Clinical-Stage Biopharmaceutical Company Focused on Next Generation Therapeutics Meeting Unmet Patient Needs

SEPTEMBER 2021
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OUR MISSION

Hoth Therapeutics is a biopharmaceutical visionary dedicated to finding, investigating and developing early-stage therapeutics that will change the way diseases are managed and treated. Guided by the belief that treatment should not make you sicker than the disease, Hoth Therapeutics seeks out overlooked drugs that hold the promise to improve treatments and address significant unmet needs for patients. Hoth Therapeutics follows the science to find the ideal indications for each asset and partners with leading companies in the space to bring therapies to market.

At Hoth Therapeutics, we understand how devastating it can be to live with a chronic illness, be diagnosed with a rare disease, or the only option is to take a medicine that causes unrelenting side effects. We believe that every patient deserves to get the therapies they need to address their disease and improve their quality of life.
Key Investment Highlights

- 2 Clinical Programs
- Robust Pre-Clinical Development Programs
- Targeting Unmet Medical Needs to Address Broad Market
- Experienced Management and Advisory Board
# Pipeline: Multiple Shots on Goal

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<th>Drug</th>
<th>Indication</th>
<th>Optimization/Proof of Concept</th>
<th>Preclinical</th>
<th>IND Enabling</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Launched</th>
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<td>BioLexa</td>
<td>Eczema</td>
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<td>HT-001</td>
<td>Skin Toxicity associated with EGFR inhibitors</td>
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<td>HT-KIT</td>
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<td>HT-005 Zpods</td>
<td>Cutaneous Lupus</td>
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<td>COVID-19</td>
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<td>VaxCelerate</td>
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BioLexa Lotion

Phase 1b Clinical Trial in Humans for Treatment of Mild to Moderate Atopic Dermatitis in 2021

HT-001

IND-Enabling Studies in 2021 & Phase 2a Clinical Trial in Patients Targeted for Q1 2022
BioLexa Lotion : Value Proposition

**Market Growth:** Atopic dermatitis market predicted to grow from $6.4B in 2017 to $18.3B by end of 2027*

**Mechanism of Action:** Novel mixture of two previously approved compounds targeting the underlying *Staphylococcus aureus* infection hypothesize to potentiate Atopic Dermatitis (AD) or eczema flares - First compound prevents biofilm formation, which protects the underlying infection, allowing the second, an antibiotic, to more effectively treat the underlying infection.

**Addresses Unmet Need:** Non-corticosteroid treatment targeted for treatment of both pediatric and adult mild to moderate AD populations

*Atopic Dermatitis Market – Global Industry Analysis, Size and Forecast, 2017-2027*
Recent Milestones: BioLexa Lotion

- HREC Approval on December 9, 2020 to conduct phase 1b clinical trial in Australia
- Site-Recruitment Completed
- Dosing of Cohort 1 Complete
- The interim safety review indicates that BioLexa was well tolerated with no serious adverse events and no drug-related treatment-emergent adverse events observed.
- Cohort 2 submission and screening expected to start in Autumn of 2021
A Randomised, Double-Blind, Vehicle Controlled, Sequential Group Study to Determine the Safety, Tolerability, Pharmacokinetics and Efficacy of Twice Daily Application of Topical BioLexa™ in Adult Healthy Subjects and Patients with Mild to Moderate Atopic Dermatitis

BioLexa Phase 1b Clinical Study Design
BioLexa: Proof-of-Concept Results

This study concluded that the combination of gentamicin and Ca-DTPA is more effective to reduce bacteria growth and inhibit the formation of biofilms than each compound individually.

Either Alone Not Adequate

Combination Works Best

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

Figure 5
Planktonic and Biofilm bacterial counts of Staphylococcus aureus ATCC6538
(DTPA alone)

LOQ = limit of quantification
Planktonic > Biofilm

DTPA alone
Gentamicin alone

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
HT-001 : Value Proposition

**Market Growth:** EGFR Inhibitor Skin Toxicity market predicted to grow from $52M in 2018 to $391M by end of 2030*

**Mechanism of Action:** 12-week study conducted at GW suggests the topical application of HT-001 significantly reduces erlotinib-induced cutaneous toxicities (71% reduction compared to control). It supports that HT-001 may be used as a topical intervention to treat EGFR-inhibitor-induced cutaneous toxicity.**

**Addresses Unmet Need:** No current approved product on the market that specifically treats EGFR inhibitor cutaneous toxicities, which occur in up to 90% of patients*** undergoing EGFR inhibitor therapy

*EGFR Inhibitors-Induced Skin Disorders-Market Insights, Epidemiology, and Market Forecast-2030
**https://ir.hoththerapeutics.com/ht-001
***https://jamanetwork.com/journals/jamadermatology/article-abstract/2767656
Recent Milestones: HT-001

- Pre-IND Meeting Submission in December 2020
- Pre-IND WRO from FDA Received in February 2021
- Final formulation selected and GLP/GMP manufacturing contracts executed
- IND-Enabling studies initiated in Q2 2021
- IND Submission/Clinical Trial target for Early 2022
Proposed HT-001 Phase 2a Clinical Trial Design

A Randomized, Placebo-Controlled, Parallel Phase 2a Dose Ranging Study to Investigate the Efficacy, Safety, and Tolerability of Topical HT-001 for the Treatment of Skin Toxicities Associated with EGFR Inhibitors

- Screening
  - Cancer patients initiate EGFR inhibitor therapy (n = 130)

- Randomization
  - Development of Rash (grade ≤3)
  - 0-4 weeks
    - Arm 1: 0.5% HT-001, QD
    - Arm 2: 1.0% HT-001, QD
    - Arm 3: 2.0% HT-001, QD
    - Arm 4: Placebo HT-001, QD

- Follow-up Cohort
  - 6 weeks Treatment HT-001 + EGFR Inhibitor Therapy*
  - 1 year follow-up: Progression Free Survival, Overall Survival, Tumor Response

*Oral antibiotics will be provided for rash severity 3; topical rescue therapy for all patients as needed
HT-001 : Topical HT-001 Proof-of-Concept Results

- HT-001 administered either via oral or topical application is effective to significantly reduce EGFR inhibitor-induced skin toxicities in rats
Recent Milestones and Upcoming Catalysts: Clinical Programs

<table>
<thead>
<tr>
<th>BioLexa Lotion</th>
<th>Initiate Phase 1 Cohort 1 dosing</th>
<th>Official Cohort 1 Results</th>
<th>Initiate Phase 1b Cohort 2 Patient Dosing</th>
<th>Preliminary Results</th>
<th>Phase 1b Cohort 2 Results</th>
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<tbody>
<tr>
<td>(Atopic Dermatitis)</td>
<td>Preliminary Cohort 1 results</td>
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<td>Official Cohort 1 Results</td>
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<td>Initiate Phase 1b Cohort 2 Patient Dosing</td>
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| HT-001                | GMP Development                          | GLP Toxicology Studies    | Clinical Site Selection                   | US IND submission   | Preliminary Results      |
| (Cutaneous toxicity of EGFR Inhibitors) | Non-GLP toxicology studies                 |                           |                                           | Clinical Site Activation |                          |
|                      | Clinical Protocol Development             |                           |                                           | Initiate Phase 2a Clinical Trial |                          |
|                      |                                          |                           |                                           |                      |                          |
LATE STAGE PRE-CLINICAL PROGRAMS

HT-003
Acne, Psoriasis

HT-004
Asthma, Allergic Inflammation

HT-005
Cutaneous Lupus Erythematosus (CLE)

Vaxcelerate
COVID-19 Vaccine
Recent Preclinical Development Milestones

- **HT-003**: Preclinical results show the ability of HT-003 to inhibit TLR2 signaling pathway suggesting that HT-003 is a potentially effective therapeutic for acne.* Additional animal model studies are currently underway to explore other inflammatory-driven dermatological indications.

- **HT-004**: Mouse asthma model study demonstrates that HT-004 delivered by inhalation is effective to reduce inflammatory cell recruitment around bronchioles, supporting a robust therapeutic response with no signs of tissue irritation. Development of a humanized mouse model is currently in progress to finalize the lead actives for further development.***

- **HT-005 Z-Pods**: Rat model of Lupus with cutaneous lesions showed HT-005 Z-Pods provided long term therapeutic response over 10 weeks to prevent development of lesions.**

- **Vaxcelerate**: A near GLP preclinical mouse study demonstrated that the self-assembling vaccine construct significantly increased both helper and cytotoxic T cell responses to the vaccine targeted antigens compared to controls.**** IND-enabling studies are planned with a Pre-IND meeting request targeted for Q4 2021.

*See Appendix for HT-003 preclinical results  
**See Appendix for HT-005 Z-Pod preclinical results  
***See Appendix for HT-004 preclinical results  
****Results reported from Voltron
Recent Milestones and Upcoming Catalysts: Late Pre-Clinical

<table>
<thead>
<tr>
<th>Product</th>
<th>Milestone</th>
<th>Q2 2021</th>
<th>Q3 2021</th>
<th>Q4 2021</th>
<th>Q1 2022</th>
<th>Q2 2022</th>
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<tbody>
<tr>
<td>HT-003 (Acne / Psoriasis)</td>
<td>Mouse model studies, Study Results, Preliminary toxicology studies</td>
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<tr>
<td>HT-004 (Asthma / Allergy)</td>
<td>Humanized mouse model development</td>
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<tr>
<td>HT-005 Z-Pods (Cuttaneous Lupus Erythematosus)</td>
<td>Statistically significant preclinical proof of concept in mouse model</td>
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<tr>
<td>Vaxcelerate (COVID-19 Vaccine)</td>
<td>Positive preclinical results announced, IND-enabling toxicology studies, Pre-IND submission target</td>
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EARLY PRE-CLINICAL PROGRAMS

HT-003
Inflammatory Bowel Diseases

HT-006
Hospital-Acquired Pneumonia/ Ventilator-Acquired Pneumonia

HT-ALZ
Alzheimer’s Disease

HT-KIT
Mast Cell Neoplasms/ Anaphylaxis

HT-002
COVID-19 Treatment/Prevention
# Recent Milestones and Upcoming Catalysts: Preclinical Candidates

<table>
<thead>
<tr>
<th>Preclinical Candidate</th>
<th>Milestone 1 (Q2 2021)</th>
<th>Milestone 2 (Q3 2021)</th>
<th>Milestone 3 (Q4 2021)</th>
<th>Milestone 4 (Q1 2022)</th>
<th>Milestone 5 (Q2 2022)</th>
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<tr>
<td><strong>HT-003</strong> (IBD)</td>
<td>Initiate proof of concept ex vivo studies</td>
<td>Results from Proof of Concept Studies&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Preliminary toxicology studies</td>
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<tr>
<td><strong>HT-006</strong> (Antibiotic for VAP/HAP)</td>
<td>Antimicrobial characterization phase 1</td>
<td>Inhalation feasibility animal studies start</td>
<td>Antimicrobial characterization phase 2</td>
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<tr>
<td><strong>HT-ALZ</strong> (Alzheimer’s disease)</td>
<td>Establish Research Plan with AD Research Leader</td>
<td>Initiate proof of concept animal model studies at WashU</td>
<td>Results from proof of concept studies</td>
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</tr>
<tr>
<td><strong>HT-KIT</strong> (mast cell neoplasms/anaphylaxis)</td>
<td>Contract with CMO for drug development signed</td>
<td>Initiate API synthesis</td>
<td>Analytical method development</td>
<td>Initiate drug product development</td>
<td>Preliminary toxicology studies Pre-IND Request</td>
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<tr>
<td><strong>HT-002</strong> (COVID-19 Therapy)</td>
<td>New preclinical studies with SARS-CoV-2 Variants</td>
<td>Preliminary study results</td>
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<sup>a</sup>See slides 30 and 31 for preclinical results
Diagnostic Device

*U.S. Provisional Application No. 62/639,328
Direct Detect Breath Diagnostic Device System

• Novel nanohole array (NHA) technology platform with direct sensing from breath sample type
  • Potential for home use by patients
  • Results in minutes
  • Technology licensed from George Washington University

• Development of platform prototype in progress (6-9 months)

• Future development will include selection of target analytes
## Investment Highlights

### Two Programs in Clinical Stage of Development
- Addressing multi-billion dollar unmet market opportunities across indications
- BioLexa Lotion - Novel mixture of two FDA-approved compounds – in clinical phase of development
- HT-001 – no approved product/competitor currently on the market, clinical trial projected for early 2022

### Diverse and Robust Pipeline of Pre-Clinical Candidates
- Offers strong intellectual property portfolio, including exclusive licenses to patents and trademarks
- Multiple shots on goal with diversified portfolio and market
- Multiple assets have platform technology possibilities

### Clean Financials
- 23.9 million shares outstanding (as of August 31, 2021)
- Cash on hand is sufficient to take company through the clinical and pre-clinical programs in current pipeline

### Experienced Management, Board and Scientific Advisors
- Experienced management team, board of directors and scientific advisors with proven financial, capital markets and drug development experience
Appendix
HT-003-D : Dermal Preclinical Study Results

TLR2 is one of the most critical genes for acne pathophysiology.

Data shows that HT-003 significantly downregulates TLR2 expression after challenge with PGN (TLR2 agonist) in an in vitro human keratinocyte model.
HT-004: Asthma & Allergic Inflammation

- Peribronchiolar Inflammation was reduced by inhalation of HT-004 that targets FcER1-beta alternative exon splicing.
- Ovalbumin inhalation induced airway-centric recruitment of inflammatory cells predominated by eosinophils admixed with lymphocytes, macrophages, and fewer mast cells.
- Inflammatory cell recruitment was minimal in lungs of mice lacking the ovalbumin-induced allergic airway disease and administered only PBS vehicle control.
- Inflammatory cell recruitment was moderate to marked resulting in expansion of peribronchiolar connective tissues by several cells thick in some areas for mice in control treatment groups with ovalbumin-induced allergic airway disease (vehicle control and oligo (non-target) control.
- Despite ovalbumin-induced allergic airway induction, lungs from mice receiving inhalation of HT-004 had reduced inflammatory cell recruitment around bronchioles.
HT-005 Z-Pod Results Show Strong Therapeutic Potential

HT-005 in coconut oil ("neat") provides a small therapeutic effect (although the lesions continue to progress), but this same active loaded in Z-pods™ provides an actual reduction in lesion score.

Controlling Rapid Metabolism.

Overcoming Poor Dermal Penetration.
Animal Data

Untreated

Control: Empty Z-pods™

HT-005 Z-pods™
HT-003-IBD: Preclinical Study Results

Ulcerative Colitis Ex Vivo Tissue (n = 2 donors)

HT-003 reduces inflammatory cytokines associated with IBD and promotes intestinal homeostasis
HT-003-IBD: Preclinical Study Results

Crohn’s Ex Vivo Tissue (n = 1 donor)

HT-003 reduces inflammatory cytokines associated with IBD and promotes intestinal homeostasis.

CFW = HT-003
BIRB796 = positive therapeutic control
Management Team

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Stefanie Johns, Ph.D.  
*Chief Scientific Officer*

David Briones  
*Chief Financial Officer*

Jonathan Zippin, M.D., Ph.D.  
*Senior Scientific Advisor*

Associate Attending Dermatologist  
Vice Chair of Research  
Associate Professor of Dermatology & Pharmacology  
Weill Cornell Medical College

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