

Company Overview



Mission

Tissue Genesis, Inc. is an emerging high-growth company in the field of regenerative medicine, using a patient's own therapeutic cells to coat implants, repair damaged tissue, heal disease, and other uses. Tissue Genesis is leveraging its perfusion platform and expertise to deliver products to the tissue engineering market. Current near term applications include vascular grafts and wound healing using patients' own regenerative cells.

Highlights

Founded:	In 2001, began operations 2002
Employees:	25 with five PhDs
Lead Products:	Vascular Conduit Solutions, Wound Healing, Tissue Repair, BOS® Product Line
Intellectual Property:	· Derivation and Use of Fat-Derived Autologous (Patient's Own)Therapeutic Cells · Exclusive license of Dr. Stewart Williams' pioneering patent portfolio from Thomas Jefferson University. · Connective Tissue Engineering · Exclusive license of Dr. Paul Kosnik's patent portfolio from University of Michigan. · Bio-Optimization System (BOS) Line of Products · Patent applications pending. · Sustained Pressure Sodding of Implants Using Therapeutic Cells · Developed at Tissue Genesis – patents pending on advanced cell deposition technology and hardware.
Ownership:	Privately Held
Funding:	Capital Investment, Contracts and Grants
Annual Revenues:	\$4 million

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Executive Summary

Tissue Genesis' Business

Tissue Genesis, Inc. seeks to advance tissue engineering and cell therapy solutions that save lives and improve the quality of life for patients with illness and disease. Tissue Genesis' business strategy is to promote the use of a patient's own adipose (fat) derived therapeutic cells in repairing damaged tissue and coating of implants. These cells can be delivered in a wound dressing, or can be delivered to damaged tissue by means of a catheter or direct injection, such as injection into damaged heart tissue. These therapeutic cells can also be coated onto implants, such as vascular grafts and stents. In addition to enabling these applications through its intellectual property, Tissue Genesis will manufacture operating room systems for the derivation of these cells from the patient's adipose tissue during a medical procedure, leveraging the company's versatile enabling platform technology, to add to the value chain for customers and their patients. Both our systems and these specific applications represent significant potential revenue streams for TGI.

Tissue Genesis was incorporated in the State of Hawaii in 2001 by founders Anton Krucky, Thomas Cannon and Bill Weismann, M.D. The company currently has 25 full time employees, including a team of five PhDs who conduct top tier research and development in bioengineering, vascular tissue engineering, musculoskeletal tissue engineering, cell therapy, and related regenerative medicine fields. In 2003, Tissue Genesis built a world class research facility in the newly developed Kaka'ako Biomedical Park, site of the University of Hawaii's new John A. Burns School of Medicine. Tissue Genesis' facilities include office space; a 4200 square-foot Class A wet lab, and a 3200 square-foot pre-manufacturing area. Tissue Genesis is located in Honolulu, Hawaii and our website address is www.tissuegenesis.com.

Opportunity

The growing health care market represents a significant opportunity for innovative medical solutions that improve treatment outcomes and lower costs. Health care costs in the U.S. alone reached an estimated \$1.8 trillion in 2004, projected to hit \$3.6 trillion by 2014. The estimated cost of treatment for people who suffer tissue loss or organ failure in the U.S. is more than \$400 billion annually, based on the cost of eight million procedures performed for patients that suffer end stage organ failure or tissue loss¹. The implications for tissue engineered and cell therapy medical solutions are significant. These products hold the promise of improved efficacy and therefore, greater long term and cost effective solutions to illness and disease.

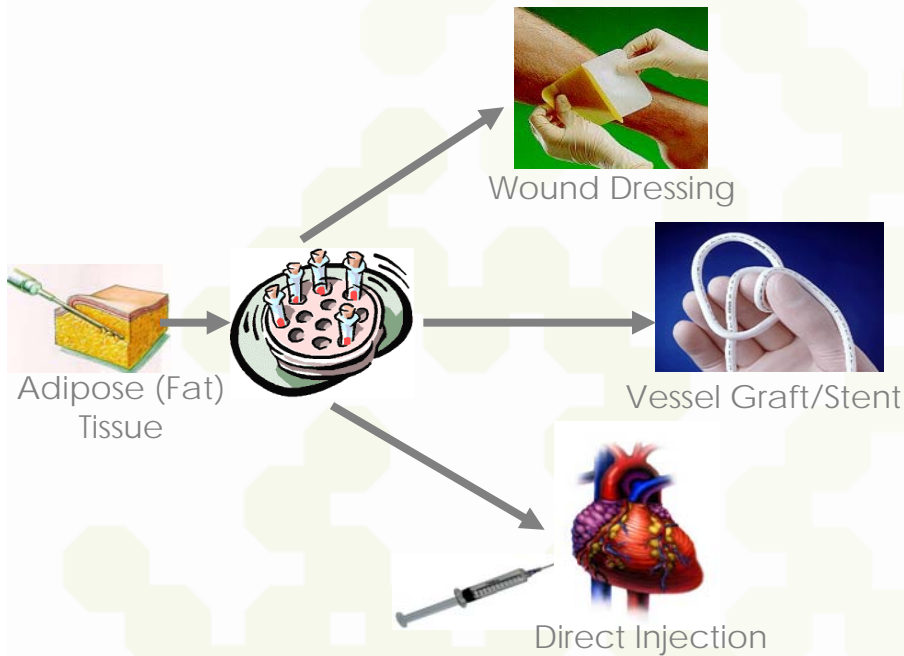
Tissue engineering and cell therapy have been in research labs for over twenty years, and now represent the potential of advanced, cost effective alternatives to current therapies for disease and injury. Biotechnology companies, universities, and research institutes are developing regenerative cell applications, such as tissue engineered implants, as innovative alternatives that may improve the health care solutions for disease and illness. Over \$450 billion has been invested in research and development. We believe there is a common requirement for low cost, flexible, sterile processes and efficient automated systems to help bring the new tissue engineered and cell based products to market.

One of the most promising areas that Tissue Genesis has been working on extensively is the development of a single step, autologous, endothelialized vascular graft. The most significant opportunity for this product is the Cardiovascular Artery Bypass Graft ("CABG") surgical market, which represents an estimated \$1.8 billion market opportunity in the U.S. alone for grafts (based on 515,000 procedures in 2002 on 306,000 patients)². Other sub-segments of the vascular graft market provide excellent opportunities with end stage renal dialysis (ESRD) patients, as well as peripheral bypass graft procedures. Each of these market sub-segments are high value opportunities and will likely provide

easier market entries for Tissue Genesis' graft. Additionally, the areas of wound care, and other damaged tissue regeneration, offer significant opportunities for the company's technologies.

Tissue Genesis Solution

Tissue Genesis is the exclusive licensee to adipose (fat) derived therapeutic cell technology developed by Dr. Stewart Williams PhD, at Thomas Jefferson University. This technology includes the pioneering method for derivation of these cells, and various applications of these cells.

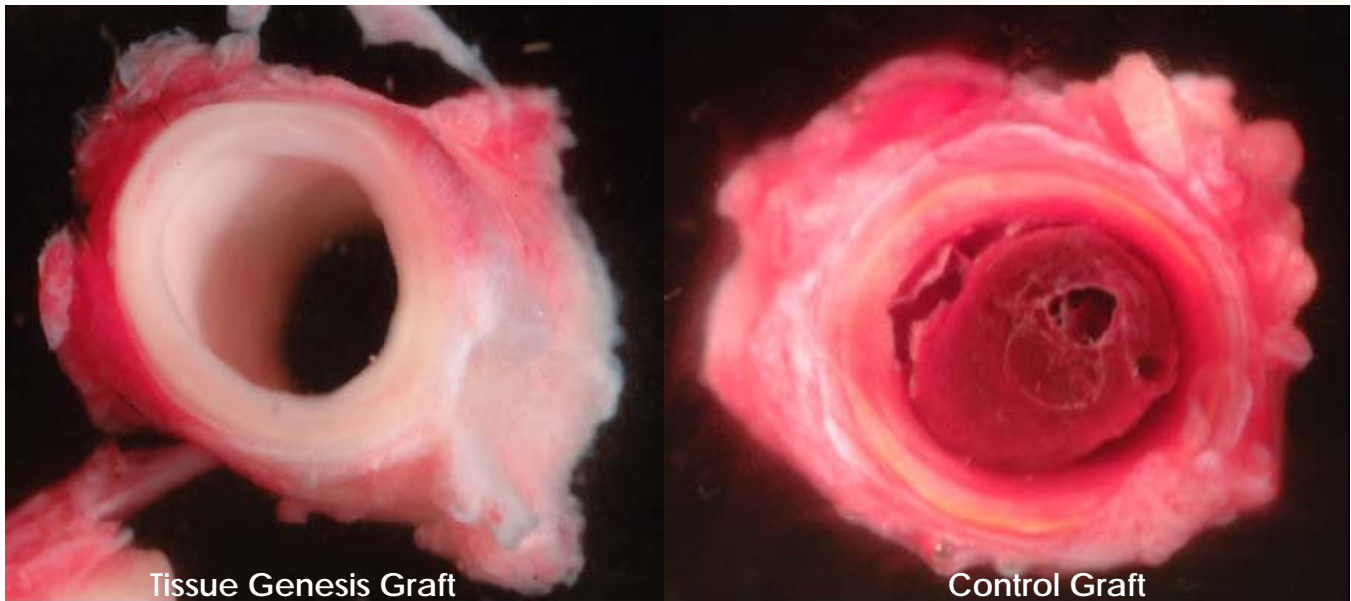


In Tissue Genesis' patented process, a small amount (about 60cc) of a patient's adipose (fat) tissue is needle-liposuctioned and processed into a pellet of therapeutic cells, including micro-vascular endothelial cells, stem cells and other regenerative cells. These cells can be delivered back to the patient in a self-dissolving wound dressing, can be coated onto a vascular graft or stent, or can be directly injected into damaged tissue, such as a damaged heart tissue.

Tissue Genesis has developed the Bio-Optimization System (BOS), a proprietary platform that accelerates cell expansion and adhesion in a small, automated, self contained, closed system. The BOS platform utilizes a proprietary cell-culture enabling technology with broad application across the cell culture and tissue engineering markets. This platform has been developed specifically for the production of products for human implantation, but its flexible design facilitates additional applications including basic research and development. The system consists of a set of six cartridges that each houses a disposable biochamber and disposable flowpath cartridge, all contained in one unit, the docking station, which is the size of a breadbox.

Leveraging off the BOS technology, the company is developing specific clinical products to address needs in certain market segments. When available, the TGI 100™ kit, TGI 100™ system, and TGI 1001™ system will be operating room compatible applications that will allow doctors to process adipose tissue, liposuctioned from a patient, deriving the therapeutic cells for immediate implantation back into the patient. The initial applications include wound dressings, endothelialized ePTFE grafts for the kidney dialysis, cardiovascular and peripheral vascular markets, and direct injection into damaged tissue.

The Tissue Genesis therapeutic cell coated grafts are targeted to compete with currently used AV fistulae or catheters in the renal dialysis market, saphenous veins used in CABG surgeries and alternatives used in peripheral bypass graft procedures. The Tissue Genesis graft is expected to offer a longer patency rate and a cost effective alternative in these markets due to the use of the patient's own endothelial cell lining of the graft. Using Tissue Genesis' proprietary cell sodding technology with the Tissue Genesis BOS line of products, a patient's own therapeutic cells will be extracted and used to create a cell-lined vessel for surgical implantation in a matter of hours.



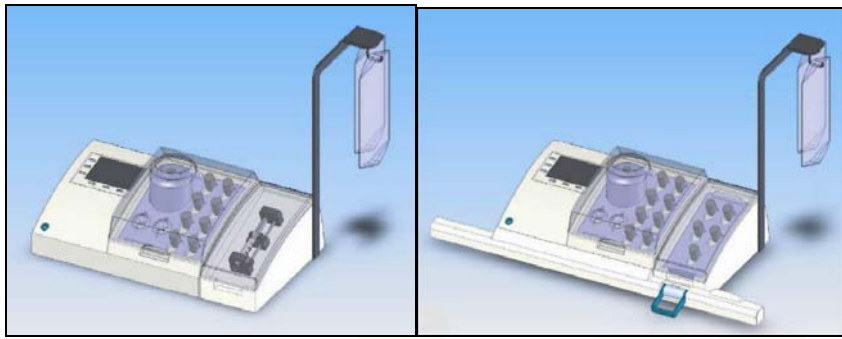
Mid-graft gross morphology of endothelialized (left) and control (right) ePTFE grafts after three month implantation in a canine carotid segmental replacement model.

Regulatory and Commercialization Plan

Over the next several years, Tissue Genesis plans to introduce various autologous adipose-derived therapeutic cell products to the market. Tissue Genesis expects to markets for wound healing, implant coating and directly delivery of therapeutic cells through products and applications, by a potential combination of sales, licensing and/or partnering. Tissue Genesis expects to commercialize its BOS product line systems over the next two years.

Tissue Genesis has completed its final prototypes of the BOS platform. The BOS platform provides an enabling platform for the company's clinical applications. The BOS platform was co-developed with a major medical products company since 2001. This co-development relationship has resulted in commercial revenues for Tissue Genesis of \$0.5 million. Development of the BOS platform has enabled the company to develop the other products in the BOS line, including the mini-BOS system, the TGI 100 kit, the TGI 1000 system, and the TGI 1001 system. Tissue Genesis plans to create ongoing revenue streams from the disposables for the TGI 1000 and TGI 1001, which will be required for each procedure performed on those systems.

- BOS Platform customizable bio-profusion platform that can be adapted for different products and applications
- mini-BOS System low-cost, single chamber bio-profusion system for research and production use
- TGI 100 Kit operating room kit to derive therapeutic cells from adipose tissue
- TGI 1000 System self-contained operating room system to derive therapeutic cells from adipose tissue
- TGI 1001 System TGI1000 system with a low pressure vascular graft sodding system



Design concepts for the TGI 1000 System for derivation of therapeutic cells for delivery in syringe, and the TGI1001 System for low pressure sodding of a vascular graft.

Tissue Genesis wound care and the TGI grafts in the peripheral position are currently in pre-clinical studies. The company anticipates that there will be separate paths for the United States Food and Drug Administration (FDA) clinical trials for wound care, peripheral vascular graft, and for the Cardiovascular Artery Bypass Graft (CABG). Based on the pre-clinical studies, sufficient data will be collected this year for application for FDA approval. TGI expects its first applications in 2006 into the FDA to be wound care followed by the peripheral vascular graft. The company anticipates obtaining 510K clearance from the FDA based on previous data and trials. Tissue Genesis estimates that approval could be obtained within two years. Tissue Genesis anticipates initial sales for the wound care, and the peripheral vascular graft in the renal dialysis markets, in late 2008 or in 2009. Successful data from the clinical studies and commercial use of the peripheral vascular graft will support exploratory clinical trials for the CABG graft. The clinical trials for the CABG market will take several years due to the higher risk and invasive nature, in addition to the fact that CABG grafts generally have a longer patency than renal dialysis alternatives. This will require longer periods of patient observation. Tissue Genesis estimates that market approval for the CABG graft may be obtained within five years of initial clinical trials.

One of the initial markets for the company's adipose-derived therapeutic cells is expected to be the wound care market. Another initial target market will likely be non-option patients in the peripheral vascular market and the CABG market. Tissue Genesis will seek an alliance with a major distributor to penetrate the highly competitive medical device market. Tissue Genesis will focus on speed, volume and broad penetration with an established industry partner rather than on developing its own sales force, which would be time consuming and costly.

Tissue Genesis has generated a pipeline of federal contracts to fund research and development, enabling the company to operate without debt. This has resulted in \$11.8 million in funding to date, with an additional \$10 million expected over the next 2 years. In addition to these amounts, Tissue Genesis has raised over \$4 million from private equity investors since 2001. Of this \$4 million, \$1 million relates to the research foundation arm of a large Blue Cross and Blue Shield Member. Through our existing funding sources, the company anticipates meeting its financial needs up to FDA clinical trials. In anticipation of human FDA trials, Tissue Genesis anticipates raising an additional \$10 million through a strategic alliance or private placement investors to be deployed in the next 12 to 30 months.

Tissue Genesis Competitive Advantage

Tissue Genesis targets products that have certain attributes that make them more cost efficient and effective than products currently being used or published. For cell culture platforms, techniques and adipose-derived therapeutic cells, we believe there is no other system on the market with as much functionality or cost efficiency which includes:

- a customizable platform that can be adapted for different products and applications
- automation that reduces manual manipulation and contamination
- efficient use of space due to compact size
- remote monitoring and system control interfaces
- injection of media and drugs automatically
- “on demand” daily samples and programmed fraction collection.

Unlike other wound care solutions, such as Apligraf™ and Dermagraft™, the company's application uses the patient's own microvascular endothelial and stem cells. Additionally, we believe that Tissue Genesis' vascular grafts are the only cell lined grafts or vessels that can be produced using the patient's own harvested cells within a matter of hours. Tissue Genesis' enabling, proprietary technique is based on patented and patent pending processes. There are several companies that have tissue generated grafts made of various materials either in development, in trials or on the market. Tissue Genesis' competitive advantage is that its graft has an extremely short development time enabling patients to receive their wound dressing or graft the same day they enter the hospital. The company anticipates that the cost of the Tissue Genesis wound care solution and graft will be competitive with the cost of current methods of providing other wound dressings and vessel replacements.

Management Team

Tissue Genesis is led by Anton C. Krucky, who has decades of experience in product development, marketing, and sales experience as the General Manager of Operations for IBM Pacific. He has since consulted to numerous corporations, invested in small and emerging start ups, and is actively involved in the emerging biotech/healthcare industry in Hawaii. Tom Cannon, co-inventor of the Bio-Optimization System, oversees operations for the company, including supervision of Tissue Genesis' science team, grants administration and technology/product development. An internationally recognized expert in vascular tissue engineering, Dr. Stuart Williams from the University of Arizona, leads Tissue Genesis' vascular product development, while Dr. Paul Kosnik, co-inventor of Tissue Genesis' proprietary technology, leads the science team and technology development. Bradley Perkins, a registered patent attorney, brings 25 years of corporate and startup, legal and management experience. The management team is rounded out with a group of experienced corporate executives, complementing a strong technology development team lead by nationally trained PhDs in the fields of tissue engineering and cell therapy. Tissue Genesis has obtained the support of key scientific players in the tissue engineering industry that include Dr. Robert Dennis from the University of North Carolina, and Co-founder Bill Wiesmann, M.D., who are active advisors to the company.

Capitalization

Since inception in 2001, Tissue Genesis has raised close to \$16 million in public and private funds, with approximately \$10 million in future government contracts in the pipeline. Approximately \$4 million has been contributed by seed investors. The last round of \$2.5 million raised in late 2004 and 2005 valued the equity of the company at approximately \$20 million post-money. The current Series B round being initiated will end with a post-money value of slightly more than \$33,000,000, with anticipated investment of \$11,337,600. Past and projected sources of funding include:

Development Stage Company

Tissue Genesis has a limited operating history, and has not yet commercialized any products and therefore, has not generated product revenues. To date, the company has focused on development of its BOS platform products and the development of autologous adipose-derived cells for use in various applications, including wound care solutions and endothelialized grafts for vascular applications. The company has been profitable in its early R & D stages due to government contract revenues. For the year ended December 31, 2004 and the four months ended April 30, 2005, Tissue Genesis' preliminary net loss was approximately \$1,092,024 and \$314,558 respectively.

References

¹ ResearchandMarkets Report Abstract on Tissue Engineering: Technologies, Markets, and Opportunities, 3rd Edition, Drug and Market Development Publishing, Dec. 2001 at www.researchandmarkets.com/reportinfo

² American Heart Association: 2005 Heart and Stroke Statistical Update, 2005.