## Pioneering Regenerative Medicine OneMedForum

Presented by: Steven Victor MD Chairman/CEO



IntelliCell<sup>®</sup> BioSciences

## Safe Harbor



Statements in this presentation that are not descriptions of historical facts are forward-looking statements relating to future events, and as such all forward-looking statements are made pursuant to the Securities Litigation Reform Act of 1995. Statements may contain certain forward-looking statements pertaining to future anticipated or projected plans, performance and developments, as well as other statements relating to future operations and results. Any statements in this presentation that are not statements of historical fact may be considered to be forward-looking statements. Words such as "may," "will," "expect," "believe," "anticipate," "estimate," "intends," "goal," "objective," "seek," "attempt," or variations of these or similar words, identify forward-looking statements. These forward-looking statements by their nature are estimates of future results only and involve substantial risks and uncertainties, including but not limited to risks associated with the uncertainty of future financial results, additional financing requirements, development of new products, successful completion of the Company's proposed restructuring, the impact of competitive products or pricing, technological changes, the effect of economic conditions and other uncertainties detailed from time to time in our reports filed with the Securities and Exchange Commission. There can be no assurance that our actual results will not differ materially from expectations and other factors more fully described in our public filings with the U.S. Securities and Exchange Commission, which can be reviewed at www.sec.gov.

## **Corporate Profile**



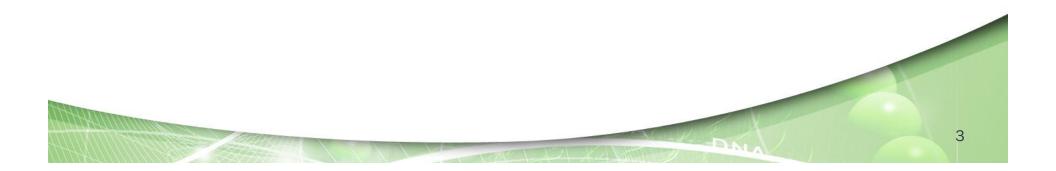
- Intellicell<sup>™</sup> Biosciences, Inc. is an emerging leader in regenerative medicine using adult autologous stromal vascular cells (SVCs) derived from the blood vessels in adipose tissue also know as stromal vascular fraction containing adult stem cells
- To date, the Company has developed proprietary technologies that allow for the efficient and reproducible separation of SVCs (branded "IntelliCell™") containing adipose stem cells that can be performed under strict cGTPs in Centers of Excellence
- Intellicell has opened a flagship model at 460 Park Ave, 17<sup>th</sup> floor New York City consisting of physician offices, a tissue processing laboratory and 2 AAAA surgical suites.
- The Intellicell business model is to acquire existing cash flow positive Ambulatory Surgical Centers and add its proprietary cGTP tissue processing labs and offer cellular therapy.
- The Company's wholly owned sub ICBS Research will be engaging in clinical studies at major medical centers to obtain FDA approval for clinical indications for their IntelliCells™



## **Essential Facts**

Y Symbol SVFC.QB
 Y Fully diluted 74,000,000 shares
 Y Last trade \$0.34
 Y Present Market Cap \$23.7 MILLION
 Y Fully reporting and current
 Y New Facility fully operational September 1, 2012
 Y Projected revenue \$10, 12 Million

Y Projected revenue \$10-12 Million



## What Is Regenerative Medicine?

Regenerative Medicine is a rapidly expanding set of innovative medical technologies that restore function by enabling the body to repair, replace, and regenerate damaged, aging or diseased cells, tissues and organs.



# Why the Excitement Over IntelliCell™ BioSciences?



Using Adult Autologous Stromal Vascular Cells derived from blood vessels in the adipose tissue:

- No risk of disease transfer
- No risk of rejection or allergic reaction
- Easy to harvest fat
- High number of stem cells harvested
- Same day-same clinic procedure
- Point of care FDA Compliant cGTP lab and extempt
- FDA 361 Compliant
- Or CFR 1271.15 Compliant

## FDA 1271.10 (a)



#### Title 21: Food and Drugs

#### PART 1271: HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS

Subpart A: General Provisions

1271.10 - Are my HCT/P's regulated solely under section 361 of the PHS Act and the regulations in this part, and if so what must I do

(a) An HCT/P is regulated solely under section 361 of the PHS Act and the regulations in this part if it meets all of the following criteria:

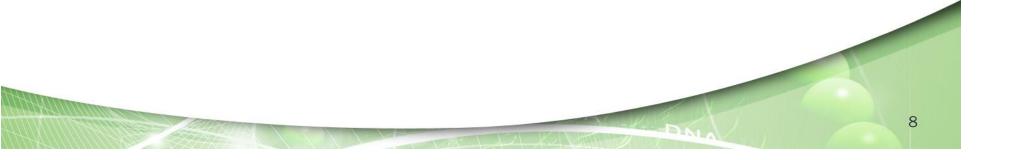
- (1) The HCT/P is minimally manipulated;
- (2) The HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent;
- (3) The manufacture of the HCT/P does not involve the combination of the cells or tissues with another article, except for water, crystalloids, or a sterilizing, preserving, or storage agent, provided that the addition of water, crystalloids, or the sterilizing, preserving, or storage agent does not raise new clinical safety concerns with respect to the HCT/P;
- (4) Either:
  - (i) The HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or
  - (ii) The HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and
    - (a) Is for autologous use;
    - (b) Is for allogeneic use in a first-degree or second-degree blood relative; or
    - (c) Is for reproductive use.



## IMPLEMENTED NEW ACTIONS



Moved to new facility
 Controlled lab environment
 Implemented Class 100 Isolator Hood
 Established QA Unit
 Hired third party expertise





## cGTPs Lab Procedures

- It is extremely important to manufacture the SVCs under the strict cGTP
- IntelliCell has hired a Director of QA and will have all SOPs necessary to be totally compliant
- Y Each specimen produced will have to be released by our QA director
- $\frac{1}{3}$  For other sites we will employ a Modular Clean Room set up

## cGTPs

- **∛ GTP Components**
- ⅓ Staff Training
- ∛ SOP Development
- Processing Records
- Equipment Records
- Equipment Calibration and Cleaning
- Facility Requirements Validation Procedures
- § Quality Assurance (QA)
- Delivery of Cellular Products
- Management Systems
- Controlled Labeling Operations
- Release Criteria Principles

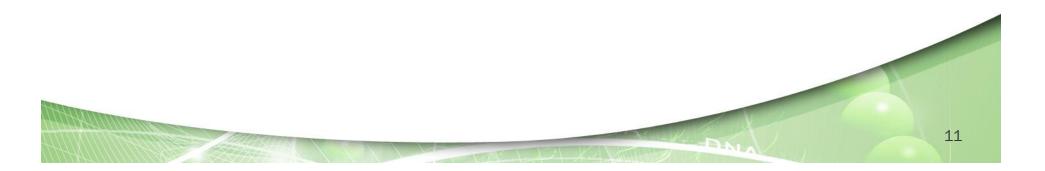






## •GRAM STAIN- NEGATIVE •ENDOTOXIN TESTING-WITHIN STANDARDS •FLOW CYTOMETRY 80% + VIABILITY

- **∛ Other testing:**
- •14 day sterility assay
- Intra process plating



## Pharmagard NR-797 Caci Compounding Aseptic Containment Isolato

Guidance for Industry Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER) Center for Biologics Evaluation and Research (CBER) Office of Regulatory affairs (ORA) September 2004 Pharmaceutical CGMPs

A Cabinet shall provide performance as specified.



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#### ł

⅓ b. Cabinet shall provide better than ISO Class 5 (Federal Standard 209E Class 100) within work-zone and interchange.

#### ł

⅓ c. Supply HEPA filter shall be the full length of the cabinet work-zone providing better than ISO Class 5 laminar down-flow designed to eliminate cross contamination on the work-surface.

#### ł

 A. Supply HEPA filter shall be protected by perforated metal diffusers covering the entire top of both work-zone and interchange.

# Modular Hard Wall Clean Room with Isolator







## ULTRASONIC CAVITATION SAFETY FACTS

DNA

DN





## ALL USES FDA CLEARED

- Used in Ultrasonic liposuction
- Used in Lithotripsy
- Used to destroy prostate cancer
- Used to destroy uterine fibroids

Used on millions of patients over decades without any reported changes in the normal tissue that was effected that is adjacent to the destroyed tissue

## **Minimal Manipulation**



(1) For structural tissue, processing that does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement; and

## (2) For cells or nonstructural tissues, processing that does not alter the relevant biological characteristics of the cells or tissues

Guidance for Industry and FDA Staff: Minimal Manipulation for Structural Tissue Jurisdiction Update

For purposes of determining whether a structural tissue product is minimally manipulated, a tissue characteristic is "original" if it is present in the tissue in the donor. A tissue characteristic is "relevant" if it could have a meaningful bearing on how the tissue performs when utilized for reconstruction, repair, or replacement. A characteristic of structural tissue would be relevant when it could potentially increase or decrease the utility of the original tissue for reconstruction, repair or replacement.

### IntelliCell BioSciences Protocol

**Ultrasonic Cavitation** 

Normal Saline

Millipore Filter

Centrifuge

CD Antibody Millipore Study

## Homologous Use



**Definition:** a use of the stem cells for the same type or purpose as the origin of that particular stem cell. Thus, a homologous use for a stem cell obtained from the bone marrow would be for a blood or hematological condition.

Adipose Derived Regenerative Cells. These SVF cells DO NOT originate in the fat. This terminology is misleading and inaccurate.

**Stromal Vascular Fraction.** These SVF cells actually reside in the outer wall of the blood vessels that are in the adipose tissue

Homologous use of these cells is remove cells from blood vessel walls and re-inject into blood vessels



## **Testing Using a Flow Cytometer**



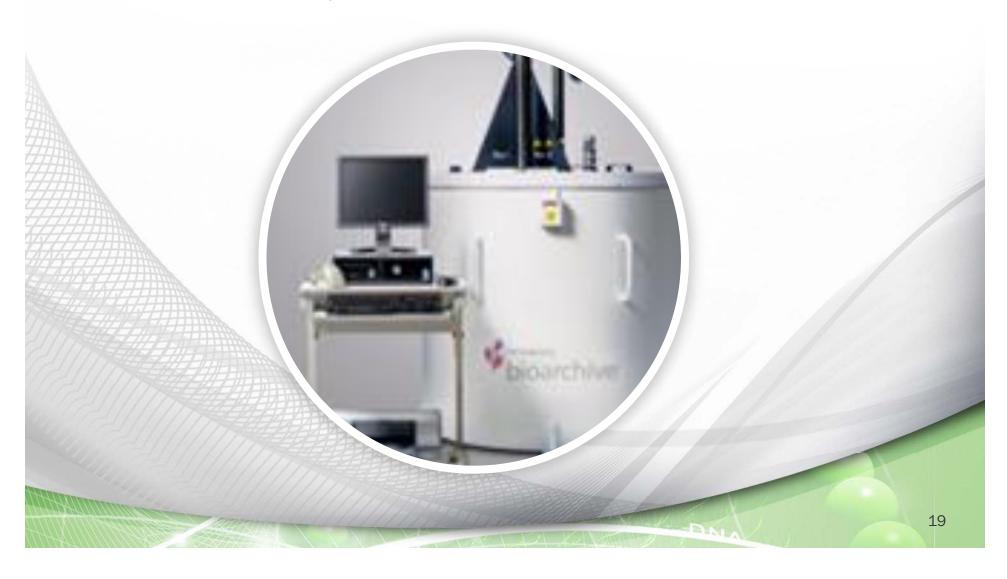
This is a laser that measures cell count and viability



## **Cryo-Preservation**



IntelliCells<sup>™</sup> can be cryo-preserved for future use.





## Adipose Tissue Composition

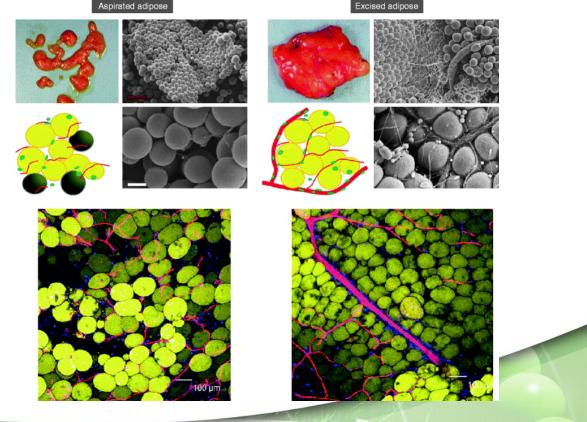
There is a well-known and well-characterized network of blood vessels that surround the adipocytes. These blood vessels, primarily capillaries, do contain the cellular basis of stromal vascular fraction. These are by definition vascular cells. The composition of autologous stromal vascular fraction is known to contain various cell types, including but not limited to, endothelial cells, fibroblast cells, adult pluripotent stem cells, red blood cells, white blood cells, etc. All of these cellular types are found to be present in the vascular system originating in bone marrow. It is indeed this vascular tissue which is the source of stromal vascular fraction.

## SVCs Come from Bone Marrow



HERE IS A DIAGRAM AND ELECTRON MICROSCOPY PICTURE SHOWING THE CELL'S LOCATION. THE CELLS ARE IN THE OUTER WALL OF THE BLOOD VESSELS (APPROX 80-90%) AND THE STROMAL ENVELOPE OF THE

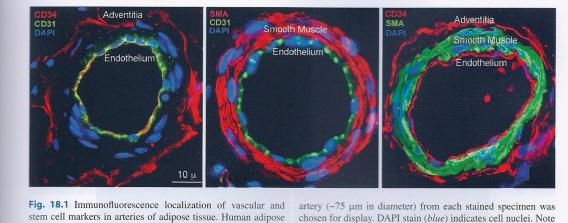
ADIPOCYTE.



## SVCs come from Bone Marrow



Immunophenotype assessed by flow cytometry. BM-derived MSCs, UCB-derived MSCs, and ADSCs were labeled with antibodies against the indicated antigens and analyzed by flow cytometry. Representative histograms are displayed. On the y axis is the % Max (the cell count in each bin divided by the cell count in the bin that contained the largest number of cells), and the x axis is the fluorescence intensity in a log  $(10^{0}-10^{4})$  scale. The isotype control is shown as a thick black-line histogram.



the lack of CD31 (or CD34) and SMA co-localization

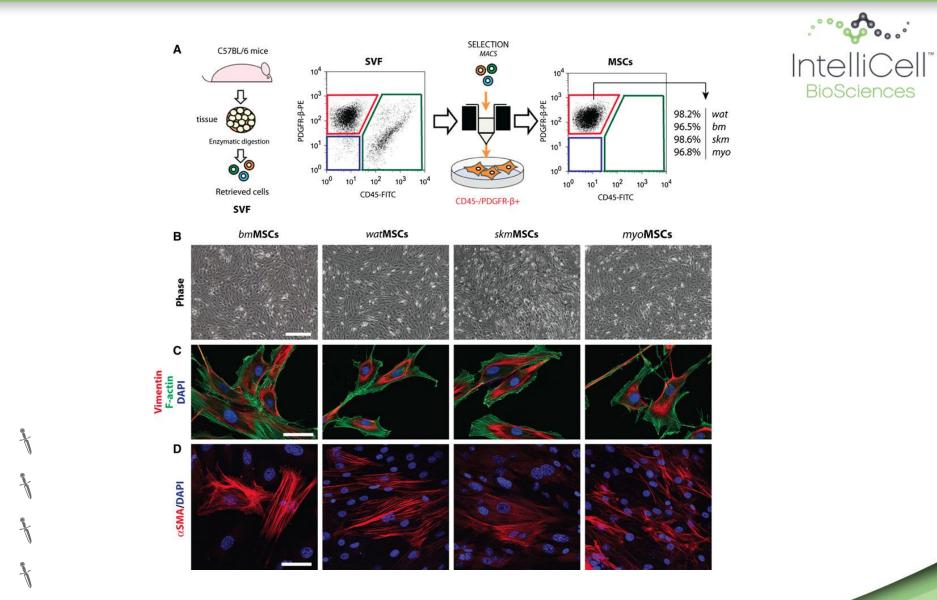


Fig. 1 Isolation and characterization of MSCs from four different murine tissues. a Tissue-resident MSCs were isolated from the stromal vascular fraction (SVF) of four different murine tissues: white adipose tissue (wat), bone marrow (bm), skeletal muscle (skm), myocardium (myo). MSCs were selected based on their negative expression of CD45 and positive expression of PDGFR-b using magnetic activated cell sorting (MACS). b Phase-contrast micrographs of confluent MSCs after 3 passages in culture (scale

bar 100 lm). c Indirect immunofluorescent staining of MSCs using an anti-vimentin antibody. Cells were counterstained with phalloidin for F-actin filaments and DAPI for nuclei (scale bar 20 lm)

d Immunofluorescent staining of MSCs using an anti-a-SMA antibody and DAPI (scale bar 20 Im)

## IntelliCell<sup>™</sup> Stromal Vascular Fraction "The Soup"



#### SVF cellular composition:

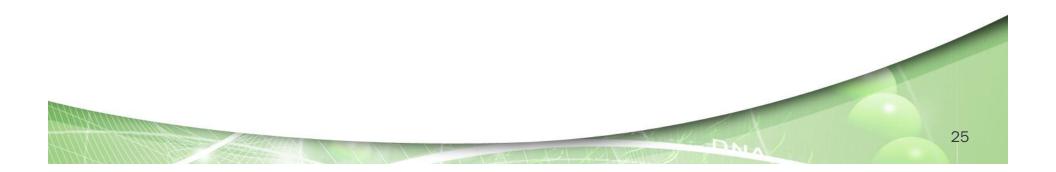
Adult adipose stem cells (Mesenchymal) Pre-adipocytes cells Endothelial Cells Smooth muscle cells Pericytes Fibroblasts Growth Factors

## Also Blood Cells from the capillaries supplying the fat cells including:

Erythrocytes B &T cells Macrophages Monocytes Mast Cells Natural killer (NK) cells Hematopoietic stem cells Endothelial progenitor cells IntelliCell<sup>™</sup> BioSciences Patent & Provisional Patents Filed



- UltraSonic Cavitation for the production of SVF (IntelliCell<sup>™</sup>) from Adipose Tissue
- Intradermal injections of SVF (IntelliCell<sup>™</sup>) for the treatment of wrinkles, skin tightening, acne scars, burns, scars, hair growth and gum recession
- Intradermal injection for hair loss



## UltraSonic Cavitation vs. Enzymatic 60 cc Adipose Tissue

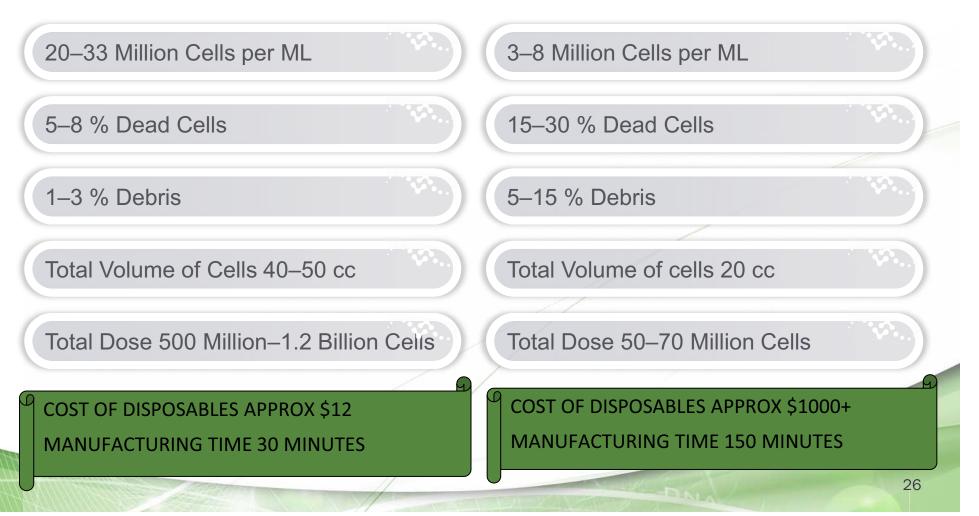


## **UltraSonic Cavitation**

**Patent Pending** 

## Collaganese Enzyme

Maybe Maximal Manipulated by FDA





BioSciences

Intelli

SUMMARY

THE CELLS IN SVF ARE VASCULAR IN ORIGIN AND NOT FROM ADIPOSE CELLS

#### **EVERY BLOOD VESSEL IN THE BODY CONTAIN SVF**

- THE CELLULAR COMPONENTS ARE SEPARATED FROM THE ADIPOSE TISSUE USING A PHYSICAL METHOD (ULTRASONIC CAVITATION ) SO NOT TO ALTER THE BIOLOGICAL ACTIVITY OF THE CELLS
- THE SVF ARE RELEASED FROM THE BLOOD VESSELS ANY TIME THERE IS AN INJURY AND THEY ARE RELEASED IN RESPONSE TO NATURAL INFLAMMATION (WHICH OCCURS EVERY DAY)
- THE SVF THAT ICBS PROCESSES AND RELEASES FROM THE BLOOD VESSEL ARE DOING THEIR NATURAL FUNCTIONS AND BIOLOGICAL ACTIVITY
- THE NORMAL BIOLOGICAL ACTIVITY OF SVF IS MODULATION OF INFLAMMATION AND REPAIR OF TISSUE

## The Science



How it Works:

IntelliCell<sup>™</sup> technology process yields stromal vascular fraction which is a functionally diverse population of cells that is believed to be synergistic and able to communicate with other cells in their local environment. The mechanism of action of the stromal vascular fraction which we have branded as "IntelliCell<sup>™</sup>" is more than regenerative. The mixture of cells have multiple functions and are highly integrated and we believe more potent then the adipose stem cells themselves

 IntelliCell<sup>™</sup> technology should be viewed as an autologous multiple function complex solution to therapeutic treatments. Due to these unique characteristics, IntelliCell<sup>™</sup> therapy can be applied in a vast variety of traumatic and developmental diseases

## Panacrine Secretion



Adipose tissue actively participates in endocrine processes by secreting cytokines and growth factors. ASCs secrete high levels of <u>epidermal growth</u> <u>factor (EGF)</u>, <u>vascular endothelial growth factor (VEGF)</u>, basic fibroblast growth factor (<u>bFGF</u>), <u>keratinocyte</u> growth factor (KGF), platelet-derived growth factor (PDGF), <u>hepatocyte</u> growth factor (HGF), transforming growth factor-beta (TGF- $\beta$ ), insulin-like growth factor (IGF), and <u>brain-derived</u> <u>neurotrophic factor (BDNF</u>)

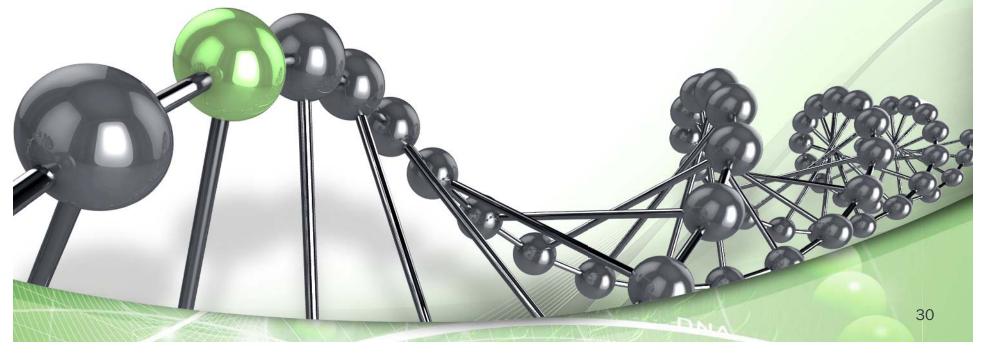
They also secrete cytokines such as Flt-3 ligand, granulocyte colony stimulating factor

(G-CSF), granulocyte/<u>macrophage</u> colony stimulating factor (<u>GM-CSF</u>), macrophage colony stimulating factor (M-CSF), interleukin-6 (<u>IL-</u> <u>6</u>), <u>interleukin-7</u> (<u>IL-7</u>), interleukin-8 (<u>IL-8</u>), interleukin-11 (IL-11), <u>interleukin-12</u> (<u>IL-12</u>), <u>leukemia</u> inhibitory factor (LIF), and <u>tumor necrosis factor</u>-alpha (<u>TNF</u>- $\alpha$ ).

## Regenerative cell functions include



Anti-inflammatory / Immunomodulation Trophic Support - Angiogenesis via cytokine secretion Differentiation - makes new tissue NEURAL TISSUE Homing - goes to the site of damage Revascularization - growing of new blood vessel Anti-apoptosis - stops cell death





## **Clinical Experience-REGEN Medical PC**

Physician Group Medical Practice (Cosmetic Dermatologist, Cosmetic Surgeon Plastic Surgeon, ENT, 3 Orthopedics, Internal Medicine)

## **§** Summary AEs for SVFs:

•NO ADVERSE REACTIONS; OVER 200 PATIENTS TREATED

•4 LOCAL INFECTIONS OF PUNCTURE SITE OF HARVESTING (DUE TO POOR WOUND CARE BY PATIENT)

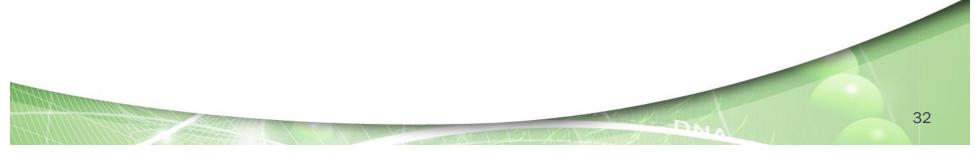
## **Business Model- Revenues**



- 1. Acquire Ambulatory Surgery Centers (ASC) that are profitable and add our cGTP labs making the center a cellular therapy ASC
- 2. Cryo-storage
- 3. International License Program

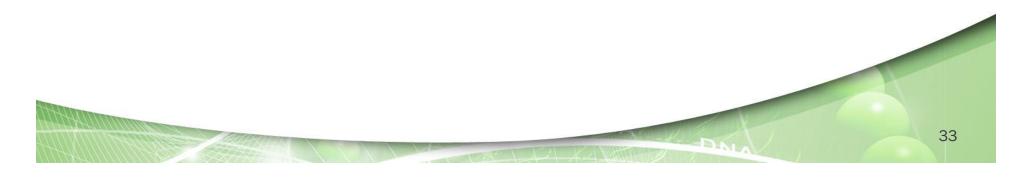
a. Canadian License secured by RegenaStem Inc. who will operate as IntelliCell Biosciences of Canada Inc.

- b. Australian and New Zealand License signed
- c. Thailand License signed
- 4. License out indications such as cardiac, vascular, wound healing etc



## Potential Collaborations & Collaborations

- 1. Millipore, Division of Merck Germany for accumulation of data and quality control of specimens by flow cytometry
- Medical Center Studies
   a. University of Florida
- 3. Numoda acting as our CRO









## **CONCLUSIONS:**



IntelliCell<sup>®</sup> BioSciences

ICBS collects SVF cells and NOT adipose-derived stem cells.

- SVF cells do not come from adipocytes as found in adipose tissue.
- SVF cells can come from anywhere in the circulatory system and are omnipresent in the human body.
- ICBS meets requirements for minimal manipulation.
  - ICBS cells are for homologous use.
  - Meets criteria of 1271.15 b
  - NEXT STEPS....FUTURE DIALOGUES WITH OCTGT

## Management for USA



### Y Dr. Steven Victor, Chairman and CEO

In Steven Victor, founder and CEO of IntelliCell has been at the forefront of clinical product and process development for over 20 years. The patent pending process that Dr. Victor has developed for IntelliCell<sup>™</sup> has been in research for over 4 years. In addition to developing clinical products that are used nationally and internationally in the medical aesthetics field, Dr. Victor is a practicing dermatologist in New York City. Dr. Victor's interest in regenerative medicine began well over a decade ago with the clinical use of autologous fibroblast cells for the purpose of dermal regeneration. Dr. Victor received his medical degree from New York College and a Bachelor of Arts degree from New York University and has held hospital based teaching positions. He has been a sought after international figure for teaching physicians new clinical techniques worldwide for over 20 years. Dr. Victor has also been featured in international and local media as a clinical subject matter expert in regenerative medicine, medical aesthetics, and dermatology.

### Sarah R. Young, Quality Assurance Manager

Prior to joining IntelliCell, Ms. Young managed the QA departments for RTI Biologics, Inc. and Southeast Tissue Alliance, Inc. She is an experienced QA Director with nine years of experience working in high-volume manufacturing settings of human cellular and tissue-based products (HCT/Ps) and medical device products regulated under stringent good manufacturing practices (cGTPs/cGMPs) by the US Food and Drug Administration (FDA) as well as state specific statutes/regulations. She has held a Certified Tissue Bank Specialist certification from the tissue banking industry's quality standards setting organization, the American Association of Tissue Banks (AATB), since 2001, where she has also been a member of AATB's Quality Assurance Committee helping establish quality standards, guidance's and providing training to the industry since 2005. She has experience with building new quality programs for partner agencies/satellite offices and training staff, writing standard operating procedures, engineering/designing validation protocols (R&D product development, processing, sterilization/decontamination, labeling, implementing effective corrective and preventive action systems, managing complaints and recalls, auditing and site inspections/qualifications, medical records management and healthcare experience, as well as prior experience with FDA.

## Management cont.



## Robert J. Sexauer, Executive Vice President Clinical Development

- Mr. Sexauer has been in the medical technology industry since 1979 and has served in a series of executive corporate positions with a specialization in international clinical, corporate and product development. In 2006, he formed InterMark Associates Ltd., a London based consulting organization focused on the regenerative medicine industry. Among projects undertaken included a turn around as CEO of a California based nanotechnology company that resulted in a settlement with the SEC and redirection of the company's business. Also, Mr. Sexauer directed the first ever in human clinical trial utilizing two autologous cell lines for regenerative medicine. Prior to InterMark, he was responsible for the corporate launch of Isolagen Europe, Ltd. Isolagen developed a pioneering regenerative medicine autologous cellular application for the anti-aging and dermal regeneration market.
- Mr. Sexauer has worked extensively outside the United States while also directing mergers and acquisitions at the corporate level and has been a featured guest lecturer at DePaul University in the graduate school of International Marketing. He has also been a featured speaker at national conferences in the medical and information technology sectors addressing market conditions and valuations for mergers and acquisitions.

### Anna Rhodes, Executive VP Operations

Anna Rhodes, our Executive Vice President of Operations, has been actively involved in the cosmetic and cosmeceuticals industries for over 9 years. From 2001 through 2009, Ms. Rhodes held various executive sales and marketing positions with Victor Cosmeceuticals, Inc. and Victor Products Inc., with primary responsibility for the development of many of the marketing and collateral materials, formulations and training materials for new product launches as well as managing domestic and international distribution. Prior to 2001, Ms. Rhodes held corporate executive managerial and sales positions in the high fashion industry with companies including Calvin Klein, Alberta Ferretti, Michael Kors and Agnona. She was a Magnum Cum Laude graduate of the University of Texas with a Bachelor of Science degree in Business Administration.

## Management Cont.



- Angela Metelitsa currently serves as the Vice President of business administration at Intellicell Biosciences, Inc. Ms. Metelitsa assists in day-to-day operations of the company including structuring and negotiating capital raising efforts.
- Ms. Metelitsa has over 15 years of experience in the financial industry previously serving as the head of alternative investments and equity syndicate at National Securities Corp. Throughout her career she has been part of over \$500 million in placement of capital for both public and private companies. From 2000 through 2007, Ms. Metelitsa managed the equity syndicate department at Montauk Financial Group, as part of an investment banking team that was consistently nationally ranked in PIPE's report. MS. Metelitsa began her career working for companies such as Coleman and Co. and Hyde Park Group and has experience working through all levels of marketing and sales including both retail and institutional sales.



## **Corporate: Subject Matter Specialists**



**Dr. Arnold I. Caplan**, Professor of Biology & General Medical Sciences & Director of the Skeletal Research Center at Case Western Reserve University in Cleveland, Ohio.

#### **Biologics Consulting Group**

- Andra E. Miller Ph.D. Senior Consultant Director Cell and Gene Therapies Dr. Miller joined the group in 2000 with 9 years experience as a molecular biologist and product reviewer with the FDA.
- Stephen Rhodes M.S. Senior Consultant Stephen joined Biologics Consulting Group, Inc., as a Senior Consultant (Medical Devices) on March 15, 2010. Mr. Rhodes comes to BCG with a wealth of knowledge from over 20 years of experience with the Food and Drug Administration, Center for Devices and Radiological Health.
- Holly Scott Senior Consultant Holly joined BCG in September 2009 as a Senior Consultant. She brings approximately 19 years of multi-office experience with the Food and Drug Administration, including 4 years as a Consumer Safety Officer with FDA/CBER, and 15 years as a Field Investigator with the FDA Office of Regulatory Affairs/ Florida District Office (Miami & Orlando).
- Huchanan Ingersoll & Rooney, PC
- Edward John Allera focuses his practice on the development of new products and business opportunities in the areas of pharmaceuticals and technology, especially regarding the regulation and promotion of drugs, biologics and devices.
- Theodore M. Sullivan counsels clients subject to Food and Drug Administration (FDA) regulations, advising them in matters related to over-the-counter drug regulation, drug exclusivity issues, food and dietary supplement labeling and advertising and import detention of FDA-regulated products.

### **Board of Directors**



Leonard Mazur, COO Triax, former EVP Sales & Marketing, Medicis Steven Victor, MD Chairman/CEO IntelliCell BioSciences

#### **Board of Advisors**

- Dr Alberto Goldman, Plastic Surgeon, Brazil
- Dr James Andrews, Sports Orthopedics Andrews Institute for Sports Medicine
- Dr Joshua Hackel, Andrews Sports Medicine Center, Florida
- Wilson Tawe MBA. PhD. Millipore Inc
- Dr Sydney Coleman, Plastic Surgeon, New York
- Dr Greg Cavaliere, Orthopedic Surgeon, NY Rangers
- Dr Anthony Maddalo, Orthopedic Surgeon, NY Rangers
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