

# Geoff Mackay, President and CEO Organogenesis, Inc. 'Living Technology'

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**F**or Geoff Mackay, President and CEO of Organogenesis (Canton, Mass), the pharmaceutical business feels more and more like a second home. He has become increasingly familiar with the industry through various leadership positions during his 11 years with Novartis AG (Basel, Switzerland) and other international companies and he is proud of his role in fulfilling the promise of regenerative medicine.

Geoff has been involved in regenerative medicine and wound care since 1996. "My initial focus areas were immunology and dermatology," he says. "I was the head of Sales and Marketing for Novartis Biotech Europe, head of Global Sales of Novartis Transplantation and Immunology, and Vice President of Sales and Marketing for Novartis Tissue Engineering in the US. At Novartis, I learned a lot about the life science industry and management. Novartis was initially a partner with Organogenesis, and through this exposure in the 1990's, I became fascinated with the potential of regenerative medicine."

Regenerative medicine is a revolutionary medical approach that utilizes the body's innate ability to regenerate or heal in a healthy way. Regenerative medicine technologies now can deliver living, cell-based products to stimulate the body's own natural healing process. Geoff is confident in Organogenesis' ability to deliver this comprehensive therapy to patients. "We've mastered the scientific and business challenges of bringing a living therapy to patients," he says. "A key milestone is that Organogenesis is the first company to receive FDA approval for an allogeneic living cell-based therapy — Apligraf®, our living cell-based product, which is indicated for venous leg and diabetic foot ulcers. At this point in time, the product is the leading regenerative medicine brand in the world with more than a quarter of a million patients successfully treated. Currently, the top US wound centers use Apligraf. It is being applied once every 2 minutes throughout the country."

After 20 years of intense research, regenerative medicine has come of age. Substantial growth and commercial success, in addition to overall excitement and worthwhile investment in the closely related area of stem cell research, are some of the factors that contribute to the invigoration of this field. "The entire preceding decade will be remembered as the period when living, cell-based regenerative products began to transform medicine," Geoff says. "These products and this technology can enhance, prolong and, in many cases, save lives. The leading role that Organogenesis is playing in bringing this entire field into the mainstream is a source of pride for me and my fellow employees. We



are the world's first successful regenerative medicine company. We specialize in soft tissue regeneration and our focus is primarily in the areas of wound healing, oral soft tissue, regeneration, and biosurgery."

Apligraf is the culmination of two decades of cutting-edge research initiated by scientists at MIT and continued by a dedicated team within Organogenesis. In addition to the product's success, there are the rewards of patient satisfaction. "Since joining Organogenesis, I've led the effort to make Apligraf available to more and more patients with nonhealing chronic wounds," Geoff says. "I often get thank you cards mailed to me from grateful patients who have suffered from chronic wounds for years and were bounced around the healthcare system. They are happy and relieved to finally receive Apligraf at a well-run, multidisciplinary wound care center. Their wounds can heal within 8 to 12 weeks.

"From an industry perspective this can really give you a boost," Geoff continues. "This is the type of gratitude that must occur as part of a normal day at the office for a wound care clinician, but for us in the industry, it is less common and one of the most satisfying parts of working in this field."

Several crucial steps are in place at Organogenesis to ensure successful operations. "Our cell banks are the foundation for our cell-based technology," Geoff explains. "It all begins with procuring donor tissue donated for skin from routine infant



An Organogenesis Scientist diligently working on cell research.



Apligraf®, the living cell-based therapy indicated for the treatment of venous leg ulcers and diabetic foot ulcers.

circumcision. We partner with hospitals and physicians to identify an appropriate donor candidate. Once a donor agrees to participate, an extensive series of tests are performed to maximize the safety profile of the donated tissue. The donated tissue is dissociated at our manufacturing facility into either human keratinocytes or human fibroblasts. It is essential that both cell types work in concert — they are expanded over the course of several weeks, eventually becoming master and working cell banks.”

In order to meet their manufacturing needs, the company developed a method for producing and manufacturing scale cell cultures and cell banks of both epidermal keratinocytes and dermal fibroblasts. During a 20-day growing process for the product, a complex, differentiated epidermis is formed that contains multiple layers of living cells. The product undergoes rigorous quality control throughout the growing process before being prepared in a temperature-controlled packaging environment for shipping to physicians and customers throughout world.

Organogenesis’ mission is to bring regenerative medicine to patients and standardize its use in everyday medical care. Geoff’s personal business philosophy is parallel to this corporate one. “Throughout the past 10 years of my involvement with regenerative medicine, I’ve been fortunate to play a leadership role in what I believe is the most exciting emerging field in medicine,” he says. “This field has the potential to reset treatment paradigms for disease, injuries, and aging.”

Within the biosurgery arena, Organogenesis has developed and commercialized bioengineered collagen matrices that are used for heart and tendon repair surgery. The matrices are commercially available in many markets. CelTx™, a living bilayered cell therapy for oral soft tissue regeneration, is a recent design for use as an alternative for tissue from the palate graft that surrounds teeth — the first living-cell therapy designed for oral soft tissue. “We’ve just completed a successful Phase-III trial and submitted to the

FDA,” Geoff explained. “When it is approved, it will be first living cell-based technology FDA-approved for use in the dental market.”

Unlike many companies, Organogenesis is weathering the challenging economic climate. The level of success and growth of 2009 holds promise for 2010 and beyond. “Organogenesis has grown dramatically in 2009 throughout this tough economic crisis in terms of the number of patients treated and the size of our company,” Geoff says. “We’re tripling the total square footage of our facility and adding staff across all departments. We’ve grown from 12 employees in 2003 to 375 employees today, primarily due to the significant adoption of Apligraf.”

While Organogenesis’ number one priority is to make Apligraf the standard of care for all patients, an additional project is the source of great pride. The company is part of a consortium of institutions that has been given the largest grant by the US Military in regenerative medicine of the US Department of Defense and the National Institutes of Health to work as part of the Armed Forces Institute of Regenerative Medicine (AFIRM). AFIRM is dedicated to the development of regenerative medicine therapy for the treatment and repair of battlefield injuries. The goal is to work with top scientific researchers of Wake Forest University and the US Military to expedite the development of living-cell therapies and deliver them to the soldiers returning with battlefield injuries.

Organogenesis is not resting on its laurels in terms of the number of patients successfully treated with Apligraf. The company intends to continue to build the infrastructure and skill set to help clinicians properly integrate Apligraf into their care protocols. “We are very proud the top US wound centers use Apligraf,” Geoff says. “But we believe that our job — ie, to do everything possible to ensure this advanced modality is used appropriately and to its best advantage — is just getting started.” ■