HOTH THERAPEUTICS

Next generation therapeutics for indications such as atopic dermatitis

Investor Presentation

January 2018

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Investment Highlights

- Development stage biopharmaceutical company focused on unique targeted therapeutics for patients suffering from indications such as atopic dermatitis or eczema
- Proprietary platform technology combines two existing approved drugs enabling reliance on existing safety data for those drugs reducing expected time to market from 10-12 years to 3-4 years
- Strong intellectual property position including issued patents in the United States and Europe
- Management team, board of directors and advisors with prominent financial services and drug development experience
- According to National Eczema Association, estimated U.S. market opportunity for aesthetic dermatology conditions is $2.0 billion

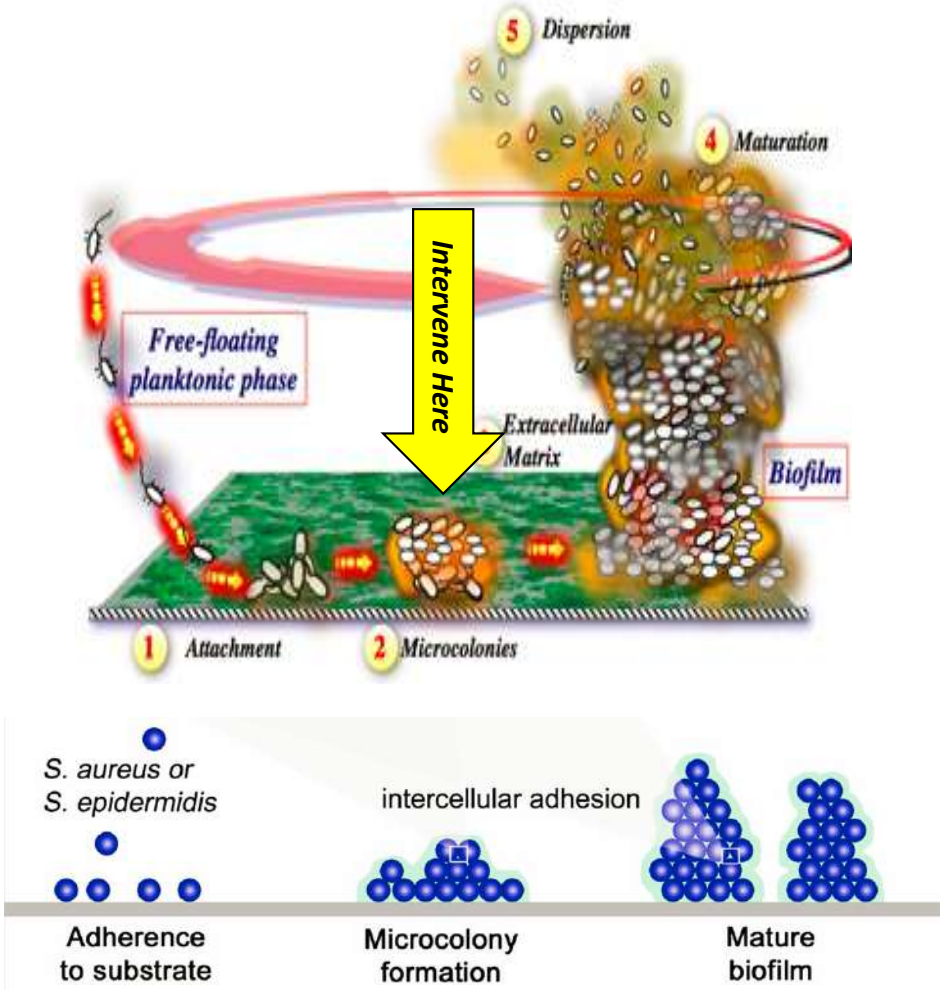
Biolexa Platform Technology

Topical agent combining chelating agent with an antibiotic to fight bacterial infections

- Biofilms are matrices produced by bacterial colonies that shield the colony from attack by the immune system and make the bacteria up to 1000 times more resistant to antibiotics
- CDC data indicate that biofilms are implicated in over 2/3 of all skin infections
- Bacteria rely on Zn+2 ions to colonize and build biofilms to protect colonies

Combining Chelating Agent with an Antibiotic

- BioLexa platform technology combines a chelating agent with an antibiotic to form a synergistic compound combination for inhibiting biofilm formation and fighting bacterial infection
- BioLexa works by using DTPA to chelate the Zn+2 ions necessary to form bacterial colonies and biofilms while using gentamicin, a potent antibiotic, to fight existing bacteria



Source: Image, Biofilms in Infections, Dr. TV RAO, MD https://slideshare.net/doctorrao/biofilms-2172226

Biolexa Development Strategy

Topical cream and expand platform to include gel and sprayable formulations

Development Background

- Select elements of initial product
  - Target bacteria: Staph aureus/Staph epidermidis
  - Chelating agent: Ca DTPA
  - Antibiotic: Gentamicin 0.1%
- Develop topical dosage form
  - GRAS cream vehicle available
- Demonstrate proof of concept
  - Select appropriate animal model
  - University of Miami, contract for study

1st Generation Product

- Immediate release topically applied
- Unit dose delivery
- Neutral cream formulation
- 0.1% Gentamicin active antibiotic

2nd Generation Product

- Gel and sprayable
- Bio-resorbable occlusion product
- Multiple antibiotics in both topical and occlusion formats

BioLexa Development Timeline

Consistent milestones exhibits strong momentum in product development

Activity	Cost	Partner	1Q	2Q	3Q	4Q	Yr 2	Yr 3	Yr 4
Non-Clinical	$125K	UMiami	→						
CMC: formulation, cGMP, stability	$300K	CMO	→						
Pre-IND and IND	$140K	Legal, CRO		→					
Phase 2b study	$1.1M	CRO			→				
CMC for Phase 3	$900K	CMO				→			
Phase 3 trial 1	$2.5M	CRO					→		
Phase 3 trial 2	$2.5M	CRO						→	
NDA prep and submission	$1,250K	CRO							→
FDA review and approval	$215K	Reg, CRO							→
Total investment*	**$9,015K**								

*Costs do not include internal overhead

Intellectual Property and License Terms Summary

Country	Patent	Expiration	Issue Date	Issued	Pending
EU	Patent covering compositions and methods	2028	October 2014	✓	
US & PCT	Allowed claims covering formulation, manufacture and impregnation of wound dressings, bandages and clothing.	Estimated 2033	2016	✓	

BioLexa License Terms

- Master License from University of Cincinnati
- Worldwide, exclusive license to develop, manufacture and sell with right to sub-license
- No milestones, minimal annual license fee
- Minimal royalty to the University

Biolexa Market Opportunity

Indication	Medical Need	Target Patients	US Market Opportunity (USD)
Eczema and atopic dermatitis	Extend time between flare up	32M[1]	$9.5B[1]
Aesthetic dermatology	Improve healing, improve cosmetic outcomes	8.8M[2]	$1.9B[2]

Source: 1. According to the National Eczema Association , this chronic skin condition affects approximately 32 million Americans, spending $300 per annum per patient on average, represents an approximate $9.5 billion market in the U.S.

2. The American Society for Aesthetic Plastic Surgery (ASAPS) 17th annual multi-specialty statistical data

Eczema US Market Opportunity Analysis

- By 2021, approximately 35M people will be affected by eczema
- 20% of the expected population will be children
- We assume that with the following dose specifications, revenue projections by 2026 will be approximately $500M

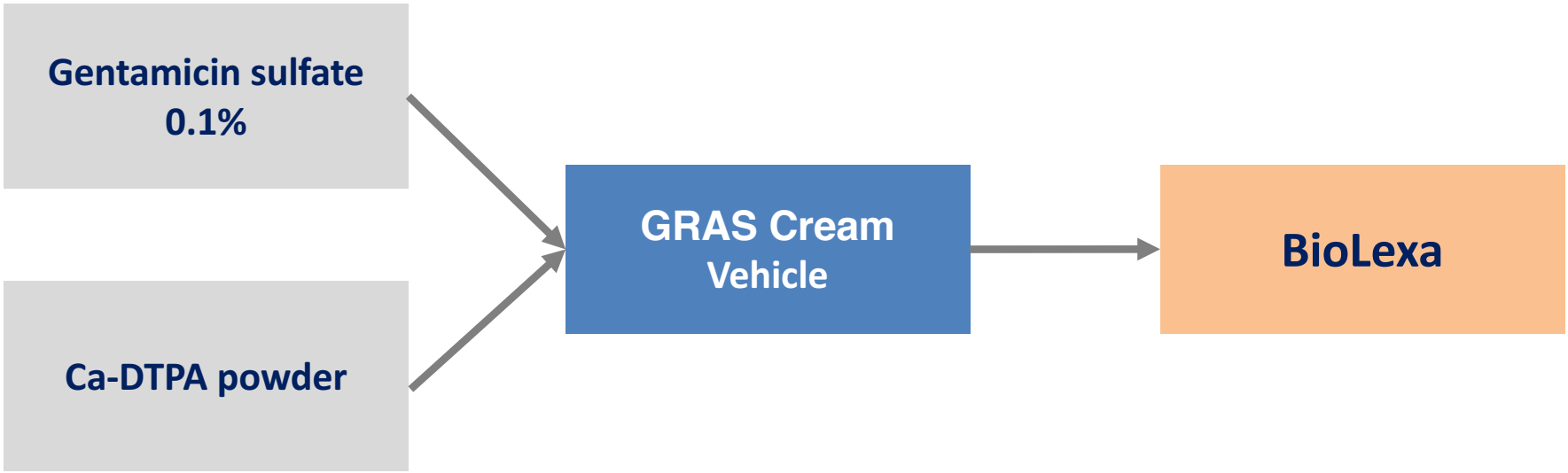
Dose size	15 gram tube
CGS per dose	$9.00
Retail per dose	$45.00
Wholesale discount	35%
Wholesale price/dose	$29.25
Doses/patient	6

	2021	2022	2023	2024	2025	2026
Patient share	.05%	.5%	1.0%	2.5%	5.0%	7.5%
Total treated patients	17.5K	177.9K	361.3K	916.9K	1,861.1K	2,833.6K
Total doses	105,213	1,067,915	2,167,867	5,500,964	11,186,956	17,001,680
Revenue at wholesale	$3,077,489	$31,236,313	$63,410,121	$160,903,103	$326,633,461	$497,299,444

Source: National Eczema Association

BioLexa Formulation

Manufactured using simple process combining gentamicin, DTPA and cream base



- Topical cream made up of Glycerl Stearate/PEG-100 Stearate, Lanolin Alcohol, Mineral Oil, Sorbitol 70% Solution, and active components; Gentamicin and Ca-DTPA, Gentamicin 0.1% cream
- Broad spectrum antibiotic exhibiting bactericidal activity against both gram-positive and gram-negative bacteria
- FDA cleared for both internal and external applications and provides highly effective topical treatment in primary and secondary bacterial infections of the skin

Eczema Disease Overview

Biofilms and staph aureus infections contribute to Eczema

- Eczema is a general term for many types of skin inflammation including atopic dermatitis, which is the most common
- Atopic dermatitis is a chronic inflammatory disease of the skin, often referred to as 'childhood eczema' involving the breakdown of the skin barrier
- Atopic dermatitis is the most common form of pediatric eczema
- In a study conducted by Dr. Herbert Allen of Drexel University skin swabs, scrapings, and biopsies from AD patients' inflamed skin were compared to control samples where skin was unaffected
  - All samples taken from skin affected by AD had multi-drug resistant Staph (aureus and epidermidis) and all were positive for biofilm formation

Biofilms in Eczema

- Staph aureus makes up 20% of the bacteria on skin and 40% on lesions
- Exposure to water or salt and slight perspiration prompts biofilm formation and clogs the sweat ducts which triggers and immune response
- Immune response combined with gene deficiency results in itching and rash

Source: 1. http://www.easeeczema.org/erc/symptoms_of_eczema.htm

Unmet Medical Need

Existing treatments for eczema are messy, expensive

- Thirty five million eczema and atopic dermatitis patients in the US and 20% are pediatric[1]

- Current treatments for eczema include topical steroids, OTC moisturizers, oatmeal baths
  - Avoiding irritants and soap may alleviate symptoms

- Current treatments lack efficacy in reducing symptoms of eczema
  - Often messy and expensive and cause undesirable side effects

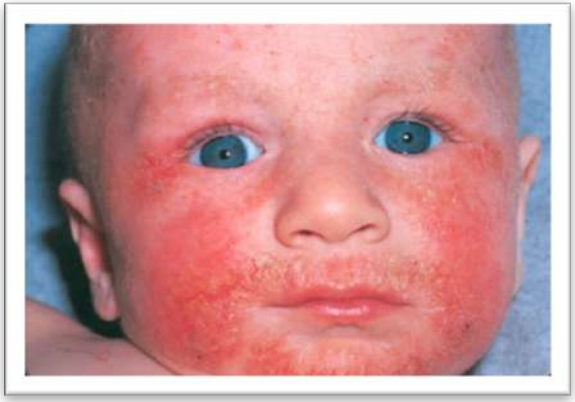
- Products in development have several shortcomings
  - Systemic delivery that may lead to potential systemic safety risks
  - Intended to only treat symptoms post occurrence
  - Complex MOAs and costly

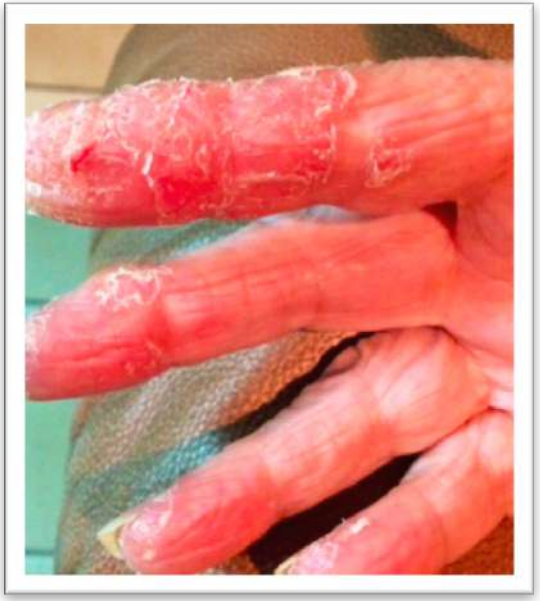
Source: 1. Grand Rounds Nation CME on ReachMD. This is the National Jewish Health and Prova Education segment, Assessing the Current Treatment of Atopic Dermatitis: Unmet Needs. The faculty for this activity is Donald Leung, MD, PhD, Professor and Head of the Division of Pediatric Allergy and Immunology in the Department of Pediatrics at the National Jewish Medical Center in Denver, CO

2. National Eczema Institute – remainder of bullets on slide

BioLexa Solutions

- Topical localized delivery
- Intended to delay or prevent flare-ups of symptoms
- Ability to use jointly with other treatments to maximize patient benefit





Key People

Name & Title	Background
Robb Knie President and CEO, Director	• General partner of Lifleline Ind. Inc, since 1995 • 20+ years of equity markets experience, semiconductor and telecommunications analyst PAW Partners • Board positions with NASDAQ listed companies and management positions with American Express Financial Advisors
Vadim Mats Director	• CFO of Point Capital, Inc., and CFO of FWS Capital Ltd. • Previously CFO of Whalehaven Group of Funds, Assistant Controller at Eton Park Capital Management, and Senior Fund Accountant at Bank of New York Mellon • B.S. Business Administration *cum laude*, M.S. Accounting, Finance from Zicklin School of Business, Bernard Baruch College • CAIA Charterholder and CPA
Kenneth Rice Director	• President and CFO of LikeMinds, Inc. • 25+ years of experience in operations, finance, marketing and sales and business development in private and public life sciences companies • Previously EVP, CFO and in house counsel of Alseres Pharmaceuticals, Inc., and was also with Aderis Pharmaceuticals in a similar capacity
Anthony Hayes Director	• President, CEO and Director of Spherix, Inc., (Nasdaq: SPEX) • Founder and managing member of Atwater Partners of Texas LLC and former partner at Nelson Mullins Riley & Scarborough LLP • B.A. Economics, Mary Washington College, J.D. Tulane University School of Law

Key People

Name & Title	Background
Dr. Andrew Herr **Scientific Advisory Board**	• Dr. Andrew Herr, PhD, is an associate professor in the Division of Immunobiology and Center for Systems Immunology, with an affiliate appointment in the Division of Infectious Diseases at Cincinnati Children's Hospital within the UC Department of Pediatrics. Dr. Herr completed his thesis work in molecular biophysics from Washington University in St. Louis, and completed his postdoctoral work in structural immunology at the California Institute of Technology as a Damon Runyon Research Fellow. He was recruited to the University of Cincinnati College of Medicine as an Ohio Eminent Scholar in Structural Biology before moving to Cincinnati Children's Hospital.
Dr. Richard Granstein **Scientific Advisory Board**	• Richard D. Granstein, M.D. is the George W. Hambrick, Jr. Professor and Chairman of the Department of Dermatology. Dr. Granstein obtained his undergraduate education at the Massachusetts Institute of Technology and his medical education at the UCLA School of Medicine. After completing his internship in 1979, he trained in dermatology at the Massachusetts General Hospital. As a Research Fellow, Dr. Granstein studied immunology and tumor biology at the National Cancer Institute-Frederick Cancer Research Facility and at Harvard Medical School. Dr. Granstein joined the faculty of the Department of Dermatology at Harvard Medical School and the Massachusetts General Hospital in 1984. In 1995 he left Harvard to become Chairman of the Department of Dermatology at the Weill Medical College of Cornell University and Dermatologist-in-Chief at the NewYork-Presbyterian/Weill Cornell Medical Center.

Platform Companies

Market precedent supports premium value for dermatology focused companies

Key Companies

Company	Ticker Symbol	Market Cap $mm
Regeneron Pharmaceuticals, Inc.	NASDAQ:REGN	50,537
Teligent, Inc.	NASDAQ:TLGT	361.5
Pfizer, Inc.	NYSE:PFE	199,624

- March 2017 – Sanofi and Regeneron win FDA approval for dupilumab (brand name Dupixent) to treat skin rash atopic dermatitis, aka eczema
  - Dupixent has potential for $3B in annual sales
- Teligent manufactures and markets generic topical products in the US and Canada for eczema, dermatitis, psoriasis
- Pfizer acquired Anacor and secured market share in growing market for eczema treatments
- Limited public company exposure to eczema, dermatitis indications presents opportunity

Source: CapitalIQ, August 10, 2017
http://fortune.com/2017/03/28/fda-eczema-drug-sanofi-regeneron/

Notable Transactions

Acquisition activity can be a significant driver of value creation

Acquired Company	Acquirer	Transaction Size	Date	Transaction Details
Anacor Pharmaceuticals Inc.	Pfizer, Inc. (NYSE: PFE)	$5.2B	5/13/2016	55% premium over Anacor share price Anacor lead product, Crisaborole, topical treatment for mild to moderate atopic dermatitis
Renaissance Acquisition Holdings, LLC	Mylan N.V.	$950M plus contingent payments up to $50M	5/13/2016	Announces acquisition of topicals-focused specialty and generics business
Topokine Therapeutics, Inc.	Allergan plc (NYSE:AGN)	$85M upfront payment	4/22/2016	Topokine specializes in topical cosmetic dermatology
Astellas Pharma, Inc.	LEO Pharma, Inc.	$725M	11/12/2015	LEO Pharma acquires Astellas' dermatology business

- Large pharmaceutical companies such as Pfizer recognize need for safe and novel treatments in dermatology indications
- Attractive revenue potential for acquirers that is represented by a large and growing patient population with atopic dermatitis and eczema

Source(s):1. http://www.pfizer.com/news/press-release/press-release-detail/pfizer_to_acquire_anacor ; 2. http://www.nytimes.com/2016/05/17/business/dealbook/pfizer-to-acquire-anacor-pharmaceuticals-for-5-2-billion.html ; 3. http://www.marketwatch.com/story/4-things-to-know-about-pfizers-52-billion-acquisition-target-anacor-2016-05-16 ; 3. http://newsroom.mylan.com/2016-05-13-Mylan-to-Acquire-Renaissances-Leading-Topicals-Focused-Specialty-and-Generics-Business ; 4. http://www.genengnews.com/gen-news-highlights/allergan-acquires-topokine-therapeutics-for-85m-upfront/81252646/; 5. http://www.genengnews.com/gen-news-highlights/leo-pharma-buys-astellas-dermatology-business-for-725m/81251969/

Development Strategy and Regulatory Pathway

505(b)(2) strategy reduces development time and cost

Regulation	Description	Time Needed	Explanation
505(b)(1) NDA	New drug	8-12 years	Extensive non-clinical and clinical studies to demonstrate safety and efficacy of a given drug for the target indication. Significant data requirements result in long development cycles and high costs
505(j) ANDA	Generic drug	1-2 years	An abbreviated application for a "me too" drug containing only bioavailability / bioequivalence data comparing the proposed product to the innovator product
505(b)(2) NDA	New drug containing similar active ingredient(s) as previously approved drug	3 years	Modified version of a previously approved product(s) that requires additional non-clinical and clinical testing to demonstrate safety and efficacy. However, **sponsors are allowed to rely on FDA"s finding of safety and efficacy for the previously approved reference drug(s)** thereby dramatically shortening time frames and lowering costs

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APPENDIX

Completed In-Vivo Study Overview

- Demonstrate in a robust porcine deep partial thickness wound “challenge” model that when Ca-DTPA is combined with Gentamicin 0.1% *Staph aureus* biofilm formation is prevented and planktonic bacteria are eliminated

- Study conducted at University of Miami Miller School of Medicine in the Laboratory of Dr. Steve Davis under the direction of Dr. Robert Kirsner

In-Vivo Study Design

- Two (2) young female Yorkshire/landrace swine
- Forty-four (44) wounds per animal
- Each wound inoculated with *Staph aureus* 10^6
- Multiple arms:
  - Vehicle
  - Untreated
  - Varying concentrations of DTPA alone
  - Gentamicin 0.1% alone
  - BioLexa cream with varying doses of DTPA
- At conclusion: collect samples, measure biofilm and planktonic bacteria

Time 0

- Culture Staph
- Inoculate
- Initial treatment
- occlude

Time +24h

- Second treatment

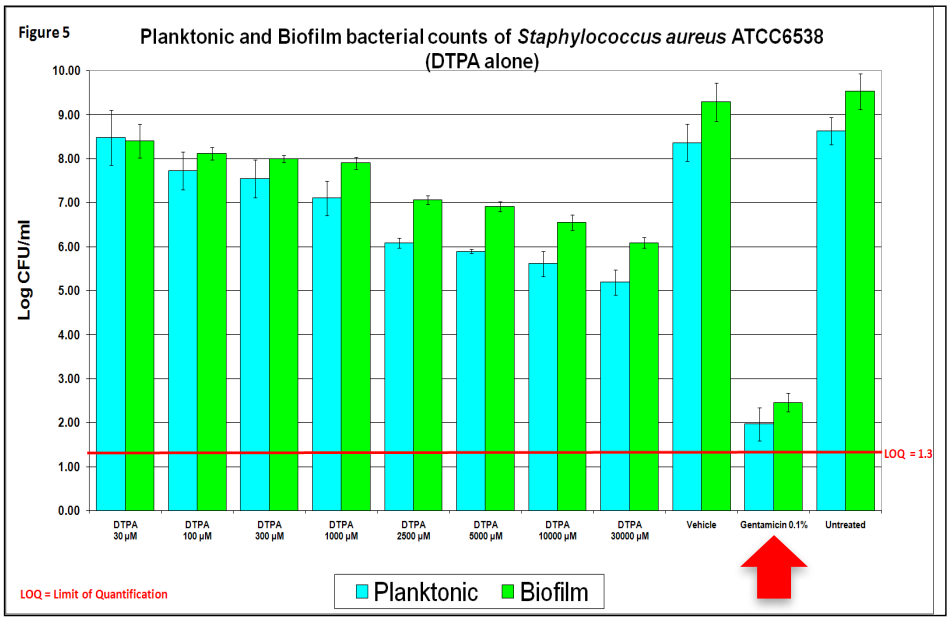
Time +48h

- Collect samples
- Culture
- Measure

Summary Results

In-vivo Porcine partial thickness wound study

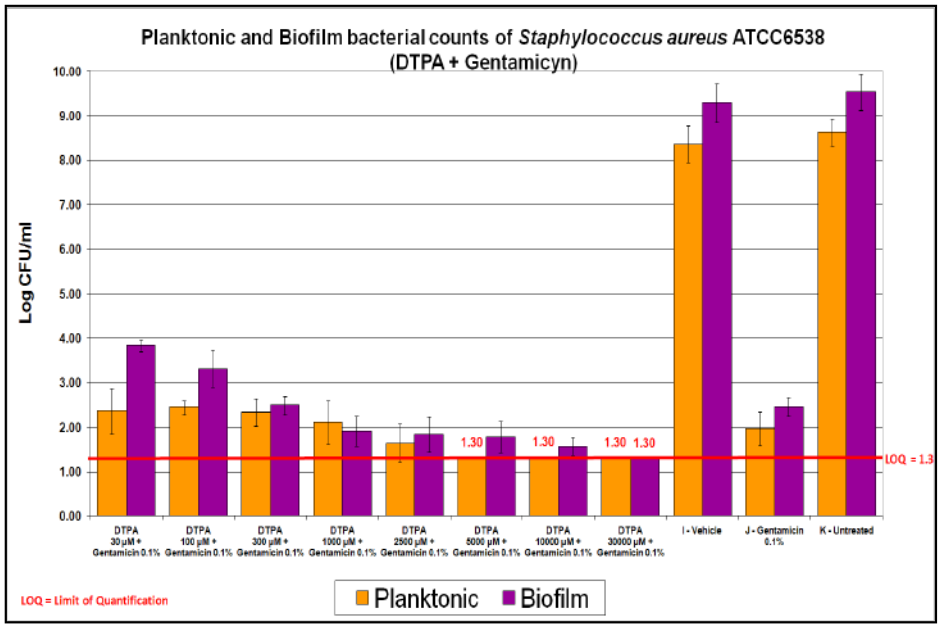
Either Alone Not Adequate



Gentamicin alone

DTPA alone

Combination Works Best



Combination reduced bacteria below LOD

Key Development Information

BioLexa Clinical and Non-Clinical Development

- Non-clinical:
  - Stability studies from cGMP vendor
  - Porcine study to include systemic absorption measurements and wound closure rates
  - Guinea pig study for local irritation

- Clinical:
  - Two possible programs:
    - Flare prevention in eczema
    - Outcome management in post-laser ablation
  - Both initial programs utilize the same drug product
  - Additional indications to be pursued under sNDA provisions and/or 505(b)(2) depending on label and dosage form

Key Data in IND

- FDA determination of safety and efficacy for gentamicin including Basis of Approval
- Published literature documenting safety and toxicity profile of gentamicin
- Published literature documenting safety and toxicity profile of DTPA

Product Composition

- Vehicle: GRAS components
- DTPA: excipient concentration limited to FDA levels in inactive ingredient list
- Gentamicin: 0.1% concentration as per long-approved product

Formulation and cGMP

- Utilize cGMP master vendor for:
  - Analytical methods development
  - Optimizing current cream formulation
  - Developing a new and proprietary cream formulation
  - Stability and shelf life optimization
  - Production of cGMP batches
  - Full documentation set

Eczema Phase 2 Development

	Phase 2b – Safety
Design	• Double-blind, placebo controlled study to evaluate the safety and efficacy of topical BioLexa Preparation in patients with at least a 2 year history of Eczema symptom flare-ups. All subjects will be their own control
Sample size	• 100 pediatric subjects. Each subject to receive active product on one body area and placebo on another
Treatment Schedule	• Once daily topical application directly on skin, 1 mm thickness for 2 week duration of study
Endpoint 1	• Safety
Endpoint 2	• Time to symptom flare-up
Centers	• 3
Inclusion	• Pediatric subjects with at least 2 year history of eczema symptoms on multiple body parts
Exclusion	• As per indication
Duration	• 14 days active phase

Eczema Phase 3 Development

	Phase 3 Pivotal Study	Phase 3 Confirmatory Study
Design	• Double-blind, placebo controlled study to evaluate the safety and efficacy of topical BioLexa Preparation in patients with recurring eczema symptoms	• Double-blind, placebo controlled study to evaluate the safety and efficacy of topical BioLexa Preparation in patients with recurring eczema symptoms

Sample size	• 150
	  • 150 placebo
	  • 150 active
		• 150
		  • 150 placebo
		  • 150 active

Statistical hypothesis	• Time to symptom occurrence improved versus placebo	• Time to symptom occurrence improved versus placebo
Treatment Schedule	• As per phase 2b results	• As per phase 2b results
Endpoint 1	• Time to symptom occurrence improved versus placebo	• Time to symptom occurrence improved versus placebo
Endpoint 2	• TBD	• TBD
Endpoint 3	• TBD	• TBD
Centers	• 10	• 10
Inclusion	• Patients with at least 2 year history of recurring eczema symptoms	• Patients with at least 2 year history of recurring eczema symptoms
Exclusion	• As per indication	• As per indication
Duration	• 21 days active phase	• 21 days active phase

ECZEMA OPPORTUNITY ALONE – PROGRAM VALUATION

$000	2016-20	2021	2022	2023	2024	2025	2026
Revenue at wholesale	n/a	$3,077	$31,236	$63,410	$160,903	$326,633	$497,299
CGS	n/a	($947)	($9,611)	($19,510)	($49,509)	($100,503)	($153,015)
Gross Margin	n/a	$2,130	$21,625	$43,900	$111,394	$226,130	$344,284
Royalties	n/a	($200)	($2,030)	($4,121)	($10,458)	($21,231)	($32,324)
Development	($9,015)						
G&A	($3,160)	($1,000)	($2,186)	($4,438)	($11,263)	($22,864)	($34,811)
Marketing & Sales	($500)	($923)	($9,370)	($19,023)	($48,271)	($97,990)	($149,190)
PTP	($12,675)	$7	$8,039	$16,318	$41,402	$84,045	$127,959
Taxes	n/a	n/a	($3,215)	($6,526)	($16,561)	($33,618)	($51,184)
ATP	($12,675)	$7	$4,824	$9,792	$24,841	$50,427	$76,775
Terminal Value(3x)							$1,491,898
Total Cash flows	($12,675)	$7	$4,824	$9,792	$24,841	$50,427	$1,568,673
Probability	95%	50%	50%	50%	50%	50%	50%
Risk Adjusted	($12,041)	$4	$2,412	$4,896	$12,420	$25,213	$784,336
NPV at 30%	**$43,216**						

Aesthetic Dermatology

BioLexa will reduce post-procedure infections, accelerate healing and improve clinical outcomes for patients undergoing aesthetic dermatology procedures

Indication	Annual US Procedures	Estimated Procedure Revenues (USD)	Estimated US BioLexa Market (USD)
Laser skin resurfacing (laser dermal ablation)	2.4M	$5.3B	$480M
Skin cancer	3.0M	$4.5B	$450M
Acne scar repair	2.0M	$2.0B	$300M
Cosmetic plastic surgery	1.4M	$7.0B	$750M

Revenue Drivers

- Post procedure infection risk:
  - 4-6% of patients undergoing aesthetic dermatology procedures develop infections and over 40% of these infections involve Staph aureus
  - For elective procedures, post-procedure infection treatment is an added cost to the patient that their insurance will likely not reimburse
- Time to healing:
  - Infections slow down skin repair and therefore increasing healing time
  - Infections often result in sub-par skin regeneration potentially jeopardizing the outcomes of the aesthetic procedure
  - Typical time to complete closure is 10-15 days post-procedure
  - Acceleration of complete closure by 2-3 days results in high statistical differences between treatment groups

BioLexa's ability to fight bacterial growth will enable the innate immune system to focus on healing quality rather than fighting post-procedure infection.

Laser Dermal Ablation

- Laser Ablation patients have 4-6% overall post-procedure infection rates.
- Infections disrupt overall healing time and impact cosmetic outcomes
- Typical time to complete closure is 10-15 days post-procedure
- Acceleration of complete closure by 2-3 days results in high statistical differences between treatment groups
- BioLexa's modulation of bacterial growth will enable the innate immune system to focus on healing quality instead of fighting post-procedure infection

Laser Ablation Phase 2 Development Program: 2 Distinct Trials

	Phase 2a – PILOT STUDY	Phase 2b – DOSE RANGING
Design	• Double-blind, placebo controlled pilot study to evaluate the safety and efficacy of topical BioLexa Preparation in patients undergoing carbon dioxide laser ablation of the face – 2a	• Double-blind, placebo controlled dose-ranging study to evaluate the safety and efficacy of topical BioLexa Preparation in patients undergoing carbon dioxide laser ablation of the face – 2b

Sample size	• 12
	  • 6 PLA
	  • 6 active
		• 60
		  • 20 PLA
		  • 20 active once daily for 5 days
		  • 20 active every other day for duration of study

Statistical hypothesis	• Descriptive statistics	• TBD from phase 2a • Delta in time-to-healing, incidence of infection, cosmetic outcomes
Treatment Schedule	• Once daily topical application directly on injured area, 1 mm thickness for duration of study	• Once daily topical application directly on injured area, 1 mm thickness for duration of study • Once daily topical application directly on injured area, 1 mm thickness for initial 5 days after laser ablation
Endpoint 1	• Adverse events	• Time-to-healing, cosmetic outcomes
Endpoint 2	• Time-to-healing	• Incidence of infection
Endpoint 3	• Incidence of infection	• Adverse events
Centers	• 2	• 4-6
Inclusion	• Pts. Undergoing carbon-dioxide laser ablation	• Pts. Undergoing carbon-dioxide laser ablation
Exclusion	• As per indication	• As per indication
Duration	• 21 days active phase • 6 week control visit (safety outcomes)	• 21 days active phase • 6 week control visit (cosmetic outcomes)

Laser Ablation Phase 3 Development

	Phase 3 Pivotal Study	Phase 3 Confirmatory Study
Design	• Double-blind, placebo controlled study to evaluate the safety and efficacy of topical BioLexa preparation in patients undergoing carbon dioxide laser ablation of the face	• Double-blind, placebo controlled study to evaluate the safety and efficacy of topical BioLexa preparation in patients undergoing carbon dioxide laser ablation of the face

Sample Size	• 300
	  • 150 PLA
	  • 150 active
		• 300
		  • 150 PLA
		  • 150 active

Statistical Hypothesis	• Cosmetic outcomes improved vs. PLA after month 3 and 6 (Fitzpatrick Wrinkle Scale)	• Cosmetic outcomes improved vs. PLA after month 3 and 6 (Fitzpatrick Wrinkle Scale)
Treatment Schedule	• As per phase 2b results	• As per phase 2 results
Endpoint 1	• Cosmetic outcomes improved vs. PLA after month 3 and 6 (Fitzpatrick Wrinkle Scale)	• Cosmetic outcomes improved vs. PLA after month 3 and 6 (Fitzpatrick Wrinkle Scale)
Endpoint 2	• TBD	• TBD
Endpoint 3	• TBD	• TBD
Centers	• 10-20	• 10-20
Inclusion	• Pts. Undergoing carbon-dioxide laser ablation	• Pts. Undergoing carbon-dioxide laser ablation
Exclusion	• As per indication	• As per indication
Duration	• 21 days active phase • 6 week control visit (safety outcomes)	• 21 days active phase • 6 week control visit (cosmetic outcomes)

Overall Development Timeline and Cost: Laser Dermal Ablation

Development of BioLexa in laser dermal ablation will cost approximately $6.3M. FDA approval in first indication is planned for 3 years from start.

Activity	Cost	Partner	1Q	2Q	3Q	4Q	Year 2	Yr. 3	Yr. 4
CMC: formulation, cGMP, stability	$250K	CMO							
Pre-IND and IND	$125K	Legal, CRO							
Phase 2a Pilot Study	$200K	CRO							
Phase 2b dose ranging	$500K	CRO							
CMC for Phase 3	$750K	CRO							
Phase 3 trial 1	$2M	CRO							
Phase 3 trial 2	$2M	CRO							
NDA prep and submission	$750K	CRO							
FDA review and approval	$150K	Reg, CRO							
Total investment*	**$6.275M**								

*Costs do not include internal overhead