



Cambium Medical Technologies

Allogeneic Pooled Human Platelet Lysate

GRA Report

December 13, 2011



EMORY
UNIVERSITY
SCHOOL OF
MEDICINE



**Emory Personalized
Immunotherapy
Center**

Background

- Geoff Crouse, MBA/MPH
 - 10 years senior management experience in Life Science and Diagnostic
 - Most recently COO of Immucor, blood typing diagnostic company in Atlanta
- Ian Copland, PhD
 - Assistant Professor Hem/Onc
 - Manager of Emory Personalized Immunotherapy Center
 - Co-Inventor of Product

Executive Summary

- A novel technology for the processing of human platelets
- Strong supply of low-cost raw material
- Platelet lysates are rich in growth-factors and anti-inflammatory factors
- Potential utilization in topical and injectable applications
- Market research complete and initial indication of use determined

Current PRP Market

- No allogeneic source of platelet rich plasma
- Autologous PRP market nascent with early data suggesting efficacy in a broad range of indications
- Primary utilization and clinical research in sports medicine applications
- Various companies selling fractionation equipment and PRP kits with 510(k) approval
- Some data suggests patient self-administration and physician utilization in KCS
- 40 patient study in ocular ulcers showed autologous PRP promoted healing and reduced inflammation
- Method of action and benefits of growth factors and anti-inflammatory factors within PRP are not well studied

Potential Indications of Use

Wound Care

- Large and growing market in chronic wound ulcers. 3-6M patients with \$5-10B annual cost
- Difficult to improve outcomes due to concomitant peripheral perfusion deficiencies and lack of complete wound healing
- Topically applied platelet derived growth factors have been widely studied (PDGF)
 - Regranex is derived from recombinant factors
 - Centrifuge blood to isolate platelets and add thrombin (Curative Technologies - remote autologous processing, Autogel and SafeBlood - bedside processing)
- Potential to work with DOD on severe wound care

Sports Medicine

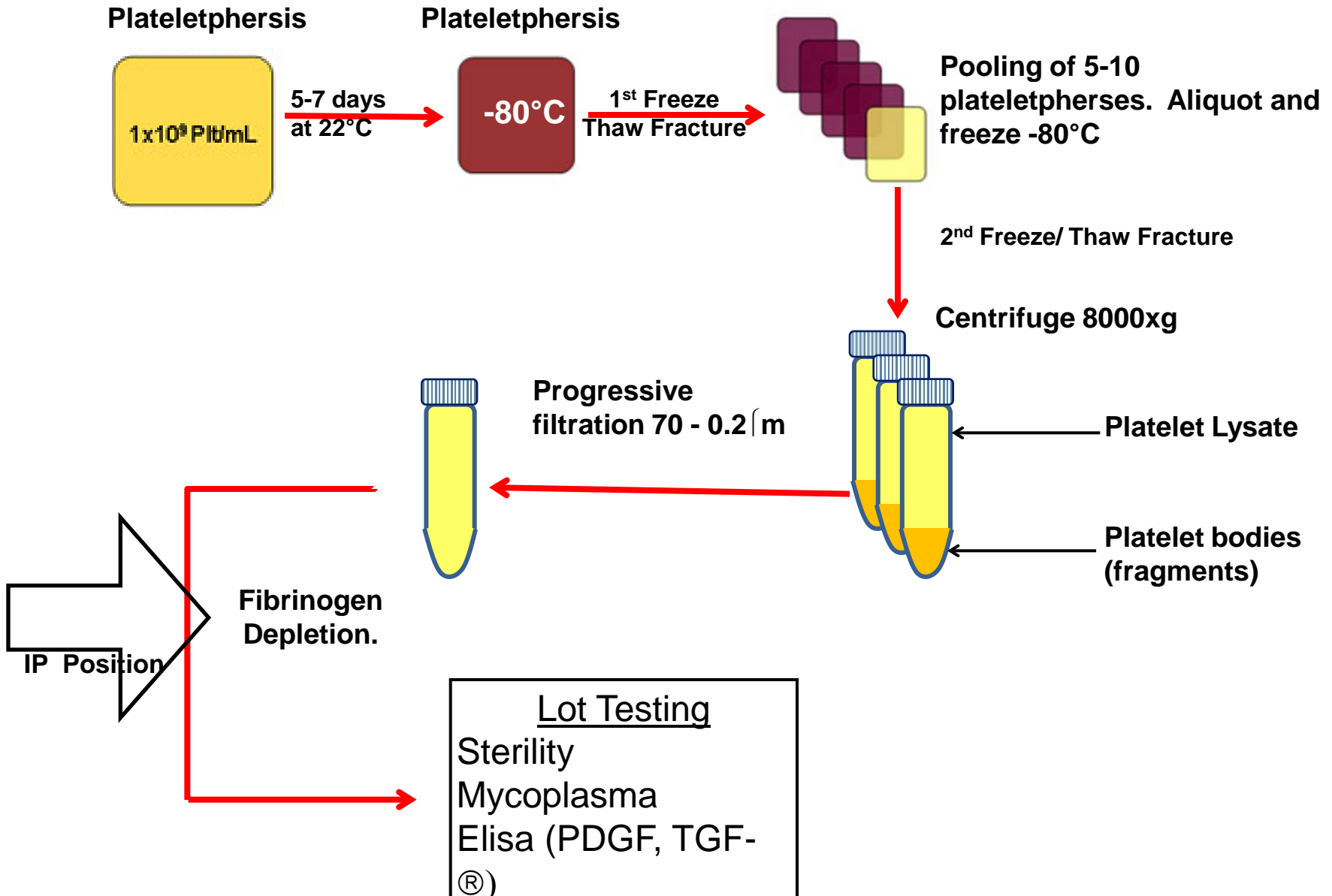
- Current market for autologous PRP is estimated at \$40M annually - most common use
- Considered by many as "snake oil" due to lack of clinical data to support utilization
- Physicians income stream from self-pay market

KCS Indication

Keratoconjunctivitis Sicca ("KCS") or Dry Eye

- Market for ocular drugs and eye care products \$12B
- Dry-eye prevalence 4.9M in US population over 50 years old
- Market estimated for Dry Eye drugs estimated at 10% growth and ~\$1B in 2015
- Therapeutics in Dry Eye space have been difficult to bring to market due to multifactorial disease, various levels of severity and difficult endpoints
- Most successful drug in the space is Restasis with \$620M sales in 2010
 - 15% efficacy measured by increased tear productivity (vs 5% Endura)
 - 17% of patients experiencing severe ocular burning side-effect in 1200 patient study
- **We will segment the patient population to focus on severe KCS (co-morbidities) to increase likelihood of statistically significant clinical improvement within a limited patient population**

Preparation of Human Platelet Lysate



Human Platelet Lysate Processing

- Proprietary process developed with patent pending
 - Completely acellular product with no debris
 - Fibrinogen depletion prevents clotting allowing growth and anti-inflammatory factors to be
- Consistency across lots vs lack of control and variability in autologous processing
- Raw material comes from healthy repeat donors that are confirmed negative for infectious disease markers

Engagement with Emory Eye Experts

- Dr. Tim Olsen: Chair Emory Eye Center
- Dr. Bhairavi Dholakia: Clinician Scientist
- Dr. Henry Edelhauser: Pre-clinical Specialist
 - Mentored developer of Restasis
- Dr. Benard McCarey: Pre-clinical Specialist
 - Regularly tests solutions and devices of Ophthalmology product manufacturers
- Already developed strong relationships with FDA reviewers in Ophthalmology (i.e. Wiley Chambers Head of Pharmacology)

Recommendations by Eye Experts

- KCS is the right indication. Multiple secondary indications also possible. (i.e. Lye Injury, corneal repair follow surgery etc.)
- No good animal or in vitro models for Dry Eye or KCS
- May not require animal/in vitro efficacy to initiate Phase I trial
- In vitro models are not good predictors of toxicology
- FDA will require we perform a modified Draize test
- Better understanding of stability profile, pH, osmolality, dosage and diluent need to be defined

Next Steps

- Apply for GRA Phase 1B grant to fund pre-clinical work
 - GRA Phase 1A grant used to complete technical work and market research
- Recruit key members from Emory Eye Center in advisory capacity
- Complete pre-IND work for KCS indication by April 2012
- Supplement Patent Application prior to May 2012
- Complete business plan and determine commercial funding pathway in summer of 2012