

MARKET COMMENTARY

Avita Medical: Pioneering the Paradigm Shift in Skin Regeneration

The Investment Team at Blackcrane Capital evaluates a revolutionary product that is transforming skin regeneration treatment.

Addressing a Critical Need

For the better part of the last 25 years, there have been no meaningful advancements in the treatment paradigm for burn victims. With close to 500,000 burn victims annually in the US, many of these patients must deal with two very different types of injuries: disfiguring external scars that limit their physical capabilities and the much deeper psychological scars that can often deprive individuals of their lifelong ambitions. A burn is not like a broken bone, in that, if it heals, the patient tends to return to adequate functionality and life goes on as usual. The scars from burns are permanent, and the road to recovery for patients is long, complicated and uncertain.

The current standard of care is skin grafting, an archaic, painful and expensive procedure. Serious burn victims often endure multiple surgeries and skin grafts, over many months. And since scar tissue is less elastic than normal tissue, skin grafts are not only cosmetically disfiguring, they can also severely impair function. As a result, the second phase of recovery for burn patients often includes reconstructive surgery, physical therapy and psychiatric counseling.

For the first time, there is a medical breakthrough that is making it possible for burn patients to regenerate their damaged skin in a much more aesthetically and functionally natural manner, all while reducing recovery times meaningfully.

Avita Medical: On a Mission to Transform Lives

Avita Medical has developed a novel approach to skin regeneration that is set to disrupt the burn industry. Their revolutionary RECELL System uses a small amount of a patient's own skin to create a suspension of disaggregated cells, which include keratinocytes, fibroblasts and melanocytes. These cells, combined with proprietary enzymes and buffer formulations, create the system's trademarked Spray-On Skin™ Cells within 30 minutes. Spray-On Skin Cells are applied at the point of care and provide a new way to treat thermal burns, trauma and chronic wounds, and skin pigmentation disorders. The RECELL System is autologous, self-contained and sterile and can treat up to 80 times the size of the donor site. RECELL's ability to stimulate healing throughout the wound bed (vs. wound edges) and to provide 80 times the treatment coverage (vs. four times for meshed skin grafts) changes the game in burn treatment. Avita Medical's proprietary technology for a rapid skin graft culture and spray-on delivery system was invented by Australian of the Year and renowned burn surgeon Dr. Fiona Wood and her scientific collaborator, Marie Stoner.



Source: Avita Medical

We believe Avita Medical has the potential to revolutionize skin regeneration treatment for multiple indications. The elegance of its science, simplicity of the procedure and superior clinical outcomes define the RECELL System. We are confident Avita’s RECELL System will become the standard of care for skin regeneration.

Investment Highlights

RECELL as the Next Standard of Care

RECELL is the first FDA Class III medical device for burn surgeons that has been approved since 1997. Skin grafts are not only archaic and painful but also extremely expensive, with the average cost for a patient with a 40% total body surface area (TBSA) burn at \$790,000 and 50 days in hospital¹. Luckily, thanks to Wood, Stoner, and the team at Avita Medical, we are seeing a genuine paradigm shift.

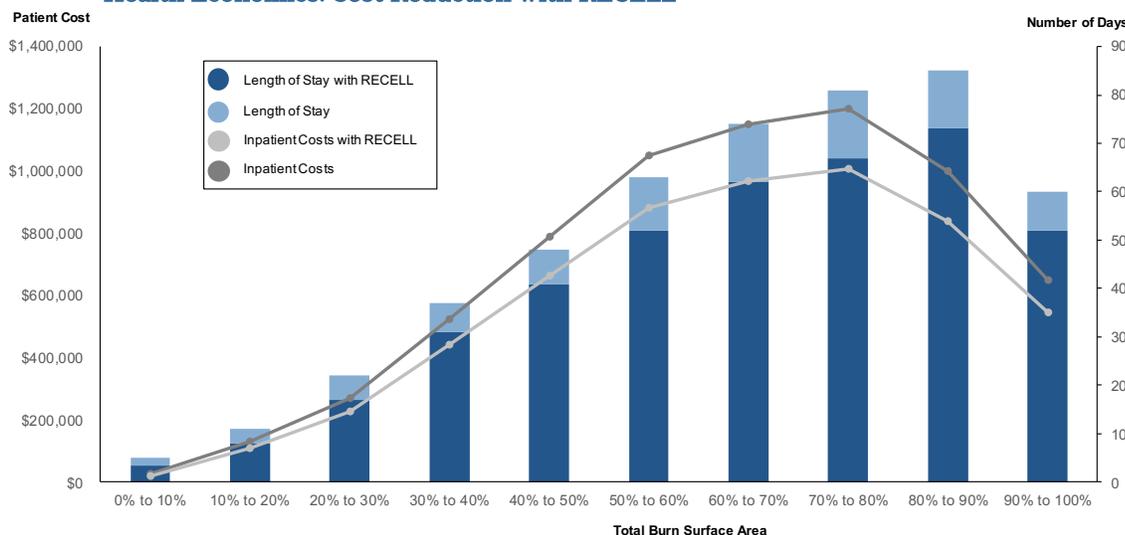
Burn Market Is Ripe for Disruption

It has been over 22 years since burn surgeons have been given a new option to treat their patients. Now, with two successful randomized, controlled clinical trials, Avita has the clinical data to fundamentally change how burns are treated. The company has effectively demonstrated the method’s superior clinical benefit, improved patient outcomes, and lower total cost of treatment.

Compelling Value Proposition

The RECELL system significantly reduces the donor skin requirement, accelerates healing both at the burn and donor site, and improves the cosmetic appearance of scarring. RECELL is autologous and self-contained, which prevents any risk of infection or contamination. Due to faster healing, fewer procedures and reduced length of hospitalization, RECELL offers burn centers a significant cost savings opportunity. Health economic models have shown cost savings of up to \$28 million or approximately 16% of the typical burn center’s total budget².

Health Economics: Cost Reduction with RECELL



Source: Foster, K., et al. 2018, 2019

¹Foster, K., et al. Cost-effectiveness of RECELL Autologous Cell Harvesting Device (ACHD) Versus STSG for Treatment of Severe Burns in the United States. Presented at ABA, April 2018, Chicago, IL.

²Foster, K., et al. Budget Impact of Autologous Cell Harvesting Device (ACHD) Use versus Standard of Care (SOC) for Treatment of Severe Burns: A Case Study. Presented at ABA, April 2019, Las Vegas, NV.

US Market Strategy

The US burn market is highly concentrated with only 134 burn centers and 300 burn surgeons, who treat approximately 42,000 patients per year. The largest and most experienced burn centers, which represent over 30% of the burn market, are already using RECELL through participation in the clinical trials and compassionate use programs. We believe there is a “follow-the-leader” approach among surgeons due to their close-knit community. Our discussion with seven key opinion leaders (KOLs) across multiple burn centers was overwhelmingly positive; all would consider RECELL in a majority of their cases. Additionally, they highlighted that they have never experienced a failure using RECELL.

Strong Patent Portfolio

We are confident Avita is well protected beyond their patent expirations. RECELL is not a small molecule drug, which face significant patent cliffs (e.g. Lipitor, Viagra, Plavix) due to a simple product replacement scenario. RECELL’s composition of matter and method patents are set to expire in 2024 and 2032, respectively, but the Company has filed for patent extensions under the rules of extension for time lost during the regulatory approval. These patent extensions could provide up to five additional years, and we believe there is a high probability of a positive ruling. A decision from the US Patent Trademark Office (USPTO) could come in the second half of 2019.

High Barriers to Entry

Avita’s deep relationships with burn centers serve as another barrier to entry for would-be competitors. Post patents, each new entrant would need to complete randomized clinical trials for FDA approval because the device manipulates and changes the skin tissue. Meanwhile, RECELL is becoming fully entrenched within burn centers, and given the low value proposition of a similar product, it will be difficult for a competitor to find a clinical trial sponsor and recruit enough patients within a practical timeframe. It takes a meaningful amount of procedures for surgeons to gain expertise with a new device, and we believe that once RECELL is trusted by burn surgeons, it will take significant medical advancement to change their practice protocol.

Achieving Information Targets: The Key Sources of Investment Upside

We believe that the RECELL system—administered to burn victims as a standalone market—has the potential to generate significant upside to Wall Street earnings expectations over the next several years. Additionally, it is highly probable that RECELL will transcend beyond burns and become a “platform” medical device across multiple geographies and indications, including trauma wounds, chronic wounds, hypopigmentation, and cell therapy. Consensus expectations seem to exclude these add-on markets. Given the multiple sources of upside provided by these completely new end markets, a bolt-on acquisition funded by a potential capital raise could meaningfully accelerate the company’s path to commercialization. If this were to occur, we would need to revise our medium-term revenue projections accordingly. Over the longer term, Avita’s rich medical pipeline in regenerative wound therapy, regenerative dermatology and cell-based gene therapy will likely support even further growth for the next 5-10 years.

Upside #1: RECELL could generate an estimated \$250 million in US burn treatment revenues.

In terms of target markets, Avita’s lowest hanging fruit would be treating burn patients that have suffered a TBSA ratio of 10% or greater, which is roughly 14,000 patients per year. This patient pool, coupled with those slightly under the 10% TBSA, would generate roughly \$200 million in annual sales based on our market model. Additionally, RECELL could be suitable for patients with burns to the face, hands, or joints, which require effective healing and the formation of elastic skin. Lastly, the company has two ongoing pediatric clinical trials (data expected H2

2020) that would provide additional upside through donor site treatments, indeterminate depth burns, and non-ABA accredited pediatric burn accounts. We estimate these would collectively add another \$50 million in revenues.

Upside #2: Among international markets, Japan could surprise meaningfully.

Avita Medical has recently created a partnership with a very strategic player in Japan, COSMOTEC/M3. We believe this relationship is underappreciated because the market is generally unaware of the extent of M3's deep ties within the Japanese healthcare industry. The company has relationships with over 90% of Japan's high-level acute care hospitals, and its web platform for medical professionals has the ability to very quickly deliver RECELL marketing to over 90% of plastic surgeons and dermatologists in the country. The company has already submitted its application to Japan's Pharmaceuticals and Medical Devices Agency (JPMDA), and we believe broad label (burn, wounds & cosmetic) approval is a strong possibility. Given its large patient population (~6K severe burns/year, ~183K chronic wounds, and ~2 million vitiligo patients) coupled with attractive reimbursement coverage, Japan is an auspicious market for the RECELL system.

In other parts of the world, Avita has already gathered momentum. The company enjoys direct funding from the China National Health and Family Planning Commission / National Health Commission to run clinical trials in China and has a collaboration with the Plastic Surgery Department of Peking Union Medical College Hospital (PUMCH) to establish a RECELL training center based in Beijing. With over 3.4 million burn patients (7x the US) and 7 million vitiligo sufferers, the Chinese market is a significant growth opportunity for Avita. Lastly, we continue to expect the European market to remain a promising medium-term opportunity.

Upside #3: Patients suffering trauma wounds, chronic wounds or hypopigmentation (vitiligo) could also benefit.

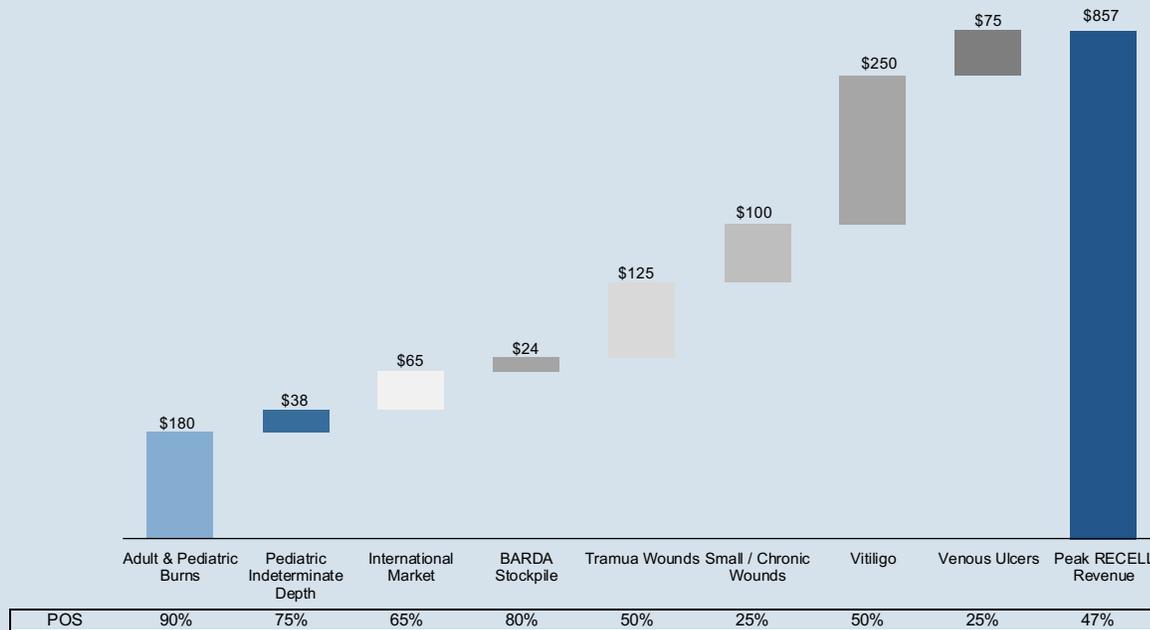
There are natural synergies for RECELL to expand into the trauma wound market. Over 50% of burn surgeons also work in trauma centers, burns centers are often co-located with trauma centers, and over one-third of all skin grafts are trauma related. International surgeons have already used RECELL in trauma wounds with positive outcomes. Overall, trauma wounds could add an additional 10,000 procedures for RECELL. Hypopigmentation also remains a very exciting opportunity based on the size of the market (over 14 million patients globally) and poor treatment alternatives. Avita has five positive RECELL & vitiligo medical publications, and private clinics in China and Australia already offer RECELL for skin repigmentation.

Upside #4: Strategic partnership with the US Government continues.

Avita has a long-term strategic relationship with the US Government. Avita was originally awarded a five-year contract, worth up to \$61.9 million, with the Biomedical Advanced Research and Development Authority (BARDA) in September 2015. Since then, the agreement has been expanded twice and has funded two multi-center clinical trials, compassionate use and continued access programs, development of the health economic model, and two pediatric clinical trials. The contract now extends to 2022 with a total potential value of \$80.1 million. The remaining amount, which we believe is close to \$30 million, could be used for the purchase of more than 5,000 RECELL devices as part of a US mass-casualty preparedness program and stockpile.

Revenue Build by Indication

Our analysis shows that Avita’s peak revenue potential is over \$800 million on a risk-adjusted basis. There are a number of indications beyond burns where RECELL has a clear benefit over today’s standard of care, a strong probability of success (POS), and a meaningful opportunity for commercial triumph. We expect the company to announce a number of updates to their development programs in the near horizon, which will help crystalize the revenue opportunity.



Sources: Blackcrane Capital estimates and Avita Medical company filings & presentations

An Attractive Entry Point and Increased Conviction

The security’s initial weakness after the third quarter FY2019 company update (on April 30, 2019) created an attractive opportunity to add to our position. There was a significant amount of confusion and misguided expectations due to a lack of research analyst coverage and investor communication. After researching and analyzing numerous precedent medical device launches that have been both successful and underwhelming, we continue to believe RECELL will track the former based on its tremendous value proposition to patients, physicians and payers. Lastly after a day-long meeting with the entire Avita management team and a visit to their manufacturing facility, we came away even more confident that RECELL has an opportunity to revolutionize skin regeneration.

Review of the First Quarter

RECELL US sales were A\$2.179 million for the quarter, a 98% increase and a great start for a revolutionary product. Based on our discussion with management, third-party studies and a review of precedent medical device launches, it takes approximately 20-26 months for a new medical device to reach full potential within a hospital. The adoption curve can be broken out into four phases: awareness & interest (2 months), institutional-level evaluation (6 months), surgeon adoption post hospital approval (6 months), and expansion to other surgeons within the hospital (6-12 months). Quite frankly, we believe it’s unprecedented that Avita was able to add 26 new burn centers within the first four months. To create a seamless process with new

burn centers, Avita allowed centers to order RECELL on an ad hoc basis, which for some burn centers resulted in multiple orders per month and provided no stocking for the quarter. As surgeons build comfort over time, we expect larger and more minimum orders, which will help build inventory and reduce shipping costs.

Site Visit at Both Headquarters and Manufacturing Facility with all Key Management

We had the opportunity to sit down with management for over six hours following their quarterly update to discuss the US commercial launch, international strategy, pipeline, BARDA and future programs. We came away from the meeting confident that the US launch is ahead of schedule and Street expectations. The team has made incredible strides in building awareness throughout the year and highlighted that over 300 healthcare professionals attended the RECELL launch workshop during the American Burn Association (ABA) Annual Meeting in early April. Clearly, we're seeing a leadership team, with the right expertise, that is focused on maximizing shareholder value.

Experienced and Laser-Focused US Commercial Team

We were completely blown away by the commercial team at Avita. Even with their tremendous experience launching multi-billion-dollar products across multiple geographies, they genuinely expressed that they have never launched a product as exciting as RECELL. There is simply nothing more rewarding than launching a product with substantial clinical benefit and patient outcomes. We were very impressed as they explained their internal systems and ability to track and analyze KPIs in real time. The team, top through bottom, gave us confidence in a strong commercial execution.

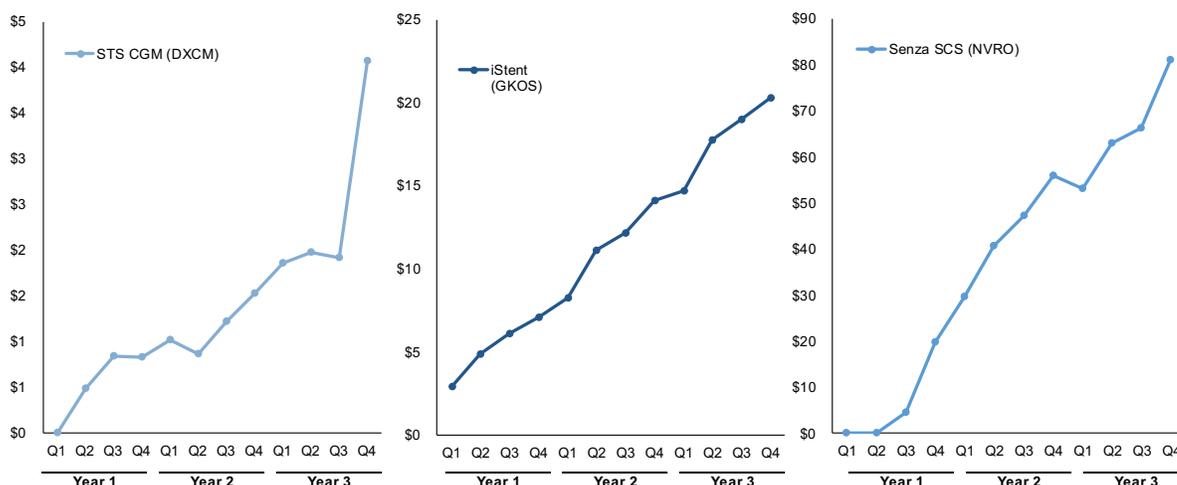
Scalable Manufacturing Facility

We had the opportunity to visit the Avita manufacturing facility in Ventura, California. Avita was able to strategically acquire the manufacturing facility from their previous contract manufacturer, Parker Hannifin Medical Systems, as they consolidated their manufacturing operations. The world-class manufacturing facility has all the capabilities of a multi-billion-dollar medical device company. The fact that the company even owns and operates their own manufacturing facility is an incredible opportunity from a quality, development and gross margin standpoint. There are multiple initiatives to improve costs and for new product development. At full utilization with additional staffing, Avita will be able to manufacture over 4,000 RECELL units per month with the opportunity to achieve 90% gross margins.

Case Study of Previous Medical Device Launches

When compared with prior successful medical device launches, we believe RECELL will track a similar ramp. Based on market research, the biggest hurdles for a new medical device in the hospital are independent product evaluations and approval through the value analysis committee (VAC). Although it will take 20-26 months for RECELL to reach full adoption, robust quarter-over-quarter growth seems likely. The fact that 26 of the 134 burn centers have already ordered product only four months into the launch is a phenomenal accomplishment.

Precedent Medical Device Launches

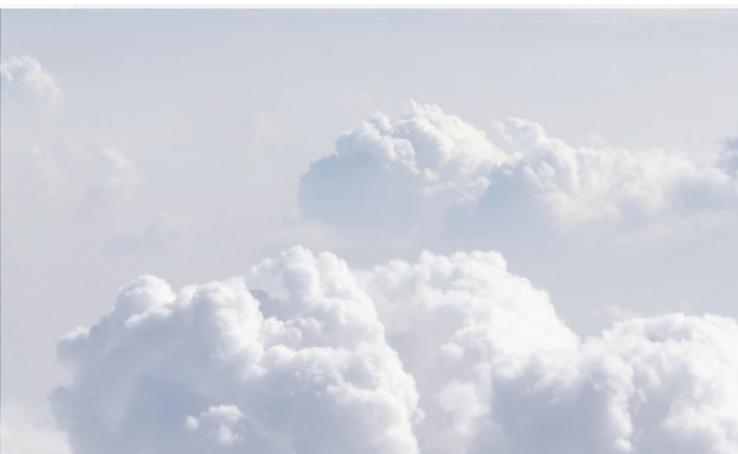


Source: Company Filings

Conclusion

We believe Avita Medical has the potential to revolutionize skin regeneration worldwide. Given the large unmet medical need and lack of new tools, we believe the burn market is ripe for disruption. RECELL’s unassailable value proposition to patients, surgeons, burn centers and payers will drive strong adoption. Additionally, the high concentration of burn centers and surgeons enables Avita to tactically build market awareness and optimize its salesforce for maximum impact. Lastly, as the Avita story continues to build and RECELL adoption takes off, we believe Street estimates will begin to converge with our projections.

Avita has a tremendous runway for future growth across burns, trauma wounds, chronic wounds, and hypopigmentation. We are confident Avita’s RECELL System will become the standard of care for skin regeneration. The elegance of its science, simplicity of the procedure and superior clinical outcomes define the RECELL System.



ABOUT BLACKCRANE

Founded in 2012, Blackcrane Capital is a boutique asset management firm focused on global and international equities, based in Bellevue, Washington. Blackcrane manages more than US\$730.3 million in AUM (as of April 30, 2019).

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