

# Derma Sciences

## Complete wound care

Using cash generated from the slow-growing but stable traditional wound care business unit, Derma Sciences was able to invest in its advanced wound care unit, which has seen an annual growth rate of 40-55%. The company has also started a Phase III trial of DSC127, a drug developed for diabetic foot ulcers, which could generate peak sales of \$400m+, and is the largest value driver for the stock. We think Derma Sciences' shares are undervalued based on its revenue growth perspectives and the risk potential of DSC127.

| Year end | Revenue (\$m) | PBT* (\$m) | EPS* (\$) | DPS (\$) | P/E (x) | Yield (%) |
|----------|---------------|------------|-----------|----------|---------|-----------|
| 12/11    | 62.6          | (2.5)      | (0.32)    | 0.0      | N/A     | N/A       |
| 12/12    | 72.6          | (12.2)     | (0.78)    | 0.0      | N/A     | N/A       |
| 12/13e   | 82.2          | (24.5)     | (1.44)    | 0.0      | N/A     | N/A       |
| 12/14e   | 95.3          | (26.1)     | (1.48)    | 0.0      | N/A     | N/A       |

Note: \*PBT and EPS are normalised, excluding intangible amortisation, exceptional items and share-based payments.

### Traditional wound care (TWC) provides cash

Derma Sciences' TWC business unit has been profitable since 2007 and has generated operating profit of c \$24m in aggregate from 2010-12. Split between the company's own brands and private labels for several major clients, Derma expects to maintain 0-2% top-line growth while improving operating margin, and continue to generate cash to be invested in the fast-growing advanced wound care (AWC) unit.

### Advanced wound care (AWC) provides robust growth

Two major brands, MEDIHONEY and TCC-EZ, out of the six brands that comprised the AWC unit, have seen phenomenal growth in that last few years. They are expected to grow in the 30-35% range in the coming years, to bring the total revenue from AWC to \$129m by 2018 from \$24.8m in 2012. Both MEDIHONEY and TCC-EZ have unique features that could, in our opinion, capture greater market share with the company's expanded sales force both in the US and internationally.

### DSC127 provides the greatest potential

DSC127, a peptide with a unique wound healing mechanism with encouraging pre-clinical and clinical efficacy data, is being tested in two well-designed Phase III trials for diabetes foot ulcers (DFUs), one of three major types of chronic wounds. Assuming the drug meets the Phase III primary end point when data is available in H115, it should gain approval and could reach potential sales as high as \$412m globally.

### Valuation: Undervalued at present

We value the company at \$357.3m with a DCF model that measures TWC, AWC, DSC127 and cash, separately. The firm value translates to \$20.7 per basic share (\$15.7 per diluted), which is significantly higher than the current market value.

Initiation of coverage

Pharma & biotech

19 September 2013

**Price** **US\$13.5**  
**Market cap** **US\$232m**

|                           |        |
|---------------------------|--------|
| Net cash at 30 June (\$m) | 37.94  |
| Shares in issue           | 17.2m  |
| Free float                | 86%    |
| Code                      | DSCI   |
| Primary exchange          | NASDAQ |
| Secondary exchange        | None   |

#### Share price performance



|                  |           |          |      |
|------------------|-----------|----------|------|
| %                | 1m        | 3m       | 12m  |
| Abs              | 0.1       | 0.1      | 31.1 |
| Rel (local)      | (4.0)     | (4.2)    | 10.6 |
| 52-week high/low | US\$15.00 | US\$9.32 |      |

#### Business description

Derma Sciences is a specialty medical device/pharmaceutical company. It focuses on developing and commercialising traditional and novel advanced wound care products, including MEDIHONEY and TCC-EZ, among other brands, and DSC127, a novel pharmaceutical agent for wound healing. It is headquartered in Princeton, New Jersey, US.

#### Next events

|                                   |      |
|-----------------------------------|------|
| MEDIHONEY update                  | Q413 |
| TCC-EZ update                     | Q413 |
| End of DSC127 Phase III enrolment | YE14 |
| DSC 127 Phase III top line data   | H115 |

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## Investment summary

### Company description: Complete wound healing

Derma Sciences operates in three segments of the wound care business: traditional wound care (TWC), advanced wound care (AWC) and pharmaceutical wound care (PWC). The slow-growing, but cash positive TWC unit provides the company with investment capital for the fast-growing AWC unit, which has seen a five-year (2007-12) CAGR of 53.2% and is expected to continue to grow in the 30% to 40% range in the next few years. Derma Sciences' most important future value is in DSC127, a wound healing therapy currently in two Phase III trials for diabetic foot ulcer (DFU).

**Exhibit 1: Derma Sciences' main products**

| Business segment                 | Product(s)                                         | 2012 sales (\$m) | Est. 2013 sales (\$m) | Growth rate | Note                  |
|----------------------------------|----------------------------------------------------|------------------|-----------------------|-------------|-----------------------|
| Traditional wound care (TWC)     | Many                                               | 47.8             | 47.3                  | 0-2%        |                       |
| Advanced wound care (AWC)        | MEDIHONEY, TCC-EZ, XTRASORB, ALGICELL and BIOGUARD | 24.8             | 34.9                  | 30-40%      |                       |
| Pharmaceuticals wound care (PWC) | DSC127                                             | N/A              | N/A                   | N/A         | Potential 2016 launch |

Source: Derma Sciences and Edison Investment Research

### Sensitivities: Watch for DSC127 Phase III outcome

The biggest value driver of the company, hence the most sensitive aspect of Derma Sciences' investment thesis, is DSC127. With a unique mechanism of action and encouraging clinical activities in a Phase II trial, the drug has an above-average probability of success in a well-designed Phase III programme for DFU. But a negative outcome of the Phase III programme would have a significant impact on the stock. Our investment thesis is also based on growth prospects of its advanced wound care business unit, in particularly MEDIHONEY and TCC-EZ. These two offer unique advantages over many other wound care products in the market place, but the ultimate success will depend on how effective Derma Sciences' marketing and sales efforts are.

### Valuation: Undervalued currently

We value Derma Sciences using a discounted cash flow model. We value the three segments, AWC, TWC and DSC127, separately because each segment has its own operating profit margin and growth trajectory. We forecast sales to 2023 and apply a terminal value (1.5x for AWC, 0x for TWC and 3x for DSC127) based on patent lives of major products in each segment, a universal 12.5% discount rate and a 35% tax rate to arrive at an after tax total present value (PV) for each segment, of \$130.1m, \$36.7m and \$165.5m, respectively, for a total of \$332.3m. Our probability of success of DSC127 in the Phase III is 65%. Adding cash of \$25m estimated at the end of 2013, we arrive at a total firm value of \$357.3m, or \$20.7 per basic share.

### Financials: Cash sufficient for now

Derma Sciences reported net sales for Q213 of \$18.1m, vs \$17.6m for Q212, an increase of 3%. AWC net sales were \$7.9m, an increase of 36% over Q212, while sales of TWC were \$10.2m, a decrease of 13% from Q212, affected by lower sales in Canada and partially offset by higher sales of private-label products. The loss for the quarter was \$7.3m, or \$0.43 per share, vs \$2.8m, or \$0.23 per share in Q212.

As of 30 June 2013, Derma Sciences had cash, cash equivalents and investments of \$39.4m. We believe the company has enough cash to finish the Phase III programme of DSC127 in H115, but needs additional funds to get DSC127 through regulatory approvals and launched in major markets, including North America and major EU countries possibly in 2016.

## Outlook: DSC127 moving towards end of Phase III

Derma Sciences operates in three segments of the wound care business, traditional wound care (TWC), advanced wound care (AWC) and pharmaceutical wound care (PWC). The slow-growing, but cash positive TWC unit provides the company with investment capital for the fast-growing AWC unit, which has seen a five-year (2007-12) CAGR of 53.2% and is expected to continue to grow in the 30% to 40% range in the next few years. Derma Sciences' most important future value is in DSC127, a wound healing therapy currently in two Phase III trials for diabetic foot ulcer (DFU). Assuming the Phase III is positive, the prospect of which we believe is better than Phase III trials of other tested DFU drugs because of DSC127's positive Phase II data, we estimate the drug could be on the market in 2016 and reach potential peak sales of \$412m globally. We think Derma Sciences' shares are undervalued based on its revenue growth prospects and the potential of DSC127.

## The wound care market

Wounds come in various forms and prevalence (Exhibit 2). Chronic wounds, defined as those that are not closing in 30 days or not responding to initial treatments, are results of various diseases and medical conditions, including cancer, diabetes, poor circulation, surgery and burns. Ischemia (lack of oxygen), bacterial infection and colonisation, increase of proteolytic enzymes and inflammation are common underlying pathophysiological culprits for non-healing wounds. Three types, vascular ulcers, diabetic foot ulcers and pressure ulcers, comprise the vast majority of chronic wounds (Exhibit 2).

**Exhibit 2: US and worldwide wound prevalence**

| Types of wound                  | US prevalence (m) | Worldwide prevalence (m) | Healing time (days) | Estimated CAGR (2007-16) |
|---------------------------------|-------------------|--------------------------|---------------------|--------------------------|
| Surgical wounds                 | 67                | 110.3                    | 14                  | 3.6%                     |
| Traumatic wounds                | N/A               | 1.6                      | 28                  | 1.7%                     |
| Lacerations                     | N/A               | 20.4                     | 14                  | 1.2%                     |
| Burn wounds (outpatient)        | 1.3               | 3.4                      | 21                  | 1.0%                     |
| Burn wounds (medically treated) | N/A               | 6.5                      | 21                  | 1.3%                     |
| Burn wounds (hospitalized)      | N/A               | 0.2                      | 50                  | 1.1%                     |
| Pressure ulcers                 | 2.5               | 8.5                      | N/A                 | 6.9%                     |
| Venous ulcers                   | 2.5               | 12.5                     | N/A                 | 6.7%                     |
| Diabetic ulcers                 | 1.5               | 13.5                     | 70-150              | 9.3%                     |
| Amputations                     | 0.086             | 0.2                      | N/A                 | 1.2%                     |
| Carcinomas                      | N/A               | 0.6                      | 14                  | 3.0%                     |
| Melanoma                        | N/A               | 0.1                      | 14                  | 3.2%                     |
| Complicated skin cancer         | N/A               | 0.1                      | 28                  | 3.1%                     |

Source: MedMarket Diligence, LLC

Vascular ulcers are the result of chronic venous insufficiency (venous leg ulcers, 80-95%), or arterial insufficiency (arterial leg ulcers, 5-10%). Between 10% and 35% of the US population has some type of venous diseases, and lower extremity skin ulcers are reported in 1% to 22% of individuals older than 60. Venous or arterial hypertension causes oedema, which leads to tissue destruction and ulcer formation.

Diabetic foot ulcer (DFU) is one of the most common and severe consequences of diabetes, occurring in about 1.5 million of the nearly 21 million people in the US with diabetes. It is estimated that about 15-25%, or 3.15 to 5.25 million, will develop a DFU in their lifetime. Treatment of DFU costs the US healthcare system about \$100bn, with each individual's cost up to \$40,000 in the first two years after diagnosis. DFU is also a major cause of amputation, which has a 45% five-year mortality rate, equal to several types of advanced cancer. DFUs are the results of atherosclerosis that impedes blood flow to the extremities and peripheral neuropathy that prevents the sensation of

discomfort associated with mechanical stress on or injury to the feet. Neuropathy is present in 60% to 70% of patients with DFUs, with 15% to 20% of patients having a combination of neuropathy and vascular problems.

Pressure ulcers, also called “bed sores,” are defined as lesions caused by unrelieved pressure or shear resulting in damage of underlying tissue. Prolonged pressure causes ischemia, which leads to tissue necrosis. Patients who are chair bound or bedridden are at increased risk of developing pressure ulcers. It is estimated that there are 2.5m cases of pressure ulcers in the US annually, occurring in up to 17% and 24% of home and long-term care patients, respectively.

Traditional wound healing protocols include risk factor modification, offloading, debridement and a protective dressing. Risk factor modification includes elimination or minimisation of causes for wounds, such as ischemia. Offloading is a method of reducing pressure to the wound. Debridement can be achieved with simple surgical tools or chemicals, whereas protective dressings are mainly for protection against infection and maintenance of moisture. Advanced care for chronic wounds includes devices or products that could speed up healing compared to usual care, such as special purpose dressings, skin grafts, drugs or biologics and negative pressure therapy.

The estimated \$6bn wound care business annually in the US covers products (Exhibit 3) for traditional care and advanced care, namely dressings, skin substitutes, drugs/biologics and negative pressure wound therapy. Conventional wound dressings are products in the forms of cotton gauze, foam, gel, films that either absorb fluids or maintain moisture, or do both around the wounds. Some dressings may contain anti-bacterial substances and therefore would reduce and prevent bacterial infection. Wound dressing products are largely undifferentiated, with thousands of brands on the market. Skin substitutes, on the other hand, are either a biomaterial (synthetic) or cellular (extensively or minimally manipulated human or animal tissues) matrix that, when applied to a wound, acts like an autologous skin graft and provides the physiological and mechanical functions of normal skin. Drugs/biologics are therapeutics that have the potential to treat wounds, such as growth factor (Regranex gel, becaplermin, J&J). Finally negative pressure wound therapy is a device that uses a vacuum device to drain fluid from the wound to facilitate healing.

Sales of wound care products are growing at a rate of c 5% a year, largely driven by an ageing population, increasing incidences of obesity and diabetes, increasing surgical site infections caused by resistant bacterial strains and the policy of accountable care, which requires hospitals and care givers to achieve better care with less costs. Among the four categories, wound dressings represents the largest segment of the pie, but with a modest growth rate (2-3%). Drugs/biologics, on the other hand, is the smallest, but has the greatest potential for growth because of the effectiveness these products typically have.

**Exhibit 3: Wound care products and estimated sales (US)**

| Types                                                 | Estimated sales (\$bn) |
|-------------------------------------------------------|------------------------|
| 510K/Class I & II dressings                           | 3                      |
| Skin substitutes (510K/PMA/361 HCT/PS)                | 1.5                    |
| Drugs/Biologics                                       | 1                      |
| Negative pressure wound therapy                       | 0.5                    |
| Source: Derma Sciences and Edison Investment Research |                        |

Derma Sciences' wound care products span three segments, including traditional wound care (TWC), comprised mainly of undifferentiated basic wound care products and a private label business, advanced wound care (AWC), comprised of five major brands (Exhibit 1), and pharmaceutical wound care, comprised of DCS127, a drug that is still under development.

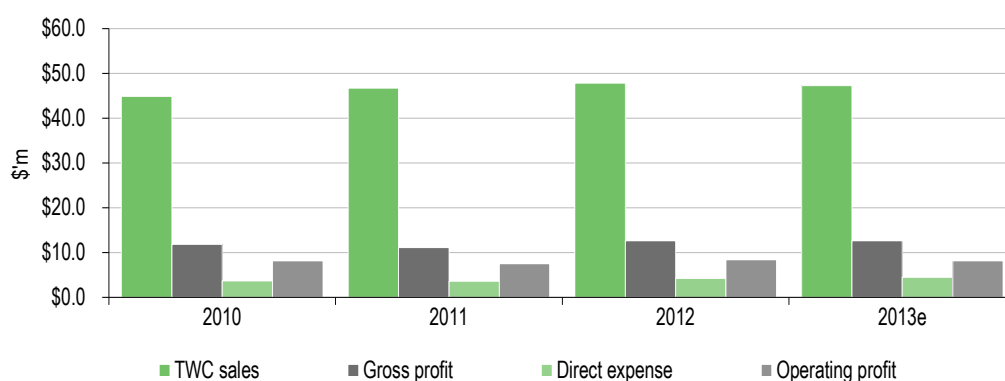
## Traditional wound care: Slow but stable

Derma Sciences' TWC line consists of gauze sponges and bandages, non-adherent impregnated dressings, retention devices, paste bandages and other compression devices. It also manufactures

and markets a broad line of adhesive bandages and related first aid products for the medical, industrial, private label and retail markets.

Derma Sciences' historical growth of the TWC segment has five-year CAGR of 8.9% from 2007 to 2012, but the growth rate in 2012 has decreased to 2.4%. The segment has been profitable since 2007 and is expected to generate in aggregate c \$32.m of operating cash to the company from 2010-13 (Exhibit 4). Derma Sciences' goal is to maintain a 0-2% growth in this segment, with an emphasis on the private-label business, which provides a higher operating margin. We estimate this segment will continue to be profitable and serve as the source of cash for investment in the other two segments.

**Exhibit 4: Derma Sciences' TWC performance**



Source: Derma Sciences and Edison Investment Research

## Advanced wound care: Robust growth expected

Derma Sciences' advanced wound care products include MEDIHONEY, TCC-EZ, XTRASORB, ALGICELL and BIOGUARD, with the first three contributing the bulk of sales. Total revenue was \$16m in 2011, and \$24.8m in 2012. Revenue in 2013 is expected to be \$34.7m, largely driven by growth of MEDIHONEY and the full impact of TCC-EZ after the product was acquired in April 2012. Derma Sciences' advanced wound care revenue has grown from \$2.9m in 2007 to \$24.9 in 2012, a CAGR of 53.2%, mainly driven by MEDIHONEY.

### MEDIHONEY: Growth in the range of 30% to 35% expected

MEDIHONEY is a line of novel, patented dressings, made up of a high percentage of active Leptospermum honey (also called manuka honey). It comes as a patch (MEDIHONEY HCS, for dry to moderately exuding superficial to partial thickness wounds), a gel (for partial to full thickness wounds) and a paste (for dry to lightly exuding wounds, or for hard to dress areas). Derma Sciences started to sell this product in 2007 after the FDA approved the product for wound healing. In February 2010 Derma Sciences licensed exclusive worldwide rights from Comvita in New Zealand for the medical use of manuka honey, including professional wound and skin cares.

MEDIHONEY's main ingredient, manuka honey, is made from the tree species Leptospermum, found in New Zealand and Australia. Honey from these trees has a particularly strong anti-bacterial effect, even in a 10% dilution. Derma Sciences gets the product from the exclusive supplier Comvita, which controls about 75% of the world's manuka honey supply and sells the product in Australia, New Zealand and Europe. Recently, Derma Sciences acquired a 7.3% stake in Comvita for \$7m, which gives Derma Sciences a board seat and provides the company with supply surety for the growing MEDIHONEY sales expected.

While honey has been used to heal wounds since the time of the ancient Egyptians and Greeks, MEDIHONEY is one of the first medically certified honeys for professional wound care, after

medical benefit, particularly the anti-inflammatory anti-bacterial activity of manuka honey, was demonstrated in recent years in various clinical trials.

It is generally believed that natural honey produces hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>), which inhibits bacterial growth. Unprocessed natural honey varies greatly in its anti-bacterial potency because of various concentrations of hydrogen peroxide. MEDIHONEY, however, does not rely on hydrogen peroxide because its anti-bacterial activity remains even when the hydrogen peroxide activity is blocked. Recent research<sup>1</sup> has demonstrated that MEDIHONEY's anti-bacterial activity may be due to its low pH (bacteria typically grow at pH>7) and high sugar content, which draws moisture out of the environment, preventing the growth of microbes. MEDIHONEY was shown to have an inhibitory effect on around 60 species of bacteria, including some of the hard-to-treat human pathogens, such as methicillin-resistant *Staphylococcus aureus* (MRSA), and *helicobacter pylori*. Because MEDIHONEY exerts its anti-bacterial activities differently from most direct anti-bacterial agents, utilisation of MEDIHONEY is particularly attractive among today's medical professionals because of the increasing emergence of drug-resistant bacteria strains.

In addition to its antibacterial properties, MEDIHONEY hastens the healing of wounds through its potential anti-inflammatory effects.<sup>2</sup> The potential anti-inflammatory action of honey reduces oedema and the amount of exudate by down-regulating the inflammatory process. It could also reduce pain, as the pain in wounds results from the nerve endings being sensitised by prostaglandins produced in the process of inflammation, as well from the pressure on tissues resulting from oedema.

MEDIHONEY has been used for wounds across a wide spectrum (Arne Simon et al. eCAM 2009, 6:165-173), including foot ulcers, cancer wounds, wounds in severely immunocompromised patients, catheter entry site wounds, oral mucositis, herpetic lesions and burns. MEDIHONEY demonstrated comparable or better wound healing efficacy than control in three<sup>3</sup> randomised controlled trials (RCTs) in a variety of wounds, including venous ulcer, unidentified, and catheter entry site wounds. In Australia, New Zealand and Europe, the product has been sold with the claim of anti-infection, whereas in the US the product is indicated for wound healing, including diabetic foot ulcers, venous stasis leg ulcers, arterial leg ulcers, leg ulcers of mixed etiology, pressure ulcers (I-IV), first and second degree burns, donor sites, traumatic and surgical wounds.

Derma Sciences owns or has licensed the use of several patents on MEDIHONEY, with one (No. 11/106,473) that covers the therapeutic composition comprising honey or a honey derivative (the key claim of the patent is the high concentration of honey in a dressing) and a second that covers the application of honey to an alginate fibre sheet. These two patents expire in the US in 2022 and 2020, respectively.

Derma Sciences started to sell MEDIHONEY in the US in 2007, targeting the prescription market initially, with a five-year supply agreement with Comvita. In 2010, the company licensed the worldwide rights from Comvita of MEDIHONEY's medical use. As a return, Derma Sciences purchased manuka honey from Comvita and also pays the company undisclosed sales milestones and royalties (nominal within our forecasted sales range). Sales of the product have been increasing at an annual rate of ~50%, increasing to \$11m in 2012 from approximately c \$2m in 2008. Over the years, the company has introduced a series of product types, such as gel, paste and various patches. Most recently, the company also started to offer the patch MEDIHONEY to a national pharmacy chain as an OTC product, resulting in \$1.2m sales in Q3 this year. We estimate that the total wound dressing market is about \$3bn in the US. However, as stated in a previous section, the market is extremely fragmented, with numerous types of products, including pads, non-adhesive pads, gel, transparent films, foams and thousands of brands. It is estimated that the

1 Arne Simon et al. eCAM 2009, 6:165-173.

2 Arne Simon et al. eCAM 2009, 6:165-173; C. Acton Br J Nurs. 2008, 17:S44, S46-8.

3 G. Gethin and S. Cowman, J Clin Nurs. 2009,18:466-74; D. W. Johnson et al. J Am Soc Nephrol 2005, 16: 1456-1462; V. Robson et al, J Adv Nurs. 2009, 65:565-75;

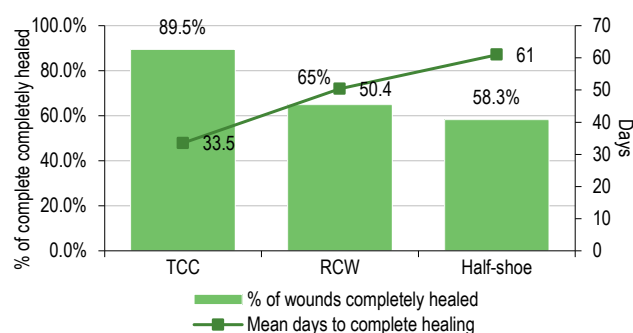
largest brands of wound dressing product have annual sales of \$35-50m. The main competitors in the wound dressing market include J&J, Covidian (Kendall), 3M, Convatec, Hollister, Smith and Nephew and Molnlycke. We estimate MEDIHONEY sales in 2013 to be \$15m, an increase of 36%. Given that MEDIHONEY is the only product of its kind on the market, its clinically proven anti-bacterial and potential anti-inflammatory efficacy and the company's increasing reach to wound care centres, we expect a CAGR of 30%, leading to sales of \$55m in 2018, putting it on a level with the largest competitor products. In terms of the advanced dressings market (Exhibit 3), that would equate to c 2% of the AWC market, assuming 5% market growth.

### TCC-EZ: A c \$50m product in a few years

TCC-EZ is a novel, patented advanced dressing system considered as a "next generation" total contact casting (TCC) system. Derma Sciences obtained the product through its acquisition of MediEfficiency in April 2012 for a total of \$14m. Prior to that, Derma Sciences had been an exclusive distributor of TCC-EZ in the US since 2008.

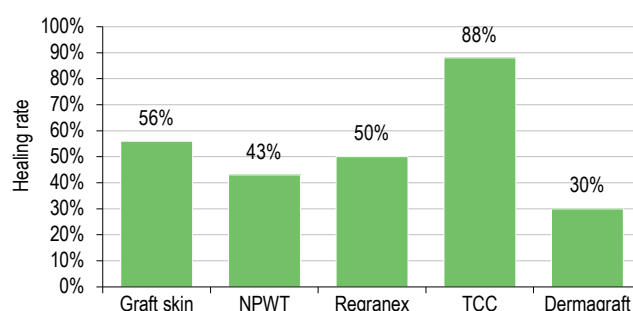
TCC is a casting technique that is used to heal diabetic foot ulcers and to protect the foot during the early phases of wound healing. It is applied in such a way that it intimately contacts the exact contour of the foot, hence the designation "total contact cast". Despite being simple in theory, TCC has been demonstrated in eight randomised control trials (RCT) to result in better and consistent healing of active diabetic foot wounds than off-loading tools<sup>4</sup> such as removable cast walkers (RCWs) and half-shoes and other treatment<sup>5</sup> (Exhibits 5 and 6). Furthermore, meta-analysis of 526 ulcers in 493 patients<sup>6</sup> showed TCC use resulted in 88% healing in mean time of 43 days. This clinical evidence has led the American Diabetes Association to designate TCC as the "gold standard" of offloading modalities in DFU treatment.<sup>7</sup> In one study of 264 DFU patients, the average cost of treatments with TCC was \$11,964 per patient, compared to \$22,494 for the average cost of treatment in which TCC was not used.<sup>8</sup>

**Exhibit 5: Comparison of healing efficiencies**



Note: TCC: total contact casting; RCW: removable cast walker.  
Source: Diabetes Care, 2001, 24:1019-1022

**Exhibit 6: Comparison of healing efficiencies**



Note: NPWT: negative pressure wound therapy.  
Source: J. of Diabetes Foot Complication, 2009, 1:4;85-93

Despite such an overwhelming clinical benefit and clear medical guidelines, adoption of TCC by physicians in wound care centres has been dismal. A survey conducted by SC Wu et al<sup>9</sup> in 2008 found that only 1.7% of the 895 responding centres in the US used TCC, whereas 41.2% used shoe modifications, and 15.2% used removable cast walkers (RCW), despite TCC being considered as the gold standard of offloading in treating DFU since 2000. The main reasons against wider adoption of TCC include patient intolerance (53%), the time needed to apply the cast

<sup>4</sup> D. Armstrong et al, Diabetes Care, 2001 24:1019-1022;

<sup>5</sup> P. Blume, et al., Diabetes Care, 2008, 31:631-6366

<sup>6</sup> P. Cavanagh et al. Foot and Ankle Clinics N Am 2006, 11:735-743

<sup>7</sup> American Diabetes Association: Consensus Development Conference on Diabetic Foot Wound Care. Diabetes Care 22:1354-1360, 1999

<sup>8</sup> C. Fife Wound Rep Reg 2010, 18: 154-158

<sup>9</sup> SC Wu et al. Diabetes Care, 2008, 31:2118-2119

(54%), cost of materials (32%), reimbursement issues (28%), familiarity with method of application (25%), customising parts (21%), staffing/ordering supplies (15%) and clinician coverage (11%).

TCC-EZ is a lightweight, customised boot that simplifies the process of casting and provides additional stability compared with traditional TCC. Its patented lightweight, roll-on, woven design makes it easy for clinicians to learn and takes less than five minutes, about a quarter of the amount of time of traditional systems, to apply. In contrast, traditional TCC is a 13-step process that takes on average 26 minutes to finish and requires substantial training time. In addition, TCC-EZ is Medicare reimbursed, and provides better patient acceptance. Realising the value of TCC-EZ as an under-utilised wound care product, mostly due to lack of promotion, Derma Sciences acquired the manufacture of TCC-EZ in April 2012. Sales of the product have quickly increased to c \$800,000 per month in Q213 from c \$400,000 a month at the time of acquisition.

In theory, TCC-EZ is applicable to all patients with DFUs. At \$98.6 per unit, the potential US market size just for DFU is c \$100m. In reality, the product is not competing with TCC because utilisation of TCC is so low in the real world. Instead, the product is competing against more advanced treatment options, such as Regranex, and Dermagraft, because physicians tend to put patients on those products earlier than they should. Another reason is that physicians can make more money by dispensing such products. However, under the Affordable Care Act, hospitals and wound treatment centres in US are to be judged and paid by quality of care. Since application of TCC-EZ actually leads to higher rate and faster time of wound healing at a much lower cost for hospitals, we expect this product to be gradually accepted by most treatment centres in the next few years. We estimate the sales of the product to be \$9m in 2013 and grow at a CAGR of 40% in the next five years, reaching sales of \$48m in 2018.

### **DSC127: the main value driver**

#### **Extensive MOA and pre-clinical research**

DSC 127's inventors, Dr GS diZerega and Dr KE Rodgers, both from the University of Southern California, made the connection between angiotensin II (All) and wound healing when they noticed a higher level of All in a woman's period. All is an octapeptide of the renin-angiotensin system (RAS) that is able to stimulate increases in blood pressure. Blockers of angiotensin-converting enzyme (ACE), the enzyme that converts angiotensin I to All in the plasma, and blockers to angiotensin receptor (ARBs), are standard of care treatments for high blood pressure. However, starting from the late 80s and early 90s, All was also shown to accelerate the healing of dermal injuries, through stimulation of keratinocyte (the predominant cell type in the epidermis) and fibroblast migration in wound tissue, increased neovascularisation (formation of functional microvascular networks), growth factor release, re-epithelialisation (regrowth of skin) and production of extracellular matrix. All binds to two receptors, angiotensin receptor 1 and 2 (AT1 and AT2) on cells. Recent research has also demonstrated that the RAS is involved in hair follicle stem cell stimulation and proliferation, further evidence that suggests this system plays a central role in tissue repair and wound healing. While All's vasoconstriction property (the cause of high blood pressure) is closely linked to AT1, the wound healing property is related to AT2, as this receptor is significantly enhanced in the dermis of the skin surrounding the wound.<sup>10</sup> Because of this, agonists of the AT2 receptor subtype may be of benefit in wound repair but do not exhibit many of the side effects of angiotensin II, such as increases in blood pressure and thirst.

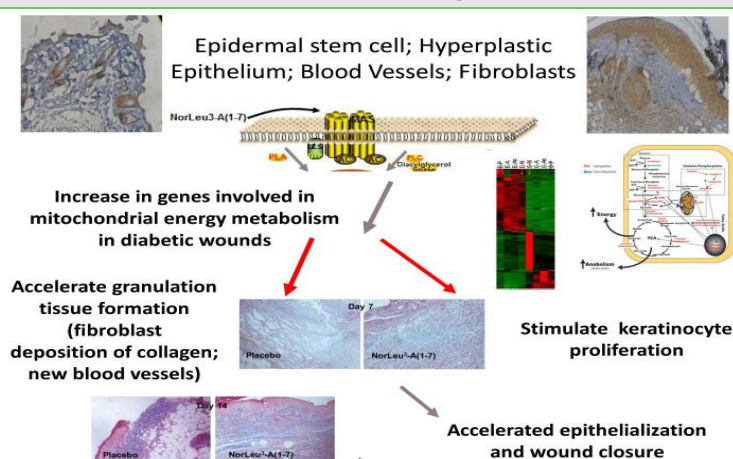
In addition to All, angiotensin 1-7 (A(1-7)), a peptide that contains the first seven amino acids of All, is also a naturally occurring hormone in the body. A(1-7) was shown to be comparable with or better than All in the acceleration of wound healing in rat models or in patients undergoing chemotherapy. Furthermore, A(1-7) does not elevate blood pressure, a significant advantage over All, due to its preferred binding to AT2, a hypothesis that is yet to be conclusively proven. The pharmaceutical

<sup>10</sup> Rodgers K. et al, Wound Rep. Reg. 1997; 5: 175–83.

ingredient of DSC127 is a derivative of A(1-7), chemically known as NorLeu<sup>3</sup>-A(1-7), which has the formula of H<sub>2</sub>NAsp-Arg-NorLeu-Tyr-Ile-His-Pro-OH. It is modified to be more resistant to proteolytic enzymes present in the wound and has increased binding to the receptor. DSC127 is a topical gel in hydroxyethyl cellulose that contains the active ingredient.

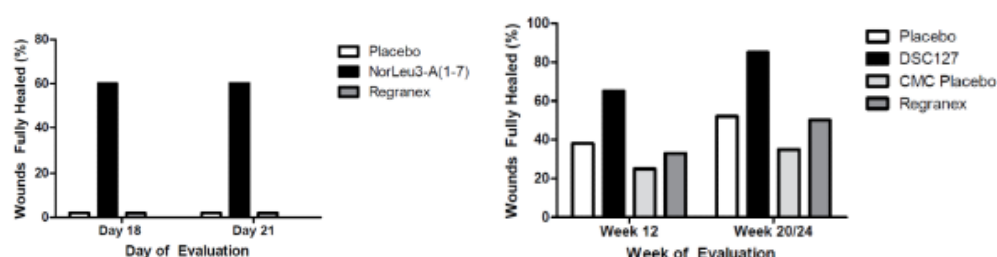
DSC127 was shown to be more effective in wound healing than A(1-7) and becaplermin (Regranex, J&J) in three models of dermal repair (Exhibit 7 and 8): rat full thickness excision, rat full thickness incision and full thickness excision in a diabetic mouse.<sup>11</sup> In the first model, DSC127 reduced the wound size by greater than 60% compared to placebo controls. A(1-7) was less effective, causing a 45% reduction in wound size and Regranex only reduced the wound size by 20%. In the third model, DSC127 completely healed approximately 60% of the wounds and reduced total wound area by greater than 80%, whereas none of the diabetic animals that received Regranex were fully healed and approximately 20% were fully healed with A(1-7) by day 18. Histological analysis in the second model also showed DSC127 reduces inflammation as well as scarring, and resulted in accelerated healing and a normalised appearance. Further histological examination revealed that DSC127 accelerated the deposition of collagen, a critical step in the wound healing process. In addition, DSC127 speeded up dermal re-epithelialisation, and increased revascularisation through enhanced angiogenesis, similar to biological activities demonstrated for AII in various wound healing models.

#### Exhibit 7: Proposed MOA of DSC127 in wound healing



Source: K. Rogers et al, Expert Opin. Investig. Drugs. 2011; 20: 1575–1581

#### Exhibit 8: DSC 127 wound healing efficacy in a diabetic mouse



Source: K. E. Rodgers et al., Exp. Dermatol., 2003; 12:784–90.

#### Encouraging Phase II results

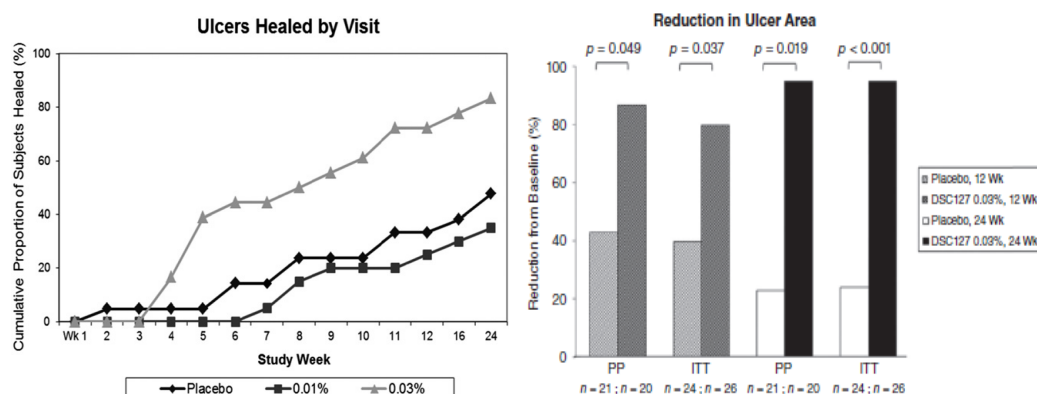
Supported by an NIH small business innovation research (SBIR) grant and Derma Sciences, Dr diZerega and his colleagues conducted a Phase II trial of DSC 127 in patients with diabetic ulcers (DFUs), comparing the drug at two doses, 0.01% and 0.03%, to placebo (vehicle gel). Per the FDA's suggestion, the trial has a two-week screening period in which patients were treated with

<sup>11</sup> K. E. Rodgers et al., Exp. Dermatol., 2003; 12:784-90.

standard of care (SOC). Only patients with ulcers that decreased in area by less than 30% (non-healing ulcers) are enrolled for treatment of four weeks, followed by eight weeks of assessment and 12 weeks of durability evaluation. The screening period in which self-healing patients are excluded is a critical step of the trial because it eliminates placebo noises common in DFU trials and ensures true efficacy of a drug (less false positive) is observed. In the ITT population (n=77), 55% in the DSC 0.03% group (DSC127 at 0.01% was not effective throughout the trial), as compared to 33% in the placebo group, had had complete healing at week 12, the trial's primary end point. The difference, however, did not reach statistical significance with a p value of 0.15. The difference between the two treatments was greater, 65% vs 38%, in the per protocol (PP: patients who completed through week 12 assessment or healed earlier). The difference is approaching statistical significance (p=0.09). The percentage of patients healed started to separate by week three and continued to week 24, at which point the difference was statistically significant in both the ITT and the PP group (Exhibit 9, 85% vs 52%).

DSC127 showed statistical significance in differences of many secondary end points, such as percent area and depth reduction the ulcer from baseline measured at 12 and 24 weeks and the time to complete closure of the wound. At week 12, treatment with DSC127 0.03% led to more than 80% of wound area reduction, compared to slightly more than 40% in the control group (PP population). By week 24, wound area reduced by 95% in the DSC127 0.03% group, vs only 22% in the control (Exhibit 9). Time to complete wound closure was 8.5 weeks in the DSC127 0.03% group, vs 22 weeks in the placebo, a significant difference (PP, p=0.047).

**Exhibit 9: DSC 127 Phase II trial in patients with DFU**



Note: Left panel: primary end point in the ITT group; right panel: secondary end point: wound area reduction. Source: P. Balingit et al., Wound Rep. Reg. 2012, 20: 482-490.

Derma Sciences also conducted an open-label, single centre, Phase 1 PK study that enrolled 21 diabetic patients who topically applied 0.03% DSC127 to the wound once each day for 28 days. DSC127 was not detected in the serum samples of any of the 18 patients who completed the trial (three withdrew due to adverse events not related to DSC127), a superb attribute of a topical drug. This result suggests that there is a low risk of an adverse systemic effect of DSC127, which is important for diabetics with foot ulcers, who typically have multiple medical problems.

To put the DSC127 data in perspective, we compared it to Regranex, the only approved pharmaceutical agent for DFU (Exhibit 10). In the four trials (two Phase III and two Phase II) that were cited by regulatory agencies (FDA and EMA) for the drug's approval, the drug missed its primary end point in two. In the Phase III where the drug demonstrated statistical significance over control, the complete closure rate at week 20 was 47%, vs 37%, a difference of 10%. It should also be noted that the standard of care in that trial used saline gauze, considered outdated by both regulators and practicing physicians. One baseline factor that may have led to the modest efficacy is the size of ulcer, ranging from 1-40cm<sup>2</sup>. In fact, the drug was shown only effective in ulcers that

have size of <5cm<sup>2</sup>. It should also be noted that two important secondary end points, % of ulcer area reduction from baseline and time to complete closure, were missed in all trials.

In contrast, DSC127 achieved complete closure in 54% of patients, vs 30% in the control, a difference of 24%. Although the difference did not reach statistical significance, it is most likely because the sample size was too small in the trial. Furthermore, the difference became even bigger at week 24, at 27%, suggesting that DSC127's impact on wound healing is durable. In addition to the primary end point, DSC127 also showed efficacy in many different second end points, such as % of ulcer area reduction from baseline and time to complete closure, reaching statistical significance in all of them.

The history of pharmaceutical agents developed for DFU is a disappointing one, with many agents failing to meet primary end points in pivotal trials (Exhibit 11). So far, only growth factors, including PDGF, EGF and FGF, have won approval in the US and other major countries (Exhibit 12). Among them, only Regranex has achieved limited commercial success (sales in 2012 estimated c \$120m).

Currently there are only seven pharmaceutical agents (Exhibit 13), to our knowledge, in active clinical trials for DFU. Among them, DSC is the only one that has demonstrated positive Phase II results and the Phase III trials are the largest in terms of patient size.

#### Exhibit 10: Regranex and DSC 127 clinical data

##### Regranex (becaplermin) clinical data\*

| Trial                          | Description                                                                      | Efficacy                       | Treatment          |                   |               | P value |
|--------------------------------|----------------------------------------------------------------------------------|--------------------------------|--------------------|-------------------|---------------|---------|
|                                |                                                                                  |                                | Becaplermin 100 µg | Becaplermin 30 µg | Placebo       |         |
| 92-22120-K, pivotal Phase III, | Rx: 20 wks, no screening; ulcer size: 1.0 and 40 cm <sup>2</sup> ; no screening, | % of complete closure at wk 20 | 49.6% (n=123)      | 36.4% (n=132)     | 34.6% (n=127) | 0.70%   |
| 90-22120-F, supp. Phase II     |                                                                                  |                                |                    | 47.5% (n=61)      | 24.6% (n=57)  | 0.016   |
| PDGF-DBFT-001, supp. Phase II  |                                                                                  |                                | 44.1% (n=34)       |                   | 35.7% (n=70)  | NS      |
| PDGF-DBFT-002, supp. Phase III |                                                                                  |                                |                    | 35.9% (n=128)     | 32% (n=122)   | NS      |

##### DSC 127 clinical data:

| Trial    | Description                                                  | Efficacy                            | Treatment      |                |              | P value |
|----------|--------------------------------------------------------------|-------------------------------------|----------------|----------------|--------------|---------|
|          |                                                              |                                     | 127 0.03%/ SOC | 127 0.01%/ SOC | Placebo/ SOC |         |
| Phase II | Ulcer size 1-6 cm <sup>2</sup> ; screening: 2 wks; Rx: 4 wks | % of complete closure at wk 12, ITT | 54% (n=26)     | 30% (n=28%)    | 33% (n=24)   | 0.15    |
|          |                                                              | % of complete closure at wk 12, PP  | 65% (n=20)     |                | 38% (n=21)   | 0.09    |
|          |                                                              | % of complete closure at wk 24, ITT | 73%            |                | 46%          | 0.05    |
|          |                                                              | % of complete closure at wk 24, PP  | 85%            |                | 52%          | 0.03    |
|          |                                                              | % of area reduction at wk 12, ITT   | 80%            |                | 40%          | 0.037   |
|          |                                                              | % of area reduction at wk 12, PP    | 87%            |                | 42%          | 0.049   |
|          |                                                              | % of area reduction at wk 24, ITT   | 95%            |                | 22%          | 0.001   |
|          |                                                              | % of area reduction at wk 24, PP    | 95%            |                | 22%          | 0.001   |
|          |                                                              | Med. time to complete Healing, ITT  | 10 wks         |                | 23 wks       | 0.088   |
|          |                                                              | Med. time to complete Healing, PP   | 8.5 wks        |                | 22 wks       | 0.047   |

Source: Product label, company reports and Edison Investment Research. Note: \*Meta analysis of all four trials showed 10-15% difference of complete healing between 100µg and vehicle; no difference in ulcer>5 cm<sup>2</sup>; no statistical difference in pivotal trial: ulcer area reduction, weekly ulcer healing rate.

#### Exhibit 11: Failed or discontinued pharmaceutical agents for DFU

| Drug                   | Company           | Pharmaceutical class             | Status                         |
|------------------------|-------------------|----------------------------------|--------------------------------|
| Talactoferrin          | Agennix           | Matrix cytokine                  | Company liquidated: 5/13       |
| Telbermin              | Genentech         | Topic VEGF                       | Missed primary end point: 3/08 |
| Protein Kinase C alpha | HealOr            | Protein Kinase C alpha modulator | Not recruiting DFU: 2009       |
| Sonedenoson (MRE0094)  | King (Pfizer)     | Adenosine receptor 2 agonist     | Missed primary end point: 6/09 |
| Atorvastatin (Lipitor) | Pfizer            | Cholesterol lowering agent       | Missed primary end point: 5/09 |
| Thymosin beta-4        | RegenRx           | inflammation/angiogenesis, ECM   | Missed primary end point: 6/9  |
| TGF beta 3             | Renovo            | 27-beta estradiol                | Missed primary end point: 6/09 |
| Collagen-ORC           | Systagenix        | Antimicrobial                    | Missed primary end point: 4/06 |
| Ad5PDGF-beta           | Tissue Repair Co. | Growth factor                    | Missed primary end point 2/08  |

Source: Company reports and Edison Investment Research

**Exhibit 12: Marketed therapeutic agents for diabetic foot ulcers**

| Product                | Pharmacological Class                                   | Company                      |
|------------------------|---------------------------------------------------------|------------------------------|
| Dermagraft             | Fibroblast derived dermal substitute                    | Shire                        |
| Apligraf               | Tissue-engineered skin                                  | Organogenesis                |
| Regranex (becaplermin) | Platelet-derived growth factor (PDGF)                   | Systagenix Johnson & Johnson |
| Easyef (nepidermin)    | Recombinant human Epidermal growth factor (rhEGF)       | Daewoong Pharmaceutical      |
| Citoprot-P             | Epidermal growth factor (EGF), Intralesional injections | Bioven                       |

Source: Edison Investment Research

**Exhibit 13: Selected pharmaceutical agents developed for DFU**

| Product             | Pharmacological Class            | Company                | Treatment                           | Trial status                                                                                                                                                                                                                                   |
|---------------------|----------------------------------|------------------------|-------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| DSC127              | Angiotensin (1-7) derivative     | Derma Sciences         | DSC 127 0.03%/SOC vs pbo/SOC vs SOC | 633-pt <a href="#">Phase III</a> (STRIDE 2), randomised, double-blind, parallel-group, vehicle and standard of care (SOC)-controlled. Primary end point (PE): % of complete closure up to 10 wks (confirmed 2 wks later). <b>Results: 7/15</b> |
|                     |                                  |                        | DSC 127 0.03%/SOC vs pbo/SOC        | 422-pt <a href="#">Phase III</a> (STRIDE 1), randomized, double-Blind, parallel-group, vehicle and standard of care (SOC)-controlled. Primary end point (PE): % of complete closure up to 10 wks (confirmed 2 wks later). <b>Results: 7/15</b> |
| WH-1 Ointment       | Plant extracts                   | Oneness Biotech Co.    | WH-1 vs Aquacel Hydrofiber dressing | 212-pt <a href="#">Phase III</a> , randomized controlled. PE: % of complete closure. <b>Results: 12/14</b>                                                                                                                                     |
| BBR-012 (isoniazid) | Anti-bacterial agent             | Bridge BioResearch     | Oral BBR-012/SOC vs pbo/SOC         | 60-pt <a href="#">Phase II</a> proof of concept (POC), PE: rate of healing. <b>Results: 8/12 (no update from the company)</b>                                                                                                                  |
| CSTC1               | Vapor fraction of Glycine seeds  | Charsire Biotechnology | DSTC1 vs vehicle                    | 100-pt <a href="#">Phase II</a> , randomized, double-blind, vehicle-controlled. PE: % of complete closure up to 12 wks. <b>Results: 9/15</b>                                                                                                   |
| Nexagon             | Cell-cell gap junction modulator | CoDa Therapeutics      | Nexagon/SOC vs pbo/SOC              | 160-pt <a href="#">Phase II</a> , randomized, double-blind, vehicle-controlled. PE: % of complete closure. <b>Result: 7/13 (no update)</b>                                                                                                     |
| IZN-6D4 Gel         | Botanical extracts               | Izun Pharma Ltd        | IZN-6D4 gel vs control gel          | 80-pt randomized, placebo-controlled, double-blind <a href="#">Phase II</a> . PE: % area reduction at wk4: <b>Results: 3/14</b>                                                                                                                |
| Topical GSK1278863  | Small-molecule HIF-PH inhibitor  | GSK                    | GSK1278863 vs pbo                   | 80-pt <a href="#">Phase I</a> . PE: safety. <b>Results: 6/14</b>                                                                                                                                                                               |

Source: Clinicaltrials.gov, company reports and Edison Investment Research

**Exhibit 14: DSC 127 Phase II and III trial features**

|                                | Phase II                                                             | Phase III, STRIDE 1              | Phase III, STRIDE 2                 |
|--------------------------------|----------------------------------------------------------------------|----------------------------------|-------------------------------------|
| Patient characteristics        | non-healing DFU, 1-6 cm <sup>2</sup> wound area, Wagner grade 1 or 2 |                                  |                                     |
| Number of patients             | 77                                                                   | 422                              | 633                                 |
| Screening                      | 2 weeks                                                              |                                  |                                     |
| Treatment                      | DSC 127 0.03%/SOC vs DSC 127 0.01%/SOC vs pbo/SOC                    | DSC 127 0.03%/SOC vs pbo/SOC     | DSC 127 0.03%/SOC vs pbo/SOC vs SOC |
| Treatment duration             | 4 weeks                                                              |                                  |                                     |
| Assessment (primary end point) | At week 12                                                           | At week 10, confirmed at week 12 |                                     |
| Durability assessment          | At week 24                                                           |                                  |                                     |

Source: Derma Sciences and Edison Investment Research

**Well-designed Phase III trials**

Derma Sciences has initiated two Phase III trials (Exhibit 14), called, STRIDE 1 and 2, based on results and the experience of the Phase II trial. In the Phase III trials, only the effective dose, 0.03%, is tested. The only noticeable difference between Phase II and Phase III is that assessment of primary efficacy in the Phase III takes place on week 10 and needs to be confirmed at week 12. STRIDE 1 is a two-arm trial, whereas in STRIDE 2, a third arm using commercially available gel is added so that comparison of the vehicle gel and a control gel can be performed. Both trials are adequately sized to demonstrate DSC127's efficacy as well as to collect sufficient patient safety data to support a regulatory approval. Derma Sciences expects that the trial will generate top-line results in Q2 of 2015.

## Sensitivities

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Our investment thesis on Derma Sciences is most sensitive to the growth prospects of its advanced wound care business units, in particularly MEDIHONEY and TCC-EZ, in the near term, and the clinical success of DSC 127 in the on-going Phase III and the product's commercial success in the long term.

In MEDIHONEY and TCC-EZ, we see two unique wound care products that have just start to show their sales potential in a competitive market place. But the ultimate success of these two products in the market place is dependent upon the company's marketing and sales strategy, which includes increasing sales representatives and targeting wound care centres and hospitals with clinical and pharmacoeconomic advantages these products have. Because Derma Sciences obtains MEDIHONEY from a single source, Comvita, our future sales forecast of the products depends on Comvita's ability to support the growing demand from the market.

We believe DSC127 possesses a unique wound care mechanism of action that was well elucidated in a series of pre-clinical models, has demonstrated encouraging clinical activities in a Phase II trial (with the caveat that number of patients in the Phase II was small) and is tested in a well-designed Phase III programme. While we believe the drug has higher probability of success as compared to other wound care therapeutics tested, a positive outcome of the Phase III trials cannot be guaranteed. We also realise how significant an impact a negative Phase III outcome would have on the stock because of the value investors ascribe to the product. We think DSC127's product profile should position the product well in a competitive wound care market place, but additional investment is needed to get the product through regulation and also successfully launched.

Derma Sciences is also subject to general financial and market risks that are typical for a medical device and biotech company, because the company's business is a hybrid of a device and biotech company. As typical for a device company, its products are subject to price competition and control in most of the territories that they operate in. Some of its products, such as TCC-EZ, could become favoured under the US Affordability Care Act because it pushes hospitals to strive for quality while controlling for cost, but it requires the company to market the products more aggressively. The potential of DSC127 and the inherited risk also put the company in the category of a biotech company, which faces higher regulatory scrutiny and harbours higher stock volatility.

## Valuation

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We value Derma Sciences using a discounted cash flow model. We value the three segments, AWC, TWC and PWC (DSC127), separately because each segment has its own operating profit margin. We forecast sales to 2023 based on our view of each segment's growth rate and estimate each segment's operating profit margin. We apply a terminal value (1.5x for AWC, 0x for TWC and 3x for DSC127) based on patent lives of major products in each segment, a universal 12.5% discount rate and a 35% tax rate to arrive at an after tax total PV for each segment, at \$130.1m, \$36.7m and \$165.5m, respectively, and for a total of \$332.3m. We have assumed a 65% of probability of clinical success rate for DSC127, which is lower than our typical 75% of clinical success rate for a Phase III product because of historically lower success rate of therapeutic wound products. Adding cash of \$25m estimated at the end of 2013, we arrive at a total firm value of \$357.3m, or \$20.7 per basic share (\$15.7 per diluted shares, Exhibit 15).

**Exhibit 15: Derma Sciences valuation model**

|                                      | 2013e          | 2014e  | 2015e  | 2016e  | 2017e   | 2018e   | 2019e   | 2020e   | 2021e   | 2022e   | 2023e   |
|--------------------------------------|----------------|--------|--------|--------|---------|---------|---------|---------|---------|---------|---------|
| <b>AWC segment:</b>                  |                |        |        |        |         |         |         |         |         |         |         |
| Sales (\$m)                          | \$34.9         | \$46.6 | \$61.3 | \$79.8 | \$102.3 | \$129.4 | \$157.2 | \$183.1 | \$204.2 | \$217.5 | \$226.2 |
| Operating profit                     | (4.2)          | 1.0    | 5.0    | 11.2   | 20.5    | 33.8    | 44.2    | 55.1    | 65.5    | 74.1    | 81.6    |
| Terminal value                       |                |        |        |        |         |         |         |         |         |         | 122.4   |
| Discount factor                      | 0              | 1      | 2      | 3      | 4       | 5       | 6       | 7       | 8       | 9       | 10      |
| Discount rate                        | 12.5%          |        |        |        |         |         |         |         |         |         |         |
| Present value (PV)                   | (4.2)          | 0.9    | 3.9    | 7.9    | 12.8    | 18.7    | 21.8    | 24.2    | 25.5    | 25.7    | 62.8    |
| Total PV after tax (\$m)             | \$130.1        |        |        |        |         |         |         |         |         |         |         |
| <b>TWC segment:</b>                  |                |        |        |        |         |         |         |         |         |         |         |
| Sales (\$m)                          | \$47.3         | \$48.7 | \$49.5 | \$50.2 | \$50.9  | \$51.7  | \$52.5  | \$53.3  | \$54.1  | \$54.9  | \$55.7  |
| Operating profit                     | 8.2            | 8.3    | 8.4    | 8.5    | 8.7     | 8.8     | 8.9     | 9.1     | 9.2     | 9.3     | 9.5     |
| Terminal value                       |                |        |        |        |         |         |         |         |         |         | 0.0     |
| PV                                   | 8.2            | 7.4    | 6.6    | 6.0    | 5.4     | 4.9     | 4.4     | 4.0     | 3.6     | 3.2     | 2.9     |
| Total PV after tax (\$m)             | \$36.7         |        |        |        |         |         |         |         |         |         |         |
| <b>DSC127:</b>                       |                |        |        |        |         |         |         |         |         |         |         |
| Sales (\$m)                          | \$0.0          | \$0.0  | \$0.0  | \$15.0 | \$30.0  | \$56.3  | \$98.4  | \$160.0 | \$239.9 | \$329.9 | \$412.4 |
| Operating profit                     | (10.0)         | (10.0) | (15.0) | (15.0) | 4.5     | 25.3    | 46.8    | 80.0    | 120.0   | 165.0   | 206.2   |
| Terminal value                       |                |        |        |        |         |         |         |         |         |         | 618.6   |
| PV                                   | (10.0)         | (8.9)  | (11.9) | (10.5) | 2.8     | 14.0    | 23.1    | 35.1    | 46.8    | 57.1    | 254.0   |
| Probability of success               | 65%            |        |        |        |         |         |         |         |         |         |         |
| Total PV after tax (\$m)             | \$165.5        |        |        |        |         |         |         |         |         |         |         |
| <b>Total of three segments (\$m)</b> | <b>\$332.3</b> |        |        |        |         |         |         |         |         |         |         |
| Cash (\$m, end of 2013)              | \$25.0         |        |        |        |         |         |         |         |         |         |         |
| <b>Total firm value (\$m)</b>        | <b>\$357.3</b> |        |        |        |         |         |         |         |         |         |         |
| Total basic shares (m)               | 17.3           |        |        |        |         |         |         |         |         |         |         |
| <b>Value per basic share (\$)</b>    | <b>\$20.7</b>  |        |        |        |         |         |         |         |         |         |         |
| Source: Edison Investment Research   |                |        |        |        |         |         |         |         |         |         |         |

## Financials

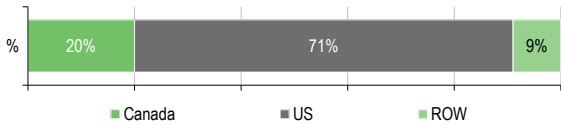
Derma Sciences reported net sales for Q213 of \$18.1m, vs \$17.6m for Q212, an increase of 3%. AWC net sales was \$7.9m, an increase of 36% over Q212, while sales of TWC were \$10.2m, a decrease of 13% from Q212, affected by lower sales in Canada and partially offset by higher sales of private-label products. The company's overall gross profit margin increased to 36.8% in Q213 from 35.2% in Q212, reflecting increased sales of higher-margin AWC (44% in Q213 vs 33% in Q212). SG&A expenses in Q213 increased slightly to \$10m, compared with \$9.2m for Q212, due mainly to higher expenditures in AWC growth initiatives. R&D expenses increased to \$3.2m in Q213, from \$1.5m in Q212, mainly due to higher expenses for the DSC127 Phase 3 programme. The loss for the quarter was \$7.3m, or \$0.43 per share, vs \$2.8m, or \$0.23 per share in Q212.

As of 30 June 2013, Derma Sciences had net cash, cash equivalents and short-term investments of \$37.9m, compared with \$45.1m as of 31 December 2012. We believe the company's cash is sufficient to finish the Phase III programme of DSC127 in H115, but additional funds are required to get DSC127 through regulatory approval and launch in major markets, including North America and major EU countries in 2016.

**Exhibit 16: Financial summary**

|                                              | \$'000s | 2010     | 2011     | 2012     | 2013e    | 2014e    | 2015e    |
|----------------------------------------------|---------|----------|----------|----------|----------|----------|----------|
| <b>31-December</b>                           |         |          |          |          |          |          |          |
| <b>PROFIT &amp; LOSS</b>                     |         |          |          |          |          |          |          |
| Revenue                                      |         | 56,474   | 62,630   | 72,648   | 82,207   | 95,285   | 112,313  |
| Cost of Sales                                |         | (39,947) | (44,218) | (47,507) | (51,831) | (58,108) | (65,080) |
| Gross Profit                                 |         | 16,527   | 18,412   | 25,141   | 30,376   | 37,177   | 47,234   |
| EBITDA                                       |         | 1,532    | 375      | (8,930)  | (20,628) | (23,341) | (19,817) |
| Operating Profit (before amort. and except.) |         | 19       | (2,250)  | (12,193) | (24,523) | (26,102) | (22,714) |
| Intangible Amortisation                      |         | 1,690    | 1,569    | 2,274    | 2,753    | 2,826    | 2,767    |
| Exceptionals                                 |         | 0        | 0        | 0        | 0        | 0        | 0        |
| Other                                        |         | 226      | (189)    | 6        | (36)     | (25)     | (25)     |
| Operating Profit                             |         | 1,935    | (871)    | (9,913)  | (21,806) | (23,301) | (19,972) |
| Net Interest                                 |         | (581)    | (263)    | 21       | 30       | 20       | 20       |
| Profit Before Tax (norm)                     |         | (561)    | (2,514)  | (12,173) | (24,493) | (26,082) | (22,694) |
| Profit Before Tax (FRS 3)                    |         | (2,025)  | (4,271)  | (14,441) | (27,282) | (28,932) | (25,486) |
| Tax                                          |         | (424)    | (70)     | 2,370    | 85       | 145      | 127      |
| Profit After Tax (norm)                      |         | (759)    | (2,772)  | (9,796)  | (24,445) | (25,962) | (22,591) |
| Profit After Tax (FRS 3)                     |         | (2,449)  | (4,340)  | (12,070) | (27,198) | (28,788) | (25,359) |
| Average Number of Shares Outstanding (m)     |         | 6.3      | 8.8      | 12.5     | 17.0     | 17.5     | 18.3     |
| EPS - normalised (c)                         |         | (12.0)   | (31.6)   | (78.4)   | (143.5)  | (148.0)  | (123.5)  |
| EPS - normalised and fully diluted (c)       |         | (7.9)    | (20.4)   | (54.8)   | (108.5)  | (111.4)  | (92.8)   |
| EPS - (IFRS) (c)                             |         | (38.7)   | (49.4)   | (96.7)   | (159.6)  | (164.1)  | (138.7)  |
| Dividend per share (c)                       |         | 0.0      | 0.0      | 0.0      | 0.0      | 0.0      | 0.0      |
| Gross Margin (%)                             |         | 29.3     | 29.4     | 34.6     | 37.0     | 39.0     | 42.1     |
| EBITDA Margin (%)                            |         | 2.7      | 0.6      | -12.3    | -25.1    | -24.5    | -17.6    |
| Operating Margin (before GW and except.) (%) |         | 0.0      | -3.6     | -16.8    | -29.8    | -27.4    | -20.2    |
| <b>BALANCE SHEET</b>                         |         |          |          |          |          |          |          |
| Fixed Assets                                 |         | 18,016   | 17,391   | 34,531   | 33,958   | 33,883   | 33,808   |
| Intangible Assets                            |         | 14,091   | 13,523   | 30,587   | 30,637   | 30,687   | 30,737   |
| Tangible Assets                              |         | 3,925    | 3,619    | 3,446    | 3,321    | 3,196    | 3,071    |
| Investments                                  |         | 0        | 249      | 498      | 0        | 0        | 0        |
| Current Assets                               |         | 18,953   | 41,233   | 69,312   | 50,297   | 29,637   | 31,909   |
| Stocks                                       |         | 12,499   | 10,531   | 13,671   | 13,771   | 13,871   | 13,971   |
| Debtors                                      |         | 5,442    | 6,268    | 7,086    | 7,886    | 8,686    | 9,486    |
| Cash                                         |         | 404      | 22,335   | 45,347   | 24,932   | 2,872    | 3,743    |
| Other                                        |         | 609      | 2,099    | 3,209    | 3,709    | 4,209    | 4,709    |
| Current Liabilities                          |         | (9,009)  | (6,378)  | (8,127)  | (10,627) | (13,127) | (35,127) |
| Creditors                                    |         | (9,004)  | (6,378)  | (8,127)  | (10,627) | (13,127) | (15,127) |
| Short term borrowings                        |         | (6)      | 0        | 0        | 0        | 0        | (20,000) |
| Long Term Liabilities                        |         | (1,280)  | (1,399)  | (2,005)  | (2,055)  | (2,555)  | (3,055)  |
| Long term borrowings                         |         | 0        | (253)    | (269)    | (269)    | (269)    | (269)    |
| Other long term liabilities                  |         | (1,280)  | (1,146)  | (1,736)  | (1,786)  | (2,286)  | (2,786)  |
| Net Assets                                   |         | 26,681   | 50,848   | 93,711   | 71,573   | 47,838   | 27,535   |
| <b>CASH FLOW</b>                             |         |          |          |          |          |          |          |
| Operating Cash Flow                          |         | (355)    | (564)    | (16,032) | (24,850) | (28,552) | (27,928) |
| Net Interest                                 |         | (581)    | (263)    | 21       | 30       | 20       | 20       |
| Tax                                          |         | 644      | 1,077    | 4,107    | 1,871    | 2,431    | 2,914    |
| Capex                                        |         | (635)    | (979)    | (779)    | (500)    | (500)    | (500)    |
| Acquisitions/disposals                       |         | 0        | 0        | (14,358) | 0        | 0        | 0        |
| Financing                                    |         | 5,365    | 22,414   | 50,036   | 3,034    | 4,541    | 6,366    |
| Dividends                                    |         | 0        | 0        | 0        | 0        | 0        | 0        |
| Net Cash Flow                                |         | 4,439    | 21,684   | 22,995   | (20,415) | (22,060) | (19,128) |
| Opening net debt/(cash)                      |         | 4,041    | (398)    | (22,083) | (45,078) | (24,663) | (2,603)  |
| HP finance leases initiated                  |         | 0        | 0        | 0        | 0        | 0        | 0        |
| Other                                        |         | 0        | 0        | 0        | 0        | 0        | 0        |
| Closing net debt/(cash)                      |         | (398)    | (22,083) | (45,078) | (24,663) | (2,603)  | 16,525   |

Source: Edison Investment Research

| Contact details                                                                                                                                                                                                                                                                                                                                                |       |                       |     | Revenue by geography                                                                                                                                                                                                                                                                                             |      |                          |       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|-----------------------|-----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|--------------------------|-------|
| Derma Sciences<br>214 Carnegie Center, Suite 300<br>Princeton, NJ 08540<br>US<br>Phone: +1 800 445 7627<br>www.dermasciences.com                                                                                                                                                                                                                               |       |                       |     |                                                                                                                                                                                                                                |      |                          |       |
| CAGR metrics                                                                                                                                                                                                                                                                                                                                                   |       | Profitability metrics |     | Balance sheet metrics                                                                                                                                                                                                                                                                                            |      | Sensitivities evaluation |       |
| EPS 2011-15e                                                                                                                                                                                                                                                                                                                                                   | N/A   | ROCE 14e              | N/A | Gearing 14e                                                                                                                                                                                                                                                                                                      | N/A  | Litigation/regulatory    | ●     |
| EPS 2013-15e                                                                                                                                                                                                                                                                                                                                                   | N/A   | Avg ROCE 2011-15e     | N/A | Interest cover 14e                                                                                                                                                                                                                                                                                               | N/A  | Pensions                 | ○     |
| EBITDA 2011-15e                                                                                                                                                                                                                                                                                                                                                | N/A   | ROE 14e               | N/A | CA/CL 14e                                                                                                                                                                                                                                                                                                        | 2.3x | Currency                 | ●     |
| EBITDA 2013-15e                                                                                                                                                                                                                                                                                                                                                | N/A   | Gross margin 14e      | N/A | Stock days 14e                                                                                                                                                                                                                                                                                                   | 53.1 | Stock overhang           | ○     |
| Sales 2011-15e                                                                                                                                                                                                                                                                                                                                                 | 15.7% | Operating margin 14e  | N/A | Debtor days 14e                                                                                                                                                                                                                                                                                                  | 33.3 | Interest rates           | ●     |
| Sales 2013-15e                                                                                                                                                                                                                                                                                                                                                 | 16.9% | Gr mgn / Op mgn 14e   | N/A | Creditor days 14e                                                                                                                                                                                                                                                                                                | N/A  | Oil/commodity prices     | ○     |
| Management team                                                                                                                                                                                                                                                                                                                                                |       |                       |     |                                                                                                                                                                                                                                                                                                                  |      |                          |       |
| Chairman and Chief Executive Officer: Edward J Quilty                                                                                                                                                                                                                                                                                                          |       |                       |     | EVP, Finance and CFO: John E Yetter                                                                                                                                                                                                                                                                              |      |                          |       |
| Mr Quilty has served as the CEO since November 1998, chairman since May 1996. He was the chairman and CEO of Palatin Technologies, and president and CEO of MedChem Products, president and CEO of Life Medical Sciences, VP at McGaw Laboratories, and held various positions at Baxter. He earned a BA from Missouri State Univ., and an MBA from Ohio Univ. |       |                       |     | Mr Yetter has served as EVP and CFO since January 2013, and previously as VP of finance beginning in August 2000. He held various financial positions with BMS, Cooper, Price Waterhouse and Hulse Manufacturing Company. He earned a BS from Boston College School of Management.                               |      |                          |       |
| Group President, TWC and Corporate Accounts: Robert C Cole                                                                                                                                                                                                                                                                                                     |       |                       |     | Group President, AWC and Pharma. Development : Barry J Wolfenson                                                                                                                                                                                                                                                 |      |                          |       |
| Mr Cole has served in the current position since January 2013, and previously as EVP for sales beginning in May 2006 and as VP of sales and marketing beginning in January 2003. Mr Cole held various sales positions with B. Braun Medical. He earned his BS from St. Vincent's College.                                                                      |       |                       |     | Mr Wolfenson has served in the current position since January 2013 and previously as EVP of global BD and marketing beginning in March 2010. He held a variety of positions with BMS and Andersen Consulting. Mr Wolfenson earned a BS from Franklin and Marshall College and an MBA from the Univ. of Michigan. |      |                          |       |
| Principal shareholders                                                                                                                                                                                                                                                                                                                                         |       |                       |     |                                                                                                                                                                                                                                                                                                                  |      |                          | (%)   |
| Baker Bros Advisors                                                                                                                                                                                                                                                                                                                                            |       |                       |     |                                                                                                                                                                                                                                                                                                                  |      |                          | 14.82 |
| FMR LLC                                                                                                                                                                                                                                                                                                                                                        |       |                       |     |                                                                                                                                                                                                                                                                                                                  |      |                          | 12.76 |
| RA Capital Management                                                                                                                                                                                                                                                                                                                                          |       |                       |     |                                                                                                                                                                                                                                                                                                                  |      |                          | 11.55 |
| Jennison Associates LLC                                                                                                                                                                                                                                                                                                                                        |       |                       |     |                                                                                                                                                                                                                                                                                                                  |      |                          | 7.34  |
| Raging Capital Management                                                                                                                                                                                                                                                                                                                                      |       |                       |     |                                                                                                                                                                                                                                                                                                                  |      |                          | 7.23  |
| Camber Capital Management                                                                                                                                                                                                                                                                                                                                      |       |                       |     |                                                                                                                                                                                                                                                                                                                  |      |                          | 5.5   |
| 12 West Capital Management                                                                                                                                                                                                                                                                                                                                     |       |                       |     |                                                                                                                                                                                                                                                                                                                  |      |                          | 5.04  |
| Companies named in this report                                                                                                                                                                                                                                                                                                                                 |       |                       |     |                                                                                                                                                                                                                                                                                                                  |      |                          |       |
| J&J (JNJ), Covidian (COV), 3M (MMM), Convatec (private), Smith and Nephew (SNN), Molnlycke (private) and Comvita (private)                                                                                                                                                                                                                                     |       |                       |     |                                                                                                                                                                                                                                                                                                                  |      |                          |       |

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