

# Osiris Therapeutics, Inc.

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## Innovation on the shelf: solving the puzzle of live-cell preservation

**Osiris Therapeutics, a regenerative medicine company with products for wound care, orthopedics and sports medicine, has developed Prestige Lyotechnology, a proprietary method to preserve living cells and tissues at ambient temperature.**

Currently, cryopreservation is the only method that allows for long-term storage of live cells and tissues. A caveat of this method is that it requires ultra-low-temperature freezers and dry ice or liquid nitrogen for shipments. As the cell therapy industry continues to advance, the way in which cellular therapies are preserved, stored and distributed has become an important factor in making them more accessible to patients and physicians, as well as in their commercial success.

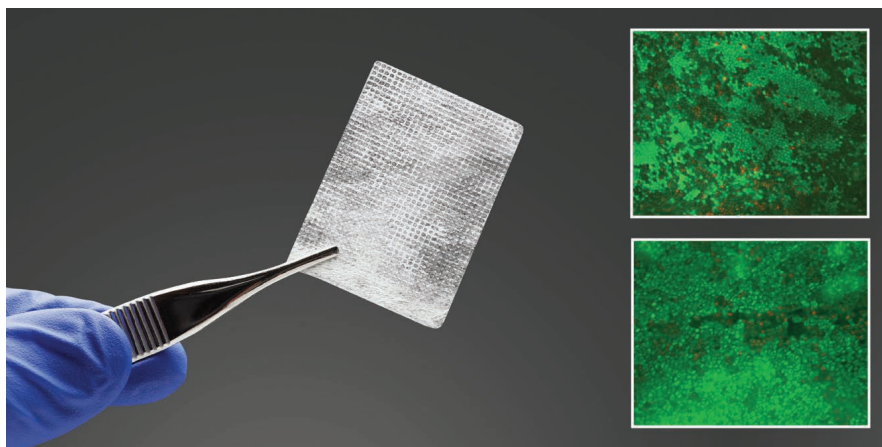
To address these limitations, Osiris Therapeutics has developed Prestige Lyotechnology, a proprietary method that keeps cells and tissues alive while allowing for long-term storage at ambient temperatures. Unlike all other known lyophilization methods, Prestige Lyotechnology both preserves cells and tissues and generates products that can be stored on the shelf (Fig. 1). Moreover, the manufacturing of lyopreserved living tissues with Prestige is scalable and can be applied to many different cell and tissue types, including but not limited to placental tissues, skin, bone and articular cartilage.

"This novel lyopreservation technology developed by Osiris is a huge win for the entire field of cellular therapies. It is expected to accelerate development, commercialization and widespread use of living cell and tissue therapies," said Alla Danilkovitch, CSO at Osiris Therapeutics.

### Leading the way in regenerative medicine

For nearly 25 years, Osiris Therapeutics has developed innovative regenerative medicine products that improve patient outcomes while reducing overall health care costs. From creating the first viable bone allograft to introducing the first approved mesenchymal stem cell drug, the Maryland-based company has been a world leader in developing and marketing cellular and tissue therapies.

Osiris was the first company to offer a treatment for patients with allogenic mesenchymal stem cells. In 2012, after 20 years of research and development, the company successfully brought to market the stem cell drug Prochymal (remestemcel-L) for the treatment of steroid-refractory acute graft-versus-host disease in children. Over the years, Osiris has evolved from solely an R&D-focused biotech company into a fully commercial diverse organization that develops regenerative products to address unmet needs in wound care, orthopedics and sports medicine. One of the company's innovations is BioSmart, an advanced proprietary platform for tissue processing



**Figure 1: Human placental membrane processed with Prestige Lyotechnology, a proprietary method for retaining viable cells at ambient temperature.** The figure shows the visual appearance (left) and a microscopic view of viable cells stained with green fluorescent dye in fresh tissue (top right) and tissue processed with Prestige Lyotechnology (bottom right).

and cryopreservation that retains the native structure, properties and inherent functionality of the tissue.

Currently, BioSmart serves as the manufacturing backbone of the company's line of marketed products, which includes Grafix, viable placental membranes for acute and chronic wounds; Stravix, a living placental tissue for surgical applications; Cartiform, a viable osteochondral allograft for cartilage repair (available exclusively from Arthrex); and BIO<sup>4</sup>, a viable bone matrix for bone repair and regeneration (available exclusively from Stryker). Given its expertise in the commercialization of cryopreserved cell and tissue therapies, Osiris understands the advantages that Prestige Lyotechnology will provide.

### Building a diverse product pipeline

Osiris is also applying Prestige Lyotechnology to new drug products in their early-stage pipeline. Currently, Osiris is developing a novel stem-cell-based bioengineered drug platform that can be used across multiple therapeutic areas and could potentially provide treatments for hundreds of different diseases. The biologically active core of this platform is an injectable formulation of stem cells and extracellular matrix proteins that can be used alone or paired with additional delivery components to meet the needs of specific applications.

For example, the delivery component might be an environmentally-responsive 'smart' biomaterial that, once combined with the stem cell component, takes

on a gel consistency appropriate for topical application to a wound. Alternatively, the delivery component may be a specialized, tunable polymeric liquid scaffold. This liquid could be mixed with the stem cell core and transform into a biomechanically strong solid, thus allowing for minimally invasive delivery for the regeneration of bone, cartilage, intervertebral discs, and other tissues and organs.

All biological drugs and combination products based on this stem cell platform will be processed with Prestige Lyotechnology and stored at ambient temperature.

"Through more than two decades of basic and clinical research, Osiris has not only defined the science and potential of cellular regenerative therapies, but has also created a body of work, advancing the medical community's understanding of cellular technology," Alla Danilkovitch said. "With the introduction of Prestige Lyotechnology, Osiris is bringing these innovative cellular therapies to more patients to address a wide range of unmet medical needs."

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