NK)
  - Third Phase 3 clinical trial (ARISE-3) targeted for completion summer 2020
  - \$4.4 billion global annual dry eye market; \$500 million global annual NK market
- RGN-137 dermal gel in Phase 2 EB orphan indication
  - 15 patient single-blinded study
  - 1<sup>st</sup> patient's treated wound completely healed
  - Other patients currently being enrolled
- Low-cost outsourced business model
  - 3 active global strategic partnerships via out-licensing and JV agreements
  - RGRX to receive royalties, regulatory and commercial milestone payments + equity in U.S. JV with no financial obligations or exposure
  - Over 20 MTA's developing potential uses of T $\beta$ 4 with little or no cost
  - Low burn rate, high flexibility
- Operating capital through Q2 2020



# How Does Tβ4 Work?

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- Tβ4 is a peptide that circulates naturally in the bloodstream and is found in all cells of the body except red blood cells. Endogenous levels of Tβ4 are reduced as we age or as a result of certain disorders
- Independent researchers have published data in hundreds of scientific and medical journals demonstrating Tβ4's potent and rapid repair of damaged ophthalmic, cardiac, CNS and dermatological tissues in animal models when administered topically or into the blood stream
- Tβ4 acts to increase stem cell recruitment, decrease inflammation, promote cell survival, increase blood supply, and decrease scar formation
- Tβ4 is very safe in animals and humans when delivered topically to the skin and eyes and injected systemically

# Utilize Outsourced/Partnership Business Model

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## ■ Objectives:

- ✓ Demonstrate proof-of-concept with R&D and early clinical trials
- ✓ Partner with companies with clinical development and/or commercialization strengths
  - Strategy enables multiple paths to commercialization
  - Mitigates risks and facilitates efficiency
- ✓ Obtain royalties and commercial milestone payments from licensees
- ✓ Retain significant equity position and royalties through U.S. joint venture
- ✓ Leverage R&D through Material Transfer Agreements (MTAs) at major research institutions around the world
- ✓ Minimize fixed costs and funding obligations to provide strong operating leverage

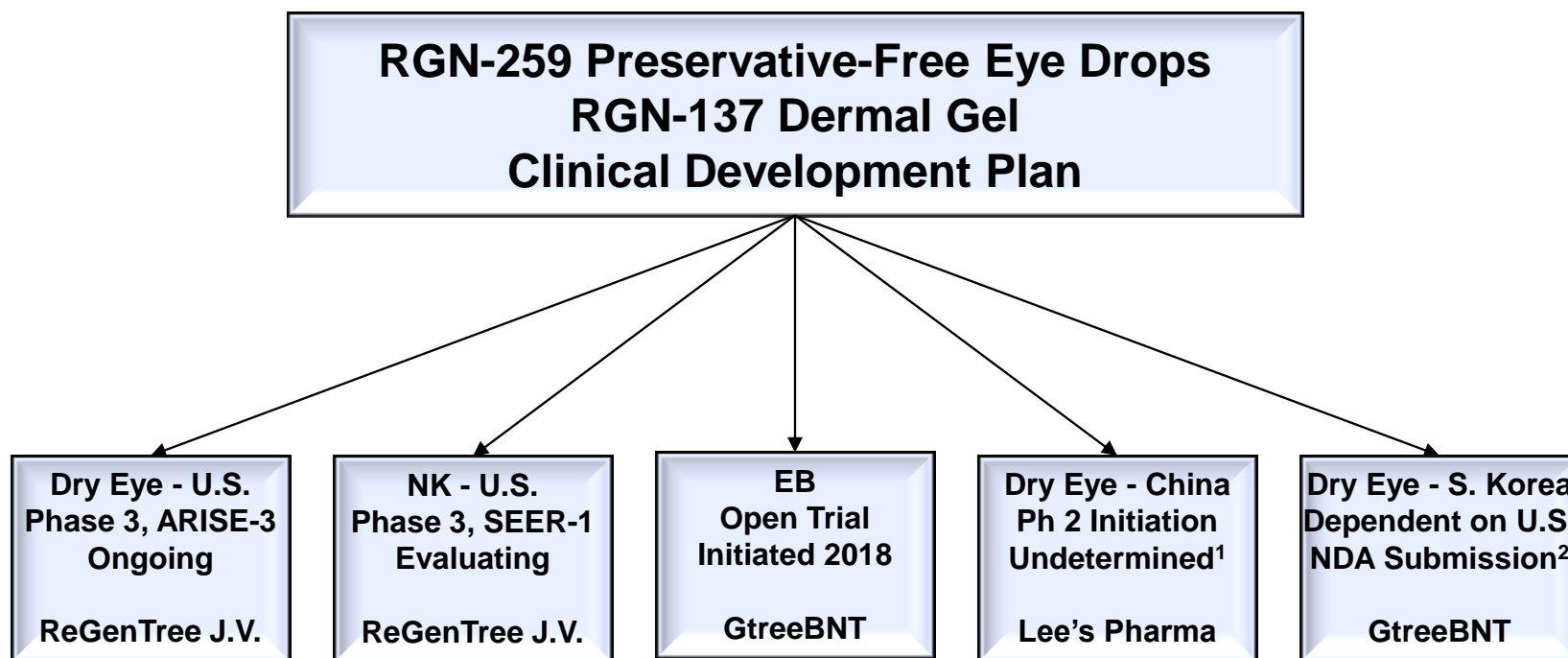
# International Partners Aligned with RegeneRx

- 3 active strategic partnerships and a U.S. joint venture in place
  - **ReGenTree Joint Venture**
    - Exclusive U.S. and Canadian ophthalmic license to RGN-259 from RegeneRx
    - GtreeBNT, as majority partner in JV, is funding all clinical development
    - RGRX retains equity and future royalties and has veto power on all material transactions
  - **GtreeBNT License**
    - Licensed RGN-259 for ophthalmology in Pan Asia territory (excluding countries licensed by Lee's)
    - Licensed RGN-137 in the U.S., Canada, EU, S. Korea, Japan and Australia
  - **Lee's Pharmaceuticals License**
    - Licensed Tβ4 product candidates for China, HK, Taiwan and Macau
    - Initially developing RGN-259 for dry eye syndrome
    - Recently completed state-of-the-art manufacturing facility for ocular products in intends to accelerate RGN-259 development
- RegeneRx retains significant rights to product candidates
  - EU rights to RGN-259
  - World-wide rights to RGN-352 (except China)





# Worldwide Clinical Development



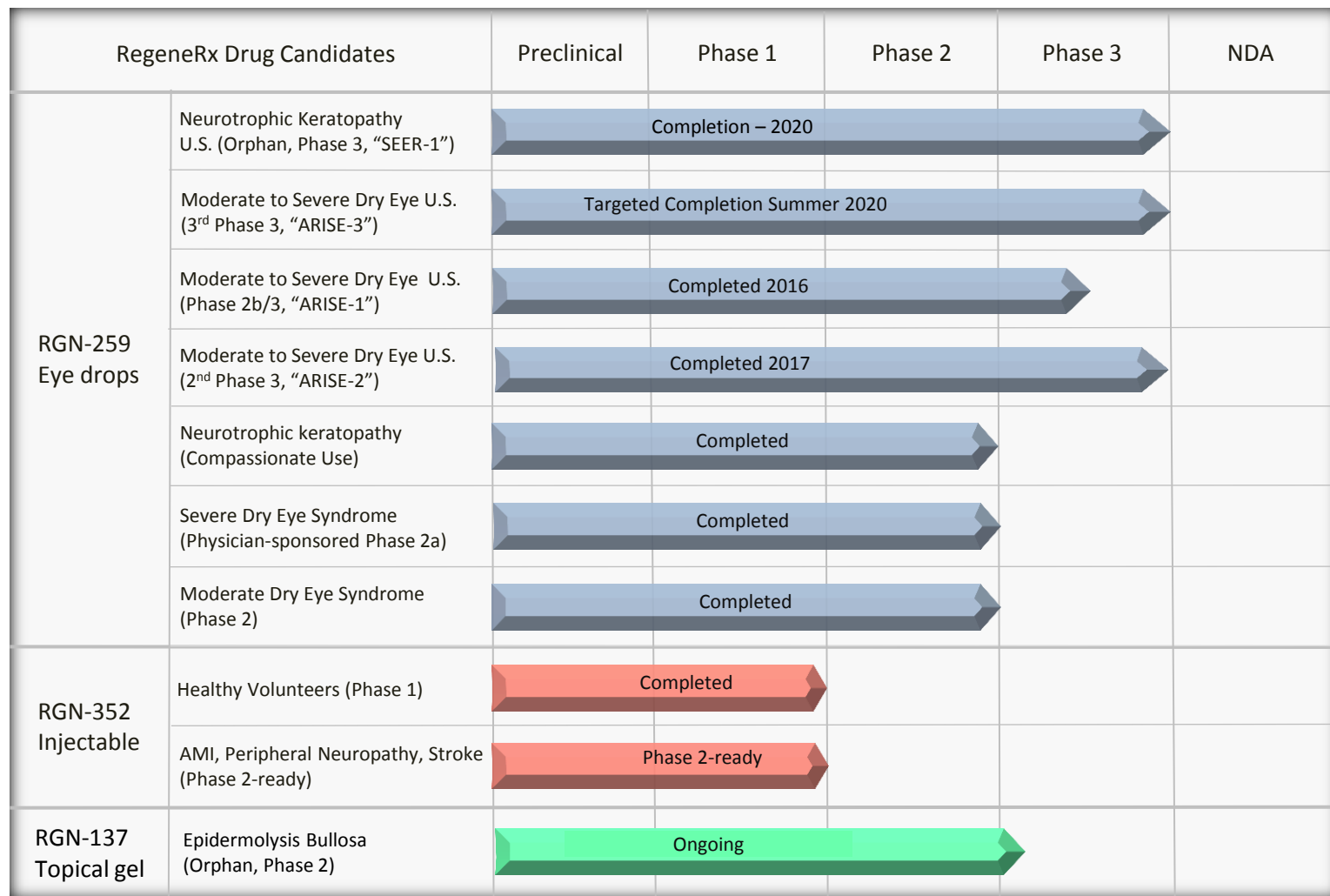
<sup>1</sup> Planning Phase 2 dry eye trial in China but initiation as yet undetermined

<sup>2</sup> U.S. NDA would likely allow commercial marketing in S. Korea w/o clinical trials

**Multiple Partners Create Multiple Paths to Commercialization**



# Clinical Trials – Over 1,700 patients



# ARISE-3 Designed to Replicate Efficacy in ARISE-1 & 2



	ARISE-3 (P3)	ARISE-2 (P3)	ARISE-1 (P2/3)
Subjects	~700 (CAE Model*)	601( CAE Model*)	317 (CAE Model*)
Sign Efficacy (fluorescein staining)	Improvement in staining from baseline to Day 15 in patient subgroup	Improvement in staining from baseline to Day 15 and Day 29 (p=0.0207 and p=0.0254) in patient subgroup	Improvement in staining from baseline to Day 29 (p=0.0062) in patient subgroup
Symptom Efficacy (ocular discomfort)	Reduction of ocular discomfort* from baseline to Day 15 in ITT population	Reduction of ocular discomfort* from baseline to Day 15 (p=0.0149) in ITT population	Reduction of ocular discomfort** from baseline to Day 29 (p=0.0059) in ITT population
Size of Each Cohort	~350 patients	~300 patients***	~105 patients***
Frequency of Administration	4x daily	4x daily	4x daily
Length of Administration	15 days	28 days	28 days
Safety	TBD	Safe and well-tolerated	Safe and well-tolerated
Completion of admin. of study drugs	Summer 2020	3 <sup>rd</sup> Quarter 2017	1 <sup>st</sup> Quarter 2016

**ARISE-1 and ARISE-2 show fast-acting and global effects in dry eye patients; ARISE-3 designed to replicate ARISE-2 efficacy results**

\* CAE = Controlled Adverse Environment; Ora Calibra™ Ocular Discomfort & 4-Symptom Questionnaire

\*\* Ora Calibra™ Ocular Discomfort Scale

\*\*\* Two active doses in ARISE-1; one active dose in ARISE-2 / Note: p values compare 0.1% RGN-259 arm to the placebo arm

# U.S. Neurotrophic Keratopathy Clinical Trial

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## ■ Neurotrophic Keratopathy (NK)

- Chronic degenerative disease characterized by decreased corneal sensitivity and limited or no corneal healing
- Approximately 175,000 cases of NK in the U.S.<sup>(1)</sup>
  - Estimated 10,000 stage 2 and 3 cases
- Estimated \$500 million annual market worldwide

## ■ Orphan drug designation

- Accelerated clinical development timeline
- 7 years of market exclusivity in the U.S., 10 years in the E.U.
- Certain tax credits upon marketing approval

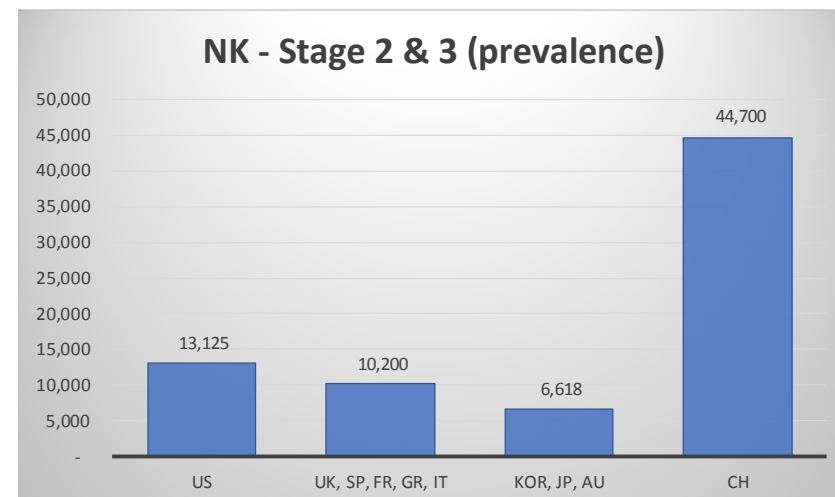
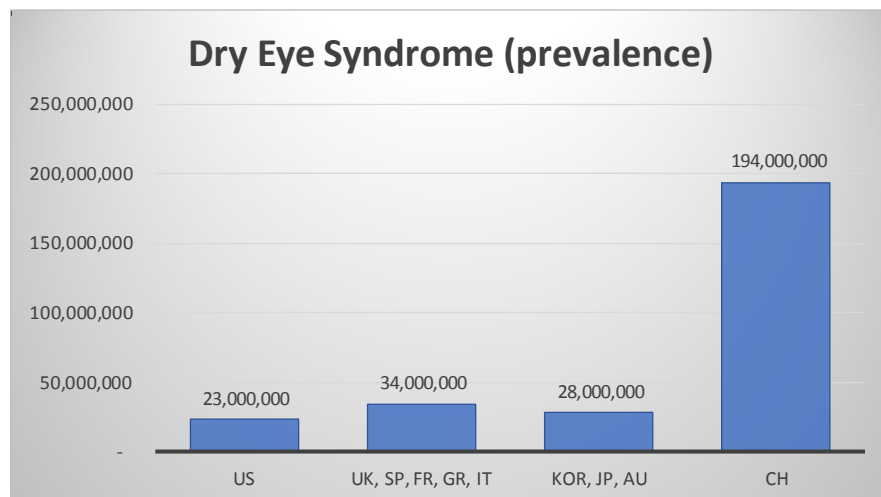
## ■ Trial data on completed patients expected in 2020\*

- RGRX will have access to clinical data for use in other territories, i.e., EU

\* Preliminary masked data indicated that 7 of 18 patients enrolled had complete healing although it is not known if the patients were in active or placebo groups.

(1) *Pharmacy Times* (2018).

# Worldwide Target Markets for RGN-259 in Ophthalmology



The information on these charts is estimated and/or derived from market data reports, scientific and medical publications, and other sources of information thought to be reliable. RGRX has extrapolated certain prevalence numbers based on reported demographic populations in specific territories. RGRX does not warrant the accuracy of the information and undertakes no obligation to publicly update any information contained herein, whether as a result of new information, future events or otherwise.

# U.S. Dry Eye Market Competition

- Restasis® and Lifitegrast (Xiidra™) are only Rx products in U.S. for dry eye
  - >\$1 billion annual Restasis® sales<sup>(1)</sup>
  - Patients experience burning & stinging with Restasis®
  - Efficacy typically not seen for 6 months
  - Package insert states Restasis® is only 15% effective vs. 5% for placebo
- Xiidra™ recently launched in U.S.
  - Estimated \$400 million in sales in 2018
  - Patients report irritation, reduced visual acuity, and dysgeusia (foul taste in mouth)
  - Purchased by Novartis from Takeda for \$5.3 billion
- Clinical data for RGN-259 shows effects are within days, with no burning, stinging or dysgeusia as indicated by Restasis® and Xiidra™
- RGN-259 demonstrated higher efficacy than Restasis® when compared side by side in animal model of dry eye

## **RGN-259 Compares Favorably to Approved Drugs for Dry Eye**

(1) Source: Drugs.com Statistics, 2013 (<http://www.drugs.com/stats/top100/sales>).

# Key Projected Milestones Over Next 15 Months

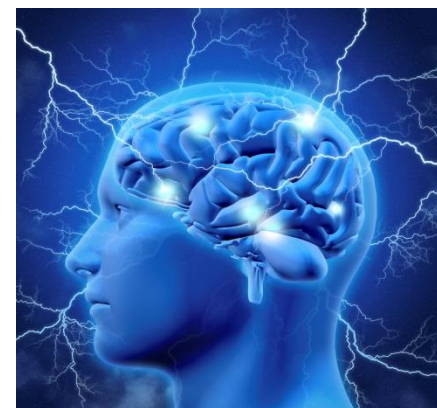
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- ✓ Q2 2018 – Positive FDA response on U.S. Phase 3 dry eye protocol (ARISE-3) with RGN-259 topical eye drop product
- ✓ Q4 2018 – GtreeBNT to begin open EB trial (orphan indication) in U.S.
- ✓ Q1 2019 – ReGenTree initiates 700-patient ARISE-3 clinical trial in U.S.
- ✓ Q1 2019 – \$1.3 million raise from management, board, and affiliates in two tranches to fund company thru Q1 2020 (Second tranche to occur upon enrollment of first patient in ARISE-3)
- ✓ Q2 2019 – First Patient, First Visit (FPFV) in ARISE-3
- ✓ Q4 2019 – Patient enrollment in ARISE-3 peaks
- H2 2019 – Complete analysis of 250 patients with severe septic shock comparing levels of Tβ4 and F-actin, sponsored by Yale, Harvard and Henry Ford Hospital
- 2020 – ReGenTree to close and report on NK trial
- 2020 – GtreeBNT targets completion and reporting of data on Phase 2 EB trial
- Summer/Fall 2020 – ReGenTree to complete and report topline results ARISE-3 clinical trial
- 2020 – ReGenTree to meet with FDA after ARISE-3 trial



**RGN-352**

**Multiple Opportunities in  
Cardiac, CNS and PNS Disorders  
and Severe Sepsis**





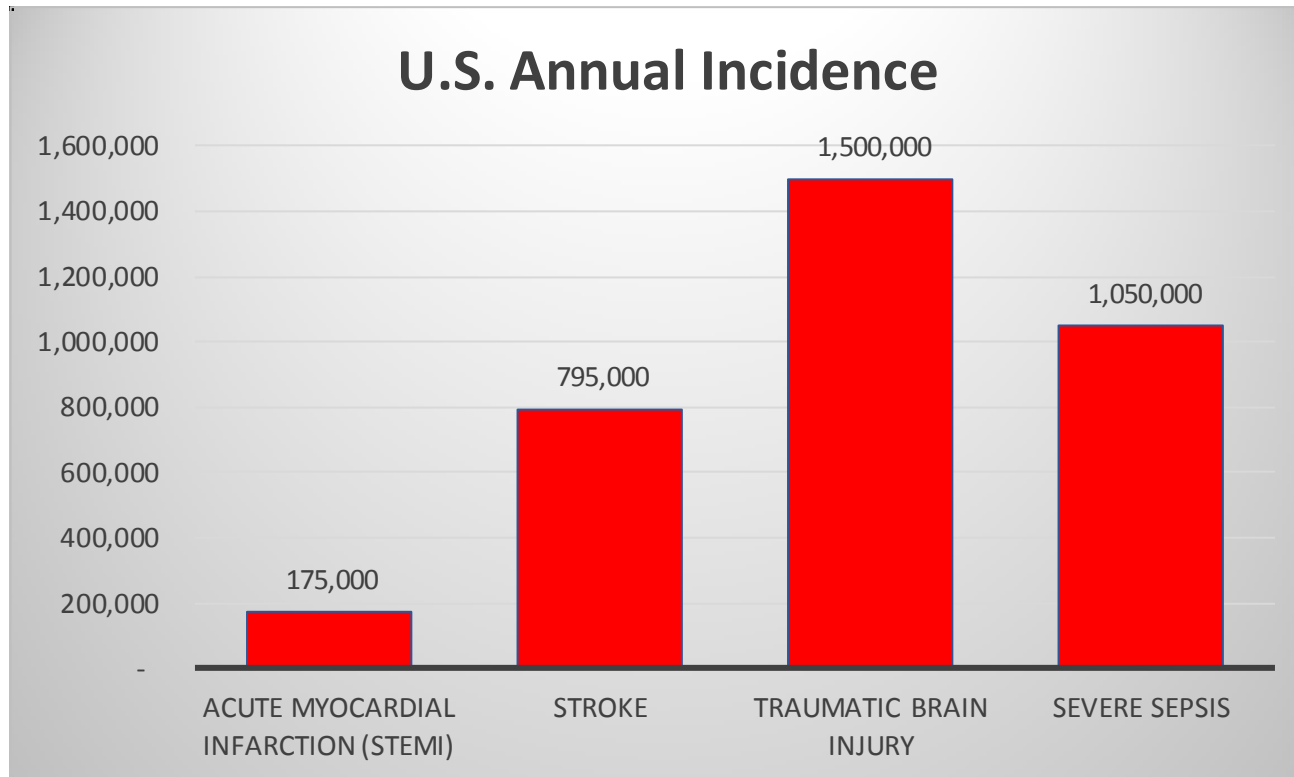
# Potential New Paradigm in the Treatment of Cardiac and Central Nervous System Disorders

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- RGN-352 (T $\beta$ 4 injectable formulation) developed to rapidly repair damaged heart and CNS tissue by multiple mechanisms of action
- Independent *in vitro* and *in vivo* animal models have shown that T $\beta$ 4...
  - increases stem cell recruitment
  - reduces inflammation
  - promotes cell survival
  - promotes blood vessel formation
  - decreases scar formation
- RGN-352 is safe and well-tolerated
  - 27 preclinical toxicology and pharmacology studies
  - Successful 80-subject Phase 1 trial with no drug related adverse events at 4 dose levels
  - Support acute systemic use

**Phase 2-Ready**

# Potential Future Markets for RGN-352 for Acute Systemic Injuries and Wound Repair



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# Financial Highlights and Capitalization

## Financial Summary and Capitalization

(\$/000s)	June 30, 2019
Cash	\$1,350
Current Liabilities	232
Full time Equivalent Employees	4
Monthly Cash Burn	~100
Projected Cash Runway	Thru Q2 2020
Fully Diluted Shares Outstanding	142,907
Insider and Closely Held Shares	~49%