

HOTHTHERAPEUTICS

Corporate Presentation

2019



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About Us

- Hoth is a biopharmaceutical company focused on unique therapeutics for patients suffering from indications such as atopic dermatitis, also known as eczema, as well as dermatological and chronic wound disorders, psoriasis and acne.
 - We are working to develop and commercialize the BioLexa Platform (“BioLexa Platform” or “BioLexa”), a proprietary, patented, drug compound platform developed at the University of Cincinnati. BioLexa has achieved positive results at preclinical studies conducted at the University of Miami.
 - We have an exclusive license from University of Maryland, Baltimore to VNLG-152 which has shown strong preclinical results, and are working to develop for treatment in psoriasis and acne patients.
 - We also have an exclusive license from University of Cincinnati for a genetic marker that will help test a person’s propensity to suffer from food allergies and/or eczema.
- NASDAQ Capital Market: HOTH CS Outstanding: 9,602,930 (as of 4/29/19)

Defined Pathway for Value Creation

- Large total addressable market with broad consumer appeal
- Proprietary BioLexa Platform technology which combines two existing approved drugs enabling reliance on existing safety data for those drugs
- VNLG 152 – strong pre-clinical data in cancer and dermatological areas
- Strong intellectual property portfolio, including exclusive licenses to patents and trademarks
- Experienced management team, board of directors and scientific advisors with proven drug development experience

Developing Pipeline

Product Candidate	Indication	Stage of Development			
CLINICAL STAGE DEVELOPMENT PROGRAMS		PRECLINICAL	PHASE 1	PHASE 2	PHASE 3
BIOLEXA PLATFORM A patented topical non-corticoid steroid approach, inhibiting the formation of biofilms	Atopic Dermatitis				
BIOLEXA PLATFORM A patented approach to inhibit the formation of S. aureus biofilms in Diabetic Foot Ulcers and Chronic Wounds	Diabetic Wounds				
EARLY STAGE DEVELOPMENT PROGRAMS		PRECLINICAL	PHASE 1	PHASE 2	PHASE 3
VNLG 152 Lead retinamide RAMBAs demonstrate antikeratinization & sebosuppressive effects in vitro and in reconstructed human epidermis	Psoriasis, Acne				
GENETIC MARKER Patented technology to determine a person's propensity to develop eczema & food allergies	Food Allergy, Eczema				

Dermatology Offers Attractive Returns and Exits

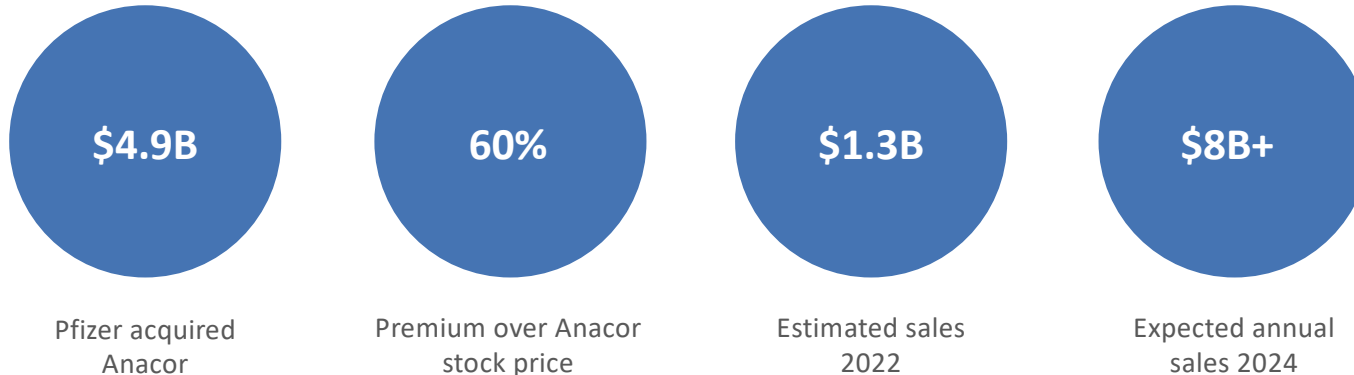
Atopic dermatitis market predicted to grow \$7.2B in 2017 to \$24B by end of 2027*

Pfizer acquired Anacor for \$4.9B on June 24, 2016

- ❑ Over 60% premium over Anacor stock price prior to announcement
- ❑ Anacor's lead product, Eucrisa, is a topical treatment for mild to moderate eczema
- ❑ Estimated sales of \$1.3B by 2022

Sanofi and Regeneron achieved approval of Dupixent in March of 2017

- ❑ Nonsteroidal, injectable treatment for moderate to severe atopic dermatitis
- ❑ Expected annual sales of \$8B+ by 2024



*Atopic Dermatitis Market – Global Industry Analysis, Size and Forecast, 2017-2027

BioLexa Platform for Atopic Dermatitis



Atopic Dermatitis is a large and growing market

- Affects more than 32 million patients in the US
- 10-20% of all pediatric patients suffer from Atopic Dermatitis
- Need for new, differentiated therapies



The BioLexa Platform offers a non corticosteroid approach to inhibit the formation of biofilms, which increases effectiveness of BioLexa in clearing current symptoms and preventing future flare ups



Phase 2 study is currently being designed by renowned doctors and scientists and on track to start enrollment in Australia by end of 2019

- Study will test efficacy, safety, and ease of use



On target to complete Phase 2 clinical trial by end of Q1 2020

A Different Approach to Atopic Dermatitis

Current Treatments	Unmet Medical Needs	BioLexa's Approach
Topical Steroids	Current treatments are messy & expensive	Topical, localized delivery
OTC moisturizers	Systemic delivery which may lead to safety risks	Intended to delay and prevent flare-ups of symptoms
Oatmeal baths	Undesirable side effects	Can be used with other drugs and/or behaviors to maximize benefits
Avoid irritants & soaps	Lack of efficacy in reducing symptoms	
	Only intended to treat symptoms after occurrence	

Biofilms Inhibit the Treatment of Atopic Dermatitis

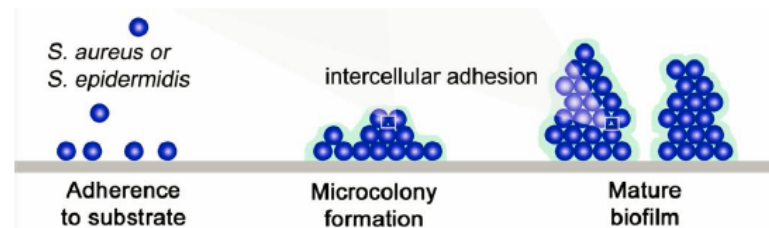
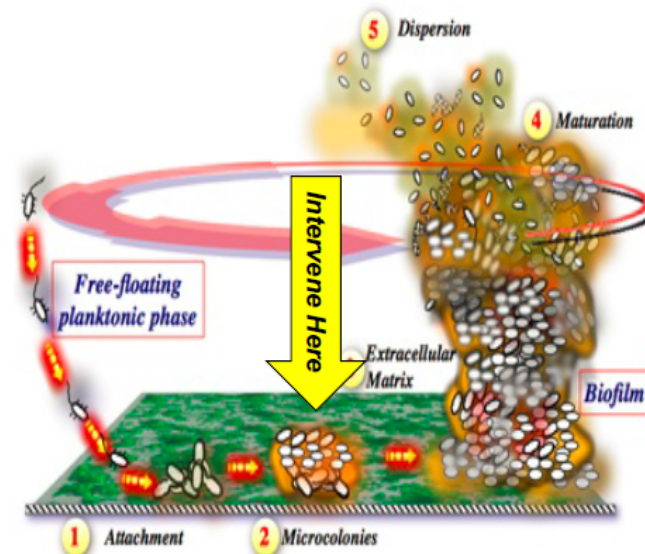
- Staph aureus makes up 20% of the bacteria on skin and 40% on lesions
- Exposure to water or salt and slight perspiration prompts biofilm formation and clogs the sweat ducts which triggers an immune response
- Immune response combined with gene deficiency results in itching and rash
- In a study conducted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

BioLexa Inhibits the Formation of Biofilms

BioLexa platform technology is a topical agent combining a chelating agent with an antibiotic to synergistically fight bacterial infections by preventing the formation of biofilms.

BioLexa Platform Technology

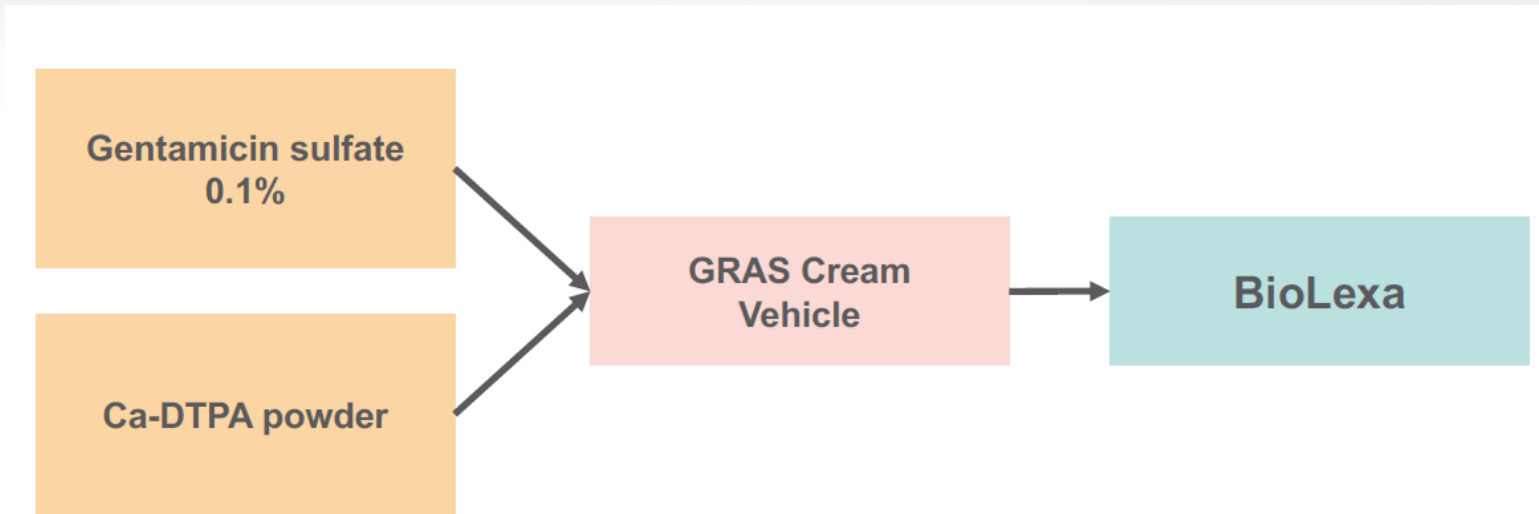
- Biofilms are matrices produced by bacterial colonies that shield the colony from attack by the immune system and make the bacteria up to 1000 times more resistant to antibiotics
- CDC data indicate that biofilms are implicated in over 2/3 of all skin infections
- Bacteria rely on Zn^{+2} ions to build biofilms to protect colonies
- BioLexa platform technology combines a chelating agent with an antibiotic to form a synergistic compound for inhibiting biofilm formation and fighting bacterial infection
- BioLexa works by using DTPA to chelate the Zn^{+2} ions necessary to form 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 Technology Overview

BioLexa is a combination of gentamicin antibiotic and the zinc ion binder DTPA

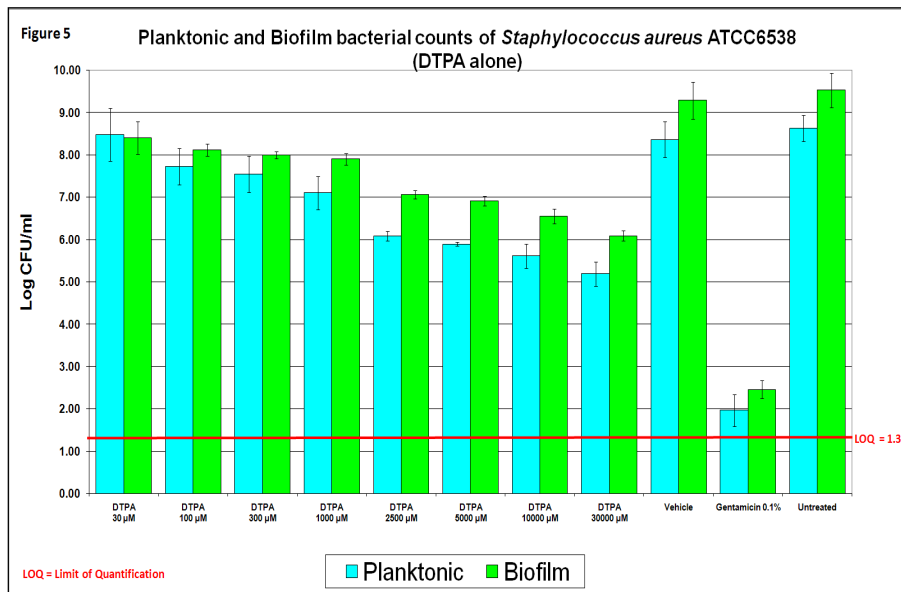


- ❑ Proprietary platform technology combines two existing approved drugs enabling reliance on existing safety data for those drugs reducing expected time to market from 10-12 years to 4-6 years
- ❑ Topical cream made up of Glyceryl Stearate/PEG-100 Stearate, Lanolin Alcohol, Mineral Oil, Sorbitol 70% 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

BioLexa Minipig Study: Results

This study concluded that the formula of the BioLexa Platform is the most effective treatment to reduce bacteria growth and inhibit the formation of biofilms.

Either Alone Not Adequate



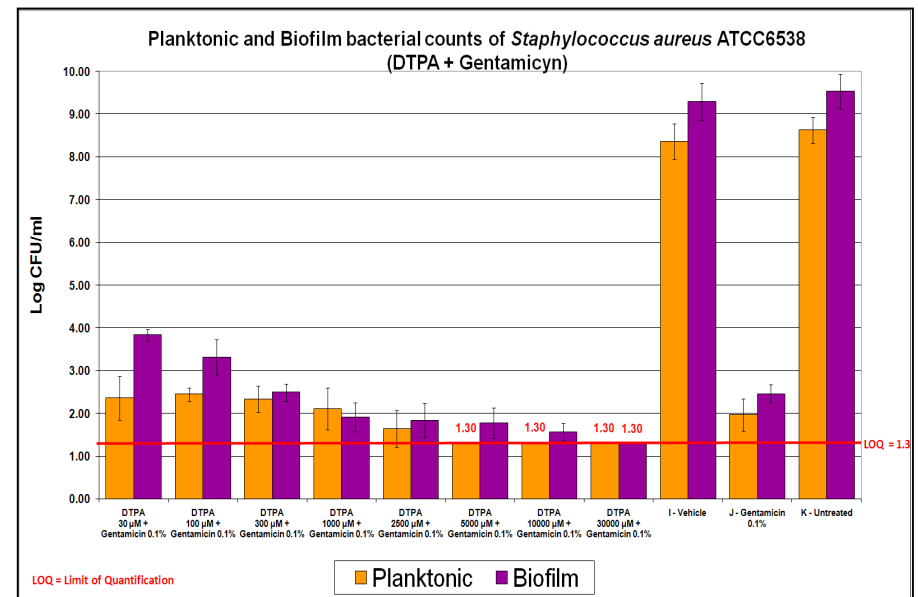
DTPA alone

Gentamicin alone

Miller School of Medicine, of the University of Miami and University of Cincinnati - Determination of the effects of a novel antimicrobial agent used in conjunction with Gentamicin on *Staphylococcus aureus* using a porcine model: preliminary evaluations Jose Valdes, Joel Gil, Andrew Herr, Andrew Harding and Stephen Davis



Combination Works Best



Combination reduced bacteria below LOQ

Miller School of Medicine, of the University of Miami and University of Cincinnati - Determination of the effects of a novel antimicrobial agent used in conjunction with Gentamicin on *Staphylococcus aureus* using a porcine model: preliminary evaluations Jose Valdes, Joel Gil, Andrew Herr, Andrew Harding and Stephen Davis

BioLexa Platform for DFU & Chronic Wound Disorders



Diabetic Foot Ulcers affect approximately 9.1-26.1M people worldwide, about 19-34% of people with diabetes are likely to be affected.*
- Unmet need for therapeutic approaches that heal wounds with *S. aureus* biofilms



The BioLexa Platform can help by
- Accelerating the healing of diabetic wounds infected with *S. aureus* forming biofilms with its patented approach to inhibit biofilms from forming



Pilot Study at Massachusetts General Hospital Vaccine & Immunotherapy Center
- Materials delivered for Module 1 of the Pilot Study in early 2019
- Focusing on applications to diabetic foot ulcers in a murine model



Results of pilot study expected by August 2019

*<https://www.nejm.org/doi/full/10.1056/NEJMra1615439>

BioLexa Platform: Chronic Wound Disorders

- Exclusive license to technology for optimizing healing of diabetic skin lesions.
- Hoth has executed an agreement with Massachusetts General Hospital to conduct a pilot study on the efficacy of BioLexa to:
 - Accelerate acute diabetic wound healing;
 - Initiate/improve chronic diabetic wound healing;
 - Heal of diabetic wounds infected with *S. aureus*; and
 - Accelerate the healing of diabetic wounds infected with *S. aureus* forming biofilms.
 - Pilot Study conducted by Mark C. Poznansky, MD, PhD. an Associate Professor of Medicine at Harvard Medical School and Attending Physician in Infectious Diseases Medicine at the Massachusetts General Hospital.
- Global diabetic foot ulcers and pressure ulcers market predicted to exhibit a positive 6.6% CAGR between 2016 and 2024*
- Current Market valuation for diabetic foot ulcers and pressure ulcers estimated at US \$2.8 billion in 2015. Market's valuation predicted to reach US \$4.9 billion by the end of 2024*

*Transparency Market Research Report, Mar 30, 2017, Diabetic-Foot Ulcer Market Report

BioLexa Platform: Market Opportunity

Indication	Medical Need	Target Patients	US Market Opportunity (USD)
Eczema and Atopic Dermatitis	Mild to Moderate	32M ¹	\$9.5B ¹
Aesthetic Dermatology	Improve healing, improve cosmetic outcomes	8.8M ²	\$1.9B ²
Chronic Diabetic Ulcers	Accelerate and improve healing	10M ³	\$2.8B ³

Source 1:

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

Source 2:

The American Society for Aesthetic Plastic Surgery 17th annual multi-specialty statistical data

Source 3:

Transparency Market Research Report, Mar 30, 2017, Diabetic-Foot Ulcer Market Report

VNLG 152: Acne & Psoriasis



Nearly 7.5 million people are affected by psoriasis in the US alone and represent about 2% of the population with approximately 100,000 new cases reported each year.*

60 million people suffering from all grades of acne in the US, 20% of which is severe enough to result in facial scarring.**



VNLG 152: Lead retinamide RAMBAs demonstrate antikeratinization & sebosuppressive effects *in vitro* and in reconstructed human epidermis, with equal or superior effects to currently marketed retinoids, 13-CRA and ATRA [*unpublished data*].



UMB researchers obtained promising early results demonstrating that lead retinamide RAMBAs have equal or superior effects over approved retinoids (ATRA and 13-CRA) to inhibit proliferation of normal human adult keratinocytes and sebocytes, and antikeratinizing effects in reconstructed human epidermis. Initial toxicity profiles for a panel of RAMBAs [*Njar et al., 2006*] also showed good indications for safe therapeutic use.



Preclinical trial for patients suffering from acne to begin late 2019

*<https://www.grandviewresearch.com/industry-analysis/psoriasis-drugs-market>

**<https://www.mordorintelligence.com/industry-reports/acne-therapeutics-market>

VNLG 152 – Psoriasis & Acne

Dermatology Applications:

- Licensed from the University of Maryland, Baltimore
- Provides a unique approach to achieve the therapeutic benefit of retinoid therapy while potentially circumventing the adverse events associated with it, a very important property for application to dermatology therapy.
- ATRA deficiencies are associated with dermatological diseases (acne and psoriasis), and retinoid derivatives have been one of the mainstay therapies for acne. Liarozole is in clinical use for the treatment of psoriasis and ichthyosis.
- Dermatological retinoid deficiencies are characterized by hyperkeratinization and desquamation and include diseases such as acne, eczema, psoriasis, cold sores, wounds, burns, sunburn, ichthyosis, skin cancer, and Kaposi's Sarcoma, all of which are plausible targets for retinamide RAMBA therapy.

VNLG 152 – Psoriasis & Acne

Acne Market

- Acne: More than 90% of the world's population is found to be affected by acne at some point in their life. In the United States, there are 60 million suffering from acne problems. This includes all grades of acne, from the mild, occasional breakout to more severe conditions. Of the 60 million, 20% have some form of acne bad enough that it results in scarring of the skin. Therefore, there is an increasing adoption of acne cure products, which helps in driving the overall market. (Mordor Intelligence)
- The global acne drugs market size is expected to reach USD 5.9 billion by 2025, according to a new report by Grand View Research, Inc., registering a 4.2% CAGR during the forecast period. Several factors such as emergence of biologics, unhealthy lifestyle, and rising disease incidence are anticipated to drive the market.

Psoriasis Market

- Global psoriasis market predicted to exhibit a positive 9.4% CAGR between 2016 and 2024
- Current Market valuation estimated at US \$11.3 billion in 2016
- Nearly 7.5 million people are affected by psoriasis in the US alone and represent about 2% of the population with approximately 100,000 new cases reported each year

<https://www.grandviewresearch.com/industry-analysis/psoriasis-drugs-market>

<https://www.grandviewresearch.com/industry-analysis/acne-drugs-market>

Genetic Marker for Food Allergies & Eczema



In the U.S., food allergies affect about 2% of adults and 4% to 8% of children

Annual estimate in U.S. of health events from food allergies - 30,000 emergency room visits; 2,000 hospitalizations; 150 deaths



Advantages over the standard of care:

- Eliminates need for potentially dangerous food-challenge test
- Earlier diagnosis, even in infancy



Designing Clinical trial for four different tests for peanut allergy, milk allergy, general food allergy and eczema



On target to conduct clinical trial and have results by end of 2019

Genetic Marker for Food Allergies & Eczema

- Hoth has an exclusive license from the University of Cincinnati
- Patent protected technology for determining a person's propensity to develop an allergic reaction to certain types of food, including:
 - Peanut allergy;
 - Milk allergy;
 - General food allergy; and
 - Eczema.
- Preliminary study performed by Dr. Gurjit Khurana Hershey, Director of the Division of Asthma Research, and endowed Professor of Pediatrics at Cincinnati Children's Hospital and the University of Cincinnati College of Medicine, identified several genetic markers that identify a patient's predisposition to these allergic reactions.

Genetic Marker for Food Allergies & Eczema

- Dr. Gurjit Khurana Hershey's study performed in association with University of Cincinnati and Cincinnati Children's Hospital Medical Center sought to identify genetic markers that would predict common food allergies and propensity to develop eczema.
- Analysis of patient blood and tissue involved in the study identified several genetic markers that indicate a propensity to develop these allergies.
- Knowing a patient's predisposition to develop these potentially dangerous allergic reactions may allow for early initiation of therapeutic intervention and may attenuate or delay a reaction.
- Applications for this technology are extensive, including the development of buccal swab ("mouth swab") test kits that would determine the presence of these markers.

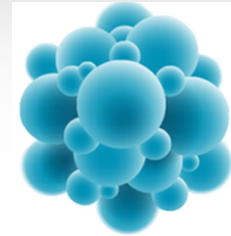
Investment Highlights



Unique small cap specialty pharma investment opportunity with multiple shots on goal and capital business model.



Multi-billion market opportunity with large unmet need for both the Company's primary and secondary asset.



Proprietary platform technology which combines two existing approved drugs enabling reliance on existing safety data for those drugs.



Experienced management team, board of directors and scientific advisors with proven drug development experience.

Appendix

Key Partnerships



Scientific Advisors

Name & Title	Background
<p>DR. JONATHAN ZIPPIN Senior Scientific Advisor</p>	<p>Jonathan Hale Zippin M.D., Ph.D. is an Associate Professor of Dermatology and Pharmacology and an Associate Attending Dermatologist at Weill Medical College of Cornell University. Dr. Zippin is the current Vice Chair of Research in the Department of Dermatology and is the Director of the Contact, Occupational, and Photo Dermatitis Unit. Dr. Zippin obtained his undergraduate education at Cornell University where he received a Bachelor's of Science with Honors. He then attended the Rockefeller/Cornell/Sloan-Kettering Tri-Institutional M.D./Ph.D. program. After completing a general medicine internship at the Mount Sinai Hospital in New York City, he trained in dermatology at the Weill Cornell Medical Center - New York Presbyterian Hospital. Following completion of his post-doctoral studies in 2010, Dr. Zippin joined the faculty of the Department of Dermatology at Weill Cornell Medical College. Dr. Zippin is a member of the American Academy of Dermatology, the Society for Investigative Dermatology, and the American Contact Dermatitis Society. He also serves on the Board of Directors of the American Contact Dermatitis Society where he helps to direct national policy on the treatment and detection of allergic-based eczema.</p>
<p>DR. ANDREW HERR Scientific Advisory Board</p>	<p>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.</p>

Scientific Advisors

Name & Title	Background
<p>DR. ADAM FRIEDMAN Scientific Advisory Board</p>	<p>Adam Friedman, MD, FAAD is a Professor of Dermatology and serves as Residency Program Director, Director of Translational Research, and Director of the Supportive Oncodermatology Program in the Department of Dermatology at The George Washington University School of Medicine & Health Sciences. Dr. Friedman is currently investigating novel nanotechnologies that allow for controlled and sustained delivery of a wide spectrum of physiologically and medicinally relevant molecules, with an emphasis on treating infectious diseases, accelerating wound healing, immune modulation, and correcting vascular dysfunction. He holds multiple patents derived from these investigations, and has published over 160 papers/chapters and 2 textbooks on both his research as well as a variety of clinical areas in dermatology with an emphasis on emerging medical therapies. He has received multiple awards such as the American Dermatologic Association Young Leader Award, the American Society for Dermatologic Surgery Cutting Edge Research Award, the 2017 Elle Beauty Genius Award, the La Roche Posay North American Foundation Research award, and was added to the Washingtonian Top Doctors list in 2017.</p>
<p>DR. STEFANIE JOHNS Scientific Advisory Board</p>	<p>Dr. Stefanie Johns, Ph.D. is the Associate Director, Regulatory Affairs at Enable Injections, LLC, a company specializing in the development and manufacture of advanced wearable infusion devices for use in combination products. Dr. Johns completed her graduate work in protein biochemistry at the University of Cincinnati College Medicine under the direction of Dr. Andrew Herr, Ph.D., which also contributed to the development of the BioLexa Platform technology. After graduate school, Dr. Johns joined Xavier Health Initiatives as the Program Manager where she assisted with collaborative initiatives across pharmaceutical and medical device industry leaders, Division leaders from the Food and Drug Administration, and members of the Senate HELP committee. She continued her career in regulatory affairs providing strategic regulatory guidance for medical device, drug, and drug-device combination product development programs at Meridian Bioscience and Camargo Pharmaceutical Services. While at Camargo, Dr. Johns led the early regulatory strategy for the BioLexa Program.</p>
<p>DR. VINCENT NJAR Scientific Advisory Board</p>	<p>Dr. Njar, Ph.D. has over 38 years of demonstrated accomplishment as a medicinal chemist and oncopharmacologist in academia at several universities, including 23 years with University of Maryland School of Medicine, Baltimore, MD, USA. He has >120 scientific publications, over 35 issued patents and 30+ pending patents; H-Index: 43; citations: 10,571. He has a Ph.D. in Chemistry (University College. London, UK) and completed a Postdoctoral Fellowship at the Worcester Foundation for Experimental biology, Shrewsbury, MA, USA. Dr. Njar co-founded Isoprene Pharmaceuticals Inc (IPI) in 2018, a cancer therapeutic company developing novel small molecules for the treatment of cancer.</p>

Scientific Advisors

Name & Title	Background
<p>DR. GURJIT HERSHEY Scientific Advisory Board</p>	<p>Dr. Gurjit Khurana Hershey is the Director of the Division of Asthma Research, and is an endowed Professor of Pediatrics at Cincinnati Children's Hospital and the University of Cincinnati College of Medicine. She received her medical and doctorate degrees from Washington University School of Medicine in St. Louis, Missouri and completed a pediatric residency and an allergy/immunology fellowship at St. Louis Children's Hospital. She is board certified in Pediatrics and Allergy and Immunology and is an active clinician and researcher. Dr. Khurana Hershey is a physician scientist who has devoted her career to clinical investigation using a combination of epidemiologic, basic, translational, and clinical research to answer fundamental questions regarding the environmental and genetic factors that contribute to the development of childhood asthma. She is an internationally recognized expert in pediatric asthma, allergy and immunology, genetics, and environmental health.</p>
<p>DR. RICHARD GRANSTEIN Scientific Advisory Board</p>	<p>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.</p>
<p>DR. LAWRENCE SCHACHNER Scientific Advisory Board</p>	<p>Lawrence A. Schachner, M.D., is the former Chairman of the Department of Dermatology and Cutaneous Surgery at UM (2003-2014) and a member of the faculty since 1978. During his tenure as Chairman of Dermatology the Department was rated in the top ten Departments nationally by The US News and World Report. Dr. Schachner previously served as Senior Associate Dean of the University of Miami Miller School of Medicine and Executive Director of Development. He currently serves as the Stiefel Family Professor of Dermatology and the Director of the Division of Pediatric Dermatology and as Professor of Pediatrics. Dr. Schachner has written more than 200 scientific publications. He is the lead author of the Schachner & Hansen textbook, Pediatric Dermatology edition 1 (1988), edition II (1995), edition III (2003), and Pediatric Dermatology edition IV (2011). Editions III and IV were nominated for the British Medical Association's "Medical Book of the Year". Edition III won first prize. Edition V is scheduled for 2019. He is also co-author of eight other books.</p>

Management Team

Name & Title	Background
<p>ROBB KNIE President and CEO, Director</p>	<ul style="list-style-type: none"> ❑ President of Lifeline Industries 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
<p>VADIM MATS Director</p>	<ul style="list-style-type: none"> ❑ CFO of Point Capital, Inc., and CFO of FWS Capital Ltd. ❑ Previously CFO of Whalehaven Group of Funds, Lust for Life Footwear & Brioclick Inc, 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, respectively ❑ CAIA Charterholder and CPA
<p>KENNETH RICE Director Scientific Advisory Board</p>	<ul style="list-style-type: none"> ❑ President and CFO of LikeMinds, Inc. ❑ Previously EVP, CFO and in house counsel of Alseres Pharmaceuticals, Inc., and was also with Aderis Pharmaceuticals in a similar capacity ❑ BSBA Babson College, MBA Babson College, J.D. Suffolk University Law School, LLM Boston University Law School
<p>DAVID SARNOFF Director</p>	<ul style="list-style-type: none"> ❑ Founder and Principal of Sarnoff Group, LLC ❑ Previously co-founder and Principal of Morandi, Taub & Sarnoff LLC ❑ B.A. Hofstra University, J.D. Rutgers University School of Law
<p>ANTHONY HAYES Director</p>	<ul style="list-style-type: none"> ❑ President, CEO and Director of Spherix, Inc., (Nasdaq: SPEX), since 2013 ❑ 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

Intellectual Property and License Terms Summary

Country	Patent	Expiration	Issue Date	Issued	Pending
EU	Patent covering compositions and methods	2028	October 2014	✓	
US & PCT	Issued claims focused on a pharmaceutical composition that inhibits bacterial colonization and biofilms, often found in skin infections such as atopic dermatitis	2034	November 2017	✓	
US	Patent covering Retinoic acid metabolism blocking agents (RAMBAs). The RAMBAs may be used for treatment of cancer, including breast and prostate cancers.	2035	October 2015	✓	
US & PCT	Issued claims of determining an individual's propensity to eczema, a peanut allergy, a milk allergy or a general food allergy	2026	June 2010	✓	

BioLexa Eczema Phase 2 Clinical Trial

	Phase 2b – Safety
Design	Double-blind, placebo controlled study to evaluate the safety and efficacy of topical BioLexa. Interventional Clinical Trial; Parallel assignment; Quadruple masking: participant, care provider, investigator, outcomes assessor. Enrollment patients with mild-moderate atopic dermatitis.
Sample size	60-80 pediatric and adolescent subjects randomized to either treatment or vehicle group
Treatment Schedule	Twice daily topical application directly on skin for 28 days duration of study.
Endpoint 1	Safety
Endpoint 2	Improvement by two grades of atopic dermatitis (eczema)
Centers	3
Inclusion	Ages 2-17 years of age. IGA 2-3. BSA 5-25%
Exclusion	History of gentamicin sensitivity
Duration	28 days with open label extensions