Carmell Therapeutics Corporation

Executive Summary

Biologically-Active Medical Devices
Manufactured from Blood Plasma

April 2009

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Executive Summary

Of the 23,000 orthopaedic surgeons in the U.S., 41% specialize in sports medicine, treating injuries to connective tissues (e.g., tendons, ligaments and cartilage). Due to the low vascularity of connective tissues, however, such injuries are difficult to heal; at best, they require months of recuperation and physical therapy before a patient can return to full use of an injured joint. Healed tendons and ligaments are additionally prone to re-tear, as the scarred tissue that forms is almost always mechanically inferior. Damaged cartilage likewise does not heal well, and current surgical therapies can not reproduce native articular (hyaline) cartilage; this represents the largest and most compelling unmet need in orthopaedics, and a simple effective product would be incredibly disruptive.

Carmell has developed biologically-active plastic materials from blood plasma. These plastics are sterile, off-the-shelf, easy to handle, shape and suture, have controlled degradation rates, contain known levels of bioactivity, and exhibit mechanical properties designed to match the repaired tissue. Carmell's plastics can be simply viewed as plastic forms of ultra-concentrated plasma clots; they therefore represent the ideal biomaterials, naturally promoting tissue healing with the potential to achieve rapid healing with less scaring and better clinical outcomes.

Carmell's first product is the **Plasmix™ Surgical Patch** for rotator cuff and tendon injuries, a sterile patch manufactured from platelet-rich plasma (PRP). The surgeon can fashion the shape of the patch by cutting with either scissors or a scalpel and suture or wrap the patch over the tendon as desired. Surgical patches are used to cover the rotator cuff tendons and muscles with a resorbable scaffold to provide reinforcement of the soft tissue during healing. Carmell's patch has been designed to degrade over a 4-6 week period, slowly releasing growth factors.

Plasmix Surgical Patch

The Company is also developing a second product for bone and cartilage. Carmell's **Plasmix Cartilage Repair Plug** is a sterile, hard rod designed to degrade over 8-12 weeks with mechanical properties similar to osteochondral tissue. Plasmix plugs can be easily shaped and contoured and replace the need for harvesting autologous bone and cartilage plugs, eliminating the associated morbidity and costs.

Market & Competition Orthopaedics represents a $30B worldwide market, and Sports Medicine is the fastest growing segment of that market, experiencing 22% CAGR growth from 2000 – 2007. Target customers are orthopaedic surgeons with sports medicine practices. There are projected to be over 430,000 rotator cuff surgeries in the U.S. by 2010. Pricing the Carmell product competitively at $2,500 per patch, the U.S. Market opportunity is over $1B with product introduction in 2011. Similarly, there are over

400,000 cartilage repair procedures annually in the U.S. Offered at a competitive price point of $5,000 for a kit, the U.S. cartilage market opportunity is $2B with product introduction in late 2012.

As no product has been clinically effective, physicians have looked for other ways to improve the healing of soft tissue and bone and have begun using platelet-rich plasma (PRP) prepared in the operating room from a patient's own blood. PRP is now being extensively used clinically to accelerate healing. Being liquid, however, PRP is quickly absorbed by the body. Since PRP is autologous and manufactured in the operating room, its bioactivity is unknown, there is risk of introducing infectious microbes, the process requires dedicated trained personnel and is subject to preparation variability, and the process is time-consuming and costly. Carmell's materials are plastic, off-the-shelf, sterile versions of PRP with none of the drawbacks.

Competitive surgical patches for tendon repair include a variety of synthetic, xenograft and allograft materials, but these patch/matrix products have not performed well, leaving a significant opportunity for Carmell. This is a well defined and reimbursed category with large market players such as Zimmer, Depuy and Stryker and newcomers such as Pegasus. The competitive landscape for cartilage repair is likewise an opportunity as no product has yet been successful in encouraging healing and providing reliable outcomes. Consequently, there are a number of different approaches being investigated, including tissue engineering methods, allografts, autografts and the use of synthetic materials, all of which have significant FDA, cost and efficacy hurdles.

Intellectual Property Carmell has exclusively licensed three pending patents from Carnegie Mellon University. The Company's broad IP is based on proprietary processing methods that result in plastics containing biologically active wound healing and regenerative growth factors, and products made from such plastic materials. The Company is aggressively pursuing new U.S. and foreign patent filings. The nationally renowned law firm of Fish & Richardson has been engaged as patent counsel.

Regulatory Strategy The Company has engaged the Washington DC firm of King & Spalding as its regulatory counsel to help develop and implement an effective strategy beginning with applications that are most likely to be considered "devices" (vs. "biologics") in their primary mode of action. The Company's first product for tendon repair has numerous surgical patch predicates that have been cleared by FDA as 510(k) devices. Even though these predicate patches were not required to show clinical data as part of their FDA clearance, Carmell currently assumes that a small (40 patient) clinical study will be necessary to support its application. Once the first product has been cleared it will become a predicate for arguing that the second cartilage product is also a device, although a more rigorous PMA pathway is assumed.

Management The Company is developing a strong management team, board of directors, and scientific and clinical advisory boards led by the following individuals:

Alan West, CEO - over 20 years of experience in managing medical device start-up companies with a track record that includes both large and small companies, including Johnson & Johnson, Boston Scientific Corporation, Vision Sciences, Inc. and Assurance Medical, Inc. In his career, he has raised more than $45M through private and public offerings and holds numerous patents.

Phil Campbell, Ph.D., CSO - a Research Professor in the Institute for Complex Engineered Systems within CMU's Carnegie Institute of Technology with joint appointments in Biomedical Engineering, Material Science and Engineering, the Molecular Biosensor and Imaging Center, and the Biological Sciences Departments. He has extensive experience in cell culture and various animal models of musculoskeletal repair.

Paul Kornblith, M.D., Chairman, Board of Directors - an entrepreneur, neurosurgeon, academic, and inventor, he founded Precision Therapeutics Inc. of Pittsburgh, which has raised over $120 million in venture capital; he also serves as Western Pennsylvania representative of the Pennsylvania Biotechnology Association, as a consultant to the Pittsburgh Life Sciences Greenhouse, and as a board member or chairman of several other companies.

Patrick J. DeMeo, M.D., Chairman, Medical Advisory Board - Chairman of the Department of Orthopaedic Surgery and Director of the Division of Sports Medicine at Allegheny General Hospital, Assistant Professor of Orthopaedic Surgery at Drexel University College of Medicine and Medical Director of the Pittsburgh Pirates.

Funding/Financial Projections The Company has raised $1.3M, $775K of which is convertible debt investments from the Pittsburgh Life Sciences Greenhouse and Innovation Works, and the rest grants including a $157K SBIR Phase I. This amount will enable the Company to complete milestones to support an $8M Series A round in 2009. The Company will need another $7M Series C round in 2011 to support sales. (See pro forma P&L on next page)

Exit Strategy The Merger and Acquisition activity in orthopaedics has historically been high. During the period 2005 – 2007 there was a total of $21.2B in orthopaedic M&A activity, representing 18% of all medical device acquisitions. The Company plans to aggressively brand itself, and a VP of Marketing/Business Development will be hired upon completion of its Series A round. The Company believes that once it launches its first tendon product in 2011 it will become a likely candidate for acquisition, leveraging clinical excitement about the use of platelet-rich plasma (PRP) with additional complementary products in the pipeline. While an even earlier exit scenario might be possible once the Company has compelling clinical data, the Company is strategically positioning itself to develop and launch a number of exciting new products over the next several years, all manufactured from nature's own wound healing catalyst.

	2009	2010	2011	2012	2013
Revenues					
Tendon Sales	$0	$0	$1,688,158	$11,425,451	$28,829,511
Cartilage Sales				$294,446	$4,377,677
Foreign Sales				$1,097,302	$7,617,933
Total Revenues	$0	$0	$1,688,158	$12,817,199	$40,825,121
Royalty to CMU			$34,945	$265,316	$845,080
NET REVENUE			$1,653,213	$12,551,883	$39,980,041
COGS			$1,020,227	$2,313,061	$4,565,583
Gross Profit	$0	$0	$667,930	$10,504,138	$36,259,538
Margin			40.4%	83.7%	90.7%
Expenses					
Marketing & Sales	$84,150	$661,450	$2,014,211	$4,208,319	7,631,784
R&D	$1,024,825	$3,696,793	$3,939,262	$3,746,257	3,857,581
G&A	$591,879	$949,922	$1,947,975	$2,259,489	2,562,749
Total Expenses	$1,700,853	$5,308,164	$7,901,448	$10,214,065	$14,052,114
Pre-Tax Operating Income (Loss)	($1,700,853)	($5,308,164)	($7,233,518)	$290,073	$22,207,424

Bottom Line Carmell represents a compelling investment opportunity:

- Multi-billion dollar market opportunities not adequately addressed with existing products and approaches;
- Truly disruptive technology that leverages current clinical excitement and success with the use of platelet-rich plasma;
- Strong IP relating to biologically-active plastic materials and products;
- Relatively short pathway to commercialization and exit in a well reimbursed market;
- World-class management team and advisors.

Carmell has a unique but simple value proposition with a material that has been designed by nature to heal tissue. With the excitement about the Company's first tendon surgical patch and follow-on cartilage and bone products, significant returns are anticipated for the investor.