# JPMorgan 25<sup>th</sup> Annual Healthcare Conference

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the science of cellular rejuvenation<sup>™</sup>

AMEX: ILE

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### Today's Agenda



- Company Vision/Strategic Intent
- Progress Update Last 6 Months
- Company Background
  - □ Isolagen Technology
  - □ Clinical Program
  - Market Overview
- Key Milestones Next 6 Months



Isolagen, Inc. is a biotechnology company focused on developing and commercializing emergent, novel skin and tissue rejuvenation technologies with broad potential in aesthetic and therapeutic markets

#### The New Isolagen...

- Company Being Built On:
  - ☐ A revitalized business strategy
  - ☐ "On time" execution of objectives
  - □ Promising novel technology with broad applications in aesthetics and therapeutics
  - ☐ Clinical development excellence
  - Marketable science & commercial know-how
  - □ A passion for lowest possible cost & highest quality manufacturing
  - Management experience and track record
  - □ Transparency



### Isolagen Lead Technology

- Novel, patented, autologous cell processing system
- Potential to provide skin rejuvenation
- Broad aesthetic potential
  - ☐ Facial aesthetics
  - Acne scars
- Broad therapeutic potential
  - ☐ Restrictive Burn Scars
  - □ Periodontal Disease





#### **Strategic Intent**

- Focus on a select number of skin and tissue rejuvenation areas with most promising market potential and unmet medical needs
- Advance the Clinical Development of the Isolagen Process<sup>™</sup> in key aesthetic and therapeutic areas
- Streamline & Drive a highly efficient and effective manufacturing system
- Expeditiously hire the best people for key positions
- Complement existing clinical pipeline through in-licensing and/or small acquisitions to expand commercial platform
- Partner to optimize development resources and market potential



# PROGRESS The Last 6 Months ...



#### **Progress – The Last 6 Months**

- ✓ Hired experienced management
  - ☐ Proven in the aesthetic and therapeutic marketplace
  - ☐ New leadership team and capabilities in critical functions:
    - Operations/Manufacturing
    - Marketing
    - Business Development and Licensing
    - Experienced BLA Regulatory Support
    - Closing in on hiring new head of Clinical Development
- ✓ Revitalized business strategy
  - ☐ Focused resources and energy on US market
  - ☐ Advancing clinical program in aesthetic and therapeutic areas
  - ☐ Finalizing five year operating/financial objectives
  - ☐ Finalizing capital structure options



### Progress (cont'd)

- ✓ Cost of Goods Outlook
  - ☐ Hired experienced operations executive
  - □ Streamlining Exton PA manufacturing into a high quality/high efficiency manufacturing center
  - □ Analysis shows cost per patient directly related to number of patients
  - □ Solid gross margin potential moving forward--- targeted to be in 50%-70%\* range; will improve as a function of scale/volume
  - Manufacturing improvements will be a continuous process



<sup>\*</sup> Market pricing strategy not yet finalized

### Progress (cont'd)

- ✓ Initiated Corporate Restructuring
  - □ UK Closure
    - Decision to close UK operations announced November 8, 2006
    - Business ran at a loss
    - Decision based on resource priorities rather than commercial failure
    - Valuable patient experience and lessons gained
    - Shutdown virtually complete
  - Switzerland Facility Sale Options Under Review
- ✓ Advanced Clinical Programs
- ✓ Two Shareholder Lawsuits Dismissed
- ✓ Finalizing Corporate Re-branding



## Isolagen Technology

**Aesthetics and Therapeutics** 

#### Isolagen Process™

- Through the Isolagen Process, a person's own collagen-producing cells, or fibroblasts, are
  - Extracted
  - Multiplied into a therapy; and
  - ☐ Approximately 15M cells re-introduced by injection

### Isolagen Therapy™

- Creates a natural, personalized therapy
- Unique skin rejuvenation treatment
  - Complements existing aesthetics treatments
  - ☐ Potential as a therapeutic application where there are unmet medical needs
- Cells can be cryogenically stored for future uses
  - ☐ Reproduces additional cells for maintenance regimen
  - ☐ Potential to create personalized topicals



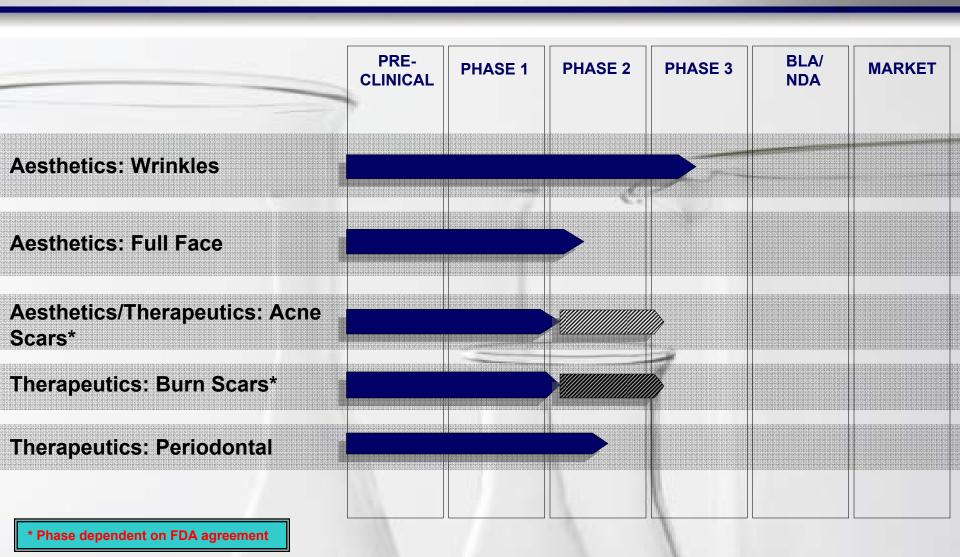
#### **UK Experience**

- Since market introduction in 2002:
  - □ Over 7,000 patients treated with Isolagen Therapy™
  - ☐ Approximately \$20M US in UK product sales
- Valuable lessons learned
  - ☐ Proper physician training, skilled injection technique
  - ☐ Appropriate marketing, patient communications
  - ☐ Better operating efficiency, managing cost of goods



### **US Clinical Program**

### Clinical Development Pipeline



#### Clinical Progress – Last 6 Months

- ✓ Gained FDA agreement on Phase III trial design
- ✓ Initiated pivotal study for nasolabial wrinkles
  - Enrollment advancing robustly
- ✓ Submitted protocol to FDA for open label study for full face wrinkles and creases
  - Investigators identified; training scheduled
- Scheduled pre-IND meeting for Phase II/III study for burn scars
- ✓ Drafted protocol for Phase II/III study for acne scars
  - ☐ Submitted a pre-IND meeting request
- ✓ Advanced Phase II open label study G-003 for treatment of interdental papillary insufficiency

#### Wrinkle Study R-003 A/B Review

#### Key Study Issues:

- □ 52 out of 213 subjects in the studies had either a Grade 2 wrinkle score (difficult to show improvement) or were randomized but not treated
- Injection and assessment techniques not standardized among investigators

#### Study Outcomes:

- ☐ 3 out of 4 objective endpoints achieved statistical significance
- Study B was statistically significant; Study A close to statistical significance
- Studies would have met SPA specifications if results combined



### Wrinkle Study (R-005/006)

- Randomized, double-blind, pivotal Phase III trials to evaluate the efficacy and safety of Isolagen Therapy<sup>™</sup> against placebo for the treatment of nasolabial skin fold wrinkles
  - ☐ Two identical clinical trials: IT-R-005 and IT-R-006; 12 sites
  - ☐ Each to include 200 patients; 100 patients of which will receive Isolagen Therapy
  - ☐ Enrollment going very well
- Under an FDA Special Protocol Assessment (SPA)
- Study design and clinical/regulatory execution informed by lessons learned from R-003 studies



#### **Open Label Full Face Study**

- Open label study for full face wrinkles and creases
- Protocol submitted to FDA in December



#### **Acne Scar Study**



- In pursuit of a Phase II/III Acne Scar study
  - Draft protocol completed
  - Submitted a pre-IND FDA meeting request
  - ☐ Objective is to initiate Phase III

    Acne scar study in 1st half of 2007
  - Need FDA non-objection

#### **Burn Scar Study**



- The Phase II/III\* Burn Scar study project
  - □ Pre-IND FDA meeting scheduled this month
  - □ Protocol under development
  - Negotiations with FDA will include the possibility of fast tracking the indication through a Phase II/III study
  - □ 1H 2007 target study enrollment start date

\*Phase dependent on FDA Agreement



#### **Periodontal Study**

- Phase II open label study IT-G-003 for treatment of interdental papillary insufficiency underway
  - ☐ 1 site, 13 subjects, study fully enrolled
- Isolagen Trial IT-G-002 results suggest autologous fibroblasts are safe and may be efficacious in increasing papillary growth
  - □ Visual Assessment Scale (VAS) assessments were superior to placebo at 4 months; objective endpoints failed to demonstrate statistical significance
- Current Study goal: test more sensitive measurement techniques and find optimal treatment protocol



#### **Market Potential**

#### Isolagen Aesthetics

#### **Aesthetics Portfolio Potential\***

Isolagen® Therapy

Wrinkles

**Acne Scars** 

\$50M - \$200M Market Potential \$25M - \$175M Market Potential

Facial Aesthetics Patient Pop: 300k-500k % Eligible for Isolagen Cosmetic: 5%-10%

Acne Scar Patient Pop: 150k-300k % Eligible for Isolagen Cosmetic: 5%-15% Agera®Skincare

Total Rx Channel: \$135M-\$160M\*\*

Agera Rx Market Potential: \$10M-\$15M

\*\* Cline & Company Report
Projected US Rx Skincare sales for 2008



### Isolagen Medical

#### Therapeutic Portfolio Potential\*

**Burn Scars** 

\$100M - \$700M Market Potential

Burn Scar Patient Pop: 250k-500k % Eligible for Therapy: 10%-30%

Periodontal

\$100M - \$400M Market Potential

Periodontal Patient Pop: 750k-1.0M % Eligible for Isolagen Therapy: 5%-15%



### Agera® Skincare

Nano-Peptide Technology (NPT)™

#### Complete Skincare System

- NPT TM (Nano-Peptide Technology TM) drives product systems
  - AM/PM Daily Systems
    - Everyday skincare for different skin types
  - □ Treatment Systems
    - Treats specific high demand skincare issues
      - □ Acne
      - Anti-Aging
      - Photo-Damaged & Pigmentation
  - □ Pre/Post Procedures
    - Designed to enhance the results of aesthetic procedures



#### Agera® Strategic Rationale

- Aligns with overall aesthetics strategy
- Establishes commercial infrastructure
- Should provide a competitive offering to existing Rx channel skin care lines
- Possibility to make inroads selling in non-Rx channels
- Deal provides access to other novel peptides
- Excellent product experience in London
- Product Systems concept with "Nano-Peptide Technology™" (NPT) has tested well



# Building on the Momentum The Next 6 Months ...



#### **Next 6 Months-- Key Milestones**

#### **Clinical**

- US "wrinkle study" fully enrolled all subjects receive all injections—move program into data collection phase
- Hire Clinical Development leader
- Seek protocol acceptance/ initiate full face aesthetics study
- Negotiate best outcome with FDA so to start burn & acne scar clinical programs
- Finalize dental program strategy

#### **Operating/Business**

- Launch Agera® Business successfully
- Continue to improve cost efficiency and quality in manufacturing process
- Finalize UK closure
- Sell Swiss facility
- Complete capital structuring plan
- Make decisions on potential acquisitions/collaborations/partner ships



#### Why Isolagen?

- New experienced management
- Revitalized business strategy
- Innovative technology in Phase III under Special Protocol Assessment
- Excellent therapeutic and aesthetics market potential
- Turnaround fundamentals firmly in place



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