

Cover: Mosaic of BioLife's three ring biopreservation continuum logo designed with fluorescent microscopy images of living cells.

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www.aabb.org | American Association of Blood Banks

WESOURCES

www.celltherapy.org | International Society for Cellular Therapy
www.asbmt.org | American Society for Blood and Marrow Transplantation
www.ishrs.org | International Society of Hair Restoration Surgery
www.alliancerm.org | Allliance for Regenerative Medicine
www.bestcollaborative.org | BEST Collaborative
www.regenerativemedicinefoundation.org | Regenerative Medicine Foundation
www.phacilitate.co.uk/pages/cgtherapy/index.html | Phacilitate

UPCOMING EVENTS

Stem Cells & Regenerative Medicine Congress, Cell Culture World Congress 2013, World Cord Blood Congress 2013
September 30 - October 1, 2013
Cambridge, MA

BEST Collaborative
Meeting
October 9-10, 2013
Denver, Colorado

AABB Annual Meeting & CTTXPO 2013
CTTXPO 2013
October 12-15, 2013
Colorado Convention Center

San Francisco, C./
TERMIS/NAVRMA



EDITOR'S CORNER

Mike Rice, Chairman & CEO, BioLife Solutions, Inc.

Thank you for your interest in BioLife Solutions.

This issue of BioPreservation Today (BPT) features an updated summary of clinical applications incorporating our HypoThermosol® cell/tissue storage and shipping medium and CryoStor® cryopreservation freeze media. We are quite pleased to report that our clinical customer base is expanding rapidly, with over 85 clinical trial and hospital-approved uses.

We recently announced an exclusive distribution agreement where BioLife will distribute precision thermal packaging products designed and manufactured by SAVSU Technologies. You can read more about this in the following pages.

On another very positive note, our product offering will soon be expanding with new pre-filled syringe and bulk storage bag options for HypoThermosol, CryoStor, and BloodStor®. More about this can be found in this issue of BPT.

Learn more about a key scientific conference and trade show addressing Opportunities and Challenges in 3D Bioprinting, to be held October 2, 2013 in Cambridge, UK.

Lastly, BioLife was recently named one of the 100 Best Places to Work in Washington state. We're very proud of this honor and wish to thank our customers, suppliers, and shareholders for the opportunity to build BioLife into a highly valued company and great place to work.

Best regards,

Mike

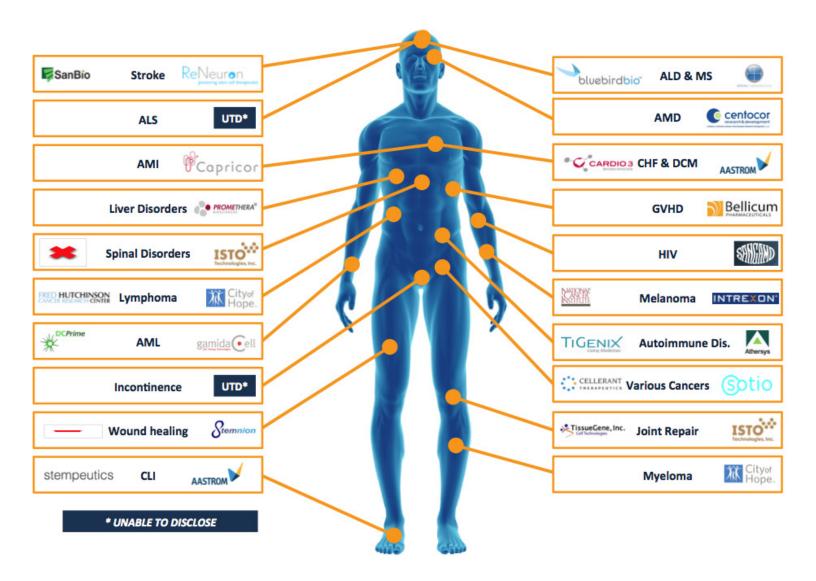
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BIOLIFE PRODUCTS IN REGENERATIVE MEDICINE APPLICATIONS

Biolife's cGMP, protein-free, serum-free CryoStor freeze media and HypoThermosol storage and shipping media are currently incorporated as ancillary or excipient reagents. These reagents are used to store, ship, and freeze cell and tissue source material such as peripheral and cord blood, bone marrow, skeletal muscle tissue, skin, and cartilage. BioLife products are also used in a great variety of final cell dose formulations currently in FDA and internationally approved clinical trials for treatment of heart disease, movement disorders, stroke, vision loss, neurologic disorders, various cancers, and other life-impacting and life-threatening diseases and disorders.

Mike Rice, BioLife Solutions President and CEO, remarked on the growing adoption of the Company's biopreservation media products by stating, "We are very pleased to provide an update to our customers, shareholders, and industry on the significant traction and franchise we have built as a supplier of critical reagents to the high growth regenerative medicine market. While the use of home-brew biopreservation media cocktails remains a traditional, non-optimized approach in clinical applications of

cells and tissues, the quality profile and superior preservation efficacy of HypoThermosol and CryoStor are causing many new groups designing clinical trials to evaluate and adopt our proprietary products. Existing customers are also maintaining their preference for our products in their subsequent applications, since the value and benefits have previously been quantified and qualified in their manufacturing and quality systems." (continued on page 07)



Use of CryoStor® in Clinical Trials of New Regenerative Medicine Products & Therapies							
Clinical Indication	Administration Route	Reagent Status	Pre-Clinical	Phase I	Phase II	Phase III	Approved
Disc Repair	N/A	Ancillary	✓	✓	✓		
Stroke	N/A	Ancillary	✓	✓	✓		
Non-Hodgkin Lymphoma	N/A	Ancillary	✓	✓	✓		
Malignant Glioma	N/A	Ancillary	✓	✓			
Wound repair	N/A	Ancillary	1	1	1		
Pediatric Blood Cancers	Intravenous	Excipient		Hopsito	al Practice of M	Nedicine	
Stress Urinary Incontinence	Intraurethral	Excipient	1	1	1	1	
Multiple Sclerosis	Subcutaneous	Excipient	1		1		
Amyotrophic Lateral Sclerosis	N/A	Ancillary	1	1			
Hematologic Malignancies	Intravenous	Excipient	1	1	1		
Sickle Cell Disease	Intravenous	Excipient	1	1	1		
AMD	Sub-retinal	Excipient	1	1			
Melanoma	N/A	Ancillary	1	√			
Melanoma	N/A	Ancillary	1	1			
Hematologic Malignancies	Intravenous	Excipient	1	√			
Melanoma	Intratumoral	Excipient	1	1			
Ischemic Heart Disease	N/A	Ancillary	1			1	
Joint Disease	Intra-articular	Excipient	1	✓	1		
Prostate Cancer	Subcutaneous	Excipient	√	✓			
AML	Intradermal	Excipient	1	√	1		
Joint Disease	N/A	Ancillary	1	✓	1	1	
CCALD	Intravenous	Excipient	1		1	1	
PLIF/TLIF	Intravertebral	Excipient	1	1			
Disc Repair	Intravertebral	Excipient	1				
Metastatic Melanoma	N/A	Ancillary	1		1		
Prostate Cancer	Intradermal	Excipient	1	1			
Prostate Cancer	Subcutaneous	Excipient	1	1	1	1	
AMI	Intracoronary	Excipient	1	1	1		
Urea Cycle Disorders	N/A	Ancillary	1	1	1		
HIV	N/A	Ancillary	1	1			
Leukemias	N/A	Ancillary	1	1	1		
Metastatic Melanoma	N/A	Ancillary	1		1		
Acute Lymphoblastic Leukemia	N/A	Ancillary	1	1			
Ovarian Cancer	Subcutaneous	Excipient	1	1	1		
Ovarian Cancer	Subcutaneous	Excipient	1	1	1		
Ovarian Cancer	Subcutaneous	Excipient	1	1	1		

BIOLIFE PRODUCTS IN REGENERATIVE MEDICINE APPLICATIONS (CONTINUED)

Clinical Indication	Administration Route	Reagent Status	Pre-Clinical	Phase I	Phase II	Phase III	Approved
Radiation Injury	N/A	Ancillary	1	1			
Urinary Sphincter Repair	Intramuscular	Excipient	1	1	1	1	
Fecal Incontinence	Intramuscular	Excipient	1	1	1		
Ischemic Heart Disease	Intramuscular	Excipient	1	1	1		
Hematologic Malignancies	Intravenous	Excipient	1	1	1		
Metastatic Melanoma	N/A	Ancillary	1	1	1		
beta-thalassemia major	Intravenous	Excipient	1	1	1		
Hematologic Malignancies	N/A	Ancillary	1	1	1		
Treg Production	N/A	Ancillary	1				
Organ Rejection	N/A	Ancillary	1	1			
Non-Hodgkin Lymphoma	N/A	Ancillary	1	1			
Occlusive Kidney Disease	Intra-arterial	Excipient	1	1			
Metastatic Cancer	N/A	Ancillary	1		1		
B Cell Malignancies	N/A	Ancillary	1	1	1		
Metastatic Cancer	N/A	Ancillary	1	1	1		
Malignant Glioma	N/A	Ancillary	1	1	1		
Metastatic Cancer	N/A	Ancillary	1	1	1		
GI Cancers	N/A	Ancillary	1		1		
Metastatic Melanoma	N/A	Ancillary	1		1		
Metastatic Melanoma	N/A	Ancillary	1		1		
Advanced Melanoma	N/A	Ancillary	1	1			
HPV Associated Cancers	N/A	Ancillary	1		1		
Metastatic Ocular Melanoma	N/A	Ancillary	1		1		
Joint Disease	N/A	Ancillary	1				
Crohn's Disease	N/A	Ancillary	1	1			
Hypoplastic Left Heart	Intracardiac	Excipient	✓	√			
Non-Hodgkin Lymphoma	Intratumoral	Excipient	✓	√			
Ovarian Cancer	N/A	Ancillary	✓	√			
Glioblastoma Multiforme	Intradermal	Excipient	✓	√			
GVHD	Intra-arterial	Excipient	✓				
Multiple System Atrophy	N/A	Ancillary	1				
Hematologic Malignancies	Intravenous	Excipient	1				
DC Vaccine Production	N/A	Ancillary	1				
Ischemic Stroke	N/A	Ancillary	1	1	1		
AMI	N/A	Ancillary	1	1	1		
Cutaneous Photoaging	N/A	Ancillary	1	1	1		

Use of HypoThermosol® in Clinical Trials of New Regenerative Medicine Products & Therapies								
Clinical Indication	Administration Route	Reagent Status	Pre-Clinical	Phase I	Phase II	Phase III	Approved	
Stress Urinary Incontinence	N/A	Ancillary	✓	✓	√	1		
Post MI CHF	IM - ventricular	Excipient	✓	✓	✓	1		
Multiple Sclerosis	Subcutaneous	Excipient	✓		✓			
Ulcerative Colitis	Intravenous	Excipient	✓		✓			
Wound healing	Subcutaneous	Excipient	✓	✓	✓			
Dilated Cardiomyopathy	Intraventricular	Excipient	✓	✓	✓			
Critical Limb Ischemia	Intramuscular	Excipient	1	✓	1	1		
Stroke	Intracranial	Excipient	1	✓				
Urinary Sphincter Repair	N/A	Ancillary	1	1	1	1		
Fecal Incontinence	N/A	Ancillary	1	✓				
Ischemic Heart Disease	N/A	Ancillary	1	1				
Safety Study	Intralymphatic	Excipient	1	✓				
PAD	Intramuscular	Excipient	1	1				
Organ Rejection	Intravenous	Excipient	1	1				
Heart Failure	N/A	Ancillary	1	1	1			
Cardiac Ischemia	Intravenous	Excipient	1	1	✓			
Heart Failure	Intraventricular	Excipient	1					

(continued from page 04)

The regenerative medicine market is expected to grow to more than \$35 billion by 2019, according to TriMark Publications' recently published "Regenerative Medicine Markets" report. Biolife's addressable portion of the market is the demand for reagents used to store, ship and freeze source material and manufactured doses of cell-based products and therapies.

Rice continued, "Most of our regenerative medicine customers are progressing to complete Phase II trials, and while we cannot predict which customers will obtain regulatory approval and successfully commercialize their cell and tissue based products, our regenerative medicine franchise represents a significant long term potential growth area for revenue, profit, and shareholder value.

"EXISTING CUSTOMERS ARE ALSO MAINTAINING THEIR PREFERENCE FOR OUR PRODUCTS IN THEIR SUBSEQUENT APPLICATIONS, SINCE THE VALUE AND BENEFITS HAVE PREVIOUSLY BEEN QUANTIFIED AND QUALIFIED IN THEIR MANUFACTURING AND QUALITY SYSTEMS."

NEW PRODUCTS PREVIEW - PRE-FILLED SYRINGES AND BULK BIOPRESERVATION MEDIA IN BAGS

BioLife Solutions' product development, quality, and manufacturing teams are hard at work completing the design, validation, and testing of several new products intended to improve aseptic processing of cells and tissues via the use of improved biopreservation media container designs offering a host of features and related benefits.



To the cord blood bank, regenerative medicine, and biobanking markets, we plan to offer syringes prefilled with our cGMP BloodStor® 55-5 and CryoStor® cryopreservation freeze media products. Material selection research has been exhaustive as our product launch goal is to come to market with the best available fluid contact materials and a leachable and extractable profile supported by 3rd party testing lab data.

These same criteria are driving our configurations for bulk bag storage products pre-filled with BloodStor, CryoStor, and HypoThermosol®. We recently completed a survey with ISCT members to collect form factor input from prospective users. Our product offering will include weldable tubing and other features to facilitate sterile, closed system processing of cells intended for clinical use.

"OUR PRODUCT OFFERING WILL INCLUDE WELDABLE TUBING AND OTHER FEATURES TO FACILITATE STERILE, CLOSED SYSTEM PROCESSING OF CELLS INTENDED FOR CLINICAL USE."



Please visit our website for additional information during the first quarter of 2014. www.biolifesolutions.com



OPPORTUNITIES AND CHALLENGES IN 3D BIO-PRINTING FOR ADVANCING MEDICAL RESEARCH

Dr. Beverley Vaughan, Director of Operations, univerCELLmarket Ltd

The field of 3D bio-printing for medical research is making headline news around the world on an almost weekly basis. Scientists working in this fast growing field will be aware of the many challenges it still presents but they will also know that 3D bio-printing holds great promise not just for academic research but also for clinical applications that aim to ultimately benefit patients.

The concept of 3D bio-printing is to further advance traditional tissue engineering models to bring cells and structure together generating functional tissues and organoids. Current protocols work upon additive manufacturing models where the desired tissue is "printed" layer-by-layer. The most successful commercial example of this is Organovo's Novogen™ bio-printer which dispenses a "bio-ink" composed of living cells in layers to a user defined design, allowing fabrication of tissues with diverse cellular compositions and geometries. Once built, bio-printed tissues share many key features with native tissues such as cellular density, heterogeneous cell populations and comparable architectural and functional features.

The goal of this technology is to create living human tissues that may be used for replacing or repairing damaged tissues as well as for use in disease modelling and toxicology studies better reflecting the in-vivo environment.

So what are the next steps for advancing this field? univerCELLmarket is aiming to answer this question on 2 October in Cambridge (UK) when it brings together research leaders from historically disparate disciplines at a meeting in to explore "Opportunities and Challenges in 3D Bio-printing".

"THE CONCEPT OF 3D BIO-PRINTING IS TO FURTHER ADVANCE TRADITIONAL TISSUE ENGINEERING MODELS TO BRING CELLS AND STRUCTURE TOGETHER GENERATING FUNCTIONAL TISSUES AND ORGANOIDS."

univerCELLmarket is an online, global source of up-to-date information for everyone working in the field of stem cells and regenerative medicine. Users can rapidly search eight separate directories for a wide range of data including therapies, stem cell banks, suppliers of GMP manufacturing services, tissues and cells, as well as academic centres, networks/societies plus news and events.



SAVSU® PRECISION THERMAL PACKAGING OVERVIEW

SAVSU® Technologies designs and builds high performance passive shipping and storage containers for the biological sciences community. The 21st century has heralded the creation of entirely new classes of drugs, assays and biological products and materials all designed to treat disease and improve health.

These new classes of drugs and biomaterials often require stringent temperature management throughout their entire life. Previously drugs or biomaterials were shipped in low performance coolers and shipped over night. However, these new materials are not only much more temperature sensitive but they are also expensive. When these materials are exposed to temperatures outside of specified ranges they can become ineffective or possibly dangerous. The consequences of temperature excursions are simply no longer acceptable. As a result SAVSU® Technologies has developed a patent pending process and technology, which allows these materials to be shipped with precision thermal management without the need for expensive priority shipping methods and management.

The guiding design principles of SAVSU® products include:

- 1. High performance temperature stability in a range of ambient environments
- 2. Reliability of high performance without the use of fragile vacuum panels
- 3. Ease of use pack out procedures
- 4. The use of easy to obtain thermal mass
- 5. The internal protection of product from shock and vibration
- 6. The potential to adapt temperature monitoring to any shipment
- 7. The potential to incorporate security features to each container
- 8. Antifreeze technology for all 2-8°C shipments
- 9. Reusable packaging to reduce the growing burden of landfill waste
- 10. The use of only natural thermal mass materials for safe disposal

SAVSU® Technologies has created 3 primary lines of shipping container systems each designed with a specific application for time, temperature and volume of shipment. The SAVSU® Technologies product line includes the NanoQTM, CryoQ[™] and PHD[™] shipping containers.

The NanoQTM is an extremely versatile container that is designed for the most extreme conditions. The NanoQTM may be used for extremely long storage times as may be needed for international shipments, and for emergency long term storage of critical materials such as medicines and vaccines in remote areas. The NanoQTM may be used for the storage of materials needing to maintain temperatures from CRT, 2-8°C, frozen and deep-frozen -80°C. One interesting application for the Nano Q^{TM} is for use in extremely cold environments where the container may be exposed to very long periods of very cold temperatures. The advanced insulation of the NanoQ™ allows for a broad range of applications.

The CryoQ™ line is designed for the shipment of small volumes of biomaterials, which need to be shipped at extremely stable deep-frozen temperatures when used with small volumes of dry ice. The CryoQTM utilizes a Vial Rack system to deliver precision temperature management even after significant sublimation of dry ice has occurred. The Vial Rack system allows for reliable temperature stability even during the most rigorous shipping conditions.

The PHD™ line is designed for the shipment of materials, which must be maintained at 2-8°C and or CRT temperatures. The PHDTM line is designed for small volume shipments from single dose to 3 Liters in volume. Utilizing our antifreeze technology the PHDTM takes the risk of freezing out of 2-8°C shipments. The outstanding insulation performance of the PHDTM will also allow for extended shipping periods and thereby give greater product safety assurance.

Each of these shipping containers results in a precision temperature management system that ensures the safe and cost effective delivery of these essential drugs and biologic materials.

"THESE NEW CLASSES OF DRUGS AND BIOMATERIALS OFTEN REQUIRE STRINGENT TEMPERATURE MANAGEMENT **THROUGHOUT** THEIR ENTIRE LIFE."



 $NanoQ^{TM}$



CryoQTM



 PHD^{TM}



PROUD AND HONORED TO BE NAMED ONE OF WASHINGTON'S BEST COMPANIES TO WORK FOR

Washington State's Top 100 Companies to Work For – BioLife Solutions Makes the List

In June of this year, BioLife was included in the prestigious list of the top 100 companies to work for in Washington state.



Now in its 23rd year, this competition salutes Washington companies setting the standard for leadership, strong benefits, ideal work environment, innovative training, happiest employees and more. Winners were recognized at an awards dinner held on June 20th at the Westin Hotel in Seattle.

Mike Rice, Chief Executive Officer, commented on the award by stating, "Our entire team is very honored and proud to receive this recognition. It is gratifying to see our people and special corporate culture acknowledged within the Washington state business community. We have built a very solid, high performance team that is the single greatest contributor to the success BioLife has achieved since the Company relocated to Bothell in early 2007. I'm honored to have the opportunity to lead such a dedicated and capable team."

In 2012, BioLife doubled revenue over 2011, doubled the size of its workforce to nearly 30 team members, and firmly established its products as best in class, clinical grade biopreservation storage and freeze media for cells, tissues, and organs. Shares of the Company have recently traded at nearly ten times above a previous low price set in January 2011.

Rice continued, "BioLife is a very special place to work. A requirement for teamwork and open and honest communication is a hallmark of our merit-based culture and a foundational principal of my management philosophy."

BioLife Solutions develops and markets patented hypothermic storage/transport and cryopreservation media products for cells, tissues, and organs. BioLife's proprietary HypoThermosol®, CryoStor®, and BloodStor® platform of biopreservation media products are marketed to academic research institutions, hospitals, and commercial companies involved in cell therapy, tissue engineering, cord blood banking, drug discovery, and toxicology testing. BioLife products are serum-free and protein-free, fully defined, and formulated to reduce preservation-induced, delayed-onset cell damage and death. BioLife's enabling technology provides research and clinical organizations significant improvement in post-preservation cell and tissue and viability and function.