



LUMINEC HOLDINGS CORPORATION

Joint-Venture Partner

JET LASIK

JET LASIK

accelerating ocular healing by cell transplantation

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Executive Brief

JET Lasik, Inc.—*Refractive & Corneal Therapeutic Surgery*

- JET Lasik is a San Diego, CA based private regenerative medicine company that is developing a novel and proprietary product that will both improve the safety and recovery time of corneal wound healing in laser vision correction, especially for older cataract patients receiving premium IOL's.
- By combining a modified collagen-coated contact lens with a layer of live cultured skin cells, the JET Lens device acts as a postoperative tissue transplant “bandage” in PRK. This device promotes more rapid recovery (like a skin graft promotes wound healing), and thus may elevate JET Lens PRK to the preferred laser vision correction procedure, providing safety combined with rapid pain-free recovery.

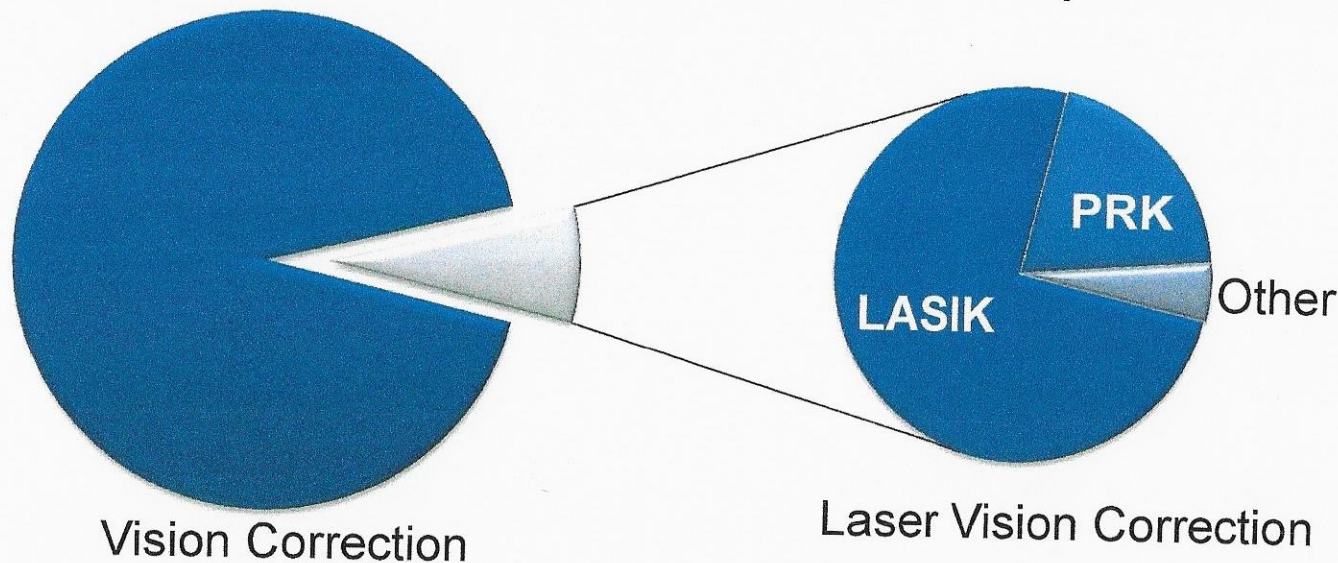
The Company is seeking \$2.5 million to construct a Master Cell Bank, file for IDE, and conduct phase 1 and 2 clinical trials. An additional \$15 million is budgeted for phase 3 and BLA filing.

Corporate Overview

- Disposable Medical Devices (JET Lens™)
 - Biologic bandage
 - For enhancement of PRK Laser Vision Correction
 - Uses materials from prior FDA approved products
 - Improves safety and patient experience
 - Follows known CBER BLA regulatory path
- Patented Technology
 - Patent number 8,158,141 issued in April 2012
 - CIP 13/436,255 allowed in May 2015

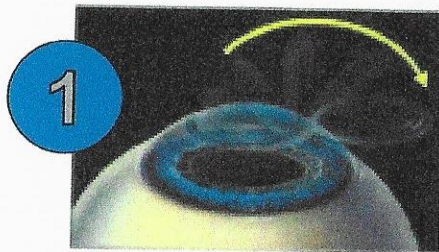
Target Market

- Vision Correction Market: \$40B
- Laser Vision Correction: \$3B
 - LASIK: 800,000 surgeries/year
 - PRK: 200,000 surgeries/year
 - Laser vision correction cost: ~\$2,000 per eye
 - LASIK/Femto-Flap Costs \$250 - \$350 per incision

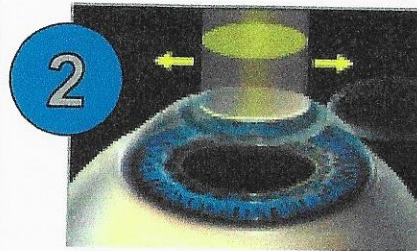


LASIK vs. PRK Surgery

LASIK treatment



Flap created and opened

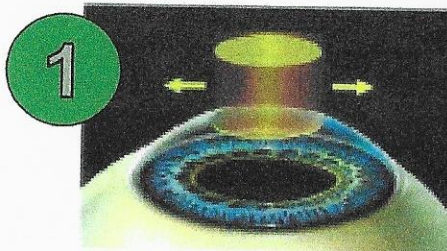


Laser Treatment Under Flap



Flap Closed

PRK treatment



Laser to Corneal Surface



Epithelium Re-Covering



Final Laser Sculpting Effect

The Problem

LASIK heals quickly, BUT has potential complications:

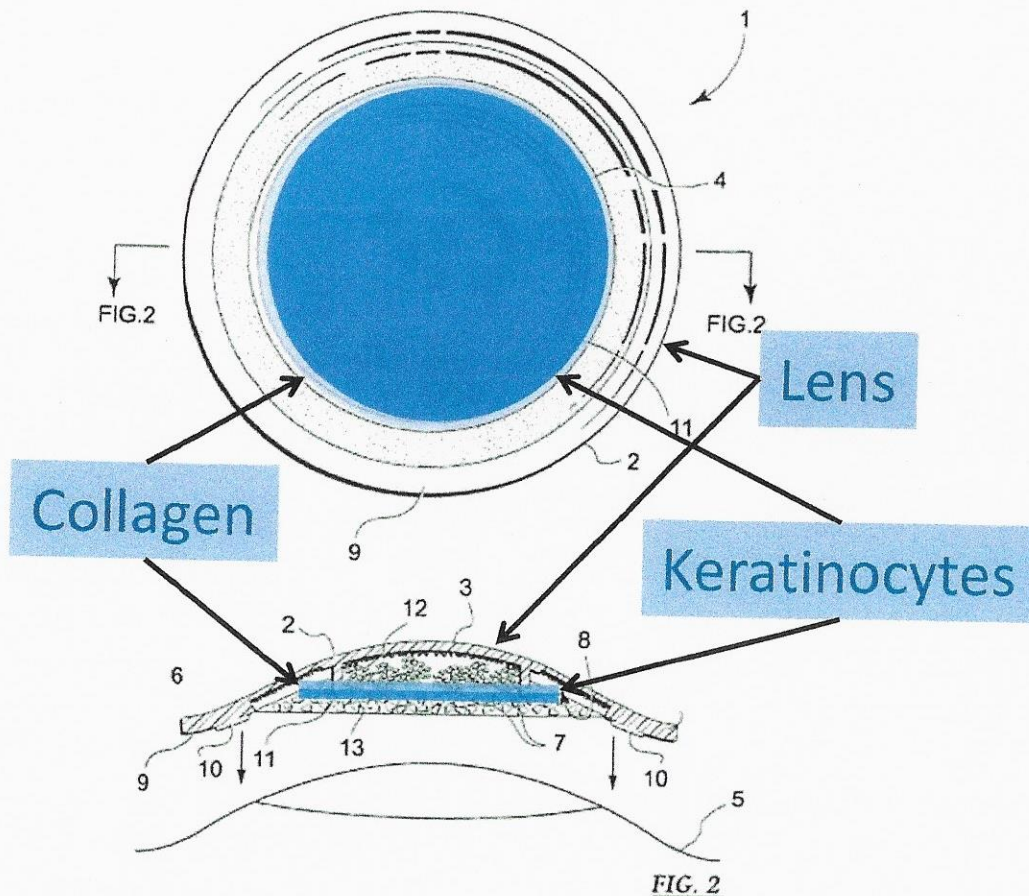
- Button holes / incomplete flaps / dislocated flaps
- Interface DLK / lamellar infections/ epithelial ingrowth
- Flap striae & Induced higher-order aberrations
- Dry eyes caused by severed corneal nerves
- Re-treatment difficulties
- Corneal ectasia risk
- 2-5% complication rate, bilateral surgery typically

Surface Ablation (PRK, Epi-Lasik) is safer, BUT:

- Pain and blurred vision during 1 to 2 week recovery time
- 1% complication rate, unilateral surgery typically

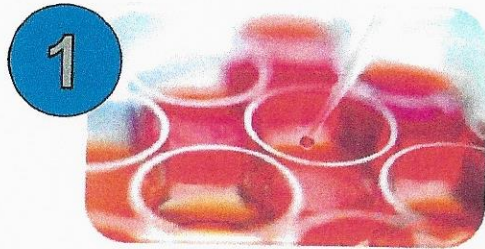
Current Choice: Increased Safety vs. Quick Recovery

Solution: The JET Lens™ (Junctional Epithelial Transplant)

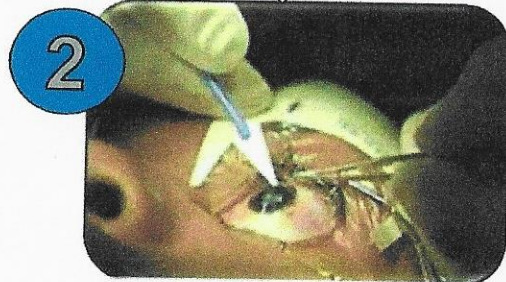


- An allogeneic skin graft for the eye
- Used following PRK to replace ablated cells
- Made of living skin cells, grown on a contact lens
- Cultured Master Cell Bank Epithelium
- Allows rapid healing - hours vs. weeks

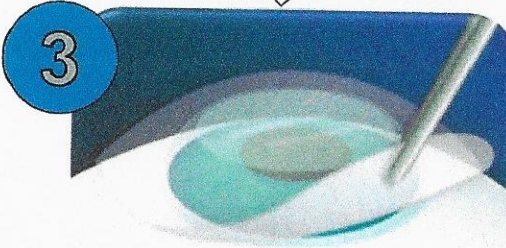
The Process



*Grow epithelial cells
on contact lenses
from a master cell bank*



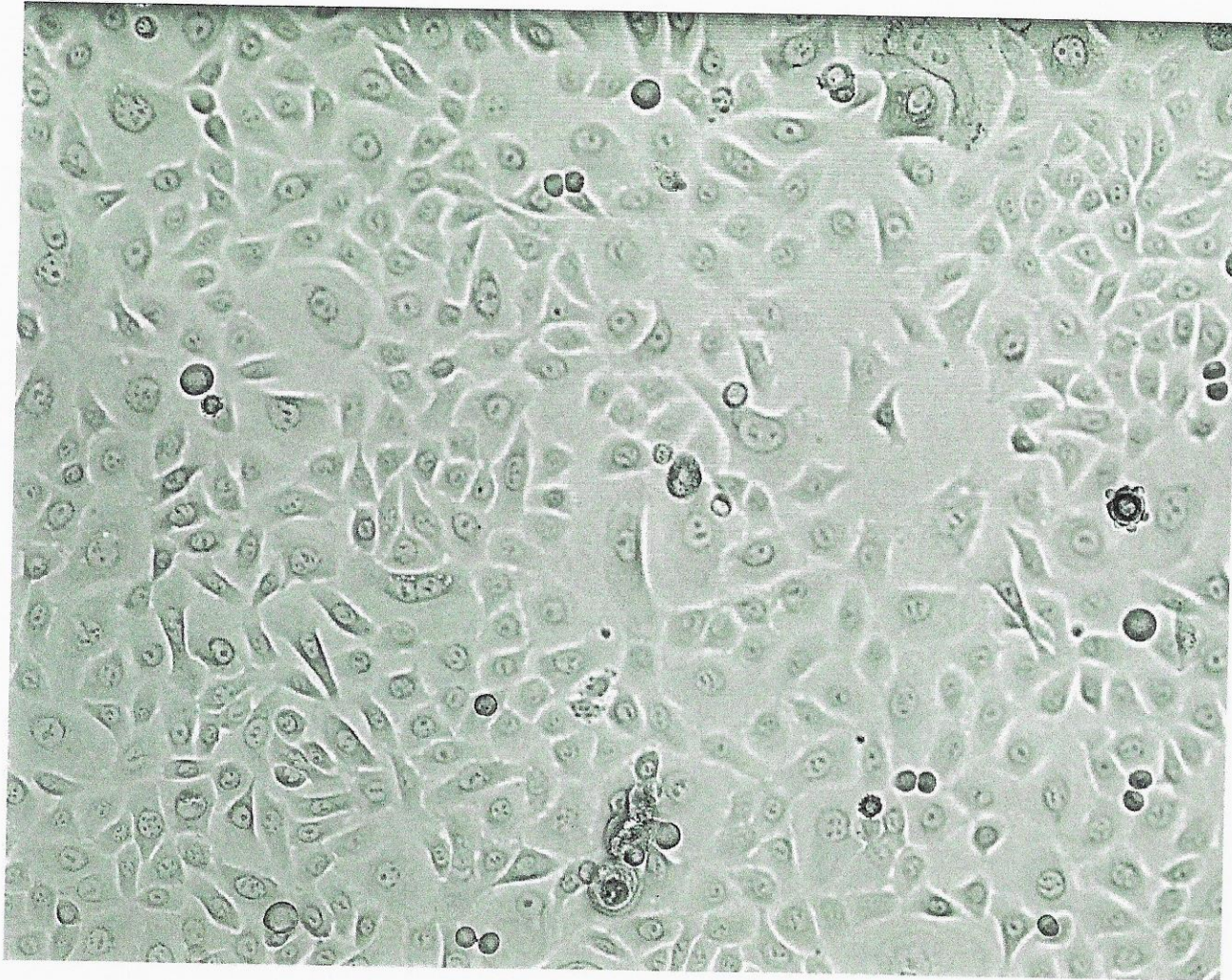
*Perform standard
PRK surgery*



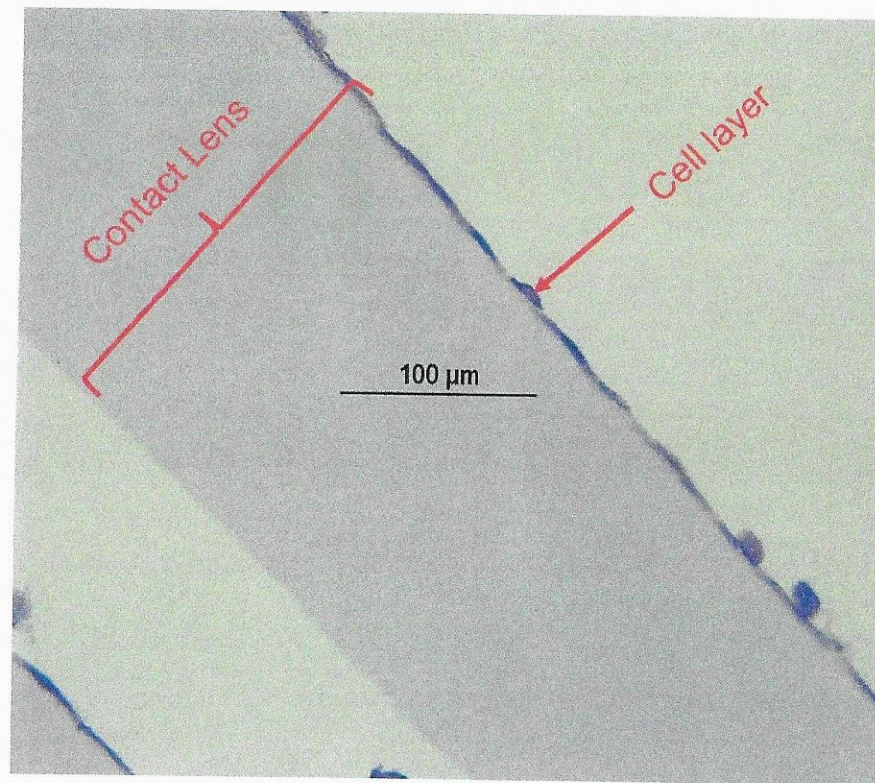
*Secure cells and
contact lens onto
eye with ocular
adhesive*

**Cells adhere in 5
minutes to overnight
providing fast results
with better safety
profile than LASIK**

Cultured Cell Monolayer

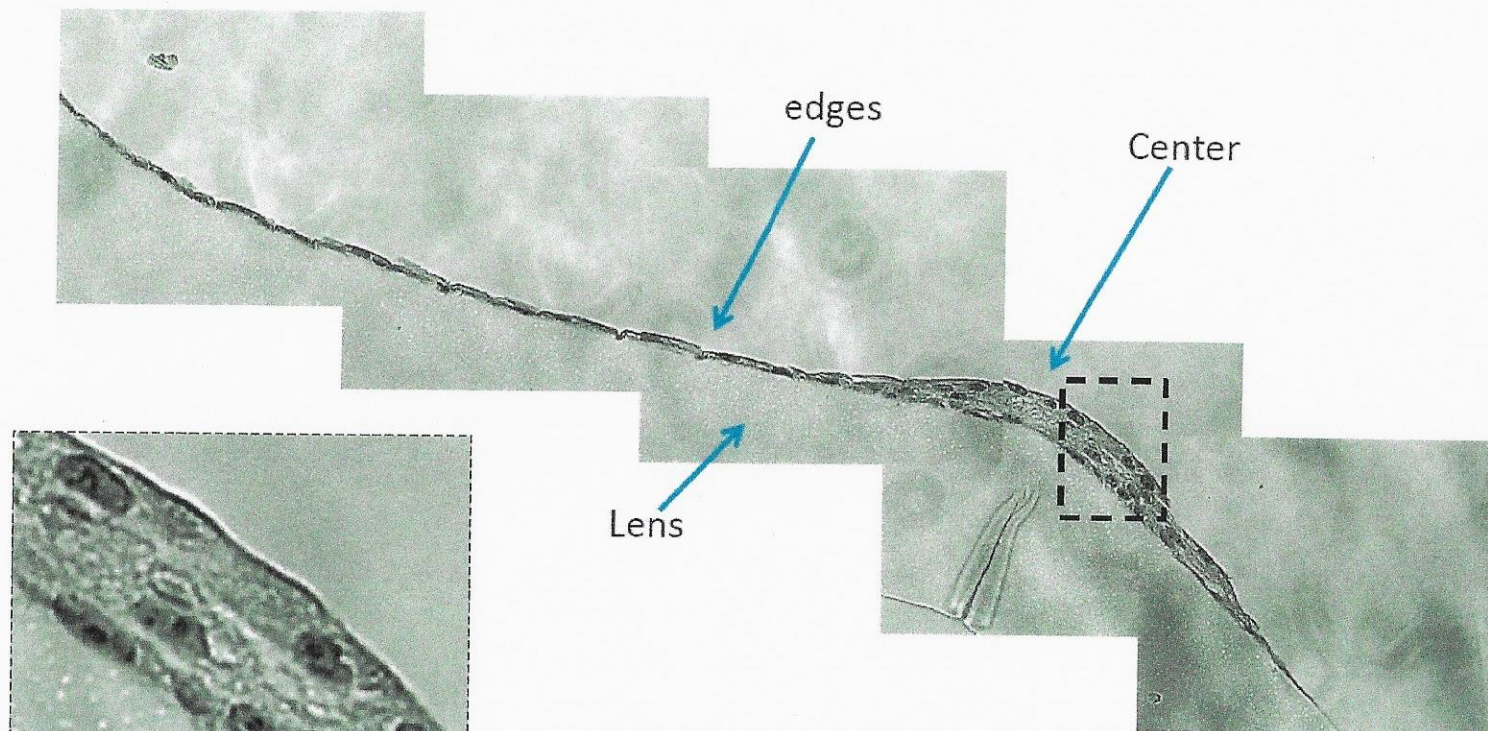


Histology



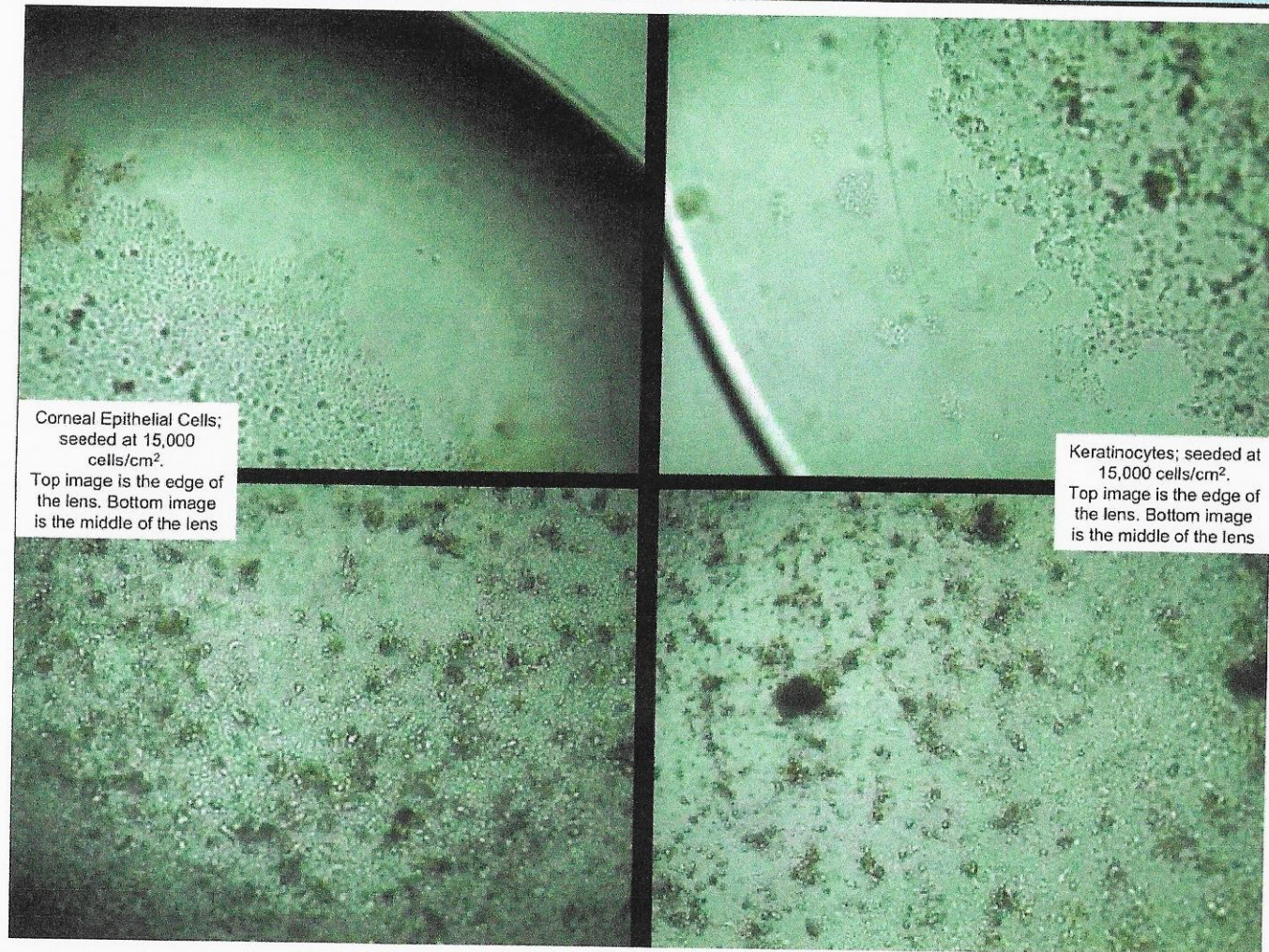
Cell monolayer on collagen coated lens

Histology



Cell monolayer on collagen coated lens

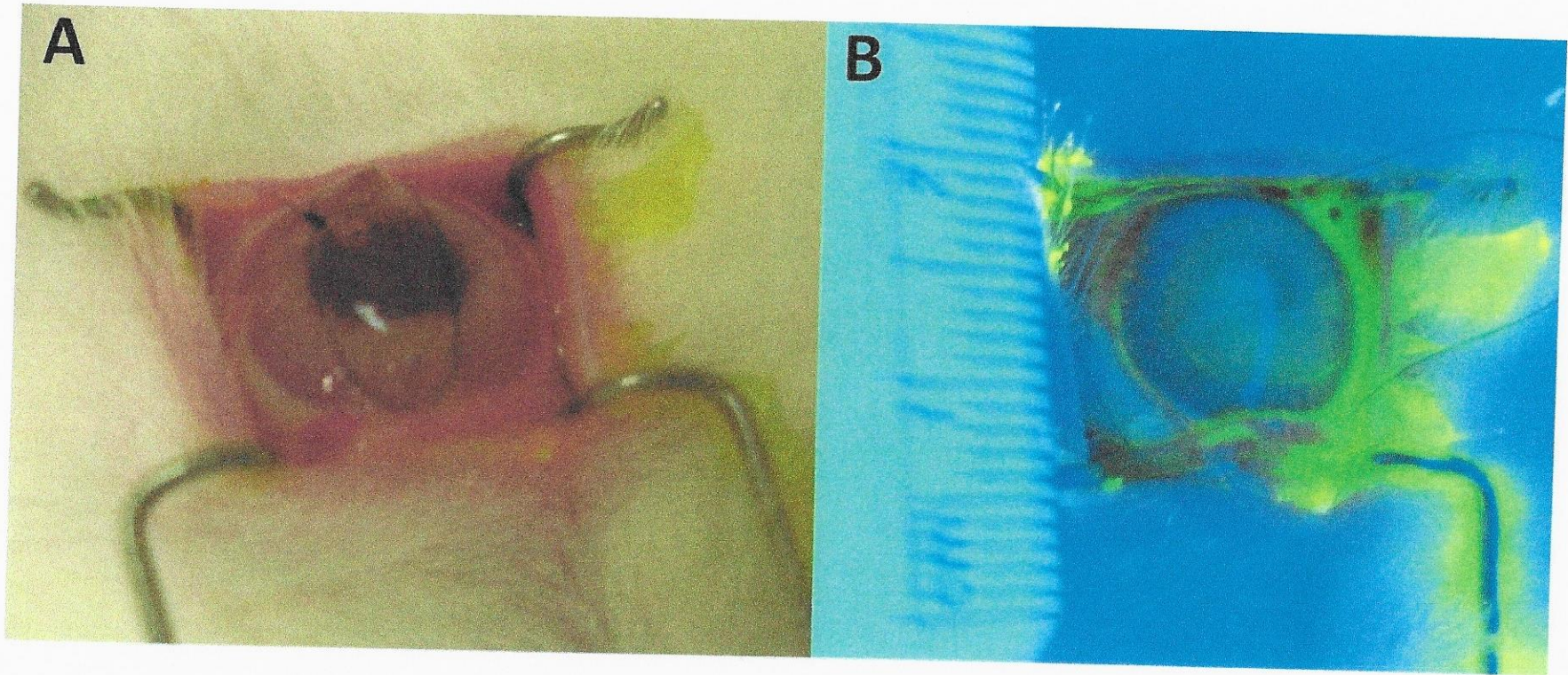
Phase Contrast View of Cells on Lens



Optical Transparency



Animal Trials: Proof of Concept & Surgical Optimization



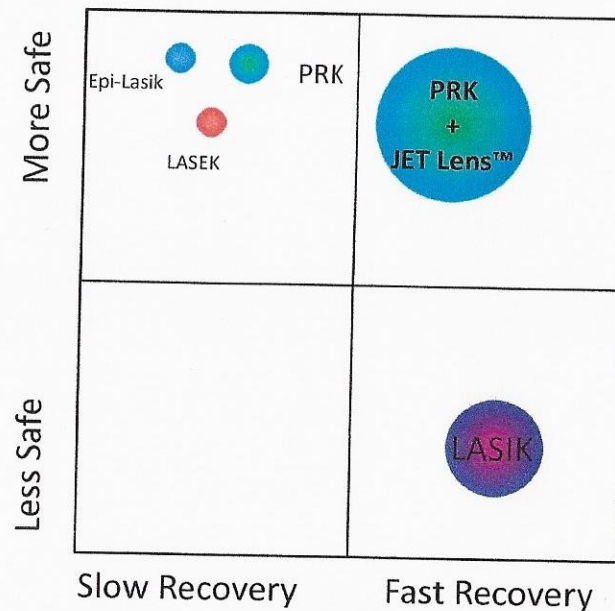
Cell transfer into epithelial defect

Benefits

- Patient
 - Reduce patient's fear of short/long term complications associated with corneal flaps (dry eyes, ectasia risk, flap interface issues)
 - Reduce patient's fear of blurry/painful recovery
 - Reduce patient's time off of work
- Surgeon
 - Reduce surgeon's facility opportunity cost with bilateral JET Lasik vs unilateral PRK
 - Reduce surgeon's fear of liability and lawsuits
 - Keep surgeon's marketing "Wow" factor like Lasik

Why we are better

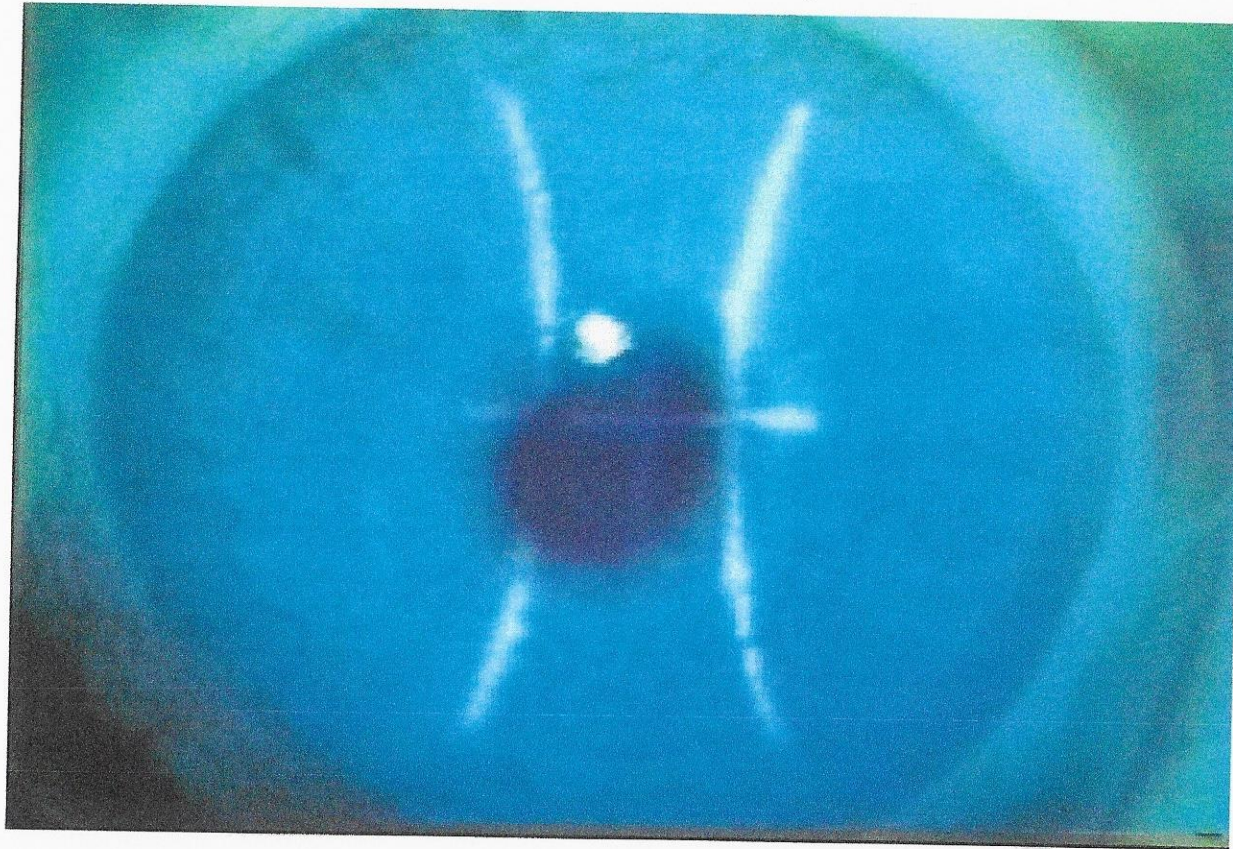
Better safety and quicker recovery at No Additional Cost



Procedure	Process	Complication	Recovery	Preference
LASIK	Flap	2-5%	1-2 days	Patients
PRK	Cell Removal	1%	1-2 weeks	Surgeons
PRK + JET Lens™	Cell Transplant	<1%?	1-2 days	Both

How it works

Hayashida *et al*, Investigative Ophthalmology & Visual Science, February 2006, Vol. 47, No. 2



Adhesion within 5 min without sutures

Others have tried...

- Nexis Vision
 - closest competitor in the PRK wound healing space, no longer active
 - part of Forsight Vision 3
 - backed by Morgenthaler Ventures, Split Rock Partners, and Versant Ventures
 - Attach water-tight contact lens to prevent corneal edema
 - their product does not use live cells, requires a longer recovery time, and does not control pain
 - <http://www.forsightlabs.com/vision3.html>

Phase I, Phase II, Phase III Cost per JET Lens

Production of Final Product (JET Lens)

Assumptions:

Stability of Final Product is 48 hours
Shipping on wet ice overnight to clinics
Assay Development requires additional information and has not been included in the price of this proposal

Recommended Process Development Activities:

Change shipping configuration (remove wet ice, substitute cool packs/validated shipper)
Media comparison

Process transfer to 10-Layer Cell Factory
Bioservices assay development
Process modification/optimization
Acquire Collagen coated Lens as a raw material
Optimization to extend shelf life of Final Product
Final Product Container System

3. Production																
Lot Size		200 Lens/lot/year				600 Lens/year				1000 Lens/year						
		200				200				200						
		QTY	Rate			QTY	Rate			QTY	Rate					
Final Product																
Production Labor		60.00	\$	190.00	\$	11,400.00	60.00	\$	190.00	\$	11,400.00	60.00	\$	190.00	\$	11,400.00
Production Labor, office		15.00	\$	150.00	\$	2,250.00	15.00	\$	150.00	\$	2,250.00	15.00	\$	150.00	\$	2,250.00
Quality Assurance		15.00	\$	150.00	\$	2,250.00	15.00	\$	150.00	\$	2,250.00	15.00	\$	150.00	\$	2,250.00
Materials/Media		1	\$	5,274.37	\$	5,274.37	1	\$	5,274.37	\$	5,274.37	1	\$	5,274.37	\$	5,274.37
Project Management		10	\$	150.00	\$	1,500.00	5	\$	150.00	\$	750.00	5	\$	150.00	\$	750.00
Admin		1	\$	85.00	\$	85.00	1	\$	85.00	\$	85.00	1	\$	85.00	\$	85.00
Testing		1	\$	10,000.00	\$	10,000.00	1	\$	10,000.00	\$	10,000.00	1	\$	10,000.00	\$	10,000.00
Shipping		2	\$	100.00	\$	200.00	2	\$	100.00	\$	200.00	2	\$	100.00	\$	200.00
Facilities		2	\$	24,000.00	\$	48,000.00	1	\$	80,000.00	\$	80,000.00	1	\$	80,000.00	\$	80,000.00
Number of Run(s)		1					3					5				
Final Product Subtotal			\$		80,959.37				176,628.12						241,046.87	
Estimated Cost per Lens			\$		404.80				294.38						241.05	
Assumptions		1 lot of 200 lenses small shared suite approx 2 week usage				3 consecutive lots small shared suite approx 1 month usage				5 consecutive lots small shared suite 1.5 month usage						

Production Level Cost per JET Lens

10,000 Lens/year				100,000 Lens/year				200,000 Lens/year			
500				1000				2000			
QTY	Rate			QTY	Rate			QTY	Rate		
100.00	\$ 190.00	\$	19,000.00	75.00	\$ 190.00	\$	14,250.00	72.50	\$ 190.00	\$	13,775.00
25.00	\$ 150.00	\$	3,750.00	18.75	\$ 150.00	\$	2,812.50	18.13	\$ 150.00	\$	2,718.75
12.00	\$ 150.00	\$	1,800.00	2.00	\$ 150.00	\$	300.00	1.00	\$ 150.00	\$	150.00
1	\$ 8,711.32	\$	8,711.32	1	\$ 14,426.23	\$	14,426.23	1	\$ 25,856.06	\$	25,856.06
3.2	\$ 150.00	\$	480.00	3	\$ 150.00	\$	450.00	1.5	\$ 150.00	\$	225.00
1	\$ 85.00	\$	85.00	1	\$ 85.00	\$	85.00	1	\$ 85.00	\$	85.00
1	\$ 10,000.00	\$	10,000.00	1	\$ 10,000.00	\$	10,000.00	1	\$ 10,000.00	\$	10,000.00
20	\$ 100.00	\$	2,000.00	100	\$ 100.00	\$	10,000.00	200	\$ 100.00	\$	20,000.00
Sub Total (per run)	\$		45,826.32	Sub Total (per run)	\$		52,323.73	Sub Total (per run)	\$		72,809.80
2	\$ 100,000.00	\$	200,000.00	6.25	\$ 175,000.00	\$	1,093,750.00	12	\$ 175,000.00	\$	2,100,000.00
20				100				100			
Final Product Subtotal	\$		1,116,526.43	Final Product Subtotal	\$		6,326,122.96	Final Product Subtotal	\$		9,380,979.58
Estimated Cost per Lens	\$		111.65	Estimated Cost per Lens	\$		63.26	Estimated Cost per Lens	\$		46.90

Assumes 10 lots/month
large shared suite
2 month usage

Assumes 6.5 months production
Large Dedicated Suite
~ 16 lots/month
~ 20% labor reduction due to automation

Assumes 8 months production
Large Dedicated Suite
25 lots/month
~ 20% labor reduction due to automation
Removal of need for media change

Unit Economics

- COGS (fully loaded)
 - Lens + collagen + cells + glue $\approx$ \$68
[@ current retail]
 - Apligraf™ comparable $\approx$ \$50
75 mm circle @ \$1,000
[SEC filings, by area]
- Distribution (FedEx) $\approx$ \$10-25 per lens
- Cost $\approx$ \$78 - \$93
- Projected retail \$250-\$350 per lens
- **Gross profit margin** **68-76%**

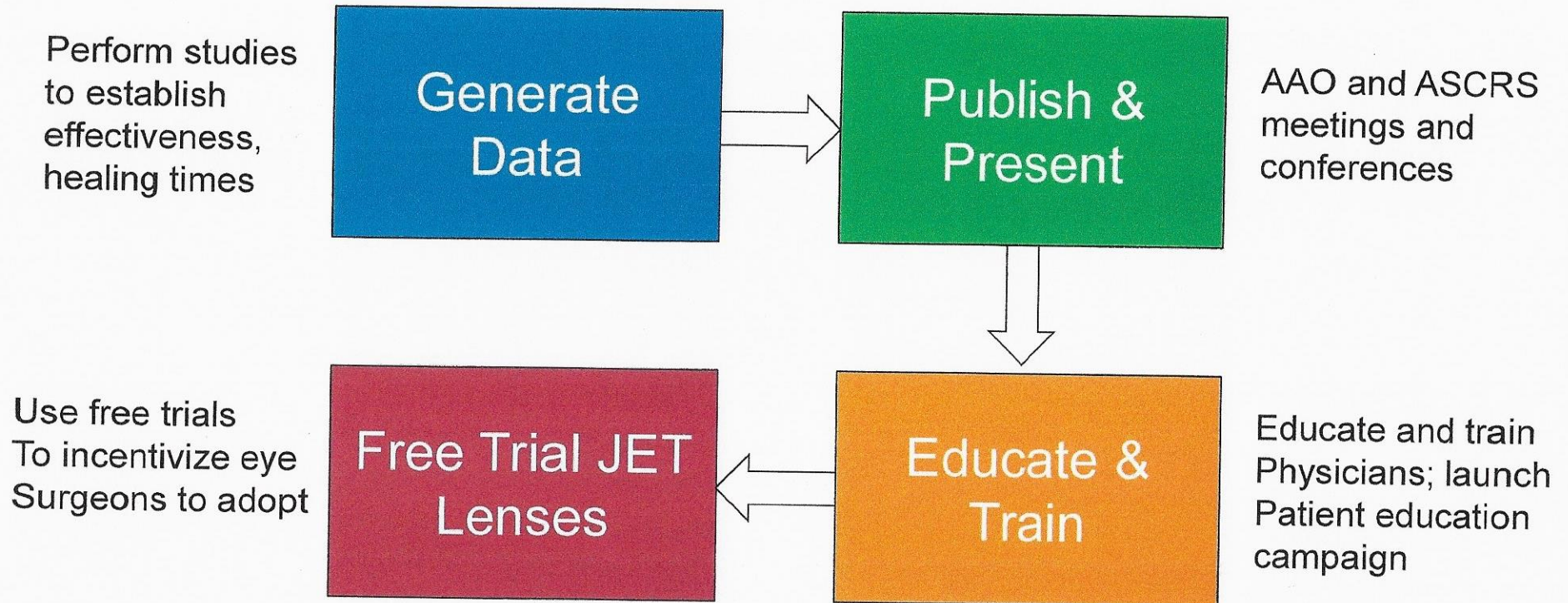
(preliminary estimates only)

Getting to market

Market Targets:

① PRK Surgery Market

② LASIK Surgery Market

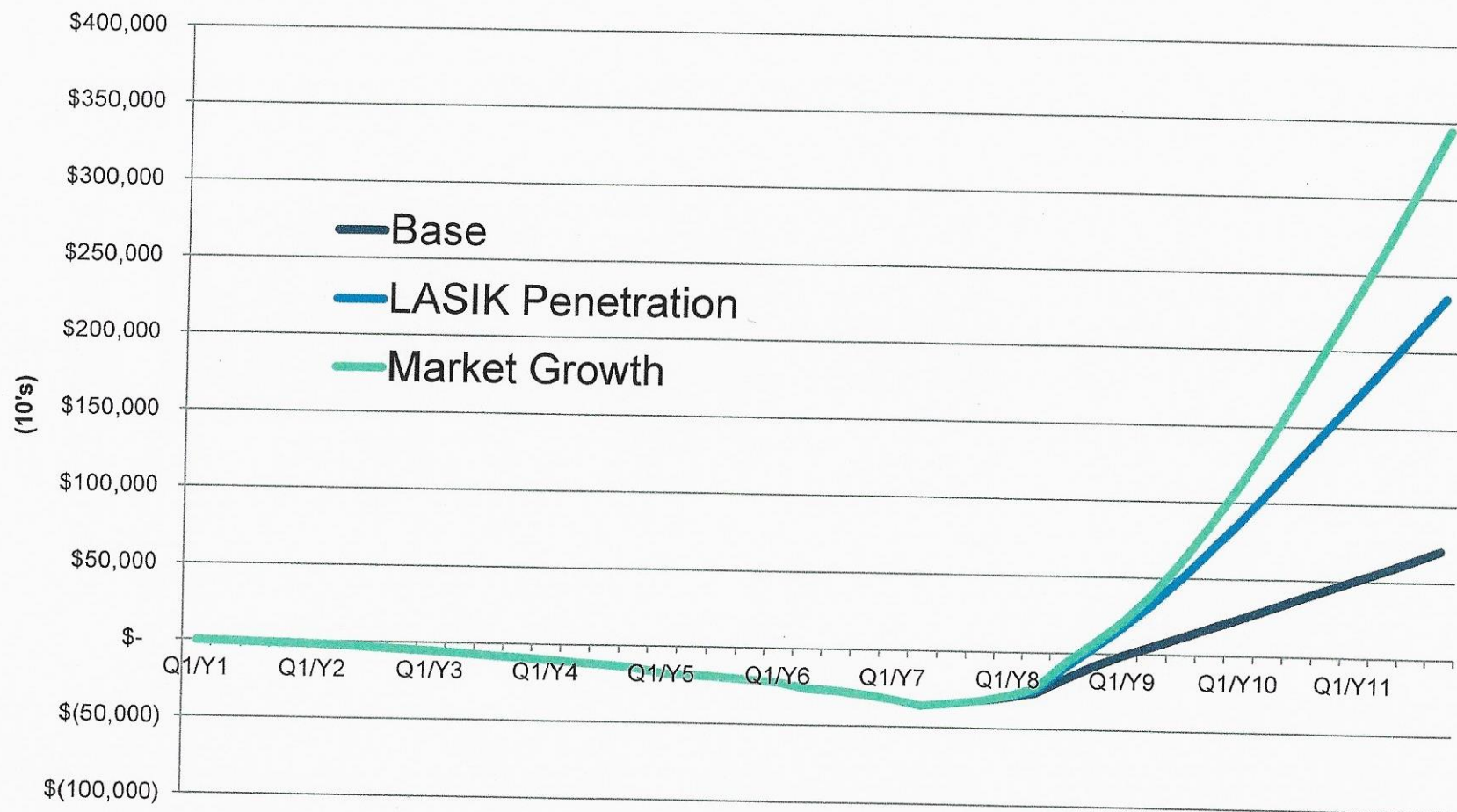


Peak Sales Scenarios

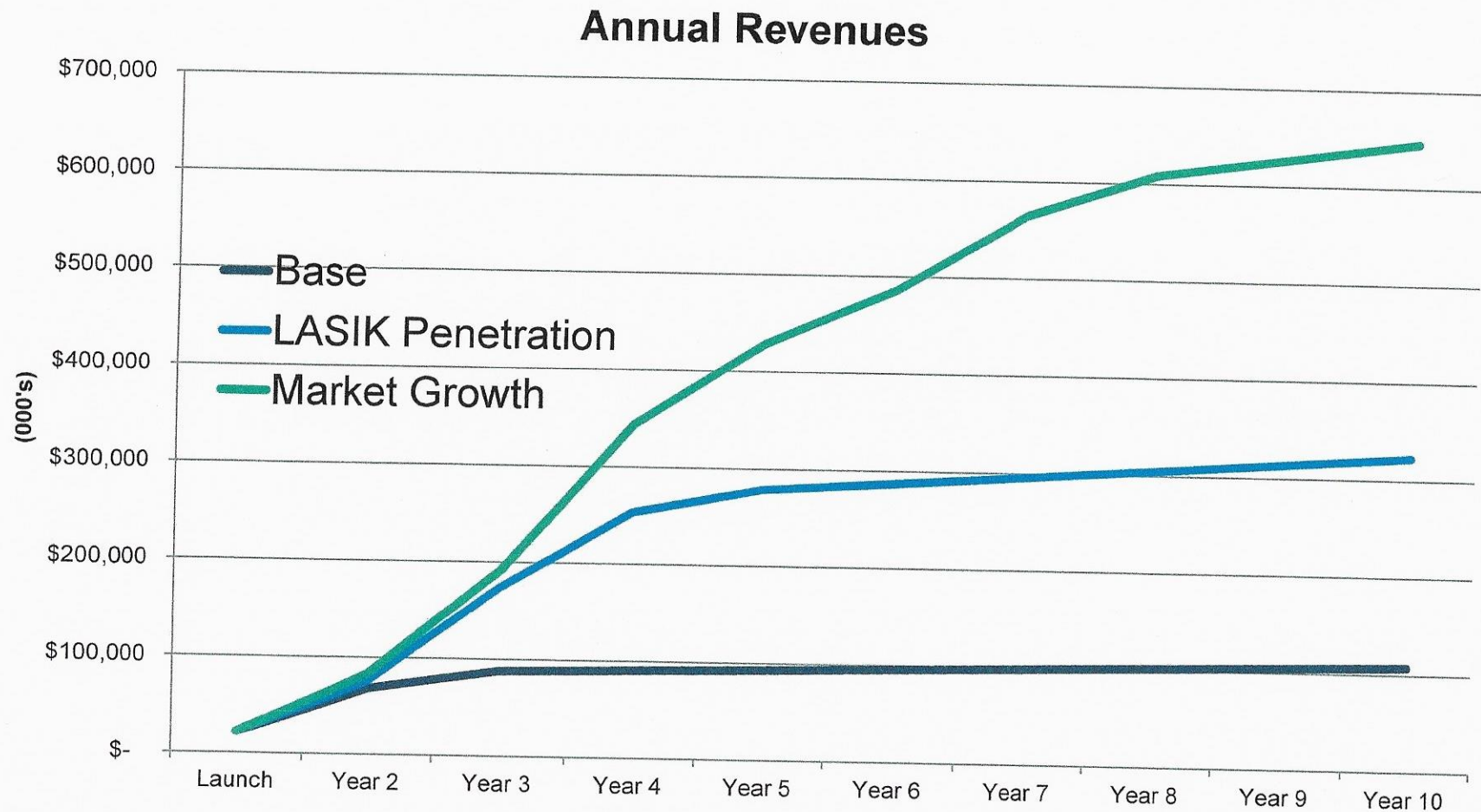
Scenario	Assumptions	Peak Sales
Base Case	75% market share for PRK procedures	\$105 MM
LASIK Penetration	50% market share for all LVC surgeries	\$350 MM
Market Growth	25% market growth, 60% market share for LVC surgeries	\$525 MM

Profit margin : 68-76%

Short & Shallow Cumulative Burn before Profitability



Financial Projections



Secondary Market Applications

- Other corneal epithelial diseases
 - diabetic neurotrophic ulcers
 - herpetic keratitis
 - hereditary corneal erosions
 - traumatic corneal abrasions & military wounds
- No corneal epithelial transplant therapy is now commercially available in the USA or world-wide

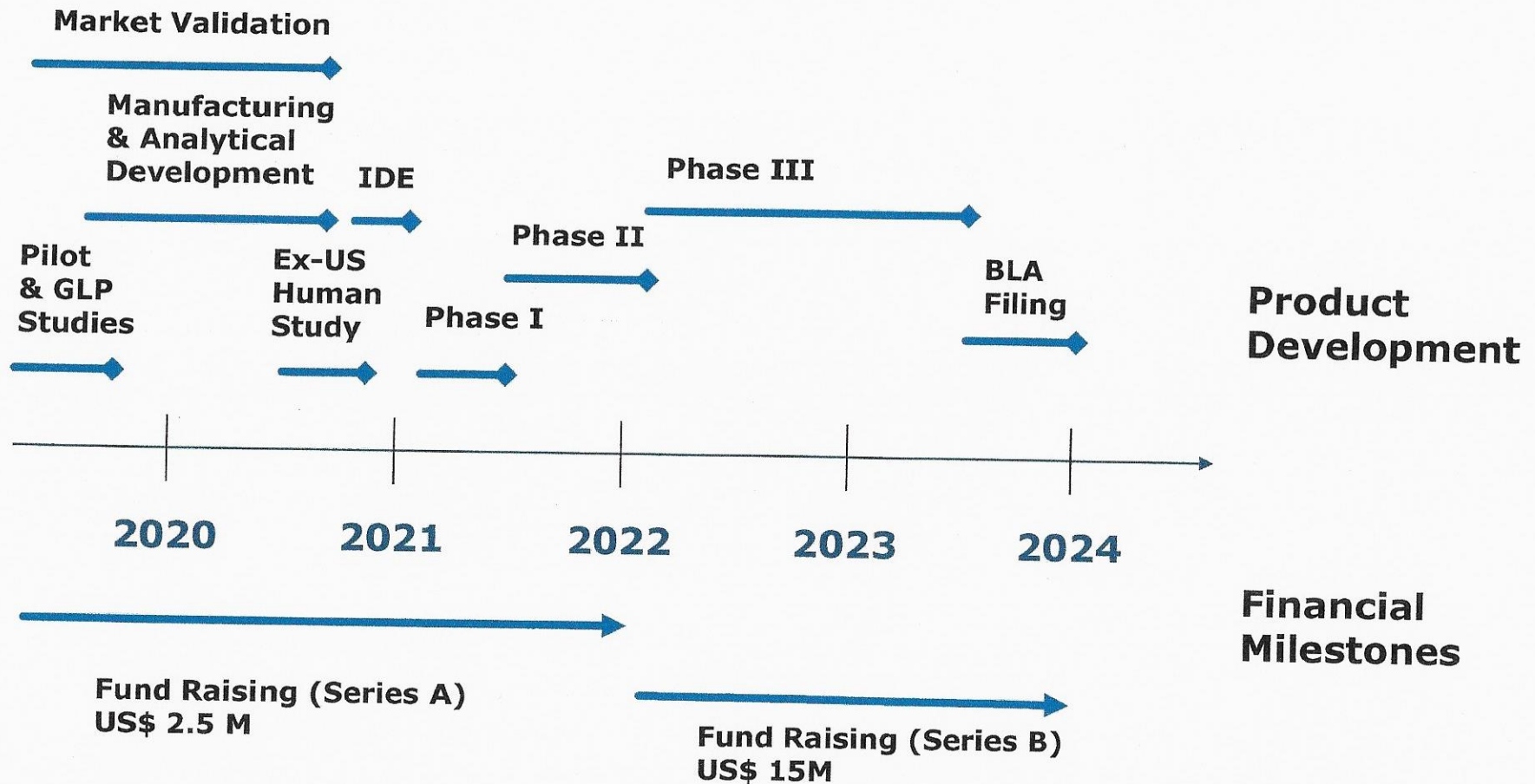
The Team

- CEO
 - Interim: Paul H Chen, MD (Inventor and Founder)
 - Candidate: Bill Ransone (BD Ophthalmics, I-Therapeutix, Katena)
- Operations Officer
 - Kathy McGee, MA (Shire/ABH, Smith & Nephew, ATS)
- Commercialization Advisor
 - Gail Naughton, PhD (Histogen, SDSU Business School Dean)
- Scientific Officers
 - Guru Sharma, OD, PhD (ReVision Optics)
 - John Ludlow, PhD (Tengion, Zen Bio)
- Medical Officers
 - Steve Schallhorn, MD (US Military Refractive Surgery, Optical Express)
 - Bill Tratler, MD (Center for Excellence in Eye Care)
 - Rob Weinstock, MD (Eye Institute of West Florida)
 - Bill Wiley, MD (Cleveland Eye Clinic)

Current Raise: \$2.5M

- Seeking \$2.5 million Series A investment:
 - ✓ Establish Master Cell Bank (\$500,000 to \$1,000,000)
 - ✓ Optional Early POC ex-USA study (\$400,000)
 - ✓ FDA required animal studies (\$250,000)
 - ✓ File IDE (\$50,000)
 - ✓ Complete Phase I clinical trial (\$200,000)
 - ✓ Complete Phase II clinical trial (\$500,000)

Milestones



Regulatory and Reimbursement

- Regulated by CBER
 - Pre-IDE meeting with FDA completed
 - Two sets of preliminary animal studies performed
 - Contact lens, collagen, and ocular adhesive components used on the eye already
 - Predicate Apligraf FDA device in the skin field
- Reimbursement
 - Laser vision correction is a self pay market
 - Price neutral relative to Lasik / Intralase flaps

Progress To Date

- IP Protection
 - Patent number 8,158,141 issued in April 2012
 - CIP 13/436,255 allowed in May 2015
- Product development
 - 8 in vitro prototypes developed
 - Device specifications finalized
- Fund raising
 - \$244,479 qualified therapeutic discovery grant
- Partnerships
 - Lonza, International Stem Cell, Histogen, Akron

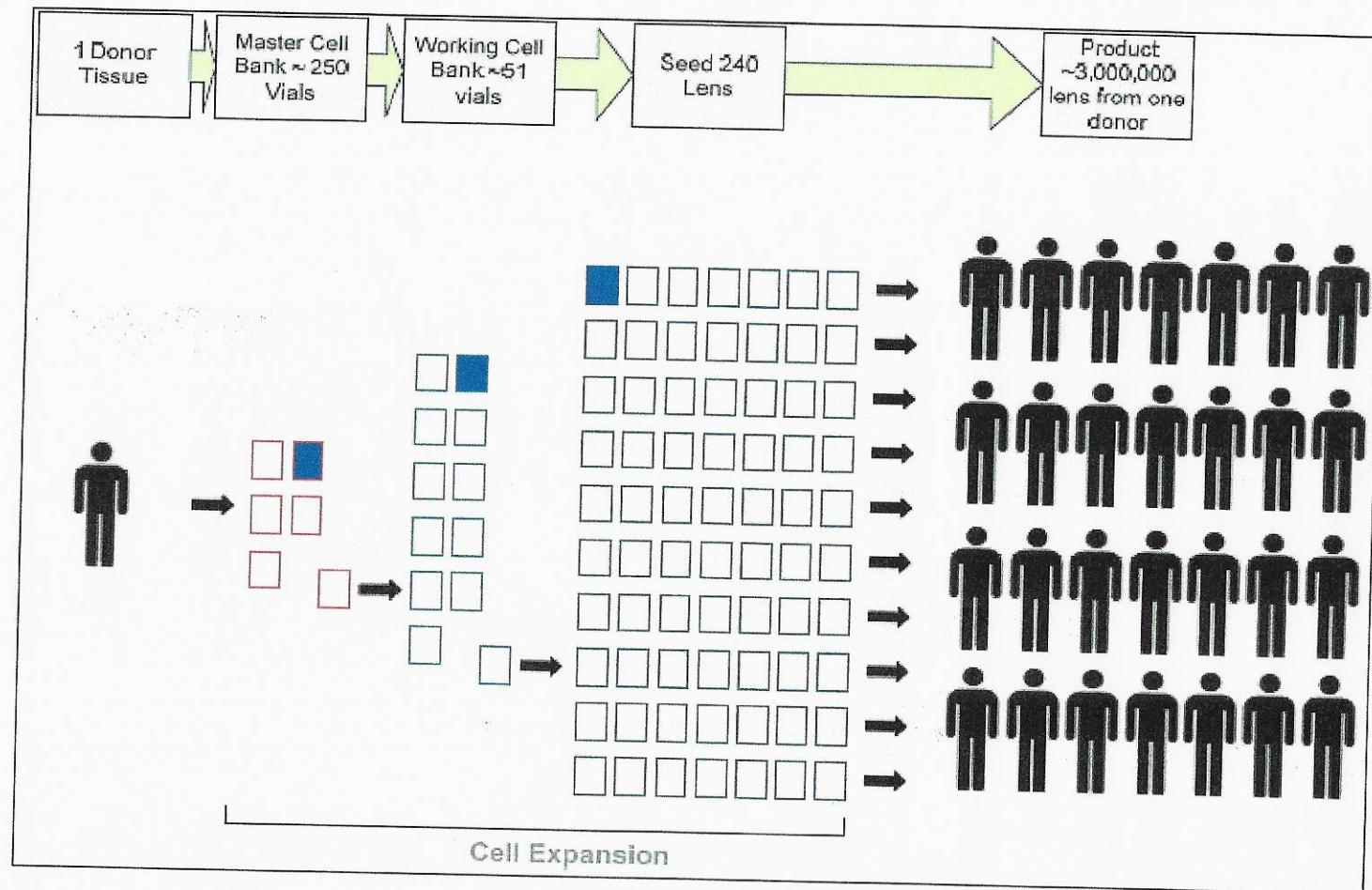
Prospective Capitalization

	Pre-Money Valuation		Raise	Post-Money Valuation		Founders	Series A Investors	Series B Investors	Exit	
Ser A	\$	2,500,000	\$	2,500,000	\$	5,000,000	50%	50%		Jul-17
							\$ 2,500,000	\$ 2,500,000		
Ser B	\$	15,000,000	\$	15,000,000	\$	30,000,000	25%	25%	50%	Mar-19
							\$ 7,500,000	\$ 7,500,000	\$ 15,000,000	
Exit						25%	25%	50%		Jan-21
							\$ 75,000,000	\$ 75,000,000	\$ 150,000,000	\$ 300,000,000
						fold	30	10		

Exit Strategies

- \$105 million to \$525 million opportunity in the \$3 billion laser surgery market
- ABH acquisition by Shire for \$750 million in 2011
- Intralase acquisition by AMO/Abbott for \$808 million in 2007
- LenSx acquisition by Alcon/Novartis for \$744 million in 2010

Product per Donor



Automated cGMP Production



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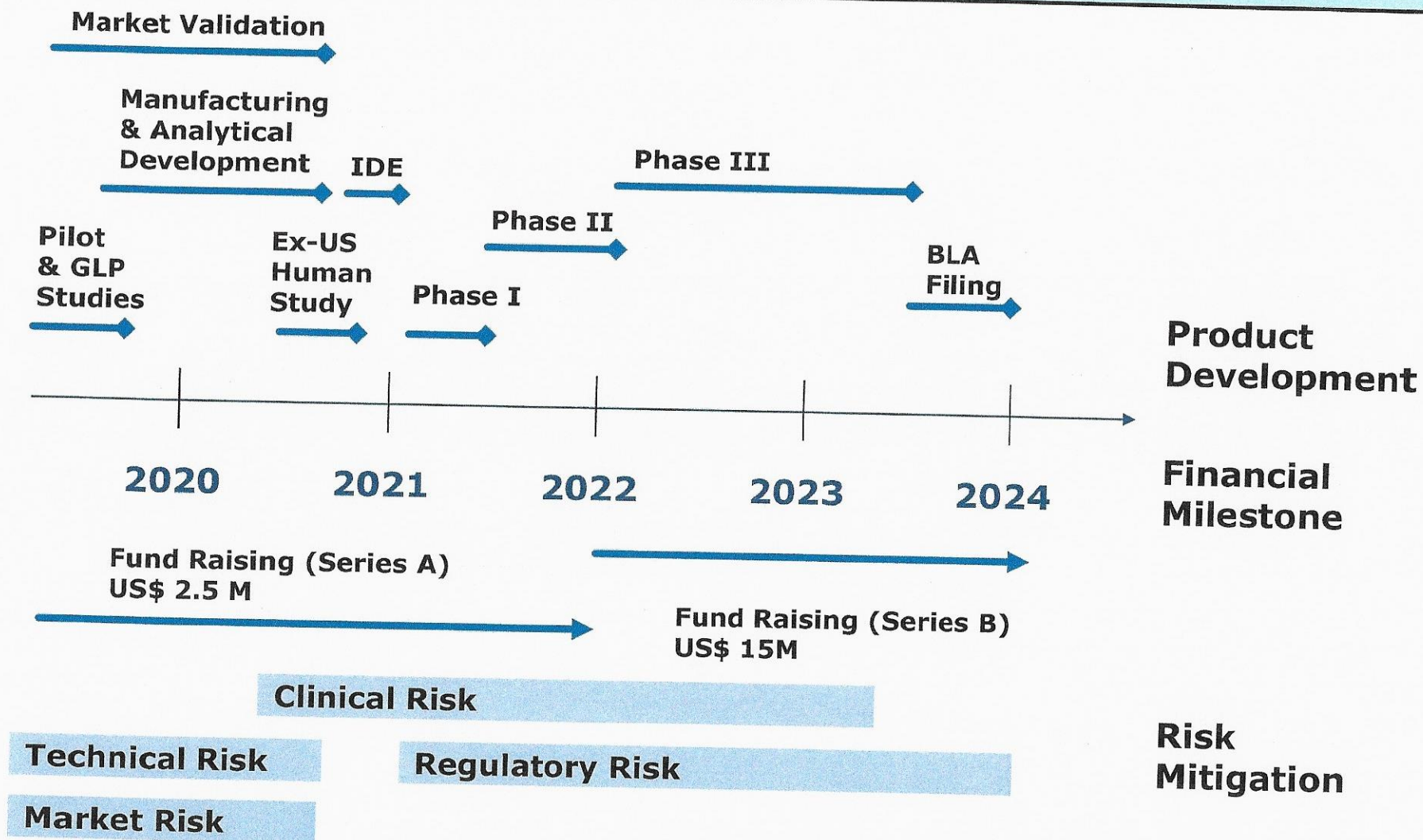
Manufacturing Already Organized

- International Stem Cell
 - cGMP biotherapeutics
 - Master Cell Bank / Working Cell Bank
 - FDA Regulatory Compliance
- Lonza
 - cGMP manufacturing facility
- The Automation Partnership
 - Robotic automation of cell culture and biologics production
 - http://www.automationpartnership.com/tap/cell_culture/CS_video_gallery/videogallery.htm

Risk Mitigation

- Intellectual Property
 - CIP 13/436,255 and US Patent 8,158,141
- Market Risk
 - Magnum Group market research study
 - Clinical Advisory Board
- Regulatory Risk
 - Second Pre-IDE meeting with FDA
- Technical Risk
 - Quick randomized prospective clinical trial
 - First-in-human study within 6 quarters
 - Ex-USA study

Development Milestones



JET Lasik Company Summary

- Patented first-in-class product
- Potential to reshape the LASIK, and presbyopia-correcting IOL, and corneal wound healing markets
- Rapid path to marketing approval
- Low initial investment, VC level returns
- High profit margins

Thank You!

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