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Avita Medical: Why This Tiny Medical Device Player Is Positioned For A Turnaround

Jason Napodano, CFA

Summary

- It's been a while since we've written on Avita Medical and ReCell. Management has made significant progress over the past several months.
- The U.S. Phase 3 burn study is enrolling well, with data expected during the second half of 2016.
- Avita has re-branded the ReCell product into three distinct opportunities with ReCell for burn, ReGenerCell for chronic wounds, and ReNovaCell for pigmentation defects.
- Avita recently secured cash to fund operations for the next year, and has several catalysts on the horizon that could lead to meaningful upside for the shares.

(Editors' note: This article contains graphic images of burn victims)

By Jason Napodano, CFA

What Is ReCell?

Avita Medical's (OTCQX:AVMXY) ReCell® is an autologous cell harvesting, processing and delivery technology that enables surgeons and clinicians to treat complicated skin defects, including chronic wounds, scars, burns, and depigmentation. ReCell also aids in rejuvenation or reconstruction procedures that utilize a patient's own skin cells to facilitate the regenerative process. The ReCell kit is made up of a proprietary enzyme formulation, a processing unit that includes three chambers, a sterile enzyme soak, buffer rinse, filtering chamber, a sterile tray for mechanical disaggregation of the skin sample, and a validated set of applicators designed to overlay the wound area with a suspension of healthy cells. A picture of the ReCell unit can be seen below.
ReCell allows rapid (30 minutes) creation of Regenerative Epithelial Suspension ("RES"), comprised of activated, autologous skin cells such as keratinocytes, fibroblasts, and melanocytes, as well as signaling factors including cytokines, chaperones like hsp90, and growth factors. As noted above, the patient-specific sample is derived from healthy areas of skin, and because each cell is disaggregated (free of neighbor cells and not contact inhibited), the RES is highly proliferative, and application allows for a substantial expansion from the biopsy site. For example, each square centimeter of skin sample can produce up to one milliliter of RES, which in turn can be used to treat 80 cm² of an affected area. In April 2015, Avita Medical received CE Mark in the EU for a new ReCell device that can cover up to 1920 cm² of skin surface area with only one application, which equates to about 10% of total body surface area ("TBSA"). This is particularly advantageous in treating burn victims with an affected area between 10-50% TBSA, or in treating subjects where split-thickness skin grafting ("STSG") is not applicable due to a lack of spared healthy skin.

- **Three Versions For Three Distinct Markets**

Clinical experience with older versions of ReCell shows that the system can be successfully used to promote healing, and the formation of new skin structure in a wide range of skin defects. Situations where ReCell can be used include: (1) after a severe injury such as a burn or scald, (2) in the healing of chronic wounds such as venous leg ulcers and diabetic foot ulcers, and (3) in the treatment of acne scars, removal of areas of discoloration, and restoration of pigment in patients with vitiligo. Since these areas fall into three distinct markets, Avita Medical has rebranded the product with newer versions, each with its own name and promotional plans. We highlight these in detail below.

**ReCell:** ReCell is the original product used for burns and scalds, now with a newly expanded platform in order to treat larger, affected areas far more efficiently. As noted above, the newly approved version can cover around 10% of the total body surface area ("TBSA"), up six-fold from the previous version. This is important because in burns covering large proportions of TBSA, there is often insufficient donor skin available to complete primary closure using a conventional meshing expansion ratio, and thus multiple staged surgeries must be planned around re-harvesting of donor sites. Using a product like ReCell in complement to mesh grafting allows for a greater mesh expansion ratio without increasing the risks of poor graft take or a compromised functional or cosmetic outcome. The clinical data also suggests that use of ReCell along with meshed autograft minimizes the mesh pattern scar, allowing better blending with the surrounding skin.

That being said, we think ReCell also has fantastic utility as a stand-alone product, especially when used in pediatric patients where harvesting healthy skin for meshed grafting often proves difficult, and for the treatment of donor sites associated with grafting procedures. In pediatric patients, the 1920 cm² coverage area obtained by one application of ReCell might be enough to cover up to 50% of the patients TBSA. The rapid epithelialization of ReCell skin is another potential large benefit for patients, with data showing re-epithelialization occurs in as little as 5-7 days for burns and acute wounds. For patients whose care requires repeated re-harvesting of donor sites, earlier healing of the donor sites shortens the waiting time between staged surgeries.

In 2007, Gravante et al. published findings from "A randomized clinical trial comparing ReCell system of epidermal cells delivery versus classic skin grafting for the treatment of deep partial thickness burns" in Burns, the Journal of the International Society for Burn Injuries The trial enrolled a total of 82 patients with deep partial thickness burns, randomized to allow homogeneous groups for age, gender, type of burns, and total burn surface area (TBSA). The primary endpoints of the study were time for complete epithelialization (in both the treated area and the biopsy site), and aesthetic and functional quality of the epithelialization (color and joint contractures). Secondary endpoints were the assessment of infections, inflammations or any adverse effects of the ReCell procedure, particular medications, and post-operative pain.
Gravante et al. concluded that the ReCell system did not alter the basic surgical indications and principles of epidermal replacement in burn patients and produced similar results to skin grafting, but was less invasive in removing small quantities of skin to cover the exposed areas as the donor site was substantially smaller with the use of ReCell. The authors suggested that the characteristics of ReCell may make the product more desirable for the treatment of large burned areas, in which the available amount of non-involved skin is often not enough to cover the affected areas. Key findings from the trial are presented below:

- No significant difference between the ReCell and STSG (Spilt-Thickness Skin Graft) group regarding healing time or number of procedures needed for complete epithelialization.
- No significant difference on aesthetic quality of healing as per surgeon assessment.
- No significant difference on pigmentation and vascularization.
- No significant difference on intra-operative or post-operative adverse events.
- Significantly less post-operative pain reported by the ReCell group.

...Compassionate Use Continues...

Beyond the work done by Gravante et al. in 2007, one of the best sources of evidence for the effectiveness of ReCell has been the continued compassionate use of the product in the U.S. For example, the Arizona Burn Center presented a poster at the 2015 American Burn Association highlighting the, "Compassionate Use of ReCell and Meshed Autografts in Three Patients with Extensive Burn Injury" in three patients with deep partial thickness or full thickness burns (K Foster, MD et al.). Three patients were treated with ReCell sprayed over meshed grafts and onto donor sites.

- Patient 1 was a 32 year-old male with a 59% TBSA flame burn to face, torso, and bilateral upper extremities.
- Patient 2 was a 21 year-old female with a 53% TBSA flame burn to face, hands, and bilateral lower extremities.
- Patient 3 was an 11 year-old female with a 47% TBSA flame burn to face, bilateral upper and bilateral lower extremities.

All underwent normal burn center management protocols including early tangential excision and allografting of burn wounds. Applications were submitted to the U.S. FDA for compassionate use of the ReCell investigational device and were approved. Patient 1 received autologous suspension over 1:1 meshed grafts on his posterior torso and thigh donor sites. Patient 2 received autologous suspension over 2:1 meshed grafts to bilateral lower extremities and back donor sites. Patient 3 received autologous suspension over 2:1 meshed grafts to bilateral lower extremities and back donor sites. Areas treated using ReCell in combination with meshed autografts were > 95% re-epithelialized in 1 week, and the usual mesh pattern associated with 2:1 expanded meshed graft was markedly diminished or absent. Long term follow-
up demonstrated remarkable absence of contracture. Donor sites treated with autologous suspension were 100% healed and ready for re-harvesting one week after harvest and ReCell treatment.

Authors of the poster conclude that the use of ReCell in combination with mesh grafts helped reduce the number of grafting procedures required to achieve closure of the patient's burn injuries and yielded a result uncharacteristic of mesh grafting over full thickness injury in the limited appearance of mesh pattern scar and no observable contracture. ReCell use on donor sites also healed donor sites in one week. The authors believe, "This technology may decrease time to healing, decrease length of hospital stay, and decrease scarring."

Surgeons at the Arizona Burn Center have significant experience with a number of skin and skin substitute products, as evidenced by a presentation at the 2012 Burn Symposium (Caruso, MD) in which the center outlines the use and effectiveness of products like Xenograft (pigskin), Allograft (cadaver skin), Dermagraft®, Integra®, Apligraf®, Grafix®, StrataGraft®, cultured epithelial autografts, and ReCell®. The picture below shows the progression of the donor site wound caused by harvest of healthy skin for (a) meshed autograft vs. (b) ReCell. The presented concludes that ReCell can "get patients out of the hospital sooner" and "can use small donor sites to treat large surface area burns".
...Phase 3 U.S. Trial Underway...

On January 27, 2015, Avita Medical announced enrollment of the first patient in the company's U.S. Phase 3 clinical trial studying ReCell in the treatment of severe burns in patients requiring skin grafts (NCT02380612). The company's goal through the Phase 3 trial is to prove that ReCell, in combination with mesh grafting, results in superior outcomes for patients vs. mesh grafting alone, as we've outlined above.

In the study, each subject serves as their own control, with a portion of their injury randomly allocated to receive skin grafting (control) and a similar portion of their injury randomly allocated to receive ReCell treatment in combination with meshed skin grafting that is further expanded than the control. The Phase 3 trial is designed to enroll up to 30 patients, with a goal to have 25 patients available after follow-up. Co-primary effectiveness endpoints will compare (1) donor site to treatment area expansion ratios, and (2) incidence of complete closure will be assessed 8 weeks after treatment by personnel blinded to the treatment received. As of late May 2015, management notes that four of the planned six clinical sites are open for patient enrollment, and that approximately one-third of the target population has
been enrolled. Assuming the company keeps up with the pace, we expect Avita to be in position to offer data from the trial during the second half of calendar year 2016.

Management is planning to show that the use of ReCell® in conjunction with mesh grafting offers comparable (non-inferior) incidence of complete closure but with a superior expansion of donor skin. For patients, this means a larger burn injury can be successfully treated with a smaller donor site. Also, it is important to note that donor site pain associated with burn surgery is often a chief complaint for burn patients. Secondary endpoints will be evaluated after 24 weeks, and are hypothesized to demonstrate subject preference for the outcome of ReCell treatment vs. control, as well as superiority of the subjects' and blinded assessors' rating of scar outcomes.

Success of the Phase 3 trial will support the filing of a PMA in the U.S. by the end of 2016. We would expect the U.S. FDA to hold an Advisory Panel meeting to discuss the product during the first half of 2017. If all goes well, U.S. approval of ReCell for acute burns could potentially occur in the third quarter 2017. However, success of the U.S. Phase 3 trial would also help enhance marketing opportunities outside the U.S. where ReCell is already approved and on the market. The more data the company can present to EU regulators, the better the odds are for receiving full reimbursement for the product in all jurisdictions. Strong Phase 3 data in the U.S. would also help the company negotiate with potential commercial partners.

We remind investors that in May 2015, the company announced the issuance of a new U.S. patent for ReCell relating to the methods of making and using an epithelial cell suspension for the product. The patent provides protection for methods for producing and using a transplantable cellular suspension of living tissue suitable for grafting to a patient. The new patent adds to the robust intellectual property portfolio for the ReCell platform that includes ReCell, ReGenerCell, and ReNovaCell. Currently, pending worldwide patents and applications will expire in 2022-2034, with additional filings pending.

We present three case studies below that give us confidence in the outcome of the Phase 3 trial. These are some of the most powerful examples of how ReCell can dramatically improve the outcome for patients suffering with acute burns and scalds.

Case-Study # 1: 12-month-old child scalded by hot cup of tea (source: Avita Medical website).

Case-Study # 2: 6-year-old child with contact burn on feet (source: Avita Medical website).
Case-Study #3: U.S. Compassionate Use Pediatric patient with 3rd degree excised burn (source: Avita Medical website).

The following table provides a summary of the potential clinical and cost benefits of using ReCell to treat severe burns and scalds:

<table>
<thead>
<tr>
<th>ReCell® Feature</th>
<th>Clinical Benefit</th>
<th>Cost Benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smaller donor site required than traditional meshed skin grafting. ReCell expansion ratio is 180 cm².</td>
<td>Primary closure achieved faster, with less pain and risk of infection. Also required less nursing and follow-up at the donor site.</td>
<td>Reduced cost of hospitalization, pain medications, and nursing follow-up.</td>
</tr>
<tr>
<td>Facilitates early wound closure by supplying melanocytes destroyed by the burn or scald.</td>
<td>Improved aesthetic outcome (less scarring), which often leads to reduced psychological impact and required or elective follow-up procedures.</td>
<td>Reduces need for elective or required surgeries, skilled-nursing care, or psychological treatment.</td>
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<td>Simple intra-operative procedure that takes 30 minutes to prepare and only minutes to apply. Stable at room-temp and ready for use immediately.</td>
<td>The burn is treated earlier, with no lost time waiting for skin culturing or laboratory facilities.</td>
<td>No cost of skin culture or specialized laboratory facilities. Less time patient spends in the ICU.</td>
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Outside the U.S., ReCell is already approved and on the market. For example, the product has CE Mark in Europe and is approved in the U.K. for the treatment of skin loss, scarring and depigmentation after a burn injury. Reimbursement in
these areas remains a challenge due to lack of real-world data. However, in September 2014, the United Kingdom’s National Institute for Health and Care Excellence (NICE) provided some guidance on potential coverage for ReCell in the U.K. NICE noted that ReCell demonstrates potential to improve healing and re-pigmentation after a burn injury, but requested additional evidence before guidance recommending its use could be issued. Facilitated and funded in part by NICE, Avita is now establishing collaborations to leverage research capabilities of NICE-affiliated external assessment centers in order to obtain supplementary data.

ReGenerCell: ReGenerCell® is the company’s version of ReCell for the treatment of chronic wounds in the hospital-based setting. The concept of ReGenerCell is identical to the original ReCell product, only with smaller volume for an emphasis on conditions such as venous leg ulcers and diabetic foot ulcers (DFUs). For example, in August 2013, Avita announced the initiation of enrollment in the CTP003 trial, a multi-center, randomized European clinical trial evaluating the use and effectiveness of ReCell in the treatment of patients with chronic venous leg ulcers. CTP003 will seek to enroll 65 patients that have unhealed venous leg ulcers for a minimum of 12 months. Following a two-week observation period, patients will be randomly assigned for treatment with ReCell or the current standard of care, and will be followed for a minimum of 12 weeks post-treatment. The design for CTP003 (NCT01743053) is based on positive preliminary results achieved with the use of ReCell in the treatment of over 50 venous leg ulcer patients. Management has been working hard to speed up enrollment in this trial, and as per guidance, anticipates enrollment to be complete by the middle of 2015. Initiatives to expedite enrollment include the addition of several new clinical sites in the UK. Final results from the trial are expected in late 2015.

Several papers have been published regarding the use of ReCell to repair chronic ulcers. A paper by De Angelis et al., published in the International Wound Journal, entitled 'The use of non-cultured autologous cell suspension to repair chronic ulcers,' (February 2013) evaluated the clinical effectiveness of ReCell in 20 patients, made up of 8 men and 12 women with an average age of 70 years. Complete ulcer healing, defined as 100% re-epithelialization, was observed between 40 and 60 days in 14 patients (70%) depending on the type of ulcer and comorbidity. At day 60 post-procedure, 80% re-epithelialization was present in five patients (25%), while one patient with concomitant psoriasis had 50% re-epithelialization. The authors found no worsening of infection post treatment with ReCell.

Additionally, pain scores improved by day 7 following the ReCell procedure, and patient satisfaction was high. The authors note that function and aesthetics of the ReCell-treated patients were good, and concluded that the ReCell technique may have provided the regenerative tissue stimulation necessary for the rapid healing of chronic ulcers, including those that were previously unresponsive to more traditional methods.
Overall, the initial data are encouraging, and although limited, suggest that the ReCell system could offer a convenient, cost-effective, and potentially more efficacious treatment for venous leg ulcers than existing treatments. If results of the VLU pilot study being conducted in the U.K. are positive, management plans to file an investigational device exemption (IDE) application in the U.S. to begin a pivotal VLU study in 2017. Management is also conducting a feasibility study on the use of ReGenerCell in diabetic foot ulcers (DFUs) in the U.K., with initial results expected in the third quarter 2015.

Another paper comparing the effectiveness of split thickness skin grafting (STSG) to STSG in combination with ReGenerCell was published in the British Journal of Surgery (BJS) by Z.C. Hu, et al. of the Department of Burn Surgery, Sun Yat-sen University Hospital in Guangzhou, China in January 2015. The study was a randomized clinical trial that enrolled 88 patients with chronic wounds between March 2012 and December 2013. Patients were assigned randomly to the active treatment received a split-thickness autograft combined with ReGenerCell. Control patients received the split-thickness autograft alone. The primary outcome was the rate of complete wound closure by postoperative day 28. Analysis was by intention to treat. Patients who achieved wound closure were followed up for a minimum of 6 months to evaluate the quality of healing.

Results show that more patients achieved complete wound closure in the STSG + ReGenerCell group than in the STSG group alone (41 vs. 34 patients; P = 0.035). Complete wound closure was observed at a median of 14 ± 2 days in the STSG + ReGenerCell group vs. 20 ± 4.3 days in the control group (P = 0.001). Additionally, the STSG + ReGenerCell group has significantly fewer complications (4 vs. 11 patients; P = 0.047), and the autografted sites displayed better physical attributes and a reduced tendency for wound recurrence in the ReGenerCell group. A video of the surgery and comments by the author can been seen online.

Similar to the burn data, we can point to several real-world case studies that suggest the clinical utility of ReGenerCell in the treatment of ulcers.

Case-Study # 4: 67-year-old female with peripheral arterial disease (PAD), Type-2 diabetes mellitus, and a venous leg ulcer (VLU) on right leg for 46 weeks (source: Avita Medical website).
Case-Study # 5: 84-year-old male with controlled high blood pressure, colon cancer, and chronic venous leg insufficiency on his left ankle for over 7 years (source: Avita Medical website).

ReNovaCell: The third key area of growth for Avita Medical with the regenerative cell therapy franchise is in the areas of aesthetics and pigmentation (specifically vitiligo) with the ReGenerCell product. It is clear that restoration of pigment in hypo-pigmented skin is a complex biological process. Skin pigmentation is proportional to the number and activity of skin melanocytes. Melanocytes are specialized skin cells containing sub-cellular structures called melanosomes that express the pigment melanin. Melanin is responsible for skin color. Each melanocyte interacts through dendrites with 30-40 keratinocytes allowing for the transfer of mature melanosomes from melanocytes to the cytoplasm of keratinocytes (below). Melanocytes are extremely sensitive to stress, and if triggered, can lead to death or senescence. Direct melanocyte injury or damaged keratinocytes causing secondary melanocyte injury/death result in de-pigmentation.
Traditionally, only the surgical procedure of a melanocyte transfer was effective in restoring pigmentation to an affected area. However, Avita’s ReNovaCell, a novel autologous cell suspension, offers a simplified "off-the shelf" solution for homogenous repigmentation of depigmented skin. The theory is that the autologous cell suspension contains new melanocytes to replace absent, dead or damaged melanocytes at the transplantation site. By responding to the local milieu of transplant and the growth factors secreted by co-transplanted keratinocytes and fibroblasts, the new melanocytes can generate a homogenous pigment at their new destination.

An important indication for the use of ReGenerCell is vitiligo, a condition that causes depigmentation of sections of the skin. It occurs when melanocytes, the cells responsible for skin pigmentation, die or are no longer able to function properly. The patches are initially small, but can often enlarge and change shape over time. When skin lesions occur, they are most prominent on the face, hands, and wrists. We note that there is no true "standard-of-care" regimen for vitiligo. Treatment for vitiligo includes a number of moderately effective options. Many patients begin with vitamin B6 creams, and make-up to hide the depigmentation of the skin. However, exposing the skin to CO2 laser abrasion plus UV-light is the most common treatment for vitiligo. For instance, PhotoMedex’s XTRAC® eximer laser delivers a beam of UVB light to areas of hypo-pigmentation, and has been shown to minimize, and even eliminate vitiligo patches in some cases. The recently completed pilot study (NCT01640678) in the Netherlands compared ReCell to CO2 laser abrasion plus UVA-light.

In the U.S., there are an estimated 2 million cases of vitiligo (~0.75% prevalence), with the most common form being non-segmental vitiligo that tends to appear in symmetrical patches, sometimes over large areas of the body. Prevalence rates outside the U.S. range from between 0.5% and 1.5% (source: NIAMSD). The cause of vitiligo is unknown, but research suggests that it may arise from a combination of autoimmune, genetic, oxidative stress, neural, and/or viral
causes. Michael Jackson announced publicly in a 90-minute interview with Oprah Winfrey in February 1993 that he had been suffering with vitiligo. This was confirmed by the autopsy report following his death in 2009 (CNN, May 2013).

In May 2014, Avita announced positive results from a clinical trial in Germany assessing the use of ReCell in treating hypopigmented scars. Areas treated with ReCell (soon to be ReNovaCell) combined with medical needling showed statistically significant repigmentation, while areas treated with medical needling alone did not. The results of the study were presented by Mr. Richard Bender, a student of the study investigator, Dr. Matthias Aust, in a presentation entitled "Combination of Medical Needling and ReCell - a promising method?" at the VDAEPC (Association of German Aesthetic Plastic Surgeons). The presentation was awarded the conference’s "Best of Europe" prize, and as a result was selected to be delivered as a German keynote lecture at the European Association of Societies of Aesthetic Plastic Surgery (EASAPS) in November 2014.

In June 2014, Avita followed up the news above with additional positive data on depigmented skin lesions from a small study in the Netherlands. The study involved 10 patients that participated in a randomized, within-subject controlled pilot trial facilitated by the Netherlands Institute for Pigment Disorders. Principal Investigator of the trial, Albert Wolkerstorfer M.D., associated with both the Netherlands Institute and the University of Amsterdam, noted that the results of the study were, "A positive indication that ReCell can be used effectively in treating patients suffering from vitiligo and piebaldism disorders" (in press, Journal of the American Academy of Dermatology).

Case studies in scars / dyspigmentation are encouraging, and we highlight a few examples below:

Case-Study # 6: 27-year-old female with hypertrophic dyspigmentation on the neck (source: Dr. Fiona Wood).

Case-Study # 7: Adult female with atrophic facial scarring from acne (source: Dr. Zahida Butt).
The Market Opportunity

As we highlighted above, Avita Medical is targeting three distinct areas with ReCell, ReGenerCell, and ReNovaCell. With ReCell for the treatment of acute burns, the patient numbers may be small, with an estimated 40,000 cases of severe burns in the U.S., according to the American Burn Association in 2013, but we see the market opportunity as large. The size of the EU burn market is similar, with Brusselaers et al. concluding the market was roughly 42,000 severe burns that required hospital admission in 2010. Severe burn patients require intensive care and are prone to numerous complications, including infections. Above we noted that the new version of ReCell can treat an affected area of 1920 cm², or about 10% of TBSA for an average sized adult male. For a pediatric patient, this can approach 25% of TBSA. The pharmacoeconomic benefits of ReCell in this population are significant, with the product contributing to shorter hospital stays, lower risk of infections, less use of concomitant pain and anti-infectant medications, and faster recovery of both the affected and donor site areas.

We see ReCell as an incredible breakthrough product for the treatment of pediatric patients with severe burns. A pediatric patient with a severe burn approaching 50% TBSA may not have enough healthy skin to successfully perform traditional meshed skin grafting. For example, data from Pinderfields Hospital Burn unit (n=22) in 2011 shows that a
product like ReCell, which requires a small donor area to cover a large affected area (1:80 ratio), becomes more cost effective the larger the wound.

The U.S. VLU and DFU market is extremely large, with an estimated 10 million chronic lower limb ulcers requiring treatment each year. The European "Big 5" countries (U.K, France, Germany, Italy, and Spain) offer a similar target market. In fact, between the U.S. and EU, the market to treat chronic lower limb ulcers is an estimated $20 billion in size. A product like ReGenerCell could find niche use both alongside usual and customary care and as an adjuvant to reduce the cost of expensive skin and skin substitute products. Results of the VLU pilot study (CTP003) being conducted in the U.K. are expected late in 2015. If successful, we believe this kicks open doors to both improved reimbursement in Europe, and the opportunity to begin the IDE process in the U.S.

Finally, with ReNovaCell, Avita has the opportunity to enter the elective cash pay market in both the U.S. and EU with the treatment of conditions like acne scars, hyperpigmentation, vitiligo, and other aesthetic-based applications. In the U.S., there were an estimated 1.7 million aesthetic procedures such as dermabrasion, resurfacing, facial rejuvenation, and Botox, etc... performed in 2013 (source: ISAPS). Between the U.S. and EU, there are an estimated 600k patients with vitiligo. We think ReNovaCell has $150 million potential based on our penetration models for the product.

Importantly, between the U.S., EU, and Australia, we believe the ReCell franchise has $500 million potential. However, when factoring in China, the market opportunity doubles to over $1 billion in potential peak sales. Avita's goal is to generate peer-reviewed data in areas like the U.S. and Europe, and then use that data to secure distribution agreements and commercial partnerships to expand sales globally.
Financial Update

Avita Medical has big plans for the ReCell franchise over the next two to three years. As such, we are pleased to see the company raise $A5.04 million (~$4.0 million) in cash in March 2015 through a private placement. The company also entered into a share purchase plan with existing shareholders which raised an additional $A1.14 million (~$1.0 million). As of March 31, 2015, the company reported having $A4.36 million in cash on the books. The company is burning an average of $A1.7 million in cash per quarter, so we believe the current cash balance is enough to fund operations into 2016. We note that in February 2015, the company announced its intention to seek an uplisting to the NASDAQ or NYSE at some point in 2015. We believe this will further facilitate the company raising additional capital and funding the ongoing pilot and registration programs with ReCell.

In February 2015, the company reported financial results for the six-month period ending December 31, 2014. Total ReCell sales were up 29% in the half-year period ending December 31, 2014 vs. the half-year period ending December 31, 2013. For the three months ending December 31, 2014, the company's fiscal second quarter, ReCell sales were up 32% year-over-year, a 17% sequential increase from the fiscal first quarter numbers. Net loss for the six-months ending December 31, 2014 totaled $3.3 million, or $0.01 per ADR. On April 29, 2015, the company reported financial results for the fiscal third quarter ending March 31, 2015. Total sales were up 8% in the quarter year-over-year. Strong results came from the U.K., where ReCell sales grew by 101% from the fiscal third quarter last year. Management has been working to reduce operating expenses as well in fiscal 2015. For example, total operating expenses were down 13% from the same period last year, and dropped 5% sequentially from the fiscal second quarter ending December 31, 2014.

Additionally, in April 2015, Avita Medical announced that Mr. Adam Kelliher has been appointed Chief Executive Officer (CEO). Mr. Kelliher has a strong marketing background, and a track record of creating and building life science companies. He previously founded Equateq Limited (2006), a cGMP-certified manufacturer providing super-pure fatty acids for the nutritional, pharmaceutical and research sectors, which was sold to BASF in 2012. He also started Equazen Limited (2000), a leading omega-3 and omega-6 supplement company with lead product, eye q™ for lipid deficiencies linked to learning conditions, and at sale, was marketed in 16 countries. Equazen was sold to Galencia of Switzerland in December 2007. Mr. Kelliher received a Master of Arts from the University of Auckland, and is a graduate of the Entrepreneurial Development Program at the Massachusetts Institute of Technology, Sloan School of Management. Tim Rooney, who has been serving as Interim Chief Executive Officer, will resume his role as the company's Chief Financial Officer and Chief Operating Officer.
Conclusion

The clinical, case-study, and compassionate use data shows that ReCell works. It is both highly effective from a clinical outcome standpoint, with data supporting claims that the product aids in accelerating complete wound closure and reducing complications, as well as offering strong pharmacoeconomic benefit by getting patients out of the hospital faster and reducing the size of the donor-site wound. For pediatric patients, we see ReCell as a breakthrough product. There are approximately 120,000 emergency room visits each year in the U.S. for pediatric patients due to a severe burn (source: Arizona Children's Center). Roughly 15,000 of these will require an overnight hospital stay, and sadly, almost 600 children die annually in the U.S from fire and burn related injuries. The U.S. Phase 3 trial is currently enrolling patients, with initial data expected in the fourth quarter 2016.

Beyond the burn market, Avita is conducting a randomized controlled pilot study in the U.K. in patients with chronic venous leg ulcers. Data from this study is expected late 2015. A separate pilot study in diabetic foot ulcers is also being conducted in Europe. Management’s goal is to expand the label for ReGenerCell in Australia, gain reimbursement in Europe, and form commercial and distribution partnerships to facilitate the rollout of the product in 2016 and 2017. We see a tremendous opportunity for the product in China as well, and believe the company will make a greater push to penetrate the Chinese market. The paper comparing the effectiveness of STSG to STSG in combination with ReGenerCell published in the British Journal of Surgery (BJS) by Z.C. Hu, et al. of the Department of Burn Surgery, Sun Yat-sen University Hospital in Guangzhou, China in January 2015 should allow for greater acceptance and penetration in China in the coming months. Finally, recent data out of Germany and The Netherlands should help support label expansion and the formation of commercial partnerships for ReNovaCell in Europe in 2016 and beyond.

We are pleased to see Avita Medical raise $A6.28 million in cash in March 2015. We believe the company now has enough cash to fund operations into 2016, with the opportunity to sign commercial partnerships in Europe or sell the Austrian respiratory franchise as important events that could bring in non-dilutive funds later in the year. We are also pleased to see the company bring in new senior management. New CEO, Adam Kelliher, wrote a letter to shareholders, in late May 2015 that outlines the company's future strategic direction and highlights much of the recent progress, including what looks to be strong interest in the ReCell product from the U.S. Military. For example, both CEO Kelliher and COO, Tim Rooney, visited Washington, DC between April 28th and 30th to meet representatives from the U.S. Department of Defense’s Clinical and Rehabilitative Medicine Research Program (CRMRP), the US Army Medical Research and Material Command (USAMRMC) and the Armed Forces Institute of Regenerative Medicine (AFIRM). The company also met with the US Senate Veterans Affairs Committee to discuss possible treatments for veterans with both chronic and acute wounds, and management visited the leading military hospital, the Walter Reed National Military Medical Center (Bethesda). Here, management spoke in detail with surgeons who successfully treated a U.S. wounded warrior with ReCell under an FDA compassionate use protocol. Potential funding under AFIRM would be a high profile event and enormously positive for Avita Medical.

Avita Medical currently trades with a market capitalization of only $25 million (USD), with institutional ownership at roughly 50%. We believe the valuation is insanely low for a company that has a potential breakthrough product currently approved in Europe, in Phase 3 in the U.S., and significant interest from both burn centers and now the U.S. Military for compassionate use. As noted above, the clinical evidence shows ReCell works. We think the U.S. Phase 3 data in 2016 will prove that to the FDA and ReCell should be on the market in the U.S. for the treatment of severe burns in late 2017. The opportunity in the U.S. burn market is easily $100+ million in size. However, with the company’s new strategy of rebranding the product into three distinct opportunities with ReCell, ReGenerCell, and ReNovaCell, we think total peak sales opportunity for Avita is over $1 billion. We have developed a detailed "NPV" model for each product line, forecasting global sales at Avita to reach $100 million by 2020. Our model pegs fair-value today at $3.00 per ADR, representing 240% upside.