## CHITOGENX

### DELIVERING HEALING POWER OF REGENERATIVE MEDICINE

CORPORATE PRESENTATION SEPTEMBER 2022 CSE: CHGX – OTCQB: CHGX



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  otherwise.



## WHO IS CHIT GENX ?

- FORMERLY ORTHO REGENERATIVE TECHNOLOGIES INC.
- Canadian Public Company CSE: CHGX
- Market Cap ~\$15M
  - Invested Capital \$15M
- Acquired IP for technology from Polytechnique de Montreal 2015
- Clinical stage Biologics company focused on the \$9B US Regenerative Medicine Market
- Patient enrolment initiated in Phase I/II clinical trial in rotator cuff repair



# WHY DID WE CHANGE NAME TO CHIT GENX?

 Our proprietary drug/ biologic biopolymer has potential for MUCH broader application in regenerative medicine than just orthopedics





## **REGENERATIVE MEDICINE**

- One of the most dynamic field of medicine
- Focused on the repair or regeneration of body tissues to restore lost function due to disease or Trauma
  - Transporting biologics (blood or blood products), stem cells, pharmaceuticals to desired repair site

#### Vexing Problem:

 Providing a reliable, biologically safe transport mechanism that would allow the targeted body system to receive the regenerative material to aid in body system repair







## **CHITOGENX** Mission

To provide reliable, biologically safe *Regenerative Medicine* delivery mechanism to targeted body systems to aid in tissue and organ repair



## SIGNIFICANT COMMERCIAL OPPORTUNITY

GLOBAL REGENERATIVE MEDICINE MARKET SNAPSHOT



## CHIT GENX BIOPOLYMER PROPERTIES

- > Muco-adhesive and cationic(+ charged)- Stays where you put it...
- > Wound healing properties
- > Potential for delivery of pharmaceuticals, peptides, proteins, and vaccines
- > Intrinsic antifungal, antimicrobial, anti-infectious properties
- > Hemostatic effects; enhances blood coagulation
- Scaffolds for bone regeneration: bone substitutes and cements; rebuilding of bone







## FIRST U.S. CLINICAL TRIAL

## ROTATOR CUFF TEAR REPAIR STUDY

Why Rotator Cuff?





### STANDARD OF CARE SURGERY SHORTCOMING: HIGH FAILURE RATE



R. Mirzayan & Al., J Am Acad Orthop Surg 2019;27: 468-478

#### HIGH UNMET MEDICAL NEED FOR MORE EFFECTIVE TREATMENTS



## Why Is There a High Failure Rate in Soft Tissue Repair?

- Soft tissues tendons, cartilage and meniscus not well vascularized (white)
  - Difficult to repair to original physiological structure
- Tendon–bone healing:
  - Standard of care healing occurs through formation of scar tissue
  - Structurally different than the native tendon–bone
  - Why re-tearing is so frequent

#### Healthy Rotator Cuff

#### Torn Rotator Cuff



#### HIGH UNMET MEDICAL NEED FOR MORE EFFECTIVE TREATMENTS

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## PLATELET-RICH PLASMA (PRP) REGENERATIVE MEDICINE

- Medically understood and characterized
  - PRP contains growth factors that affect all aspects of healing for all types of tissue

#### PROCESS OF PRP THERAPY



Collect blood

30-60ml of blood is drawn from the patient's arm.



Separate the platelets

 The blood is then placed in a centrifuge. The centrifuge spins and separates the platelets from the rest of the blood components.



Extract platelet-rich plasma

Extract 3-6ml of platelet-rich plasma.



#### Ehrenfest et al 2014

#### × Highly liquid

 Does not stay at surgical repair site long enough to significantly help healing

× Biologic activity limited (24h-72h)



### ORTHO-R TECHNOLOGY – NEW PARADIGM EASY TO PREPARE DURING THE SURGERY PROCEDURE

#### **CHITOSAN**



- Polycationic (sticky to soft tissues)
- Widely used commercially and proven safe



Freeze-dried product



- Patient's own blood
- No rejection
- Safe

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**ORTHO-R** 

Drug/biologics combination product

ORTHO-R /PRP MIX Stays on surgically repaired site for up to 6 weeks



## **ORTHO-R – ROTATOR CUFF TEARS**

Stays at site of tear repair for up to six weeks delivering regenerative treatment

ORTHO-R® delivered between tendon and bone & on repaired site surfaces

ORTHO-R<sup>®</sup> allows the PRP and Chitosan to stay between tendon and bone for weeks ORTHO-R<sup>®</sup> Delivered at REPAIRED SITE AFTER TENDON REATTACHMENT

> ORTHO-R easy adjunct to standard of care – Adds 1-3 Minutes to standard of care surgery

**Suture Anchors** 



## ORTHO-R PRECLINICAL STUDY FASTER AND BETTER TISSUE REPAIR

Normal Tendon – Not Injured

Standard of Care Surgery ANCHORS ONLY



ORTHO-R Plus Standard of Care





Tendon fibres organized in bundles

- Repaired tendon 3- months POST-SURGERY
- Standard of care surgery with Anchors ONLY
- Repaired tendon is mostly scar tissue
- Mechanically weaker and prone to retear
- Repaired tendon 3- months POST-SURGERY
- Tendon mostly organized in bundles with smaller areas of tendon-like repair tissue
- SUCCESSFUL HEALING WITH ORGANIZED REPAIRED TISSUE

### FIRST CLINICAL TRIAL ROTATOR CUFF STUDY





#### ORTHO-R PHASE I/II STUDY 10 U.S. CLINICAL SITES

Sites chosen for notoriety of surgeon and volume of procedures

9 of 10 sites fully initiated and recruiting

Florida

### **ORTHO-R PHASE I/II SAFETY STUDY** 2022-23 REGULATORY & CLINICAL VALUE CREATION MILESTONES (ESTIMATES)

PHASE I END **ENROLLMENT** PHASE I/II 10/2022 ENROLLMENT Q3-2022

START

PHASE II END ENROLLMENT Q1/2023

PHASE I/II **CLINICAL** PHASE II RESULTS 12 MONTH FOLLOW-UP H1-2024 COMPLETION Q1-2024

Attractive target for partnering or M&A - for large orthopedic companies

Already have established partnership with large ortho company for this project

CHIT

## **OPINION LEADER SUPPORT FOR PLATFORM**

Re: Anastomotic dehiscence and leakage is a real and present danger

"The implications for patients should this concept be proven would be massive - this is a large patient population with numbers around the world being very similar. Surgeons would not hesitate to use and recommend such a product were the data to support safety and efficacy".

David Jayne, Professor of Surgery.



"The potential for the chitosan product the company has developed is very attractive with multiple potential clinical applications - many proclaim to have a platform technology, but this may actually be the case!"

ann An

Ghassan S. Kassab, PhD Chair/Institute Professor



### **INTELLECTUAL PROPERTY 3 FAMILIES OF PATENTS**

- 1. Clot-activated polymer composition of PRP and chitosan (2030)
- Granted in the United States of America, Europe (Germany, Spain, France, United Kingdom and Italy), and Canada
- 2. Freeze dried chitosan and lyoprotectant for use with PRP, blood and combinations to form an injectable solution (2035)
- Granted in United States of America, Japan, Europe (Germany, Spain, France, United Kingdom and Italy), Canada and Australia
- 3. Lyophilized scaffold comprising at least one polysaccharide, to have a variety of beneficial effects for tissue repair (2035)
- Granted in Japan and Australia currently undergoing examination in United States of America, Europe and Canada





## Why Invest Now?



Important near-term clinical milestone – completion of Phase I of Rotator Cuff Phase I/II FDA clinical study



Multi Platform Potential as Regenerative Medicine delivery system



Solves a major problem in dynamic regenerative medicine market





## **THANK YOU!**

# CHITOGENX

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