



# **Corporate Presentation**

# Lobe Sciences Update



New Corporate Structure



Alera Pharma, Inc. Update



Altemia, Inc. Update



Highlights



Questions and Answers

# Lobe Sciences New Structure

## Lobe Sciences Ltd.

(CSE: LOBE)  
(OTCQB: LOBEF)  
(FWB: LOBE.F)  
Holding Company

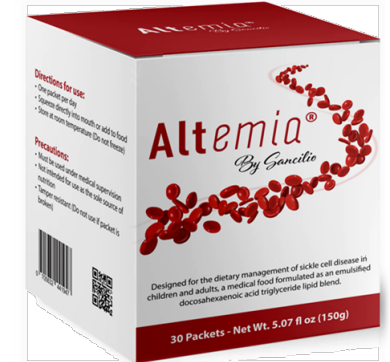
Frederick D. Sancilio MS, PhD  
CEO and Board Chairman

## Altemia, Inc.

(Florida Corporation)

Herman Williams MPH, MBA, M.D.  
CEO

- Stand-alone operating company
- Separate Executive Team
- Shared services provided by Lobe under MSA
- Medical food for dietary management of sickle cell disease in adult and pediatric patients, diabetes, chronic kidney disease



## Alera Pharma, Inc.

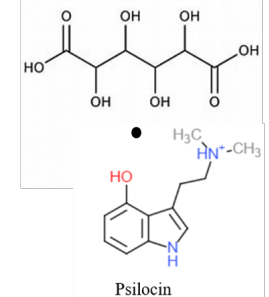
(Florida Corporation)

Rick F. Goulburn, MBA  
CEO

- Stand-alone operating company
- Separate Board of Directors and Executive Team
- Shared services provided by Lobe under MSA
- Conjugated Psilocin™ Assets and IP transferred from Lobe Sciences

## Conjugated Psilocin™

(US PTO patented psilocin mucate)



## Proven Leadership – Entrepreneurial Success



### Frederick D. Sancilio MS, PhD, CEO and Board Chairman Lobe Sciences

- 35+ years of experience in managing research and development programs for some of the world's largest brands.
- Founded the first contract research organization focused on the creation of novel dosage forms and built it into a global leader in drug development.
- Led over 1,500 development programs and has established an international network ranging from discovery through commercialization of new chemical entities, biotechnology products, unique drug delivery systems, as well as novel regulatory and clinical strategies.



### Rick F. Goulburn, MBA, CEO Cynaptec Pharmaceuticals, Inc., CEO Alera Pharma, COO and Board Member Lobe Sciences

- 25+ years of experience in the biopharmaceutical industry in global and local executive leadership positions.
- CEO of Cynaptec PharAlera Pharma, Inc. and former EVP of Vifor Pharma, a global leader in nephrology and iron deficiency including roles as Head of Global Marketing, Head - North America, Interim Head of Global Medical, and Global Rx Strategy Leader.
- Former Chief Operating Officer of Aspreva Pharmaceuticals, a NASDAQ listed start-up sold for \$1B in 2008 and former Merck World-wide Migraine Business Strategy Team Leader and US Executive Director, Migraine Franchise.
- Current Board member – CARRA (Childhood Arthritis Rheumatology Research Alliance), former Board member – VPFMC Renal Pharma.



### Harry R. Jacobson, M.D., Board Member Lobe Sciences

- 45+ years of experience as a physician, investor, and entrepreneur.
- Former Vice Chancellor for Health Affairs and CEO of Vanderbilt University Medical Center.
- Founded or co-founded multiple companies including Contact Software, Renal Care Group, Cardiovascular Care Group, Informatics Corporation of America, CeloNova Biosciences, Ambulatory Services of America, and MindCare Solutions. E&Y Southeast Entrepreneur 2002.
- Board member for Seno Medical Instruments, Gradalis, Inc., MindCare Solutions, Salus, Inc and former Board member of Merck, Renal Care Group, and Kinetic Concepts.



### Wesley Ramjeet B.A., CPA, Board Member Lobe Sciences

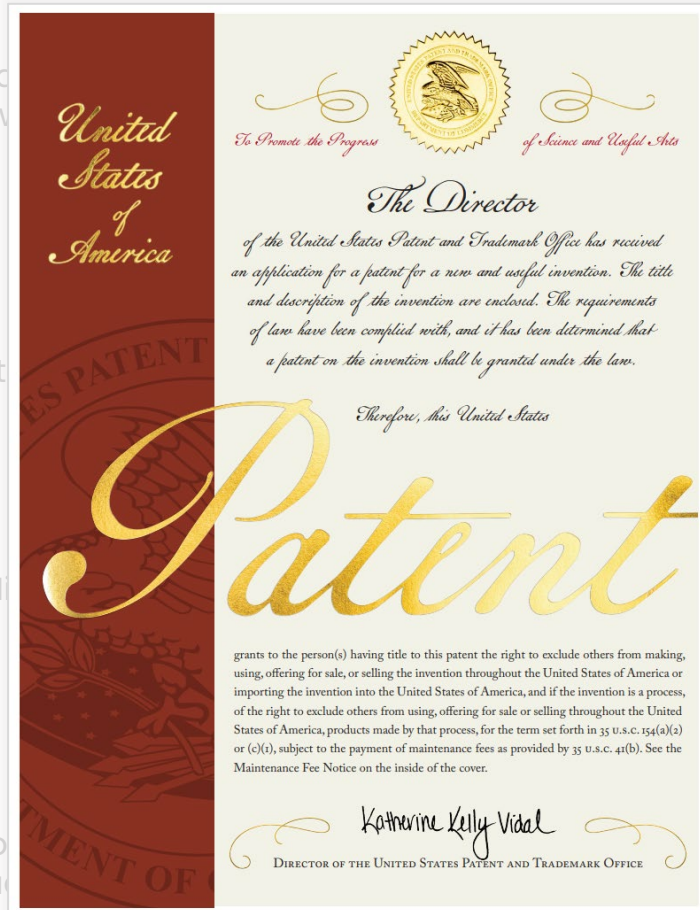
- 30+ years of experience as a CPA, CEO, Strategic Consultant and CFO with significant experience with complex transactions including acquisitions, initial public offerings, reverse mergers, and driving record growth for midcap, small businesses, and startups.
- CEO and Founder of PPMT Strategic Group, a management consulting firm, and Chairman and co-founder of MD Logic Health.
- Chairman of Stock News Now (parent company to Planet Microcap and the Microcap Magazine), founding member of the Board of Trustees of the Universal Hip Hop Museum.
- Former CFO and Board member of Olaregen Therapeutix, Inc.






# Highlights and Uses of our Cash







US012102616B2

**(12) United States Patent**  
**Sayed et al.**

**(10) Patent No.: US 12,102,616 B2**  
**(45) Date of Patent: Oct. 1, 2024**

**(54) PSILOGIN MUCATE**

**(71) Applicant:** LOBE SCIENCES LTD., Vancouver (CA)  
**Inventors:** Younsy Sayed, Wilmington, NC (US); Frederick Sanello, Stuart, FL (US); Philip J. Young, Montpelier, VA (US); Shaikhkumar Ramanlal Desai, Wilmington, NC (US); Autumn Beauchamp, Wilmington, NC (US)

**(73) Assignee:** LOBE SCIENCES LTD., Vancouver (CA)

**(\*) Notice:** Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

**(21) Appl. No.:** 18/411,576  
**(22) Filed:** Jan. 12, 2024

**(65) Prior Publication Data**  
 US 2024/0165080 A1 May 23, 2024

**Related U.S. Application Data**

**(63) Continuation-in-part of application No.** PCT/US2023/027500, filed on Jul. 12, 2023.

**(60) Provisional application No.** 63/388,414, filed on Jul. 12, 2022.

**(51) Int. Cl.**  
**A61K 31/4045** (2006.01)  
**A61K 9/00** (2006.01)  
**A61P 25/22** (2006.01)

**(52) U.S. Cl.**  
 CPC ..... **A61K 31/4045** (2013.01); **A61K 9/0053** (2013.01); **A61P 25/22** (2018.01)

**(58) Field of Classification Search**  
 CPC .... A61K 31/4045; A61K 9/0053; A61P 25/22  
 See application file for complete search history.

**(56) References Cited**

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Hastler et al. "Determination of psilocin and 4-hydroxyindole-3-acetic acid in plasma by HPLC-ECD and pharmacokinetic profiles of oral and intravenous psilocybin in man" Pharmaceutica Acta Helveticae 1997 72(3), 175-184.

Hotze et al. "Pharmacokinetics and Pharmacodynamics of Oral Psilocybin Administration in Healthy Participants" Clinical Pharmacology & Therapeutics 2023 113 (4) : 822-831. International Search Report and Written Opinion in PCT/US2023/027500 dated Oct. 13, 2023.

Kotaczynska et al. "Development and validation of an LC-MS/MS method for the bioanalysis of psilocybin's main metabolites, psilocin and 4-hydroxyindole-3-acetic acid, in human plasma" Journal of Chromatography 2021 B1164 122486.

Landenblatt et al. "Quantitation of psilocin in human plasma by high-performance liquid chromatography and electrochemical detection: comparison of liquid-liquid extraction with automated on-line solid-phase extraction" Journal of Chromatography 1998 709: 255-263.

Psilocybin Investigator Brochure by Usona Institute Jan. 17, 2021. Psych with the extension .globea/iv-formulation-of-psilocin/ Mar. 22, 2023 accessed Jan. 10, 2024.

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**Primary Examiner**— San Ming R Hui  
**(74) Attorney, Agent, or Firm**— Licata & Tyrrell PC.

**(57) ABSTRACT**  
 Psilocin formulations of psilocin mucate with improved stability, physical properties and/or handling characteristics, as well as enhanced pharmacologic activity, pharmacokinetic parameters and safety characteristics as compared to psilocin or psilocybin and methods for their use are provided.

**20 Claims, No Drawings**

Completed

Completed

Used De-Risked  
 ent Plan

## Pre-Clinical Studies Successfully Completed



### 28-day Swiss Albino Rodent Toxicology<sup>1</sup>

- Pre-clinical IND Enabling Study.
- Completed Q1 2024.
- 50x targeted dose safe and well tolerated.
- No mortality or morbidity at any dose level.
- No clinical signs of toxicity during treatment and recovery.
- No test-item related effects on general health, mean body weight, feed consumption, clinical pathology parameters, gross pathology and histopathology in both sexes.
- No test-item related effects observed during 14-day recovery period after cessation of treatment.



### Dosing Frequency Study<sup>1</sup>

- Anxiety Model.
- Completed Q2 2024.
- Determining Daily vs Weekly Dosing.
- Daily treatment of rats with L-130 at human equivalent dose of 4 mg resulted in significant anxiolytic effect.
- Daily treatment of rats with L-130 was safe with no observed toxicity or significant impact on biochemical parameters.
- Daily treated rats performed better at every task and had statistically significant decreases in cortisol level.

<sup>1</sup>) Data on file – Alera Pharma, Inc.

## Phase 1 “First-in-Man” Successfully Completed



### Rapid and Complete Bioavailability

$C_{max}$  is 2x an equal amount of psilocin generated by the ingestion of psilocybin



### Sub-hallucinogenic Dosing

Conjugated Psilocin™ did not show hallucinogenic effect in subjects given a 4 mg dose

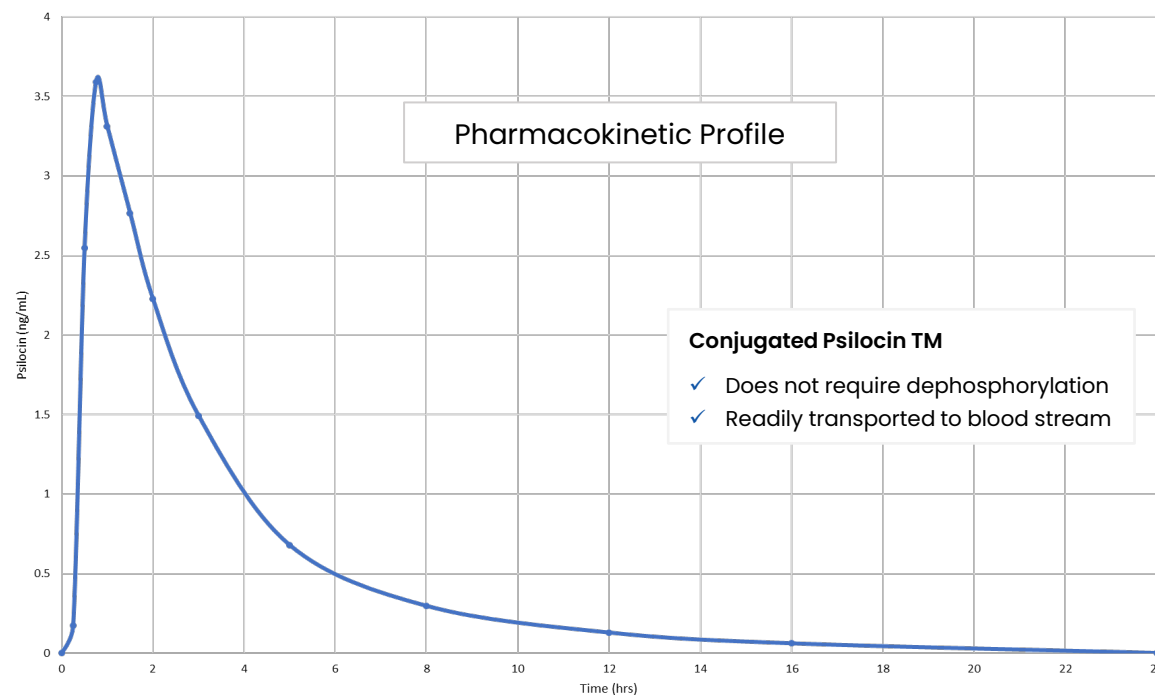


### Anxiolytic Effect

- Subjects (90%) reported an anxiolytic effect 2 hours post-drug administration
- A majority of subjects reported a sustained anxiolytic effect lasting 28-days post-dosing.
- No SAEs (serious adverse effects) were reported

1) Data on file – Alera Pharma, Inc.

## Phase 1 Safety and PK Study – 1<sup>st</sup> in Man<sup>1</sup>

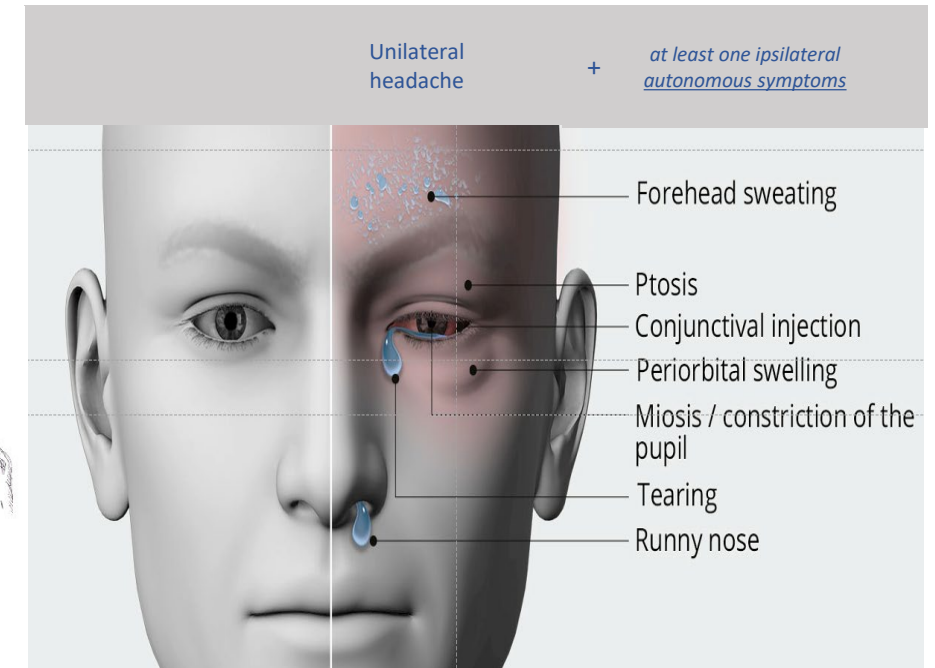


Phase 1 open-label, single-treatment, single-dose pharmacokinetic study of L-130 capsules containing 2 mg psilocin (as psilocin mucate) under fasting conditions in 10 healthy male subjects aged 21 to 46 years old.



## Most excruciating pain a human can experience

- **Epidemiology** - ~0.1 to 0.2% of population
- **Attacks up to 8x daily** - 15 minutes to 3 hours
- **Chronic – attacks with no remission** > 1 year (~19% pts)
- **Male gender** - ~3:1
- **Females often misdiagnosed with migraine**
- **Average age of onset** ~30 years old
- **Pediatric onset** ~27% of patients
- **Significant Unmet Medical Need** – patients often commit suicide
- **Orphan Disease** - with less than 100,000 patients in the US



**The most severe primary headache disorder**

The “Suicide Headache”

1) Achley S. Hattle, Cluster Headaches Attacks, 2017 ISBN 978-1-54391-237-1

## An Excellent Initial Indication for Conjugated Psilocin™

### Why Chronic Cluster Headache as the First Indication Strategy?

#### Strong Proof of Concept Data Exists

31% reduction in attack frequency; 10% of patients reported 21-weeks of complete remission<sup>1</sup>  
46% reduction in attack frequency<sup>2</sup>



Potential for Orphan Drug Designation and Fast Track

De-risked Clinical Development Program

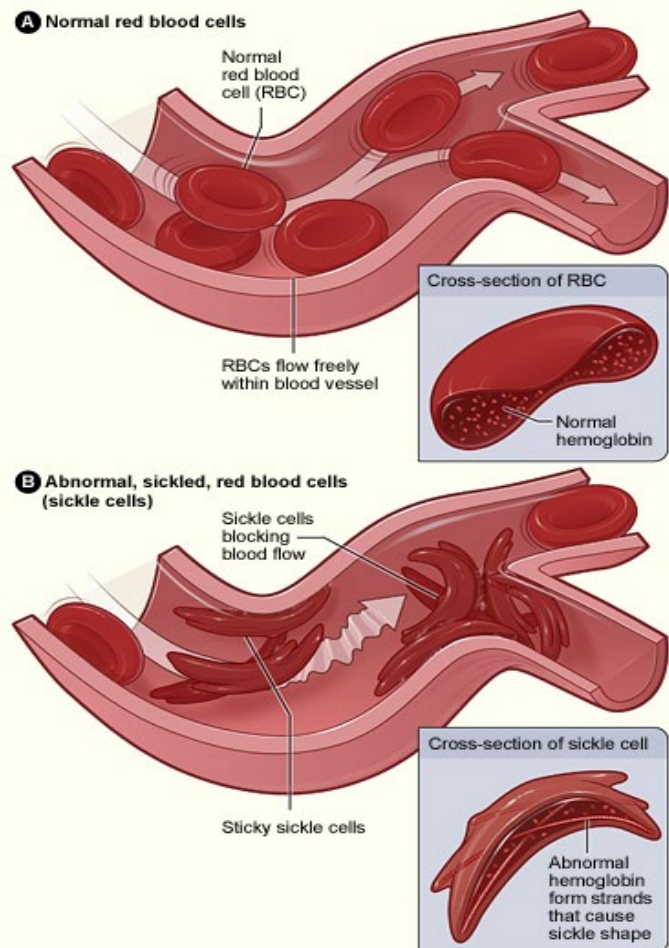


Significant Unmet Medical Need and Market Opportunity

1) Martin K. Madsen, Anja Sofie Petersen, Dea S Stenbaek, et al. CCH attack frequency reduction after psilocybin correlates with hypothalamic functional connectivity. Headache. 2024 Jan;64(1):55-67. doi: 10.1111/head.14656.  
2) Emmanuelle A D Schindler, R Andrew Sewell, Christopher H Gottschalk et al. Psilocybin pulse regimen reduces cluster headache attack frequency in the blinded extension phase of a randomized controlled trial. J Neurol Sci 2024 May 15;460:122993

# Sickle Cell Disease (SCD) – An Unmet Medical Need

## Etiology Of Sickle Cell Disease

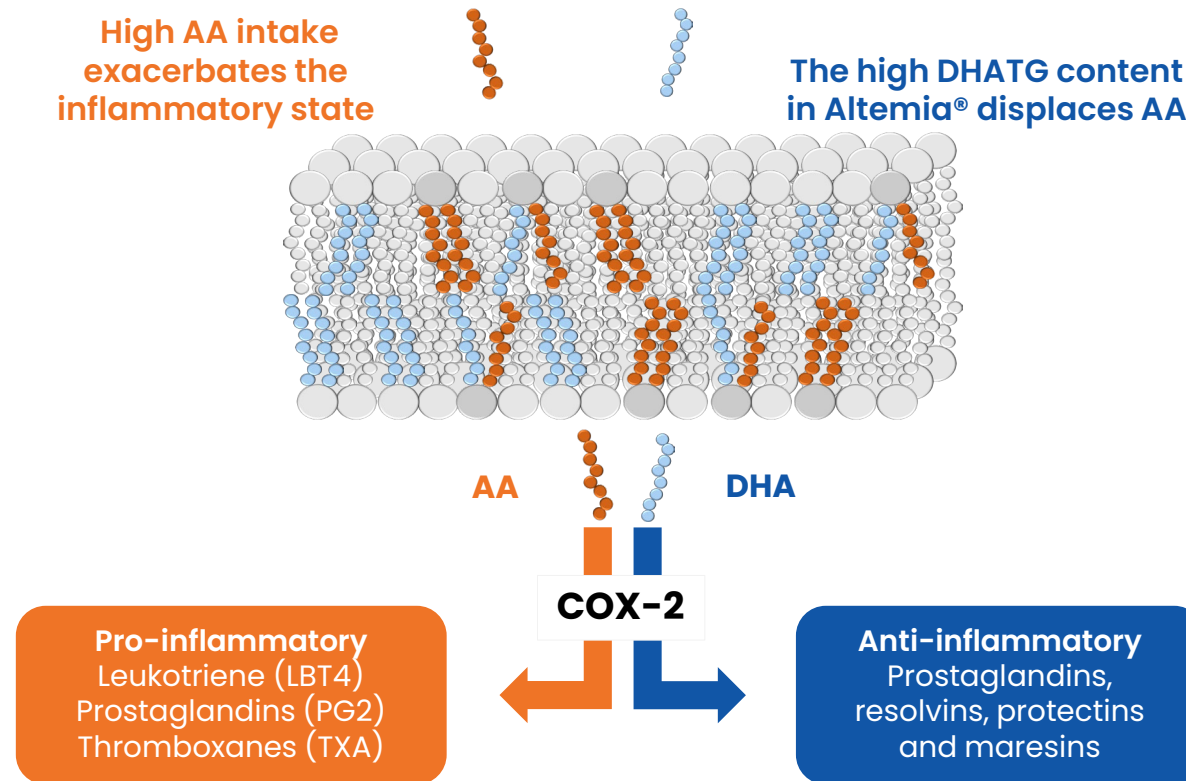


- » **SCD is an inherited genetic disorder** affecting over 100,000 people, mostly children, in the United States.
- » **Approved medication for SCD was recently withdrawn** due to post-marketing severe adverse events (death) among pediatric patients.
- » **40-year average patient age of survival**
- » **Over 12 years of research** by our scientists have confirmed that while the disease is clearly resulting from a genetic mutation of hemoglobin, it can be addressed with a safe and efficacious therapy: Very High Concentrations of Docosahexaenoic Acid (DHA).
- » **Altemia® provides hope via two pathways:**
  - » *As a Medical Food (awaiting insurer reimbursement approval)*
  - » *FDA approved oral capsule (S100)*

# Altemia™ is Designed to Re-establish

## a Natural Balance of Fatty Acids

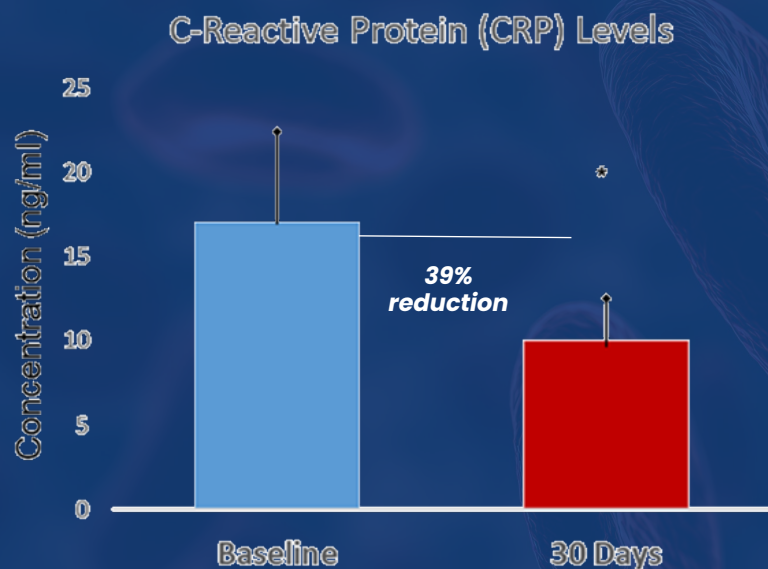
Sickle Cell Disease (SCD) patients have imbalanced cell membrane fatty acid profiles featuring high AA and low DHA. Omega-6 fatty acids like Arachidonic Acid (AA) are pro-inflammatory. High Omega-6 intake may increase chronic inflammation and exacerbate the disease severity. **Altemia™ contains no Omega-6 Arachidonic Acid to optimize safety and efficacy and rebalances the ratio for optimal health.**





# Altemia® 2021 Medical Food Clinical Study

Parameter	Baseline (Average)	At 30 Days (Average)	Increase / Decrease
<b>Docosahexaenoic Acid triglyceride (DHATG)</b>	111.59	237.97	<b>113%</b>
<b>Eicosapentaenoic Acid triglyceride (EPATG)</b>	181.33	296.45	<b>63%</b>
<b>Total Omega-3 (DHATG + EPATG)</b>	292.92	534.42	<b>82%</b>
<b>Arachidonic Acid (AA)</b>	843.36	778.43	<b>-8%</b>



- » **Formulated as an emulsified docosahexaenoic acid as a triglyceride ester (eDHATG) enriched semi-solid food** (current Altemia® medical food product)
- » **DHA dose level was safe (1900mg/day)** (equivalent to approximately 10-15 capsules of over-the-counter DHA supplements)
- » **Patients showed a:**
  - 113% increase in DHA,
  - 8% decrease in Arachidonic Acid levels,
  - 39% reduction in C-reactive protein levels



## Altemia® Medical Food – Entering Commercialization

- Partner is a major distributor of medical foods – Pentec, Inc.
- Inventory at distribution center awaiting insurance reimbursement approval



## Phase 2 Medical Food Clinical Program

- Rapid Uptake and bioavailability microemulsion
- Safe and well tolerated
- Proven reduction of inflammation, CRP



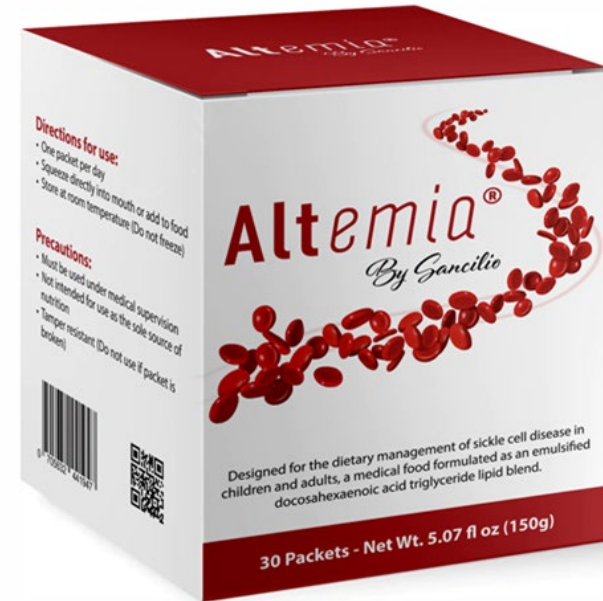
## S-100 NDA Orphan Drug Development Program

- De-risked Sickle Cell Disease drug program for an unmet medical need
- Proven safe and effective but lacks final targeted clinical program
- Phase 2 completed on a similar formula by same inventors
- 



## Multiple Potential Expansion Opportunities

- Treatment of a sub-population of diabetes
- Existing distribution agreement for EU and ME regions for sickle cell disease



# Lobe Sciences Highlights – “Two Shots on Goal”

## 01. Alera Pharma, Inc.



### Conjugated Psilocin™ – A New Chemical Entity

- Psilocin Mucate (L-130) stable orally available psilocin
- Initial application to treat Chronic Cluster Headache, an Orphan Disease



### Strong Patent Protection until 2041+

- US Patent # 12,102,616 (issued October 1, 2024)
- Patent expiry 2043+



### Highly Experienced Board and Team

- Combined 100+ years of pharmaceutical experience
- Established track record of building early-stage assets



### Possible Near-Term Value Inflection Points

- Funding necessary to drive value inflection points

## 02.

**Altemia**<sup>®</sup>  
(emulsified-docosahexaenoic acid triglyceride, eDHAtg)



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LobeSciences

**Thank you!**





# Appendix – Citations

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3. Ryan O’Hare, Imperial College Website Article, October 13, 2017, <https://www.imperial.ac.uk/news/182410/magic-mushrooms-reset-brains-depressed-patients/>
4. Johns Hopkins Medicine Newsroom release, February 15, 2022, <https://www.hopkinsmedicine.org/news/newsroom/news-releases/2022/02/psilocybin-treatment-for-major-depression-effective-for-up-to-a-year-for-most-patients-study-shows>
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8. Lincoln Tracy, Migraine Science Collaborative®, News Article February 27, 2023, <https://migrainecollaborative.org/promising-signs-for-psychedelic-use-in-cluster-headache>
9. Roland R Griffiths, Matthew W Johnson, Michael A Carducci, Annie Umbricht, William A Richards, Brian D Richards, Mary P Cosimano, Margaret A Klinedinst, Journal of Psychopharmacology, 2016 December, 30 (12):1181–1197