Hemostemix Inc.
TSXV:HEM OTCQB:HMTXF FSE:2VF0

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Harness each patient's own stem cells to heal ischemia and relieve pain—safely, ethically, and accessibly.



Peripheral arterial disease?

Diabetic foot ulcer?

CLTI?

Angina?

Congestive Heart Failure?

Ischemic Cardiomyopathy?

Non ischemic Dilated Cardiomyopathy?

Vascular Dementia?

Total Body Ischemia

Results





Fig. 2: Patient with ischemic ulceration to the right toe. The patient had intact circulation to the midcalf with no direct flow to the foot and occlusion of both the dorsalis pedis and posterior tibial arteries. They were deemed to have no revascularization options. A) Demonstrates dry wound involving the distal tip of D1 immediately prior to enrollment. B) The wound had successfully healed 4 weeks after treatment with no evidence of recurrence.





Fig. 3: Patient with large, nonhealing decubitus ulceration to heel of right foot. The patient had a history of 2 prior interventions including a failed femorotibial bypass graft with prosthetic. A) Demonstrates the ulcer at the time of enrollment with a large, mostly nonviable base. The patient had been offered below knee amputation for symptom palliation; B) 4 months posttreatment showing significant improvement. Concurrent treatment wearing an offloading orthotic and regular dressing changes

Saving a Limb is Saving a Life!

Whereas the CLTI five-year mortality is 50%, the Universities of Toronto and British Columbia presented: 83% of patients followed in the Phase II trial for up to 4.5 years experienced healing of ulcers, cessation of pain, no major amputation, or mortality.

Significant reduction in ulcer size: 1.48 cm² to 0.48 mm² within 3 months (p=0.01) while placebo did not exhibit a change (p<0.54).

At 1 year, amputation (4.8% vs 25%) and mortality (4.8% vs 12.5%), respectively.

JBRES, Feb 6, 2024

Retrospective analysis of 53 adult patients with severe cardiomyopathy, 41 ischemic, 8 non ischemic dilated cardiomyopathy. LVEF% measured at baseline, and at months 4 and 12.

ISCHEMIC

- 1.LVEF% increased from 29.9% to 34.6% at month 4 (p<0.004)
- 2.LVEF% increased to 38.2% at month 12, a 24.1% relative increase

NON ISCHEMIC DILATED CARDIOMYOPATHY

- 1.LVEF% improved from 25.9% to 33.4% at month 4 (p<0.017)
- 2.LVEF% increased to 38.1% at month 12, a 47.1% relative improvement

MOST SEVERE CASES (LVEF% < 20%)

1.LVEF% rose from 14.6% to 28.4% in this high-risk group

LVEF% = volume of blood ejected with each heart beat

21 Yrs

Development

9

Publications

\$49M

Raised

7

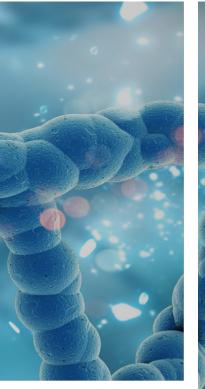
Clinical Trials

498

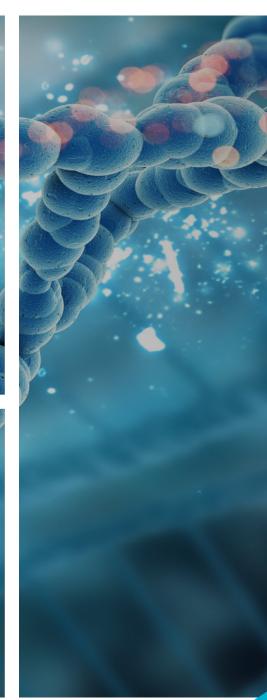
Treated

91

Patents







Safety, Clinical Relevancy and Statistical Efficacy

Type of Study	Pilot Safety/ Feasibility	Phase 1b	Phase 2	Phase 1	Phase 1	Phase 1	Retrospective
Publication	Journal of the Medical Associatio n of Thailand; 2009	CytoTherapy, 201 3 Oct. 15 (10) .	Stem Cell Research & Therapy, 2023 14:308.	Circulation, 200 6;114:II 786.	ASEAN HEART JOURNAL 2009; 17: 13-22.	Asian Cardiovasc Thoracic Annals 2008;16:14 3-148	Stem Cell Research & Therapy, 2023 14:308.
Study Design	Open Label	Open Label Randomized	Randomized Double Blind Placebo Controlled	Open Label	Open Label	Open Label	Retrospective
Number of Subject	6	20	67	24	106	41	54
Patients	Diagnosed CLI	Diagnosed PAD	Diagnosed CLI	Diagnosed Angina	Diagnoses of severe ischemic heart disease with continuous angina or heart failure symptoms	Diagnosed In- operable Ischemic Cardiomyopathy or Dilated Cardiomyopathy	Ischemic and Dilated Cardiomyopathy
Study Status	Completed and Published	Completed and Published	Completed and Published	Completed and Published	Completed and Published	Completed and Published	Completed and Published
Results	83% of Limbs Saved	At 2 Years 7 of 10 Treated Limbs Saved vs 2 Deaths and 6 of 8 Limbs Amputated	Patients with wound ulcers before ACP- 01 (21 treatment, 8 placebo). Ulcer size in the treated group decreased from a mean of 1.46 mm2 to 0.48 mm2 (p = 0.01) by 3 months.	6MW +24%. CCS decreased Exercise METs & Perfusion Defects Improved	NYHA & CCS Improved Significantly LVEF% + 4.7% SF 36 Health Survey Significant Improvement	LVEF% + 4.8% NYHA Significantly Better at 2 Months	LVEF improvement was most marked in the patients with the most severe cardiomyopathy (LVEF < 20%) improving from a mean 14.6% ± 3.4% pre-procedurally to 28.4% ± 8% at final follow-up.



Production Agreement & Equity Investment

CYTOIMMUNE PRODUCTION AGREEMENT

Fully funded two-year production agreement that includes \$1.1 Million of Revenue, CytoImmune has a \$27 Million investment in 38,000 square feet and a team of that enables Hemostemix to produce at \$12 Million/Year with volume increasing to \$144 Million per Year.

15 YEAR AGREEMENT WITH PUERTO RICO

Act 60 legislation generates 50% cash back of all current and future R&D, + a 15-year 4% tax on profit, + a 20% tax credit for offshore expenses. Renewable for a second 15-year term.

Target Markets are Very Large

The global CLTI market was valued at \$4.02 Billion in 2022. The Ischemic Heart Disease (IHD) drugs market reached US \$6.1 Billion in 2022.

Addressable Market

1/20,000 market penetration in North America and the European Union represents 240 units/month, and \$144 Million in annual revenue.

This can be achieved with six clean rooms operating two shifts at 40 batches a month, or one ACTS module producing 240 batches a month.

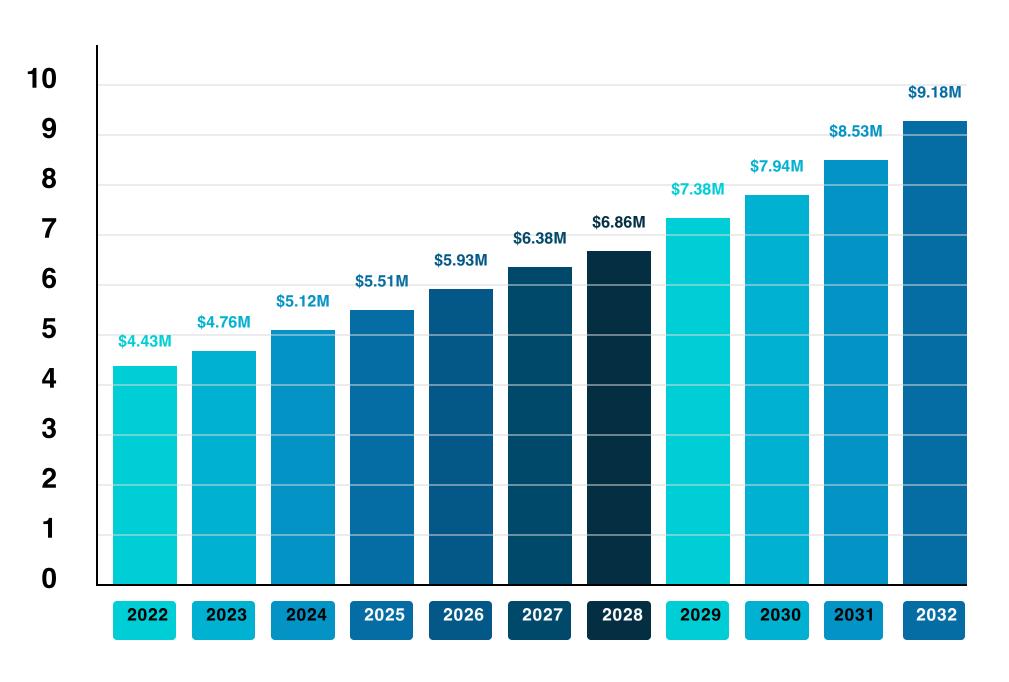
Saving Limbs Market

To "save" 5,000,000 limbs per year we calculate it requires $\sim 7\%$ of the square feet of the Mercedes Benz Sindelfingen plant.

Including physician and clinic costs, we can save ~93% of limbs at 51% of the price of a base Model S.

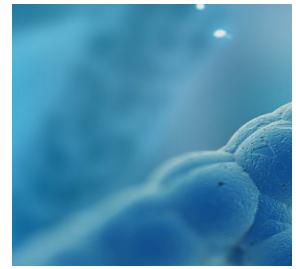
We save the healthcare system approximately 3 of 5 years of healthcare expenses for these patients.

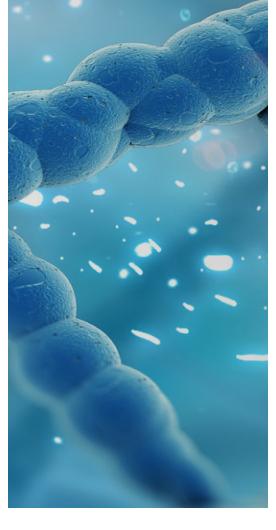
CRITICAL LIMB ISCHEMIA TREATMENT MARKET SIZE 2023 TO 2032 (USD BILLION)



Source: www.precedenceresearch.com







The Company projects to be cashflow positive by Q4 2026 selling 20-30 treatments per month to:

- 1. no-option patients suffering from pain related to end-stage CLTI, ICM, DCM, CHF, total body ischemia, and chronic pain, in Florida.
- 2. Phase I patients who pay to be treated in the Bahamas



Forward Sales of Treatments

110 Heart

Invasive Cardiologists

Organized invasive cardiology capacity to treat up to 110 patients/month with cardiologists who have completed 210 regulatory approved ACP heart treatments.

226 CLTI

Phase II Vascular Surgeons

Globally, 236 million suffer from Peripheral Arterial Disease. Approximately 20 million degenerate into CLTI.

We have physician capacity to review up to 226 patients/month – 2nd opinion before amputation.

A Multiple Treatments Technology Platform: ACP, NCP, CCP

From the patient's blood: ACP, NCP, and CCP.

Angiogenic Cell

Angiogenesis at the site of ischemia.

Enhanced migration and repopulation of

damaged tissue. Decreased inflammation,

anti-apoptotic factors. CLTI & Heart Disease

Precursors

NCP **ACP** 01 **CCP** 01

Neuronal Cell Precursors

Enhanced secretion of nerve growth factors, Homing of cells to site of injury. Neuro – regenerative!

Small animal study of motor function and neuropathic pain underway at Clemson University.

Cardiomyocyte Cell Precursors

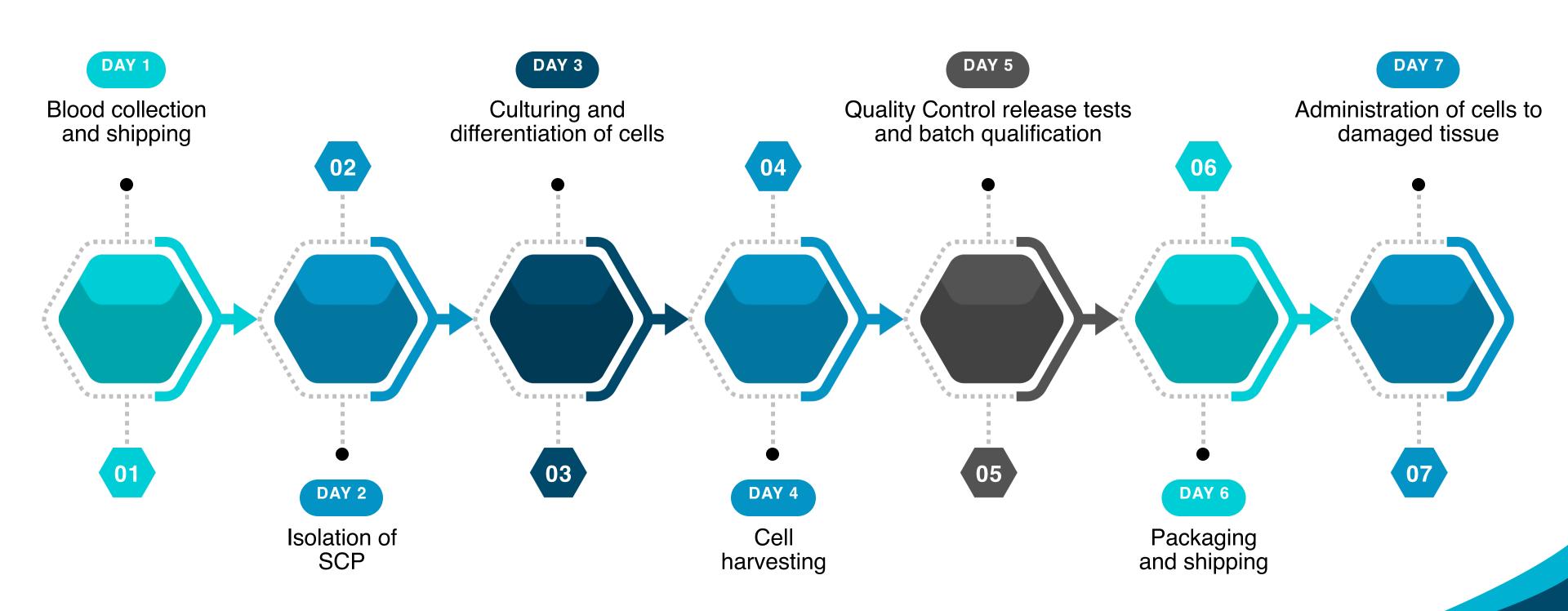
Proposed to create a heart patch in conjunction with an autologous bio scaffold

Product Development

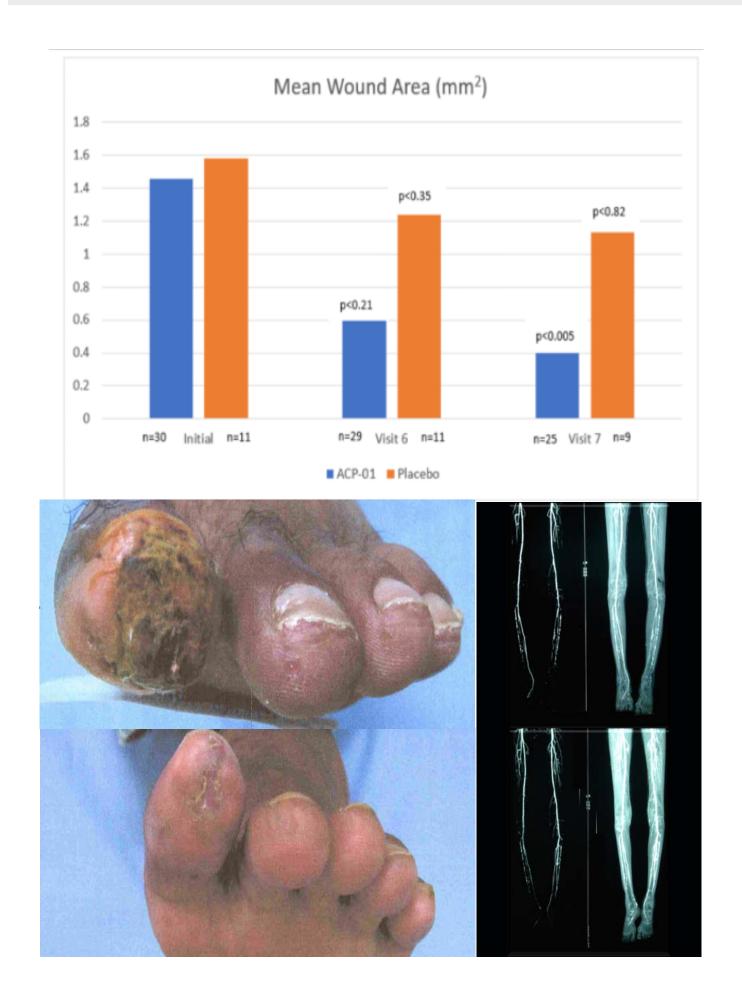


Key Process Steps with Treatment on Day 7

ACP-01 (patient's DNA) scales and ships in 3 x 10 cc ready to use syringes, to physicians globally.

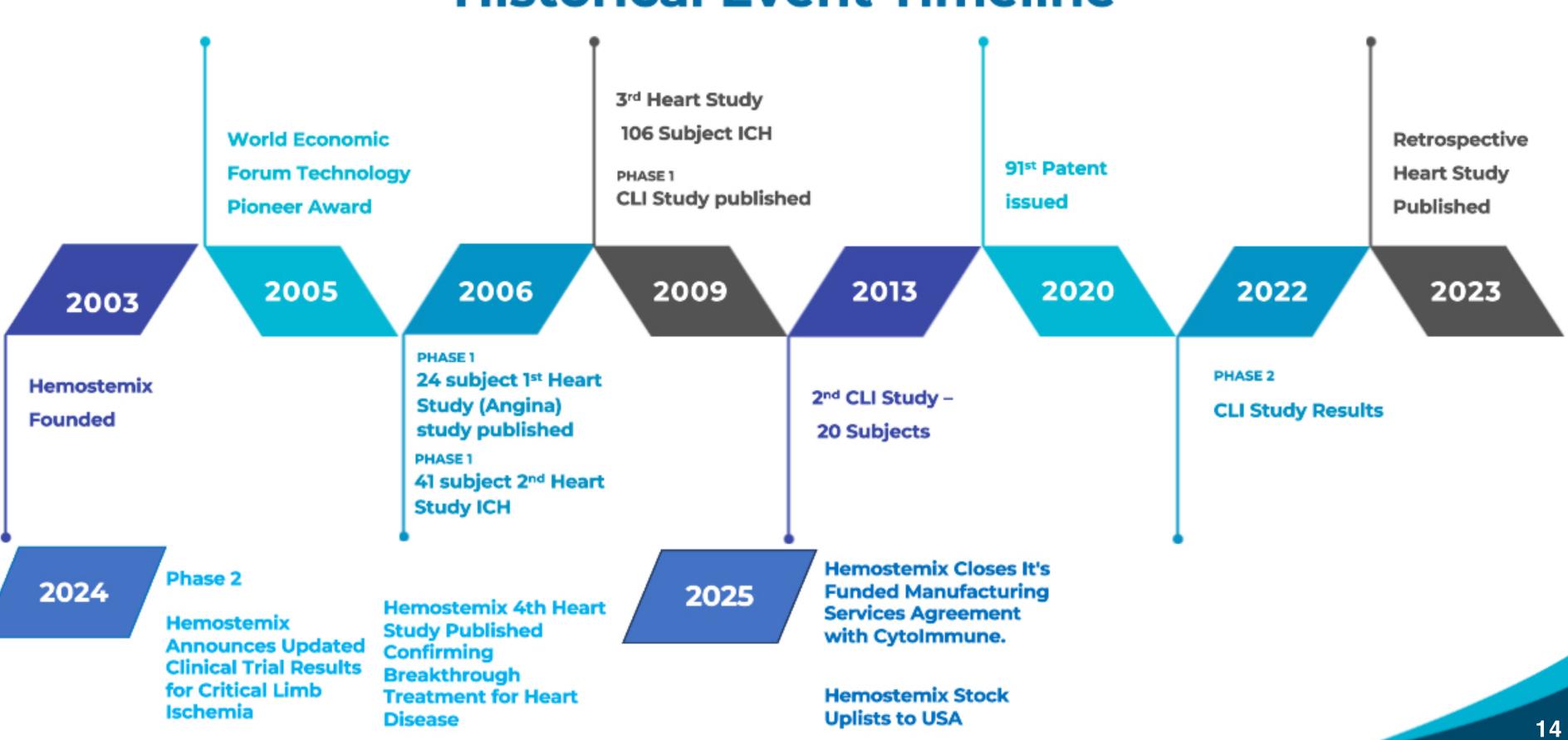


Why Physicians and Patients Like ACP





Historical Event Timeline





Autologous Regenerative Therapeutic Competitors

Company	Indications		Source		Phase	
	Ischemic Heart Disease	Chronic Limb Threatening Ischemia	Chronic Limb Threatening Ischemia	1	II	III
Hemostemix			Peripheral Blood ¹		•	
BioCardia			Bone Marrow ²			
Life Cells ³			Acellular Dermal Matrices ³			
BioGen Cells			Peripheral Blood ¹		©	

Notes:

- 1. Simple peripheral blood draw provides patient own unique DNA based source material.
- 2. Bone marrow derived stem cell source material requires hospitalization which limits scaling of the therapeutic. The procedure is painful and adds risk.
- 3. Allergen (Abbvie) paid \$2.9 B cash for Lifecell for its allogenic acellular dermal matrices that serve as scaffolds for tissue repair in surgeries: facial, breast, abdominal and burn reconstructions.
- 4. Planned closeout of completed Phase II CLTI trial, and initialization of Phase II ICM and Phase III CLTI trials
- 5. Results expected in Q4, 2024
- 6. Completed in 2016
- 7. Recruiting patients



Path to Market – No Option Patients

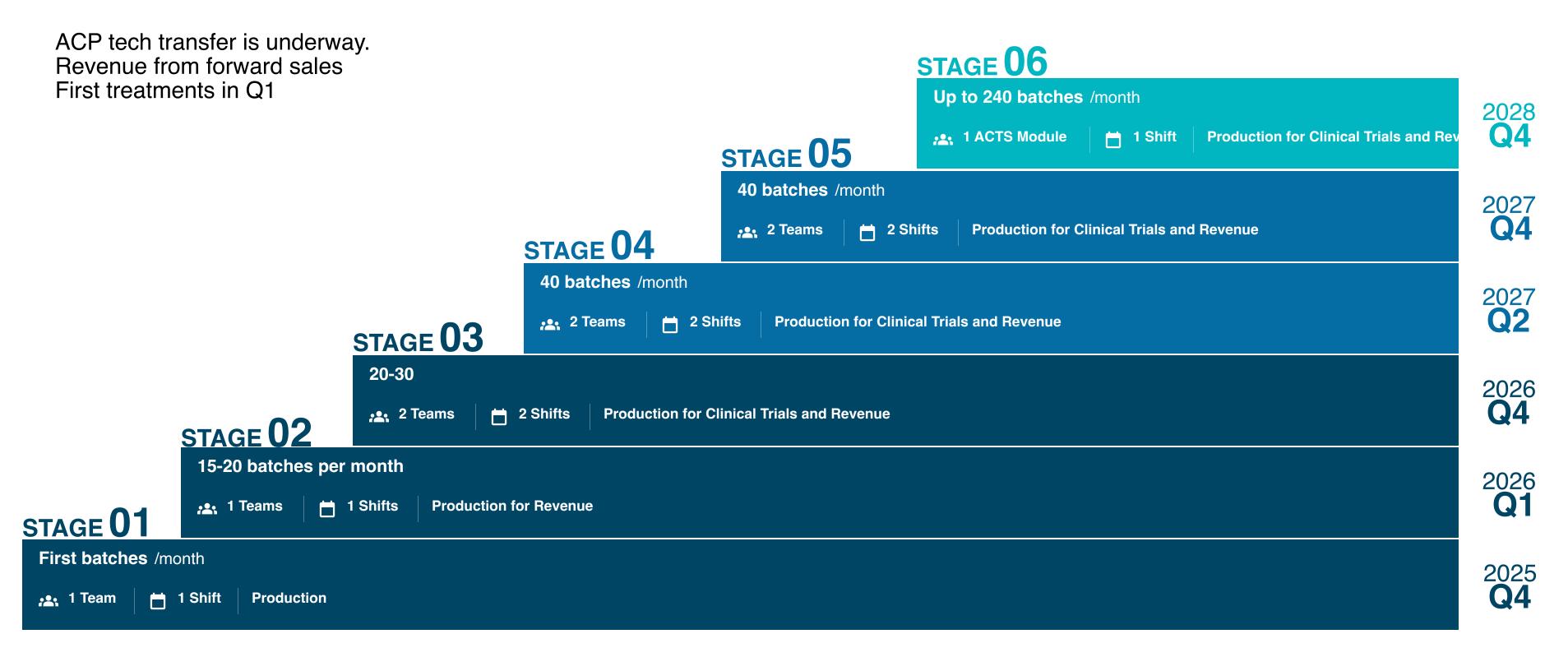
Sales of ACP for no-option patient treatments is through clinicians who have regulatory approval to treat.

In one clinic, 4 treatments per day generates \$32.5 Million annual revenue for Hemostemix.

ACP-01 heart disease treatments will be through invasive cardiologists who have completed more than 200 ACP-01 treatments. They have the capacity to treat 110 referrals per month.

To-date, seven clinical trial sites have the capacity to treat 336 Hemostemix referrals per month.

Timeline to Production





Capital Table

Notes:

1. CD2 – 5-yr secured (1st position), due April-2027, interest of 8% p.a. payable in shares, converts at \$0.175 per share.

2. Warrants – Weighted average strike price \$0.365, weighted average duration 20.6 months.

Hemostemix Inc. - Proforma Cap Table (Jan-13-2025)

Shares	144,727,414
Warrants	78,489,650
Options	12,386,694
Fully Diluted (no CD Conversion)	235,603,758
Convertible Debenture 1 ("CD1")	6,250,000
Convertible Debenture 1 ("CD1") Convertible Debenture 2 ("CD2)	6,250,000 <u>15,714,286</u>

Fully Diluted (with CD Conversion)

257,568,044



Use of Funds

Forecast Summary (CAD \$000s)

Cash Use - Manufacturing and Required Operating Costs	Year 1	Year 2	Year 3	Year 4	Year 5
Manufacturing Facility - (1 Clean Rm with 2 shifts; + working lab)	\$1,591	\$1,053	\$1,053	\$1,053	\$1,053
Manufacturing - Costs+Staffing (add 2nd shift in 1yr-Q3)	\$953	\$1,310	\$1,310	\$1,310	\$1,310
Manufacturing costs	\$2,543	\$2,363	\$2,363	\$2,363	\$2,363
Sales costs	\$886	\$987	\$1,013	\$1,013	\$1,013
Regulatory & Patents	\$340	\$120	\$120	\$120	\$120
Corporate	\$800	\$1,000	\$1,150	\$1,300	\$1,500
Other/Contingency	\$400	\$500	\$550	\$600	\$650
Corporate, regulatory and patents	\$1,540	\$1,620	\$1,820	\$2,020	\$2,270
Cash used	\$4,969	\$4,970	\$5,196	\$5,396	\$5,646

Production Information	Year 1	Year 2	Year 3	Year 4	Year 5
Max Capacity	30	450	480	480	480
Utilization Percentage (0-100%; Sensitivity and Trial batches)	75%	75%	75%	75%	75%
Batches sold (truncated, no partial batches)	22	337	360	360	360

Cash Sources	Year 1	Year 2	Year 3	Year 4	Year 5
Financing of \$6MM, net of 5% costs	\$5,700				
Batch revenue (net of direct var'l costs; Fxd are in lines 7 and 8)	\$990	\$15,165	\$16,200	\$16,200	\$16,200
Act 60 - Cash back (factored at 90%)		\$2,236	\$2,233	\$2,276	\$2,304
Licensing - based on phase II cardiac midpoint results					
Cash generated	\$6,690	\$17,401	\$18,433	\$18,476	\$ 18,504
Change in Cash - for the period	\$1,721	\$12,431	\$13,238	\$13,080	\$12,858
Cumulative cash available for debt service, trials, ACTS, W/C	\$1,721	\$14,152	\$27,389	\$40,470	\$53,328

Key Takeaways

ACP is a break-through treatment for no-option angina, dilated and ischemic cardiomyopathy and CLTI, PAD, Vascular Dementia..

Forward Sales will generate revenue from the early start of production and gear to produce for sales to no-option patients at ~ 80% Margin.

ACT 60 generates 50% cash back of all R&D, a 15-year, 4% profit tax, and a 20% tax credit for offshore expenses, for 15 years and is renewable for 15 years (30).

Management and the board have \$9.1 million invested since 2020.

ACP is effective, and because it is sourced from the patient's blood and cultured in the patient's serum. It is completely autologous and therefore safe in the short term and the long term.

ACP is protected by 91 patents, is scalable, with a team that has more than 20 years of production experience.

The company will file for orphan disease status for Dilated Cardiomyopathy.



Life Sciences Investment 2024: \$191B. 2024 M&A: 6 deals \$2.4 B. Bristol Myers \$13.8 Billion Cash for Myocardia...Compare Hemostemix?

Myocardia's Results (Lancet)

251 (59%) were enrolled and randomly assigned to mavacamten (n=123 [49%]) or placebo (n=128 [51%]). 45 (37%) of 123 patients on mavacamten versus 22 (17%) of 128 on placebo met the primary endpoint (difference +19·4%, 95% CI 8·7 to 30·1; p=0·0005). Patients on mavacamten had greater reductions than those on placebo in post-exercise LVOT gradient (–36 mm Hg, 95% CI $-43\cdot2$ to $-28\cdot1$; p<0·0001), greater increase in pVO2 (+1·4 mL/kg per min, 0·6 to 2·1; p=0·0006), and improved symptom scores (KCCQ-CSS +9·1, 5·5 to 12·7; HCMSQ-SoB $-1\cdot8$, $-2\cdot4$ to $-1\cdot2$; p<0·0001). 34% more patients in the mavacamten group improved by at least one NYHA class (80 of 123 patients in the mavacamten group vs 40 of 128 patients in the placebo group; 95% CI 22·2 to 45·4; p<0·0001). Safety and tolerability were similar to placebo.

Restrictions & Warnings

- 1. Initiation in Heart Patients with LVEF<55% not recommended.
- 2. Interrupt if LVEF% <50%, or if worsening clinical condition.
- 3. Can cause heart failure due to systolic dysfunction.

ACP-01 Results (Stem Cell Research & Therapy)

Fifty-four of 74 patients met requirements for inclusion (48 males and five females; age 68.1 ± 11.3 years). SAEs included one death (previously unrecognized silent MI), ventricular tachycardia (n = 2) requiring cardioversion, and respiratory infection (n = 2). LVEF in the ischemic subgroup (n = 41) improved by 4.7% ± 9.7 from pre-procedure to the first follow-up (4 months ± 1.9 months) (p < 0.004) and by 7.2% ± 10.9 at final follow-up (n = 25) at average 12 months (p < 0.004). The non-ischemic dilated cardiomyopathy subgroup (n = 8) improved by 7.5% ± 6.0 at the first follow-up (p < 0.017) and by 12.2% ± 6.4 at final follow-up (p < 0.003, n = 6). Overall improvement in LVEF from pre-procedure to post-procedure was significant (Fisher's exact test p < 0.004). LVEF improvement was most marked in the patients with the most severe cardiomyopathy (LVEF < 20%) improving from a mean 14.6% ± 3.4% pre-procedurally to 28.4% ± 8% at final follow-up. Quality of life statements reflected improvement in 33/50 (66%), no change in 14/50 (28%), and worse in 3/50 (66%).

ACP-01 Restrictions

- Unstable angina or Heart transplant
- Abnormal anatomy, severe valvular disease, or mechanical aortic valve
- Left ventricular ejection fraction (LVEF) ≥ 50%

Thank You!

Get in Touch!

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