



# OF REGENERATIVE MEDICINE

October, 2023

**CSE: CHGX, OTCQB: CHNXF** 



# Who is CHIT GENX

- Clinical Stage Public Company
  - CHITOGENX- CSE: CHGX OTCQB: CHNXF
  - Targeting the Skin Repair Market valued at \$77B in 2022 + 6.4% CAGR
  - Market Cap approx. \$10M
  - Invested Capital \$15M
- Acquired IP from Polytechnique De Montreal 2015
  - No-ongoing license fees
- Breakthrough Chitosan Based Biopolymer (CBB) Technology Platform to improve outcomes for tissue repair
  - Proprietary Chitosan-Based Biopolymer can provide scaffold for multiple applications





- Chitosan-based biopolymer mixed with PRP and blood products have been designated needing a Biologics License Application (BLA) regulatory pathway in US and Canada
  - FDA deemed it to have biological activity
  - BLA pathway mimics pharmaceutical development (Phase I, Phase II, 2 phase III studies)
  - Potentially long and expensive development pathway



## How do we Overcome Challenges?

- Focus on changing the regulatory path for our assets out of the BLA and into 510K or as excipient
  - Stop spending on BLA science (without a partner)
  - Launch combinations with no biological activity (skin cells, pharmaceuticals)
  - Build proof of concept to interest development partner(s) to co-fund development
- Improve Balance sheet for potential investment





# Proprietary Chitosan-based Biopolymer

Combination of chitosan-based biopolymer <u>with and without</u> blood-derived products are covered by three separate patent families bolstered by ongoing patent extension strategy

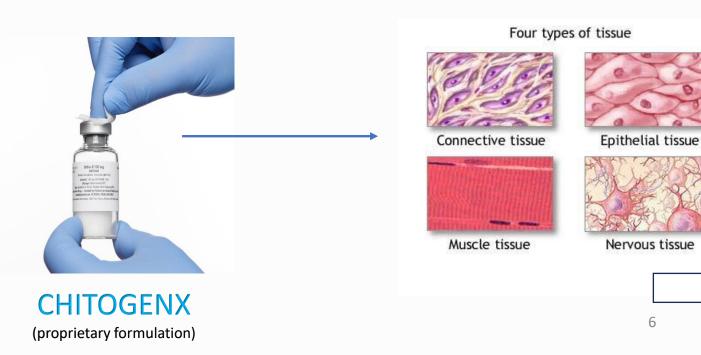
PATENT Family	Status	Expiry	Territories
Clot-activated polymer composition of PRP and chitosan	<u><b>Granted</b></u> US 9,427,469	2030	USA, CAN, EU (GER, SPN, FRA, GBR, ITA)
Freeze dried chitosan and lyo-protectant for use with PRP, blood and combinations for tissue repair and intra-articular injection	<u>Granted</u> US 11,285,100	2035	USA, CAN, JPN, AUS, EU (GER, SPN, FRA, GBR, ITA)
tissue repair and intra-articular injection	Additional claim pending US 2022/0151917	TBD	USA
Lyophilized scaffold comprising at least one polysaccharide, to have a variety of beneficial	<u>Granted</u> AUS015221390	2035	Japan and Australia, Canada
effects for tissue repair	Allowed US	2035	USA

ChitogenX purchased all IP from Polytechnique, no future royalties are due



# CHIT GENX MISSION

To provide an efficacious, safe and reliable scaffold for targeted body systems to aid in skin and tissue repair







# Company Strategic Focus

- Refocus company on Proprietary Chitosan-Based Polymer
  - Chitosan generally agreed to as safe by FDA
  - Launch skin repair program (proof of concept already underway- completion 11/30/23)
  - Investigate Osteoarthritis
- Continue to work with Polytechnique to support product characteristics
  - Science team completely paid for through grant funding
- Complete shoulder cuff repair program with 20 Patients.
  - Meaningful clinical/FDA safety data collection
  - Program complete in 06/24
  - Study report expected 9/24



# Why Skin Repair?



High unmet medical need



More efficient clinical development program



Potential for simplified regulatory pathway



## Our Proprietary Chitosan Based Biopolymer

- Skin repair scaffold leveraging ChitogenX's formulation, CMC and safety testing
  - Prior FDA review of characterization and CMC data would accelerate development
  - 510(k) pathway offers potentially faster avenue to market introduction
  - Natural properties of chitosan may allow broader claim set with clinical data generation
- Chitosan is the foundational biomaterial for several 510(k) products
  - Existing clearances for wound dressing and hemostatic agents
  - Prior clearances could serve as predicate devices for new products



### **CURRENT SKIN REPAIR MARKET OPPORTUNITY**

### **BURNS and TRAUMATIC WOUNDS**

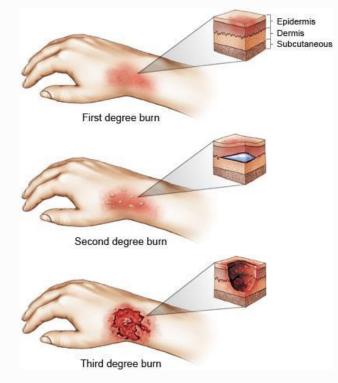
- more than 450,000 serious burn injuries occur in the United States that require medical treatment each year (American Burn Association)
- Traumatic Wound and Burn Market worth \$18B + CAGR 5.2% for 10 years

### THE PROBLEM

 Skin graft failures due to rejection, infection or lack of adherence

### **THE SOLUTION**

- ChitogenX Chitosan Based Biopolymer combination with disaggregated skin cells:
  - Reduce infection
  - Increase adherence
  - Improve healing





## GLOBAL SKIN REPAIR MARKET, BY APPLICATION, 2022-2032 (\$MILLION)

Sources: Secondary Research, Annual Reports, Press Releases, Journals, Industry News, White Papers, Articles, Expert Interviews, Blogs, and Precedence Research Analysis

	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	CAGR (2023- 32)
Burns	12,008.8	12,438.3	12,994.8	13,650.1	<mark>14,435.7</mark>	15,307.3	<mark>16,131.0</mark>	17,061.7	18,200.8	19,464.4	20,846.3	<mark>5.9%</mark>
Diabetic Foot Ulcers	18,283.5	19,256.5	20,275.9	21,465.6	22,879.3	24,451.3	25,969.7	27,684.2	29,765.2	32,082.5	34,631.4	6.7%
Surgical Wounds	14,856.3	15,668.8	16,573.6	17,625.1	18,869.5	20,254.8	21,606.2	23,131.5	24,975.9	27,033.3	29,302.1	7.2%
Traumatic Wounds	<mark>6,350.9</mark>	<mark>6,490.4</mark>	<mark>6,714.0</mark>	<mark>6,981.9</mark>	7,308.2	<mark>7,668.8</mark>	<mark>7,995.7</mark>	<mark>8,365.6</mark>	<mark>8,825.8</mark>	<mark>9,332.4</mark>	<mark>9,880.4</mark>	<mark>4.8%</mark>
Pressure Sores	5,301.5	5,459.1	5,668.4	5,917.3	6,218.4	6,551.7	6,859.5	7,207.5	7,637.4	8,112.1	8,628.2	5.2%
Others (Cosm.)	20,782.0	21,681.8	22,742.8	23,985.9	25,469.0	27,116.5	28,692.4	30,472.2	32,640.7	35,051.1	37,695.8	6.3%
Total	77,583.0	80,994.8	84,969.6	89,625.9	95,180.3	101,350.3	107,254	113,922.8	122,045.9	131,075.9	140,984.2	6.4%



## **Burn Co. Model**

#### Stats...

- \$407M market Cap \$66M in cash
- Revenue \$40.85M
- Technology limitation on more severe burns that ChitogenX tech may improve

### Rationale:

ChitogenX scaffold can expand Burn Co. regulatory indications (solving a problem)

- Ortho-R's physical and chemical characteristics well established in science
- Proof of concept protocol agreed upon with Polytechnique
  - 1 month of activity
  - Polytechnique scientists very confident proof of concept will be positive
- Assuming proof of concept positive will go directly to animal studies in burn protocol
  - Poly already working on grant funded skin generation protocol as support for Burn Co. work
  - Potential for operating capital
- Open negotiations for licensing and full development IND



# **Meniscus Data Surprise**

### Expected:

- Ortho-R>PRP alone>standard of care
- We would show superior tissue integrity (as in shoulder tendon)
- We would see function benefits

## Unexpected:

- 9 of 12 sheep in non-ORTHO-R groups developed severe OA
- None of the 6 Ortho-R developed OA



## **THANK YOU!**



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