

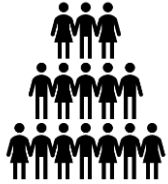


**cassderma<sub>Rx</sub>**

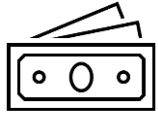
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***HEALING SKIN AND WOUNDS FASTER –  
ALLOWING PATIENTS TO GET BACK TO LIVING  
LIFE SOONER!***

# Executive Summary



20 Million Americans annually need of Wound Healing care



Over \$10 Billion per year are spent on Wound Healing in US alone



New therapeutics are necessary for more effective Wound Healing, unmet need



Serum-free nutrient rich medium supplemented with a non-steroidal anabolic hormone to successfully treat atrophic recalcitrant wounds



cassderma rx granted patent with multiple allowances on a formulation and methods for stimulating wound healing

## Stimulated Healing of Recalcitrant Wounds by Topical Application of Enriched Cell Culture Medium: A Clinical Report

Ella S. Lindenbaum, Ph.D., Yaron Har Shai, M.D., Yehuda Ullmann, M.D., Lev A. Feitelberg, M.D., Dvora Beach, M.Sc., Aviva Gamliel-Lazarovich, M.Sc., and Bernard Hirshowitz, M.D.

*Haifa, Israel*

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# Development Plan



# Target Product Profile (TPP)

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- Sterile topical drug product consisting of insulin and cell culture medium (CCM) in a gel formulation for treatment of atrophic recalcitrant wounds
  - Insulin (biologic) stimulates and supports growth of connective tissue components originating from the wound bed and its peripheral walls
  - CCM (device) provides moisture to the wound site and nutrients required for cell proliferation and the growth of the granulation tissue into the wound space
  - Gel components (excipients) provides viscosity and elasticity maintaining residence of the product at the wound site
- Dose and dosing regimen
  - Dose and dosing regimen will be determined in preclinical animal studies
  - Anticipated twice-daily (BID) or three-times-daily (TID) given the need to keep wounds moist, which can be achieved with the drug product
- Target indication
  - Wound healing (e.g., diabetic ulcers, pressure ulcers, burns, surgical wounds)
- Prescription

# cass101 Development Milestones

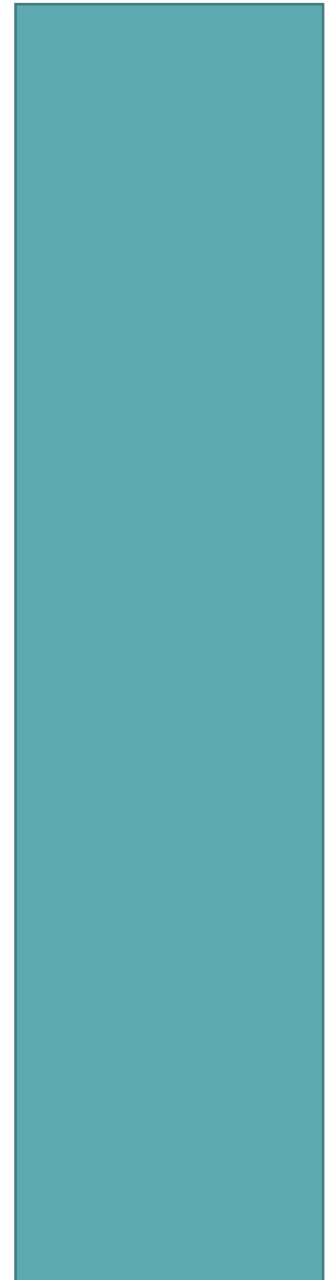
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## Early Stage

- Development of product formulation
  - Development of commercially viable product with adequate physical and chemical stability
- Preclinical efficacy studies (animal)
  - Establish dose and dosing regimen for clinical studies
- FDA Pre-IND Meeting
- Nonclinical safety studies (support clinical studies)
- Phase 1 (or Phase 1/2) clinical studies

## Mid Stage

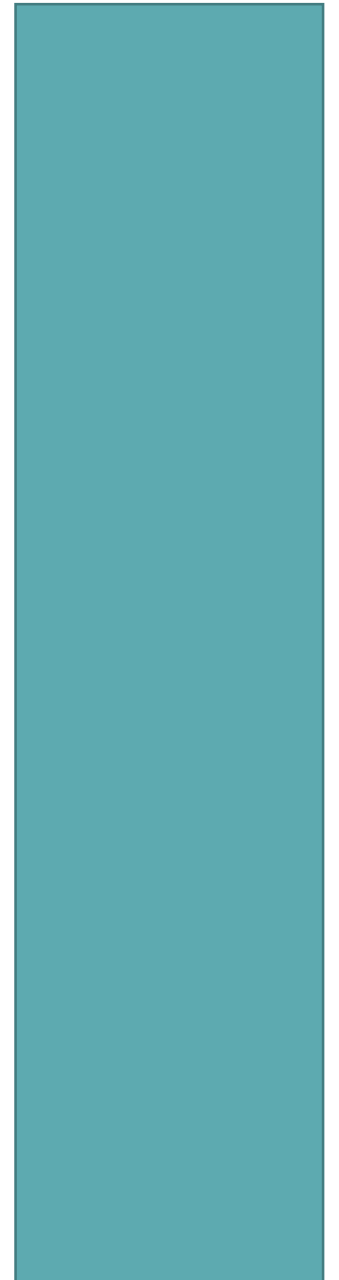
- Phase 2 clinical study(ies)
  - Optimize dose and dosing regimen
  - PK (measure potential change in insulin levels)
- Nonclinical safety studies
  - Support Phase 3 studies and BLA submission
- Quality
  - Product scale up and manufacture of Registration Lots
  - CCM scale up (if needed)
- End of Phase 2 Meeting(s)
  - FDA
  - EX-US (e.g., EU)



# cass101 Development Milestones (Late Stage)

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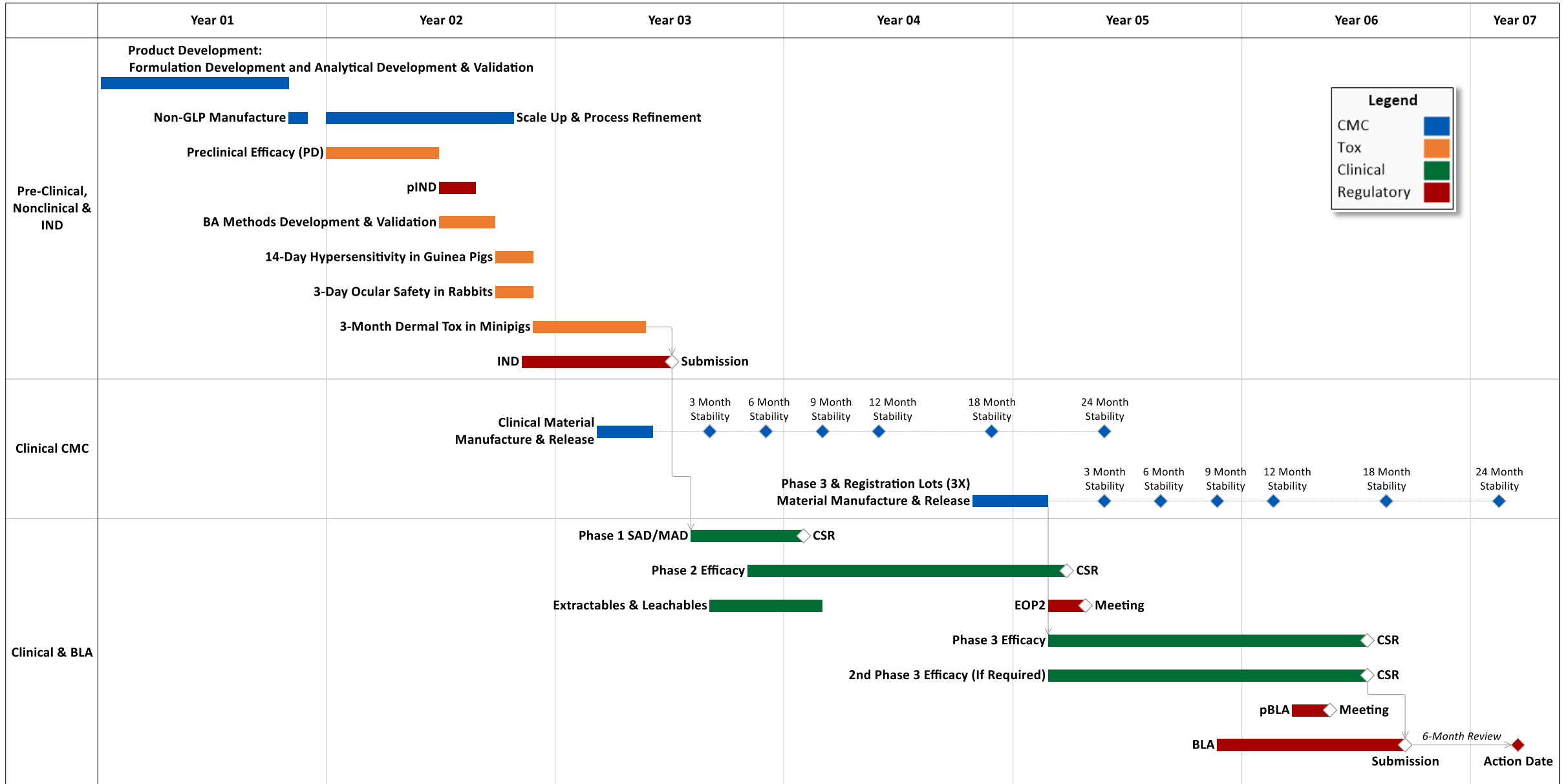
- Clinical
  - Phase 3 clinical study(ies)
    - Normally two pivotal studies are required, but a single positive Phase 3 may be sufficient if under accelerated programs (e.g., Fast Track, Breakthrough, Accelerated Approval)
- Nonclinical
  - Ongoing safety studies (as needed) to support market approvals
- Quality
  - Product manufacturing and ongoing stability studies
  - Ongoing studies to support market approvals
- Regulatory
  - Pre-BLA meeting
  - Ex-US agency meetings
  - BLA preparation and submission (conversion for ex-US market applications)



# Budget

Activity	Cost (\$)
<b>Phase 1 and 2</b>	
Quality	\$1,775,000
Nonclinical	1,024,000
Clinical	6,450,000
Regulatory	570,000
<b>Subtotal</b>	<b>\$9,819,000</b>
<b>Phase 3 to BLA</b>	
Quality	\$3,725,000
Nonclinical	1,100,000
Clinical	25,500,000
Regulatory	950,000
<b>Subtotal</b>	<b>\$31,275,000</b>
<b>Grand total</b>	<b>\$41,094,000</b>

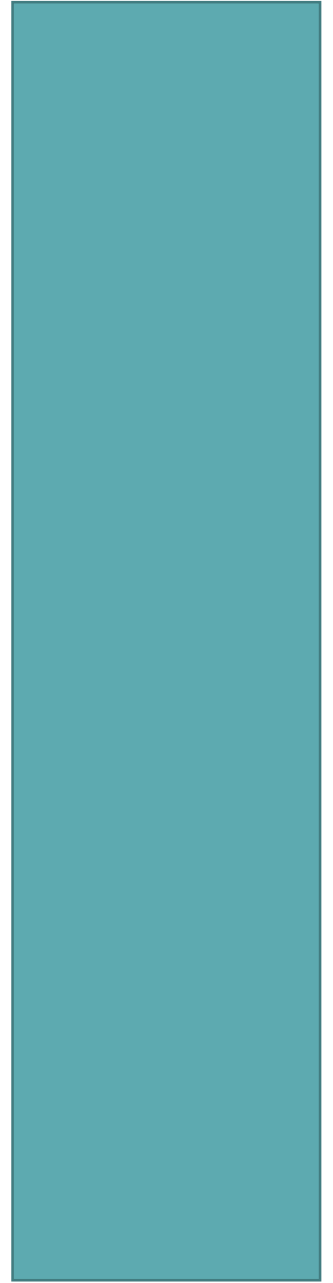
# Timeline





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# Wound Healing Landscape Analysis



# Current Treatments Options are Insufficient

## Wound and Skin Injuries

Burns	Closed Surgical Wounds	Deep Tissue Pressure Injury	Diabetic Foot Ulcers
Incontinence associated dermatitis	Leg Ulcers	Moisture Associated Skin Damage	Medical Adhesive Related Skin Damage
Medical Device Related Pressure Injuries	Open Surgical Wounds	Skin Tear	Stage 3 & 4 Pressure Injury
	Trauma	Unstageable Pressure Injury	

## Treatment Options

- Antimicrobial dressing
- Cleansers
- Compression bandage
- Filler
- Alginate dressing
- Foam Dressing
- Hydrocolloid
- Hydrofiber<sup>®</sup> Technology
- Hydrogel
- Primary dressing
- Secondary dressing (cover)
- Surgical Cover Dressing

# cass101 Used for Healing All Types of Wounds

## Pressure



FIG. 8. (Left) A chronic atrophic and pressure ulcer of 12 years duration, on the metatarsal surface of the left foot in a patient with non-insulin-dependent diabetes mellitus. (Right) Treatment with enriched cell culture medium lasted 4 months when complete wound closure was attained.

## Diabetic Ulcers

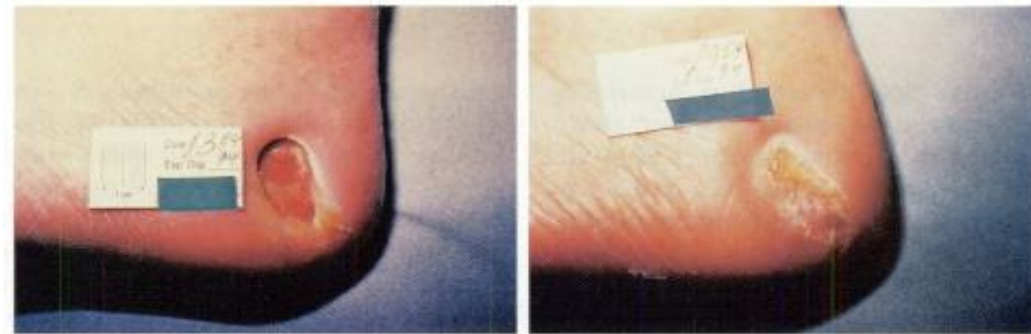


FIG. 7. (Left) A deep atrophic ulcer of 14 months duration on the lateral aspect of the left heel in an insulin-dependent neuropathic patient suffering from diabetes mellitus. (Right) Complete wound closure was achieved after 5 months of treatment with enriched cell culture medium. Follow-up after 1 year showed that the wound remained closed.

## Burns



FIG. 6. (Left) A bilateral neuropathic second- and third-degree burn of the metatarsal areas in a diabetes mellitus patient. (Right) Complete healing of the burns was accomplished in 6 weeks of treatment with enriched cell culture medium. Note the absence of scarring and the smooth skin in the affected areas.

## Surgical

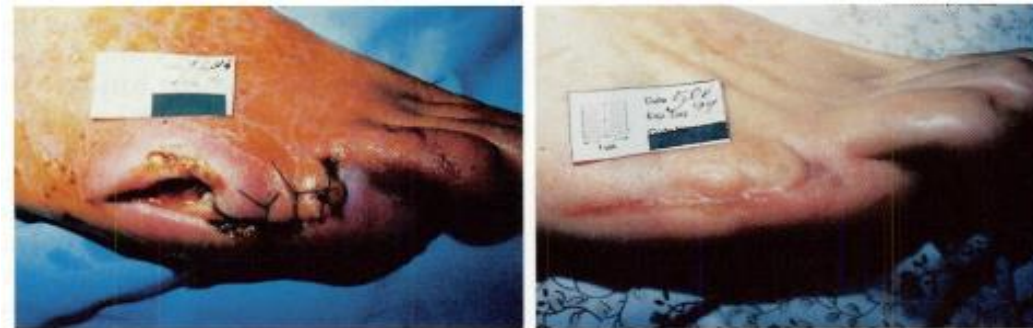
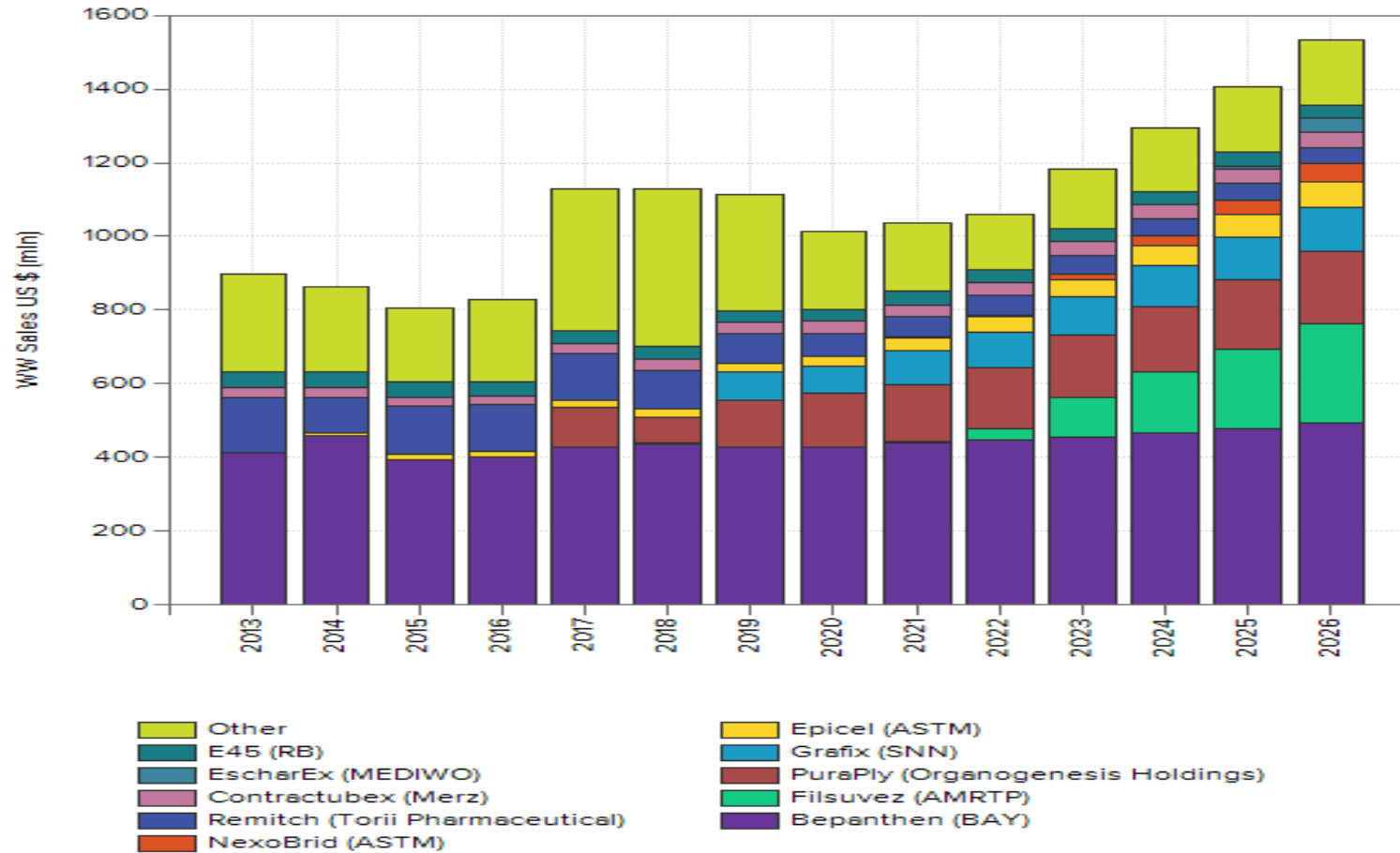


FIG. 4. (Left) One week after surgical amputation of the first left toe because of gangrene in a diabetes mellitus patient. (Right) Complete wound closure following 9 weeks of treatment with enriched cell culture medium.

# Competition

## Emollients & Wound Healing Agents : Worldwide / Overview



# Competition

## Emollients & Wound Healing Agents : Worldwide / Overview

All Financial Data in US \$ (mln)

Rank	Product	Generic Name	Company	Pharmacological Class	Patent Expiry	Annual Sales WW - Sales				F (Sales)	WW Phase (Current)	Company Product Name
						2020	2026	CAGR	Total Change			
1	<a href="#">Bepanthen</a>	<a href="#">dexpanthenol</a>	<a href="#">Bayer</a>	<a href="#">Vitamin B5</a>	-	426	493	2%	67	F	Marketed	Bepanthen
2	<a href="#">Filsuvez</a>	<a href="#">betulin</a>	<a href="#">Amryt Pharma</a>	<a href="#">Wound healing agent</a>	Dec 2030	-	269	n/a	269	F	Approved	Filsuvez
3	<a href="#">PuraPly</a>	<a href="#">polyhexamethylene biguanide hydrochloride</a>	<a href="#">Organogenesis Holdings</a>	<a href="#">Active wound dressing</a>	-	147	197	5%	50	F	Marketed	PuraPly
4	<a href="#">Grafix</a>	<a href="#">mesenchymal stem cells</a>	<a href="#">Smith &amp; Nephew</a>	<a href="#">Mesenchymal cell therapy</a>	-	75	121	8%	46	F	Marketed	Grafix
5	<a href="#">Epicel</a>	<a href="#">cultured epidermal autograft</a>	<a href="#">Vericel</a>	<a href="#">Epidermal cell therapy</a>	-	28	69	17%	41	F	Marketed	Epicel
6	<a href="#">NexoBrid</a>	<a href="#">bromelain</a>	<a href="#">Vericel</a>	<a href="#">Anti-inflammatory</a>	Dec 2029	-	51	n/a	51	F	Filed	NexoBrid
7	<a href="#">Remitch</a>	<a href="#">nalfurafine hydrochloride</a>	<a href="#">Torii Pharmaceutical</a>	<a href="#">Kappa opioid agonist</a>	-	60	42	(6%)	(18)	F	Marketed	Remitch
8	<a href="#">Contractubex</a>	<a href="#">allantoin; allium cepa extract; heparin sodium</a>	<a href="#">Merz</a>	<a href="#">Scar reducing agent</a>	-	33	41	4%	8	F	Marketed	Contractubex
9	<a href="#">EscharEx</a>	-	<a href="#">MediWound</a>	<a href="#">Wound healing agent</a>	-	-	37	n/a	37	F	Phase II	EscharEx
10	<a href="#">E45</a>	<a href="#">edetate calcium disodium; paraffin liquid; tocopherol</a>	<a href="#">Reckitt Benckiser</a>	<a href="#">Emollient</a>	-	34	36	1%	3	F	Marketed	E45
Other						210	177	(3%)	(34)			
Total						1,014	1,533	7%	519			

Source: Evaluate Pharma;

Note: shaded cells  
Indication > Skin > Skin ulcers | Ulcers, diabetic foot Report | Indication Profile Published on 21 November 2021

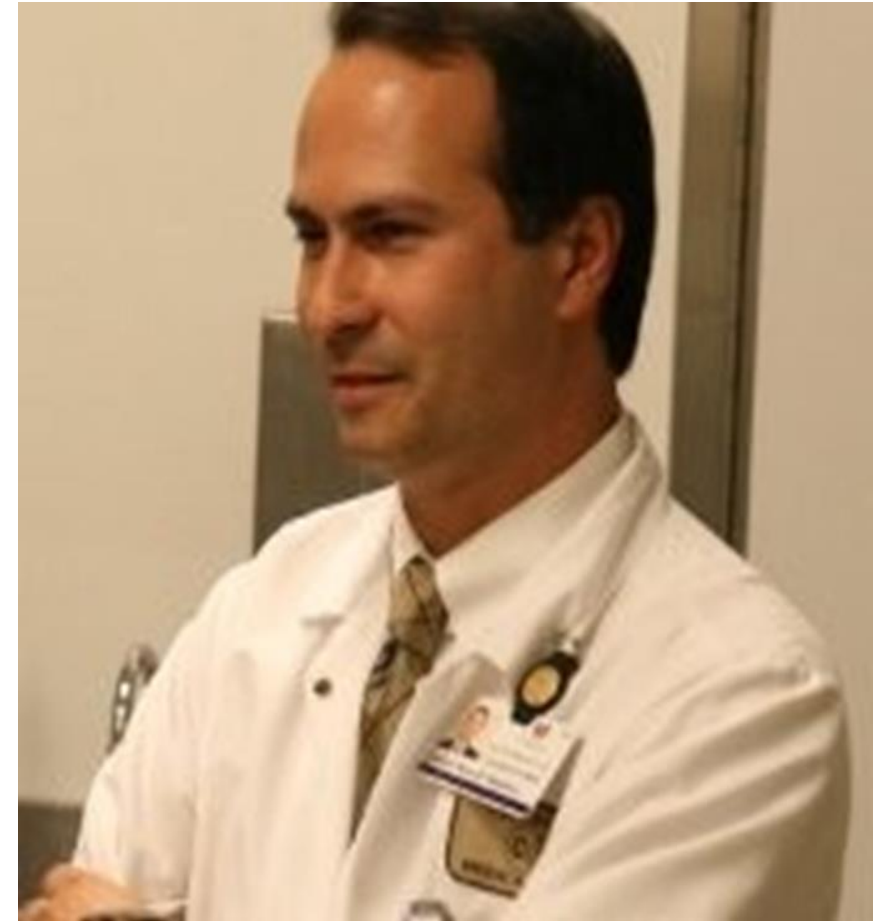
# Investment Opportunity

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- To fund the various stages of the clinical development and regulatory process, Cassderma will raise capital through a series of offerings, highlighted below up through our intended Series A
- \$500K – through SAFE note with a 20% discount and \$6M valuation cap to fund development of product formulation and pre-clinical efficacy studies
- \$4M – through SAFE note with 20% discount and \$20M valuation cap to fund FDA pre-IND meeting and non-clinical safety studies
- \$10M – Series A to fund Phase 1/2 clinical studies at a target \$50M valuation

## DANIEL NAVID RASTEIN, MD, MPH CEO & FOUNDER

*“Nothing exists in the world to stimulate wounds to heal faster – until now. In diabetes patients alone, 84% of amputations are attributed to open wounds. Historically, the only treatment is to clean, disinfect, change bandages and repeat. This is a futile cycle and millions of patients are suffering. We are here to help”*



# Cassderma Leadership Team

DANIEL NAVID RASTEIN, MD, MPH

FOUNDER & CEO



MONIL SHAH, PHARMD, MBA

CLINICAL DEVELOPMENT



KIP VOUGHT

DEVELOPMENT &  
REGULATORY AFFAIRS



MIKE SWEETING

COMMERCIALIZATION &  
MARKET ACCESS



GEORGE SHOPP

NONCLINICAL  
DEVELOPMENT



Shopp Nonclinical Consulting LLC

HERB BRINKMAN

MANUFACTURING

