DERMA SCIENCES, INC. Form S-1/A February 16, 2010

As filed with the Securities and Exchange Commission on February 16, 2010

Registration No. 333-163127

## SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

#### **Form S-1/A-4**

# REGISTRATION STATEMENT Under THE SECURITIES ACT OF 1933 DERMA SCIENCES, INC.

(Exact Name of Registrant As Specified in Its Charter)

Pennsylvania (State or Other Jurisdiction of Incorporation or Organization) 23-2328753 (I.R.S. Employer Identification No.)

214 Carnegie Center, Suite 300 Princeton, NJ 08540 (609) 514-4744

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

### Edward J. Quilty, President 214 Carnegie Center, Suite 300 Princeton, NJ 08540 (609) 514-4744

(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent for Service)

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**Approximate date of commencement of proposed sale to public:** From time to time after this registration statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer," accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer o Non-accelerated filer o (Do not check if a smaller reporting company) Accelerated filer o

Smaller reporting company x

#### **CALCULATION OF REGISTRATION FEE**

	Proposed	
Title of Fool Class of Securities to De Desister d(1)(2)	Maximum	Amount of
Title of Each Class of Securities to Be Registered <sup>(1)(2)</sup>	Aggregate	Registration Fee
	Offering Price	
Common stock, \$.01 par value per share	\$ 4,657,500	\$ 332.08
Warrants to purchase common stock	N/A	N/A (3)
Common stock underlying warrants	\$ 1,707,750	\$ 121.76
Underwriter s warrants to purchase common stock	N/A	N/A (3)
Common stock underlying underwriter s warrants	\$ 121,500	\$ 8.66
Totals	\$ 6,486,750	\$ 462.51
Paid upon initial filing and amendment no. 2		\$ 617.00
Registration fee payable		\$ 0

Pursuant to Rule 416 under the Securities Act, this registration statement also relates to an indeterminate number of (1) additional shares of common stock which may be issuable to prevent dilution resulting from stock splits, stock dividends and similar transactions.

- (2) Includes shares of common stock which may be issued pursuant to the exercise of a 45-day option granted by the Registrant to the underwriter to cover over-allotments, if any.
- In accordance with Rule 457(g) under the Securities Act, by virtue of the fact that the shares of the Registrant s (3)common stock underlying the warrants are registered hereby, no separate registration fee is required with respect to the warrants registered hereby.

THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON THE DATE OR DATES NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT FILES A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(a) OF THE SECURITIES ACT OF 1933 OR UNTIL THIS REGISTRATION STATEMENT BECOMES EFFECTIVE ON THE DATE THE SECURITIES AND EXCHANGE COMMISSION, ACTING PURSUANT TO SECTION 8(a), MAY DETERMINE.

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The information in this prospectus is not complete and may be changed. A registration statement relating to these securities has been filed with the Securities and Exchange Commission. These securities may not be sold until the registration statement is effective. This prospectus is not an offer to sell these securities and does not solicit an offer to buy these securities in any state or other jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS

**SUBJECT TO COMPLETION, DATED FEBRUARY 16, 2010** 

#### Derma Sciences, Inc.

## 810,000 Shares of Common Stock Warrants to Purchase 270,000 Shares of Common Stock

This is a firm commitment public offering. We are offering for sale 810,000 shares of our common stock and warrants to purchase up to an aggregate of 270,000 shares of our common stock. Each purchaser of a share of our common stock in this offering will receive a warrant exercisable for one-third of a share of our common stock. We will sell our common stock and warrants in this offering for \$\_\_\_ per share of common stock and warrant. Each warrant will have an exercise price based on \$\_\_\_ per full share. The warrants are exercisable immediately and will expire five years from the date of this prospectus. For a more detailed description of our common stock and warrants, see Description of Securities on page 51 of this prospectus.

The public offering price of the shares of common stock offered by this prospectus will be determined by negotiation between us and the underwriter based upon market conditions and other factors on the day we price the shares covered by this prospectus, which may not reflect the price at which our common stock trades. The trading price of our common stock is subject to change as a result of market conditions and other factors and we cannot assure you that the shares sold under this prospectus can be resold at or above the offering price or that the shares issuable upon exercise of the warrants can be resold at or above the exercise price of the warrants.

Our common stock currently trades on the NASDAQ Capital Market under the symbol DSCI. On February 12, 2010, our common stock closed at \$5.80. The warrants are not currently listed or quoted and we do not expect to seek a listing for them or expected them to be quoted on any market.

Investing in our securities involves certain risks. See Risk Factors beginning on page 4 of this prospectus for a discussion of information that should be considered in connection with an investment in our securities. Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Share <sup>(1)</sup>	Total
Public offering price	\$	\$
Underwriting discounts and commissions <sup>(2)</sup>	\$	\$
Proceeds, before expenses, to us <sup>(3)</sup>	\$	\$

- Does not include shares of common stock underlying warrants. For every share of common stock purchased, investors will receive a warrant to purchase one-third of a share of common stock.
- (2) Does not include a non-accountable expense allowance equal to 0.5% of the gross proceeds of this offering payable to Rodman & Renshaw, LLC, the representative of the underwriters.
- (3) We estimate that the total expenses of this offering, exclusive of the underwriters discount and non-accountable expense allowance, will be approximately \$\_\_\_\_\_\_.

We have granted a 45-day option to the underwriter to purchase additional shares of common stock up to an additional 121,500 shares and warrants to purchase up to 40,500 shares to be offered by us solely to cover over-allotments, if any. The shares and warrants issuable upon exercise of the underwriter option are identical to those offered by this prospectus and have been registered under the registration statement of which this prospectus forms a part.

In connection with this offering, we have agreed to issue to the underwriter a warrant to purchase up to 3% of the shares of common stock constituting the common stock component of the securities sold pursuant to the offering (excluding the over-allotment) at \$ per share (125% of the price of the shares sold in the offering), commencing one year from the effective date of the registration statement of which this prospectus is a part and expiring four years thereafter.

The underwriter expects to deliver our shares to purchasers in the offering on or about February , 2010.

#### Rodman & Renshaw, LLC

The date of this prospectus is, 2010.

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We have not authorized anyone to provide you with information different from that contained or incorporated by reference to this prospectus. Under no circumstances should the delivery to you of this prospectus or any sale made pursuant to this prospectus create any implication that the information contained in this prospectus is correct as of any time after the date of this prospectus. To the extent that any facts or events arising after the date of this prospectus, individually or in the aggregate, represent a fundamental change in the information presented in this prospectus, this prospectus will be updated to the extent required by law.

We own or license the following trademarks: DERMA SCIENCES®, DERMAGRAN®, AMERICAN WHITE CROSS®, DUMEX®, MEDIHONEY®, ALGICELL®, XTRASORB $^{TM}$ , TCC-EZ $^{TM}$ , and BIOGUARD $^{TM}$ .

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#### **PROSPECTUS SUMMARY**

This summary highlights information contained elsewhere in this prospectus. It does not contain all of the information that you should consider before investing in our securities. You should read the entire prospectus carefully, including the section entitled Risk Factors and our consolidated financial statements and the related notes. The words we, us and our refer to Derma Sciences, Inc. unless the content indicates otherwise.

#### **Our Company**

We are a specialty medical device/pharmaceutical company with a primary focus on wound care. We engage in the manufacture, marketing and sale of three proprietary dermatological related product lines: (1) wound care, (2) wound closure and specialty securement devices, and (3) skin care. In addition, we have leveraged our expanding manufacturing capabilities by building a growing private label/original equipment manufacture (OEM) business. Our customers consist of various health care agencies and institutions such as wound care centers, long-term care facilities, hospitals, home healthcare agencies, physicians offices and closed door pharmacies. We also sell our products through retail channels such as retail pharmacies, other retail outlets and first-aid kit manufacturers. While we have our own direct selling organization, our products are principally sold through medical products supply distributors. We currently sell our products in the United States, Canada and select international markets. Our principal distribution facilities are located in St. Louis, Missouri, Houston, Texas and Toronto, Canada. Our principal manufacturing facility is located in Toronto, Canada. We, through our subsidiary Derma Sciences Canada, also lease a light manufacturing facility in Nantong, China producing labor intensive wound care products.

Derma Sciences, Inc. was organized and incorporated in 1984. In 1994, we completed our initial public offering and our common stock has been publicly held since that time. Derma Sciences, Inc. and our subsidiaries Sunshine Products, Inc., Derma Sciences Canada Inc. and Derma First Aid Products, Inc. are referred to collectively in this prospectus as we or us. Our executive offices are located at 214 Carnegie Center, Suite 300, Princeton, New Jersey and our telephone number is (609) 514-4744.

#### **Our Website**

Our internet address is <a href="http://www.dermasciences.com">http://www.dermasciences.com</a>. Our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, are made available free of charge on our website as soon as practicable after these documents are filed with, or furnished to, the Securities and Exchange Commission (SEC). Information contained on our website, however, is not part of this prospectus.

#### The Offering

Securities we are offering pursuant to this prospectus supplement 810,000 shares of common stock. Each purchaser of a share of common stock will also receive a warrant to purchase one-third of a share of common stock, or 270,000 shares in the aggregate. The shares of common stock and the warrants will be issued separately, but can only be purchased together in this offering. **Purchase Price** We will sell our shares of common stock and warrants in this offering at a price of \$\_\_\_\_\_ per share and warrant. Description of warrants The warrants are exercisable at an exercise price of \$\_\_\_\_\_ per full share of common stock. The warrants are exercisable immediately and expire five years from the date of issuance. See Description of Warrants. Common stock to be outstanding after this offering 5,849,480 shares (\_\_\_\_\_, if the warrants are exercised in full). Percentage of common stock to be acquired by new investors \_\_\_\_% (\_\_\_% if all of the warrants are exercised). Use of proceeds after expenses We will use the proceeds of this offering, estimated to be \$\_\_\_\_, based on an assumed offering price of \$\_\_\_\_, to acquire world-wide rights to certain advanced wound care technology and retire a term loan. See Use of Proceeds . Risk factors This investment involves a high degree of risk. Investors purchasing our securities should not purchase the securities unless they can afford the loss of their entire investment. See Risk Factors . Market for our common stock Our common stock is quoted on The NASDAQ Capital Market under the symbol DSCI. On February 12, 2010, the last reported sale price of our common stock on The NASDAQ Capital Market was \$5.80. Market for the warrants There is no established public trading market for the offered warrants and we do not expect a market to develop. In addition, we do not intend to apply for listing of the warrants on any national securities exchange. Underwriter s warrant In connection with this offering, we have agreed to issue to the underwriter a warrant to purchase up to 3% of the shares sold in this offering (excluding the over-allotment) at \$\_\_\_\_\_ per share (125% of the price of the shares sold in the offering). Other covenants We have agreed not to issue any additional securities for a period of \_\_\_\_ days, subject to certain customary exceptions. See Underwriting. 2

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#### **Summary Financial Information**

In the table below we provide you with historical consolidated financial data for the years ended December 31, 2008 and 2007 and the nine month periods ended September 30, 2009 and 2008, derived from our audited and unaudited consolidated financial statements included elsewhere in this prospectus. Historical results are not necessarily indicative of the results that may be expected for any future period. When you read this historical selected financial data, it is important that you read it along with the appropriate historical consolidated financial statements and related notes and Management s Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this prospectus.

#### **Statement of Operations Data**

	Nine Months Ended		Years Ended	
	September 30,		December 31,	
	2009	2008	2008	2007
Net sales	\$34,877,658	\$37,641,362	\$50,199,428	\$34,135,401
Cost of sales	24,051,984	27,141,628	35,289,684	22,530,986
Gross profit	10,825,674	10,499,734	14,909,744	11,604,415
Total operating expenses	11,532,685	13,158,323	17,850,189	12,878,437
Operating loss	(707,011)	(2,658,589)	(2,940,445)	(1,274,022)
Total other expense, net	519,118	726,846	962,677	748,549
Loss before (benefit)/provision for income taxes	(1,226,129)	(3,385,435)	(3,903,122)	(2,022,571)
(Benefit)/provision for income taxes	(47,151)	(3,540)	58,815	262,034
Net loss	\$(1,178,978)	\$(3,381,895)	\$(3,961,937)	\$(2,284,605)

#### **Balance Sheet Data**

	September 30,	December 31,	Pro Forma (*)	
	2009	2008		
Current assets	\$ 15,410,282	\$ 17,103,720	\$ 17,260,282	
Total assets	\$ 33,334,583	\$ 36,207,322	\$ 33,184,583	
Current liabilities	\$ 8,745,138	\$ 10,364,069	\$ 7,545,138	
Total liabilities	\$ 11,827,456	\$ 14,814,824	\$ 8,427,456	
Total shareholders equity	\$ 21,507,127	\$ 21,392,498	\$ 24,757,127	

Pro forma amounts represent September 30, 2009 amounts adjusted to reflect the receipt of net proceeds from the offering estimated to be \$3,250,000 (based upon an assumed offering price of \$5.00 per share of common stock (\*) and warrant), the application of \$1.4 million of these proceeds toward the retirement of our term loan and the application of \$2.0 million of restricted cash currently collateralizing the term loan for the complete retirement of the loan.

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#### **RISK FACTORS**

This investment involves a high degree of risk and you should purchase shares only if you can afford a complete loss of your investment. Consider carefully these risk factors and other information in this prospectus.

#### **Risks Associated with Our Business**

#### We have a history of losses and can offer no assurance of future profitability.

We incurred losses of \$3,961,937 in 2008, \$2,284,605 in 2007, \$1,099,990 in 2005, \$2,338,693 in 2004, \$2,581,337 in 2000, \$2,998,919 in 1999 and \$1,178,978 for the nine months ended September 30, 2009 (unaudited). At September 30, 2009, we had an accumulated deficit of \$20,842,801 (unaudited). We cannot offer any assurance that we will be able to generate sustained or significant future earnings.

## Our liquidity may be dependent upon amounts available under our existing line of credit or amounts available through additional debt or equity financings.

We have a history of operating losses and negative cash flow from operating activities. As such, we have utilized funds from offerings of our equity securities and lines of credit to fund our operations. We have taken steps to improve our overall liquidity and believe we have sufficient liquidity to meet our needs for the foreseeable future. However, in the event our cash flow from operating activities is insufficient to meet our requirements, we may be forced either to refinance our current line of credit or seek additional equity financing. The sale of additional securities could result in additional dilution to our shareholders. The incurrence of indebtedness would result in increased debt service obligations and could result in operating and financing covenants that would restrict our operations. There can be no assurance that such financing would be available or, if available, that such financing could be obtained upon terms acceptable to us.

### Our foreign operations are essential to our economic success and are subject to various unique risks.

Our future operations and earnings will depend to a large extent on the results of our operations in Canada and our ability to maintain a continuous supply of basic wound care products from our operations in China and suppliers in China and Mexico. While we do not envision any adverse change to our operations in Canada, China or Mexico, adverse changes to these operations, as a result of political, governmental, regulatory, economic, exchange rate, labor, logistical or other factors, could have an adverse effect on our future operating results.

### The rate of reimbursement for the purchase of our products by government and private insurance is subject to change.

Sales of several of our wound care products depend partly on the ability of our customers to obtain reimbursement for the cost of our products from government health administration agencies such as Medicare and Medicaid. Both government health administration agencies and private insurance firms continuously seek to reduce healthcare costs. Our ability to commercialize our products successfully will depend in part on the extent to which reimbursement for

the costs of such products and related treatments will be available from government health administration authorities, private health insurers and other third-party payors. Significant uncertainty exists as to the reimbursement status of newly approved medical products. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect:

Our ability to set a price we believe is fair for our products; Our ability to generate revenues or achieve or maintain profitability; and The availability to us of capital.

Payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement, particularly for new therapeutic products or if there is a perception that the target indication of the new product is well-served by existing drugs or other treatments. Accordingly, even if coverage and reimbursement are provided, market acceptance of our products would be adversely affected if the amount of coverage and/or reimbursement available for the use of our products proved to be unprofitable for healthcare providers or less profitable than alternative treatments.

There have been federal and state proposals to subject the pricing of healthcare goods and services to government control and to make other changes to the U.S. healthcare system. While we cannot predict the outcome of current or future legislation, we anticipate, particularly given President Obama s focus on healthcare reform, that Congress and state legislatures will introduce initiatives directed at lowering the total cost of healthcare. In addition, in certain foreign markets the pricing of drugs is subject to government control and reimbursement may in some cases be unavailable or insufficient. It is uncertain if future legislative proposals, whether domestic or abroad, will be adopted that might affect our products. It is also uncertain what actions federal, state or private payors for healthcare treatment and services may take in response to any such healthcare reform proposals or legislation. Any such healthcare reforms could have a material and adverse effect on the marketability of any products for which we ultimately receive FDA or other regulatory agency approval or for which we receive government sponsored reimbursements.

## Our success may depend upon our ability to protect our patents and proprietary technology.

We own patents, both in the United States and abroad, for several of our products, and rely upon the protection afforded by our patents and trade secrets to protect our technology. Our future success, if any, may depend upon our ability to protect our intellectual property. However, the enforcement of intellectual property rights can be both expensive and time consuming. Therefore, we may not be able to devote the resources necessary to prevent infringement of our intellectual property. Also, our competitors may develop or acquire substantially similar technologies without infringing our patents or trade secrets. For these reasons, we cannot be certain that our patents and proprietary technology will provide us with a competitive advantage.

### Government regulation plays a significant role in our ability to acquire and market products.

Government regulation by the United States Food and Drug Administration and similar agencies in other countries is a significant factor in the development, manufacturing and marketing of many of our products and in our acquisition or licensing of new products. Complying with government regulations is often time consuming and expensive and may involve delays or actions adversely impacting the marketing and sale of our current or future products.

#### Approximately forty percent of our products are sourced from third parties.

Approximately forty percent of our products are sourced in raw, semi-finished and finished form directly from third party suppliers. None of these suppliers presently account for more than ten percent of our sales. We maintain good relations with our third party suppliers. There are several third party suppliers available for each of our products. If a current supplier were unable or unwilling to continue to supply our products, sale of the affected products could be delayed for the period necessary to secure a replacement.

### The technology utilized in many of our advanced wound care products is licensed from third parties and could become unavailable.

Many of our advanced wound care products utilize technology that we license on an exclusive basis from third parties. These products include *Medihoney* dressings, *Bioguard* dressings and MedEfficiency<sup>TM</sup> total contact casts. The licensing agreements that we have with the owners of these technologies are of limited duration and renewals of the agreements are in the discretion of the licensors. In addition, the maintenance of the license agreements requires that we meet various minimum sales and minimum royalty requirements. If we fail to meet the minimum sales or

minimum royalty requirements of a given license agreement, there is a possibility that the agreement will be cancelled or not renewed or that our exclusivity under the license agreement will be withdrawn. If any of these events were to occur, our ability to sell the products utilizing the licensed technology could be lost or compromised and our revenues and potential profits could be adversely affected.

## Competitors could invent products superior to ours and cause our products and technology to become obsolete.

We operate in an industry where technological developments occur at a rapid pace. We compete with a large number of established companies and institutions many of which have more capital, larger staffs and greater expertise than we do. We also compete with a number of smaller companies. Our competitors

currently manufacture and distribute a variety of products that are in many respects comparable to our products. While management has no specific knowledge of products under development by our competitors, it is possible that these competitors may develop technologies and products that are more effective than any we currently have. If this occurs, any of our products and technology affected by these developments could become obsolete.

### Although we are insured, any material product liability claims could adversely affect our business.

We sell over-the-counter products and medical devices and are exposed to the risk of lawsuits claiming alleged injury caused by our products. Among the grounds for potential claims against us are injuries due to alleged product inefficacy and injuries resulting from infection due to allegedly non-sterile products. Although we carry product liability insurance with limits of \$1.0 million per occurrence and \$2.0 million aggregate with \$10.0 million in umbrella coverage, this insurance may not be adequate to reimburse us for all damages that we could suffer as a result of successful product liability claims. No material product liability claim has ever been made against us and we are not aware of any pending product liability claims. However, a successful material product liability suit could adversely affect our business.

## Risks Associated with this Offering and Our Capital Structure

The potential increase in common shares due to the conversion, exercise or vesting of outstanding dilutive securities may have a depressive effect upon the market value of our shares.

Up to 2,563,599 shares of our common stock are potentially issuable upon the conversion, exercise or vesting of outstanding convertible preferred stock, warrants and options (dilutive securities). The shares of common stock potentially issuable upon conversion, exercise or vesting of dilutive securities are substantial compared to the 5,039,468 shares of common stock currently outstanding.

Earnings per share of common stock may be substantially diluted by the existence of these dilutive securities regardless of whether they are converted, exercised or issued. This dilution of earnings per share could have a depressive effect upon the market value of our common stock.

#### Our stock price has been volatile and this volatility is likely to continue.

Historically, the market price of our common stock has been volatile. The high and low prices for the years 2004 through 2009 are set forth in the table below:

Derma Sciences, Inc.
Trading Range Common Stock

Year Low High 2004 \$ 3.44 \$ 15.20

2005	\$ 3.36	\$ 6.24
2006	\$ 3.60	\$ 7.20
2007	\$ 4.64	\$ 11.20
2008	\$ 1.60	\$ 10.80
2009	\$ 1.92	\$ 6.80

Events that may affect our common stock price include:

Quarter to quarter variations in our operating results;
Changes in earnings estimates by securities analysts;
Changes in interest rates or other general economic conditions;
Changes in market conditions in the wound care and skin care industries;
Fluctuations in stock market prices and trading volumes of similar companies;
Discussion of us or our stock price by the financial and scientific press and in online investor communities;

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Additions or departures of key personnel; Changes in third party reimbursement policies; The introduction of new products either by us or by our competitors; and The loss of a major customer.

Although all publicly traded securities are subject to price and volume fluctuations, it is likely that our common stock will experience these fluctuations to a greater degree than the securities of more established and better capitalized organizations.

### We have not paid, and we are unlikely to pay in the near future, cash dividends on our securities.

We have never paid any cash dividends on our common or preferred stock and do not anticipate paying cash dividends in the foreseeable future. The payment of dividends by us will depend on our future earnings, financial condition and such other business and economic factors as our management may consider relevant.

If members of our management and their affiliates were to exercise all warrants and options held by them, and if substantially all of the authorized but unissued restricted stock awards that were granted to members of management and were to vest, members of management and their affiliates could acquire effective control of us.

The executive officers and directors, together with institutions with which they are affiliated, own substantial amounts of our common stock, together with outstanding options and warrants to purchase our common stock. In addition, we have adopted, and our shareholders have approved, a restricted stock plan pursuant to which our outside directors and executive officers may be awarded up to 312,500 shares of restricted stock. Outside directors have been awarded to date 21,875 shares of restricted common stock. Depending upon the warrants and options exercised by outside investors, if directors, executive officers and affiliates were to exercise their options and warrants, and if additional shares of restricted stock are awarded to our directors and executive officers and such awards vest, members of management and their affiliates could obtain effective control of us. As a result, these officers, directors and affiliates would be in a position to significantly influence our strategic direction, the composition of our board of directors and the outcome of fundamental transactions requiring shareholder approval.

### Our common stock does not have a vigorous trading market and you may not be able to sell your securities when desired.

We have a limited active public market for our common shares. We cannot assure you that a more active public market will develop thereby allowing you to sell large quantities of our shares. Consequently, you may not be able to readily liquidate your investment.

## Our common stock may be delisted from the NASDAQ Capital Market which could negatively impact the price of our common stock and our ability to access the capital markets.

The listing standards of the NASDAQ Capital Market (referred to as the NASDAQ Market ) provide that a company,

in order to qualify for continued listing, must maintain a minimum stock price of \$1.00 and satisfy standards relative to minimum shareholders—equity, minimum market value of publicly held shares and various additional requirements. If we fail to comply with all listing standards applicable to issuers listed on the NASDAQ Market, our common stock may be delisted. If our common stock is delisted, it could reduce the price of our common stock and the levels of liquidity available to our shareholders. In addition, the delisting of our common stock could materially adversely affect our access to the capital markets and any limitation on liquidity or reduction in the price of our common stock could materially adversely affect our ability to raise capital. Delisting from the NASDAQ Market could also result in other negative consequences, including the potential loss of confidence by suppliers, customers and employees, the loss of institutional investor interest and fewer business development opportunities.

### The liquidity of our common stock and market capitalization could be adversely affected by our reverse stock split.

We implemented a 1-for-8 reverse split of our common and preferred stock on January 28, 2010. A reverse stock split is often viewed negatively by the market and, consequently, can lead to a decrease in our

price per share and overall market capitalization. If the per share market price does not increase proportionately as a result of the reverse split, then our value as measured by our market capitalization will be reduced, perhaps significantly.

## CAUTION REGARDING FORWARD LOOKING STATEMENTS

This prospectus contains forward-looking statements. Such forward-looking statements include statements regarding, among other things, (a) our projected sales and profitability, (b) our growth strategies, (c) anticipated trends in our industry, (d) our future financing plans, and (e) our anticipated needs for working capital. Forward-looking statements, which involve assumptions and describe our future plans, strategies, and expectations, are generally identifiable by use of the words may, should, expect, anticipate, estimate. project or the negative of these words or other variations on these words or comparable terminology. This information may involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from the future results, performance, or achievements expressed or implied by any forward-looking statements. These statements may be found under Prospectus Management s Discussion and Analysis of Financial Condition and Results of Operations and Description of Business, as well as in this prospectus generally. Actual events or results may differ materially from those discussed in forward-looking statements as a result of various factors, including, without limitation, the risks outlined under Risk Factors and matters described in this prospectus generally. In light of these risks and uncertainties, there can be no assurance that the forward-looking statements contained in this prospectus will in fact occur. In addition to the information expressly required to be included in this filing, we will provide such further material information, if any, as may be necessary to make the required statements, in light of the circumstances under which they are made, not misleading.

#### WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and other reports, proxy statements and other information with the SEC under the Securities Exchange Act of 1934. You may read and copy any materials we file with the SEC at the SEC s public reference room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. Our SEC filings are also available to the public through the SEC s website at <a href="http://www.sec.gov">http://www.sec.gov</a>. General information about us, including our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, as well as any amendments and exhibits to those reports, are available free of charge through our website at <a href="http://www.dermasciences.com">http://www.dermasciences.com</a> as soon as reasonably practicable after we file them with, or furnish them to, the SEC. Information on our website, other than the above mentioned reports and proxy statements, is not incorporated into, and is not a part of, this prospectus.

## INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to incorporate by reference certain information we have filed with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus. The following documents we filed with the SEC are incorporated herein by reference:

- (a) Our registration statement on Form 8-A effective May 13, 1994.
- (b) Our annual report on Form 10-K filed March 31, 2009, and amended on November 12, 2009, for the year ended December 31, 2008.
  - Our notice of annual meeting of shareholders and definitive proxy statement filed April 6, 2009 relative to the
- (c) election of directors and ratification of the appointment of Ernst & Young LLP as our independent registered public accounting firm for the year ending December 31, 2009.
  - Our current report on Form 8-K filed April 6, 2009 relative to: (i) our execution of a forbearance agreement with
- (d) Western Medical, Inc. and (ii) our execution of an amendment to our credit and security agreement with GE Business Financial Services Inc.
- (e) Our quarterly report on Form 10-Q filed May 15, 2009, and amended on November 12, 2009, for the three-month period ended March 31, 2009.
- Our quarterly report on Form 10-Q filed August 14, 2009, and amended on November 12, 2009, for the six-month period ended June 30, 2009.
- (g) Our quarterly report on Form 10-Q filed November 13, 2009 for the nine-month period ended September 30, 2009. Our current report on Form 8-K filed January 29, 2010 relative to: implementation of a 1-for-8 (i) reverse split of
- (h) common and preferred stock, and (ii) a corresponding reduction in our authorized shares of common and preferred stock.
- (i) Our current report on Form 8-K filed February 11, 2010 relative to our listing on the NASDAQ Capital Market. We will provide without charge to each person, including any beneficial owner, to whom a prospectus is delivered, upon written or oral request, a copy of any or all of the reports or documents that have been incorporated by reference in this prospectus. Requests for these reports or documents should be directed to John E. Yetter, CPA, Vice President and Chief Financial Officer, Derma Sciences, Inc., 214 Carnegie Center, Suite 300, Princeton, NJ 08540. Requests for

these reports or documents may be made telephonically to Mr. Yetter at 609-514-4744 and via email to jyetter@dermasciences.com. We will not send exhibits to these filings unless we have specifically incorporated the exhibit by reference into the filing.

We have filed a registration statement with the SEC under the Securities Act that registers the issuance and sale of the securities offered by this prospectus. The registration statement, including the attached exhibits, contains additional relevant information about us. The rules and regulations of the SEC allow us to omit some information included in the registration statement from this prospectus.

#### **USE OF PROCEEDS**

Assuming the sale of \$10,000 shares of common stock and warrants to purchase 270,000 shares of common stock at a public offering price of \$5.00 per share of common stock and warrant, we would receive net proceeds of \$3,250,000 after deducting \$263,250 for underwriting discounts and commissions and estimated expenses of approximately \$536,750 for the underwriter s non-accountable expense allowance, legal, accounting, printing costs and various fees associated with the registration and listing of our shares. If the underwriter exercises its right to purchase additional shares of common stock to cover over-allotments, we would receive up to an additional \$564,975 after deducting \$42,525 for underwriting discounts, commissions and non-accountable expenses. The proceeds from the sale of the shares sold to cover over-allotments will be used for working capital. Assuming no exercise of the underwriter s over-allotment option, we intend to use the net proceeds of the offering as follows:

	Net Proceeds	Applie Percen	
Payment against the cash portion of fees in respect of world-wide licensing rights to advanced wound care technology	\$1,850,000	57	%
Retirement of term loan (*)	1,400,000	43	%
Total proceeds applied	\$3,250,000	100	%

**Applied** 

The term loan to be retired is in the amount of \$3.4 million, bears interest at a variable rate (6.03% as of September (\*) 30, 2009), matures in November, 2012 and is collateralized, in part, by \$2.0 million in a restricted cash account. Retirement of the loan will be effected by the combination of \$1.4 million of the offering proceeds and \$2.0 million from the restricted cash account.

#### **DETERMINATION OF OFFERING PRICE**

The public offering price of the securities offered by this prospectus will be determined by negotiation between us and the underwriter based upon market conditions on the day we price the securities. The offering price may not reflect the price at which the common stock currently trades. That price is subject to change as a result of market conditions and other factors and we cannot assure you that the shares constituting the common stock component of the securities can be resold at or above the public offering price.

#### **DIVIDEND POLICY**

We do not expect to declare or pay any cash dividends on our common stock in the foreseeable future and we currently intend to retain future earnings, if any, to finance the expansion of our business. The decision whether to pay cash dividends on our common stock will be made by our board of directors, in their discretion, and will depend on our financial condition, operating results, capital requirements and other factors that the board of directors considers significant.

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#### **CAPITALIZATION**

The table set forth below depicts our capitalization as of September 30, 2009, on an actual and pro forma basis, as follows:

#### On an actual basis; and

On a pro forma basis as adjusted to reflect the receipt of net proceeds of \$3,250,000 from the sale of 810,000 shares of our common stock and warrants to purchase 270,000 shares of our common stock offered hereby less underwriting discounts and estimated offering expenses and the repayment of \$3,400,000 of long term debt.

	Actual	Pro Forma
Long-term debt, excluding capital lease obligations	\$4,300,000	\$900,000
Common stock, \$0.01 par value; authorized: 18,750,000; outstanding: 5,039,468	50,395	58,495
Convertible preferred stock, \$0.01 par value; authorized: 1,468,750; outstanding: 285,051	2,851	2,851
Additional paid-in capital	41,082,067	44,323,967
Accumulated other comprehensive income	1,214,615	1,214,615
Accumulated deficit	(20,842,801)	(20,842,801)
Total capitalization	\$25,807,127	\$25,657,127

## MARKET FOR COMMON EQUITY AND RELATED SHAREHOLDER MATTERS

Our common stock is traded on the NASDAQ Capital Market under the symbol DSCI. Until February 10, 2010 our common stock traded on the OTC Bulletin Board. The following table sets forth the high and low bid prices for our common stock on the OTC Bulletin Board during each of the indicated calendar quarters:

Quarter Ended	High	Low
March 31, 2009	\$ 5.60	\$ 2.80
June 30, 2009	\$ 4.40	\$ 1.92
September 30, 2009	\$ 6.80	\$ 2.64
December 31, 2009	\$ 6.16	\$ 4.32
March 31, 2008	\$ 10.80	\$ 5.92
June 30, 2008	\$ 8.40	\$ 6.40
September 30, 2008	\$ 7.60	\$ 2.16
December 31, 2008	\$ 5.60	\$ 1.60
March 31, 2007	\$ 6.96	\$ 5.28
June 30, 2007	\$ 8.80	\$ 4.72
September 30, 2007	\$ 7.76	\$ 4.80
December 31, 2007	\$ 11.20	\$ 4.64

On February 12, 2010 our common stock closed at \$5.80. The stock prices reflect inter-dealer prices without retail mark-up, mark-down or commission and may not necessarily represent actual transactions. There is no public market for our preferred stock. As of the close of business on February 12, 2010 there were 1,173 holders of record of the

#### DILUTION

As of September 30, 2009, we had a net tangible book value of \$10,064,651 or \$1.89 per share. Net tangible book value represents our total tangible assets, less all liabilities, divided by the number of shares of common and preferred stock issued and outstanding.

Without taking into account any changes in such net tangible book value after September 30, 2009, other than to give effect to the securities offered hereby (excluding the securities covered by the underwriter s over allotment option), the proforma net tangible book value per share at September 30, 2009 was \$2.17. This amount represents an immediate increase in net tangible book value of \$0.28 per share to our current shareholders and an immediate decrease in net tangible book value of \$2.83 per share to new investors purchasing shares in this offering.

The table set forth below shows the calculation of the increase in book value to current shareholders and the decrease in book value to investors in this offering.

Post-offering net tangible book value per share	\$ 2.17	(1)
Pre-offering net tangible book value per share	1.89	(2)
Pro forma increase in book value per share attributable to new investors	\$ 0.28	
Offering price per share	\$ 5.00	
Post-offering net tangible book value per share	2.17	(1)
Pro forma decrease in book value per share experienced by new investors	\$ 2.83	

Determined by adding to our pre-offering net tangible assets of \$10,064,651 the amount of \$3,250,000 representing the estimated net proceeds of the offering (based upon an estimated public offering price of \$5.00 per share and warrant) and dividing the sum of these amounts by the post-offering outstanding common and preferred stock totaling 6,134,519 shares.

(2) Determined by dividing our pre-offering net tangible assets of \$10,064,651 by our pre-offering outstanding common and preferred stock totaling 5,324,519 shares.

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## MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

## Nine Months Ended September 30, 2009 Compared to Nine Months Ended September 30, 2008

#### **Overview**

The following table highlights the nine months ended September 30, 2009 versus 2008 operating results:

Nine Months Ended				
	September 30,		Variance	
	2009	2008		
Gross Sales	\$41,668,350	\$45,524,044	\$(3,855,694)	(8.5%)
Sales adjustments	(6,790,692)	(7,882,682)	(1,091,990)	(13.9%)
Net sales	34,877,658	37,641,362	(2,763,704)	(7.3%)
Cost of sales	24,051,984	27,141,628	(3,089,644)	(11.4%)
Gross profit	10,825,674	10,499,734	325,940	3.1 %
Selling, general and administrative expense	11,244,347	12,919,124	(1,674,777)	(13.0%)
Research and development expense	288,338	239,199	49,139	20.5 %
Interest expense	631,909	748,743	(116,834)	(15.6%)
Other income, net	(112,791)	(21,897)	(90,894)	
Total expenses	12,051,803	13,885,169	(1,833,366)	(13.2%)
Loss before income taxes	(1,226,129)	(3,385,435)	2,159,306	63.8 %
Provision for income taxes	(47,151)	(3,540)	(43,611)	
Net loss	\$(1,178,978)	\$(3,381,895)	\$2,202,917	65.1 %

**Gross to Net Sales Adjustments** 

Gross to net sales adjustments comprise the following:

	Nine Months Ended	Nine Months Ended		
	September 30,			
	2009 2008			
Gross Sales	\$41,668,350 \$45,524,044			
Trade rebates	(4,934,121) (5,831,141)			
Distributor fees	(711,980 ) (887,655 )			
Sales incentives	(453,411 ) (359,581 )			
Returns and allowances	(384,403 ) (452,702 )			
Cash discounts	(306,777 ) (351,603 )			
Total adjustments	6,790,692 7,882,682			

Net sales \$34,877,658 \$37,641,362

Trade rebates decreased in 2009 versus 2008 due principally to lower Canadian sales subject to rebate which, in turn, resulted from lower demand as a result of the exclusive Canadian distributor reducing its inventory, unfavorable exchange, and a slight increase in sales not subject to rebate. U.S. rebates increased due to an increase in regular and private label sales subject to rebate, coupled with an increase in the percentage of rebates to sales due to list price increases (without a commensurate increase in contract pricing). The decrease in distribution fee expense is commensurate with the change in Canadian net sales upon which it is based. The increase in sales incentive expense relates principally to an expansion of the FAD sales incentive program together with an increase in the level of sales subject to incentives. The sales returns and allowances decrease is principally due to the non-recurrence of higher FAD integration related returns and allowances in 2008. The decrease in cash discounts reflects lower U.S. sales subject to cash discount.

#### **Rebate Reserve Roll Forward**

A nine month roll forward of the trade rebate accruals at September 30, 2009 and 2008 is outlined below:

	Nine Months Ended September 30,	
	2009	2008
Beginning balance January 1	\$2,660,086	\$2,407,709
Rebates paid	(5,223,401)	(5,364,269)
Rebates accrued	4,934,121	5,831,141
Ending balance September 30	\$2,370,806	\$2,874,581

The \$289,280 decrease in the trade rebate reserve balance for the nine months ended September 30, 2009 reflects the timing of payment of U.S. private label rebates coupled with a reduction in the Canadian reserve due to lower sales to the exclusive Canadian distributor in response to the distributors plan to reduce its investment in inventory. There has been no other discernable change in the nature of our business year-to-date as it relates to the accrual and subsequent payment of rebates.

#### **Net Sales and Gross Margin**

The following table highlights the September 30, 2009 versus 2008 product line net sales and gross profit:

	Nine Months E	Inded			
	September 30,		Variance		
	2009	2008			
Net Sales	\$34,877,658	\$37,641,362	\$(2,763,704)	(7.3%)	
Cost of sales	24,051,984	27,141,628	(3,089,644)	(11.4%)	
Gross Profit	\$10,825,674	\$10,499,734	\$325,940	3.1 %	6
Gross Profit %	31.0 %	27 9 %			

Consolidated net sales decreased \$2,763,704, or 7.3% (4.1% adjusted for exchange), in 2009 versus 2008. Canadian net sales decreased \$1,730,747, or 18.1%, to \$7,843,218 in 2009 from \$9,573,965 in 2008. This decrease was driven by unfavorable exchange of \$1,231,370 associated with a 14.8% weakening of the Canadian dollar and lower sales of \$499,377. Inventory rationalization on the part of our Company s exclusive Canadian distributor is principally responsible for the lower sales. Real growth as measured by sales of our Company s products reported by our exclusive distributor, unadjusted for foreign exchange, approximated 7.1%. U.S. net sales decreased \$1,032,957, or 3.7%, to \$27,034,440 in 2009 from \$28,067,397 in 2008. The decrease was driven by lower FAD sales of \$3,527,817, or 27.4%, and traditional wound care sales of \$358,331, or 7.2%, partially offset by higher advanced wound care sales of \$1,965,451, or 60.5%, and private label sales of \$961,105, or 19.3%. Specialty fixation, burn care and skin care and bathing sales were down \$73,365, or 3.8%, period to period. The lower FAD sales reflect the non-recurrence of higher sales in 2008 due to integration related backorder fulfillment, lower demand and customers rationalizing their inventory in 2009 in response to the economy and lost business. The lower traditional wound care sales reflect the non-recurrence of a spot sale (customer s normal supplier was unable to supply) realized in 2008 and lower demand. The higher advanced wound care sales reflect continued growth of *Medihoney* together with the balance of the product line in response to our focused sales and marketing effort. Gross U.S. Medihoney sales increased \$928,433, or 95.9%, to \$1,896,503 in 2009 versus \$968,070 in 2008. Bioguard, our new novel anti-microbial advanced wound care product launched in June, recorded gross sales of \$397,871 in its first four months. Algicell, Xtrasorb and MedEfficiency have also exhibited strong growth in 2009. The increase in private label sales reflects improved demand from a number of

our core customers, coupled with some modest new business that is expected to contribute to the private label segments future growth. Excluding FAD, U.S. sales increased \$2,494,860, or 16.4%.

Consolidated gross profit increased \$325,940, or 3.1%, in 2009 versus 2008. The consolidated gross profit margin percentage increased to 31.0% in 2009 from 27.9% in 2008. Canadian gross profit decreased \$766,008, or 26.7%, to \$2,104,664 in 2009 from \$2,870,672 in 2008. The Canadian gross profit margin percentage decreased to 26.8% in 2009 from 30.0% in 2008. The decrease in Canadian 2009 gross profit dollars reflects the lower sales and gross profit margin percentage decrease. The change in Canadian gross profit margin percentage principally reflects the adverse effect of price erosion coupled with higher product costs, partially offset by the favorable impact of higher production volumes on labor efficiency and overhead absorption and lower overhead spending in 2009 versus 2008. U.S. gross profit increased \$1,091,947, or 14.3%, to \$8,721,010 in 2009 from \$7,629,063 in 2008. The U.S. gross profit margin percentage increased to 32.3% in 2009 from 27.2% in 2008. The increase in U.S. gross profit dollars reflects the increase in gross profit margin percentage, partially offset by the lower sales. The increase in gross profit margin percentage is principally attributable to the improvement in FAD margin due to the discontinuation of higher cost domestic manufacturing in the fourth quarter 2008, growth of the higher margined advanced wound care business and lower freight costs, partially offset by higher product costs. Excluding FAD, favorable product mix partially offset by higher product costs served to increase U.S. margin dollars \$1,150,340, or 22.5%, and the gross profit percentage to 35.4% from 33.6%.

#### Selling, General and Administrative Expenses

The following table highlights September 30, 2009 versus 2008 selling, general and administrative expenses by type:

	Nine Months Ended			
	September 30,		Variance	
	2009	2008		
Distribution	\$1,331,067	\$1,450,481	\$(119,414)	(8.2%)
Marketing	1,201,411	1,414,977	(213,566)	(15.1%)
Sales	3,743,003	4,284,762	(541,759)	(12.6%)
General and administrative	4,968,866	5,768,904	(800,038)	(13.9%)
Total	\$11,244,347	\$12,919,124	\$(1,674,777)	(13.0%)

Selling, general and administrative expenses decreased \$1,674,777, or 13.0%, in 2009 versus 2008, including a decrease of \$285,941 in Canadian selling, general and administrative expenses attributable to exchange.

Distribution expense decreased \$119,414, or 8.2%, in 2009 versus 2008. Expenses in Canada decreased \$102,164 (including a \$34,806 benefit related to exchange) while expenses in the U.S decreased \$17,250. The decrease in Canada was driven by the non-recurrence of incremental expense related to the buy out of the former distribution center lease in the second quarter 2008. The U.S. decrease was driven by the non-recurrence of incremental FAD related integration expenses in Houston incurred in 2008, partially offset by higher lease costs in Houston and St. Louis together with higher personnel and operating costs in St. Louis in support of the growing non-FAD business.

Marketing expense decreased \$213,566, or 15.1%, in 2009 versus 2008. The decrease is attributable to a U.S. decrease of \$196,177 coupled with a decrease in Canada of \$17,389 (including a \$12,012 benefit related to exchange). The U.S. decrease stems from a planned reduction in advanced wound care clinical personnel, consulting, travel and trade show and promotion expense, partially offset by higher product development expense in 2009 in order to align costs with available financial resources, coupled with an increase in FAD related marketing reflecting implementation of a full marketing plan in 2009 versus a partial transition related plan in 2008. The Canada expense decrease reflects lower advanced wound care promotion expense, partially offset by higher product sampling expenses.

Sales expense decreased \$541,759, or 12.6%, in 2009 versus 2008. Expenses in Canada decreased \$118,493 (including a \$79,314 benefit related to exchange) while expenses in the U.S. decreased \$423,269. Expenses in Canada decreased principally due to lower sales commission due to a change in the sales commission program in 2009, direct representative commission due to lower sales and lower travel costs due to cost reduction initiatives, partially offset by higher increased rate related group purchasing organization fees. The U.S. decrease was attributable to lower compensation and commission expenses associated with open (timing related) sales representative positions and the non-recurrence of incremental integration related compensation expenses in customer service, lower FAD broker commissions due to lower sales, lower travel expenses due to cost reduction initiatives, lower recruiting expenses together with the non-recurrence in 2009 of FAD integration related expenses. Offsetting these decreases were higher equity based compensation, regional show and sales tracing expenses associated with the implementation of a more structured sales tracing program in 2008.

General and administrative expense decreased \$800,038, or 13.9%, in 2009 versus 2008. Expenses in Canada decreased \$165,765 (including a \$159,809 benefit related to exchange) while expenses in the U.S. decreased \$634,273. Adjusted for exchange, the \$5,956 decrease in Canada reflects lower compensation due a change in staffing, travel, recruiting and operating expenses, partially offset by higher equity based compensation, benefits, insurance and accounting expenses. The U.S. decrease principally reflects lower bad debt expense of \$247,400 due to the non-recurrence of a significant provision for bad debts in the third quarter of 2008, lower travel of \$156,200, investor relations of \$134,200 and compensation of \$27,400 expenses due to cost reduction initiatives, non-recurring and lower legal expenses of \$95,600 and non-recurring recruiting expense of \$45,700, together with lower other professional service fees of \$27,700 due principally to timing and other net operating costs of \$65,300 due to non-recurrence and cost savings initiatives, partially offset by incremental intangible asset amortization expense of \$165,300 related to the FAD acquisition.

#### **Research and Development Expense**

Research and development expense increased \$49,139 to \$288,338 in 2009 from \$239,199 in 2008. The increase reflects higher ongoing patent related legal and development costs associated with the DSC127 Phase II clinical trial initiated in the first quarter 2008, partially offset by lower consulting expenses.

#### **Interest Expense**

Interest expense decreased \$116,834 to \$631,909 in 2009 from \$748,743 in 2008. The decrease is principally attributable to lower interest rates coupled with lower line of credit and term loan borrowing levels, partially offset by higher loan related fees and lower interest income in 2009 versus 2008.

#### Other Income

Other income increased \$90,894 to \$112,791 in 2009 from \$21,897 in 2008. The main drivers for the increase were \$66,500 of gains on miscellaneous asset sales associated with the closure of the FAD manufacturing operation together with lower exchange losses, partially offset by lower royalty income and other miscellaneous income in 2009 versus 2008.

#### **Income Taxes**

We recorded a \$47,151 tax benefit for 2009 consisting of a \$25,788 current foreign tax benefit and a \$21,363 deferred foreign tax benefit based on our Canadian subsidiary s operating results. No tax benefit was recorded for our U.S. operations in 2009 due to uncertainty surrounding our ability to use available net operating loss carry forwards and net

deferred tax assets. We recorded a \$3,540 deferred foreign tax benefit in 2008 related to our Canadian subsidiary s operating results.

Due to uncertainties surrounding our ability to use our U.S. net operating loss carry forwards and net deferred tax assets, a full valuation allowance for the U.S. net deferred tax assets has been provided.

#### **Net Loss**

We generated a net loss of \$1,178,978, or \$0.23 per share (basic and diluted), in 2009 compared to a net loss of \$3,381,895, or \$0.71 per share (basic and diluted), in 2008.

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#### Liquidity and Capital Resources

#### **Cash Flow and Working Capital**

Quarterly financial performance has improved steadily in 2009 culminating with net income of \$139,603 in the third quarter after losses in the first and second quarters. We reported a \$1,178,978 net loss for the first nine months of 2009 versus a \$3,381,895 net loss in the first nine months of 2008. While sales are lower in 2009, gross profit dollars and margin percentage increased due to a favorable sales mix (principally reflecting the growth of the higher margined advanced wound care business), the elimination of higher cost FAD domestic manufacturing in the fourth quarter 2008 and improved manufacturing performance in Canada, partially offset by higher product costs. Operating expenses were reduced as planned, to better align costs with revenues.

The launch of a number of new products bodes well for the future growth of our higher-margined advanced wound care product line. While overall FAD sales declined in the first nine months of 2009 versus 2008, we believe that the FAD product line represents a solid growth opportunity. Sales for the balance of our product lines are expected to remain relatively stable. Further, we continue to actively pursue distributors in several countries to increase our international sales.

Improving financial performance and other steps taken to improve cash management have served to improve our liquidity. Operating cash flow has improved in the first nine months of 2009 versus the full year 2008. This is attributable to a significant reduction in net operating assets and liabilities employed, together with a lower net loss. In 2008, we increased our investment in inventory approximately \$3,600,000. In 2009 this trend was reversed. Through September 2009 inventories have been reduced approximately \$1,630,000. Operating cash flow is expected to continue to improve over the next twelve months given the expected improvement in financial performance and continuation of our inventory reduction initiative.

At September 30, 2009 and December 31, 2008, we had cash and cash equivalents on hand of \$399,998 and \$391,038, respectively. The \$8,960 increase in cash reflects net cash provided by operating activities of \$1,605,607 and cash provided as a result of exchange rate changes of \$138,362. These increases were essentially offset by cash used in financing activities of \$1,610,787 and cash used in investing activities of \$124,222.

Net cash provided by operating activities of \$1,605,607 stems from \$1,998,363 cash provided from operations (net loss plus non-cash items), together with \$392,756 cash used from the net change in operating assets and liabilities. The increase in cash provided from operations reflects the non-cash items, partially offset by the operating loss. Lower accounts payable, accrued liabilities and higher accounts receivable, partially offset by lower inventory were the main drivers behind the net change in operating assets and liabilities. The decrease in accounts payable reflects a significant reduction in payables related to inventory purchases (consistent with the plan to reduce inventory), lower overall spending levels and timing. The decrease in accrued expenses and other current liabilities principally reflects payment of 2008 year end accruals and timing related changes. The increase in accounts receivable reflects higher third quarter sales. The reduced investment in inventory reflects our plan to reduce inventory levels whenever possible, without compromising customer service requirements.

Net cash used in investing activities of \$124,222 reflects capital expenditures of \$185,222, less receipt of \$61,000 cash from the sale of assets associated with the discontinuation of FAD domestic manufacturing. Capital expenditures are down in 2009 versus 2008 and no significant non discretionary expenditures are anticipated over the next twelve months.

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Net cash used in financing activities of \$1,610,787 reflects regularly scheduled debt payments of \$975,339, pay down of outstanding line of credit borrowings of \$611,016, an increase in restricted cash of \$15,142 and costs related to the issuance of stock of \$9,290.

Working capital decreased \$74,507, or 1.1%, at September 30, 2009 to \$6,665,144 from \$6,739,651 at December 31, 2008. Excluding the reclassification of the \$500,000 promissory note from long term to current debt in the second quarter 2009, working capital increased \$425,493 in the first nine months of 2009 and increased by \$702,812 in the third quarter. Working capital of this magnitude is considered sufficient to support ongoing operations.

#### **Financing Arrangements**

On March 31, 2009, our U.S. lender agreed to amend the credit and security agreement to allow us to enter into a forbearance agreement with Western Medical to postpone payment of our \$500,000 promissory note due April 2009, for one year until April 2010 and to allow subsequent payments on the subordinate debt beginning in April 2010. The Western Medical note payments are conditioned on our achieving predetermined liquidity and free cash flow (as defined) objectives and Western Medical s further extending for one year the payment of the principle balance, if any, remaining on the promissory note after giving effect to the April 2010 payment. In return for the amendment, we agreed to change our base rate for interest charged to a three month LIBOR rate from a one month LIBOR rate (an estimated increase of approximately 50 basis points) and increase our base rate margin by 150 basis points effective April 1, 2009. Using market rates as of the date of the amendment, the estimated cost of the change in interest rates is approximately \$15,000 per month.

In August 2008, we and our U.S. lender modified the terms of our five-year revolving credit and security agreement. The modified terms amend the existing minimum EBITDA, fixed charge coverage, senior debt coverage and total debt coverage covenants. Amendment of the covenants was predicated on our depositing \$2,000,000 in a blocked account controlled by the U.S. lender. Our maximum revolver borrowing capacity remained unchanged at the lesser of (a) the revolver loan commitment (\$8,000,000) or (b) the borrowing base (as defined), less \$1,500,000.

With cash on hand of \$399,998, together with available revolver capacity of \$1,725,641, we have \$2,125,639 of available liquidity at September 30, 2009, versus \$662,806 at June 30, 2009.

#### **Prospective Assessment**

Our strategic objective is to in-license, develop and launch novel higher margined advanced wound care products while utilizing our core business (to the extent possible) to fund this objective. In addition, we will continue to evaluate external opportunities to leverage our core capabilities for growth. To the extent we determine that we cannot finance our growth initiatives internally, we will evaluate the feasibility of doing so via the sale of equity.

As a result of these efforts, we launched *Algicell* in November 2006. We launched our first *Medihoney* product in October 2007. This product represents the first of its kind and interest in the product has been high. Sales have increased steadily and current indications are that the planned *Medihoney* based line of products could result in significant incremental sales. We recently launched four new products to complement our existing advanced wound care product line, the MedEfficiency line of Total Contact Cast systems (October 2008), *Xtrasorb* (November 2008) and *Bioguard*, our novel anti-microbial infection control product in June 2009. *Bioguard*, *Xtrasorb* and MedEfficiency have been well received in the marketplace and have exhibited steady growth. We continue to work on our pipeline and have identified several products that are capable of contributing to future sales growth. We anticipate our core business sales will remain relatively stable over the near term.

In recognition of our financial condition in the fourth quarter of 2008, we initiated the following actions:

1. While not compromising the overall integrity of the advanced wound care growth strategy, prospective plans in terms of sales and marketing resources were scaled back to more affordable levels resulting in an immediate reduction of expense. We have implemented a process to better measure the ongoing return on sales and marketing resources deployed. Assuming the existing resources in place are generating the expected return, we will prospectively expand our investment in sales and marketing resources in support of our advanced wound care growth strategy, as financial conditions allow. We presently have ten direct sales representatives in place and have hired several independent representatives on a commission only

basis to cover open territories.

The FAD business represents a growth opportunity. In addition to its core business opportunities, the FAD business will serve as a platform for introducing our existing advanced and traditional wound care products to new customers 2. and markets, especially the retail market. The FAD is presently working on a number of opportunities for sales growth. We began to realize the savings associated with discontinuing the FAD shigher cost U.S. production in the fourth quarter 2008. In addition, the

FAD is working to firm up a cost effective supply chain for its adhesive bandages and first aid related products. The expanded supply chain is expected to be fully operational within the next six months, at which time we expect to be able to further reduce our product costs and improve liquidity by reducing the level of inventory required to support the existing level of business.

- 3. Steps were taken to identify and eliminate all non-essential operating costs. No salary increases or bonuses are planned until our performance and liquidity improves.
  - We made a significant investment in DSC 127 beginning in December 2007. While the launch of DSC 127 is several years away, we believe the market potential for this product is considerable. The product began Phase II trials in early 2008 to achieve proof of principle in a human model. The Phase II trials are expected to be completed by the fourth quarter of 2010. The projected cost to complete the Phase II trials is approximately \$1,800,000, including \$1,072,010 incurred through September 2009. We plan to continue with this investment and anticipate spending approximately \$727,990 to complete the Phase II trial over the next fifteen months.

The results of the Phase II trial will determine the efficacy and safety of the product and further refine its market potential. The cost of the Phase III trial and bringing the product to market are expected to be significant. Should we decide to proceed with the DSC 127 development plan after completion of Phase II, we plan to fund the additional development costs out of available cash flow or the sale of equity. Alternatively, we may determine to sublicense or sell the rights to the compound.

With the planned improvement in operations and modest expected working capital requirements, together with the available cash on hand and available borrowing capacity as of September 30, 2009, we anticipate having sufficient liquidity in place to meet our operating needs and debt covenants for the foreseeable future.

Our common stock is traded on the NASDAQ Capital Market under the symbol DSCI. We have paid no cash dividends in respect of our common stock and do not intend to pay cash dividends in the near future.

#### **Additional Financial Information**

## **Forward Looking Statements**

Statements that are not historical facts, including statements about our confidence, strategies, expectations about new or existing products, technologies, opportunities, market demand or acceptance of new or existing products are forward-looking statements that involve risks and uncertainties. These uncertainties include, but are not limited to, product demand and market acceptance risk, impact of competitive products and prices, product development, commercialization or technological delays or difficulties, and trade, legal, social, financial and economic risks.

#### **Critical Accounting Policies**

Estimates and assumptions are required in the determination of sales deductions for trade rebates, sales incentives, discounts and allowances. Significant estimates and assumptions are also required in determining the appropriateness of amortization periods for identifiable intangible assets, the potential impairment of goodwill and the valuation of inventory. Some of these judgments can be subjective and complex and, consequently, actual results may differ from these estimates. For any individual estimate or assumption made by us, there may also be other reasonable estimates or assumptions. We believe, however, that given current facts and circumstances, it is unlikely that applying any such other reasonable judgment would cause a material adverse effect on the consolidated results of operations, financial position or cash flows for the periods presented. Our most critical accounting policies are described below.

## Revenue Recognition and Adjustments to Revenue

We sell our products through our own direct sales force and through independent distributors and manufacturers representatives. The primary end users of our products are nursing homes, hospitals, clinics and home healthcare agencies. We recognize revenue from the sale of our products when persuasive evidence of an arrangement exists, delivery has occurred, the sales price is fixed and determinable, and collectability is reasonably assured, which is generally at the time of shipment or receipt by our customers, depending on the terms of the related sales or distribution agreement. When we recognize revenue from the sale of our products, we simultaneously adjust revenue for estimated trade rebates and distribution fees (in Canada), and estimates of returns and allowances, cash discounts and other sales incentives.

A trade rebate represents the difference between the invoice price to the wholesaler/distributor and the end user s contract price. These rebates are estimated monthly based on historical experience, distributor rebate submission trends, estimated distributor inventory levels, and existing contract sales terms with our distributors and end users. We have a contract with our exclusive Canadian distributor and we pay a fixed fee based on sales subject to the fee (as defined) for distribution services in Canada. Because the services performed by the distributor cannot be separated from the purchase of our products by the distributor, we treat this distribution fee as a reduction of revenue. The distribution fee is accrued monthly based on net sales to the distributor multiplied by the ratio of recent historical distributor fee expense to net sales. The percentage of distributor fee expense to net sales is re-evaluated quarterly for reasonableness.

Sales incentives represent credits granted to specific customers based on attainment of pre-determined sales objectives. Sales incentives are accrued monthly in accordance with the terms of the underlying sales incentive agreement and actual customer sales. Sales incentive agreements are generally for a period of one year.

We provide our customers certain limited return rights and we have a formal returned goods policy that guides the disposition of returns with our customers. We follow the accounting guidance outlined in paragraph 605-15-25 of the FASB Accounting Standards Codification as it relates to the recognition of revenue at the time of sale when the right of return exists. We accrue for sales returns and allowances and cash discounts monthly based on current sales and historical activity. We do not offer our customers price protection rights or concessions. Returns were approximately 1% of gross sales in both 2009 and 2008.

We continually monitor the factors that influence rebates and fees, returns and allowances, and other discounts and sales incentives and make adjustments as necessary.

#### Goodwill

At September 30, 2009, we had \$7,119,726 of goodwill consisting of \$4,679,684 relating to the FAD acquisition in November 2007 and \$2,440,042 relating to the Western Medical acquisition in April 2006. We assess the impairment of goodwill annually in the fourth quarter or whenever events or changes in circumstances indicate that the carrying value of goodwill may not be recoverable. The assessment is performed using the two-step process required by FASB accounting guidance relating to goodwill. The first step is a review for potential impairment, while the second step measures the amount of the impairment, if any. The first step of the goodwill impairment test compares the fair value of a reporting unit with its carrying amount, including goodwill. For 2008 and 2007, the first step of our goodwill impairment test reflected a fair value in excess of the carrying value of our reporting units. Accordingly, we did not perform the second step of this test during these periods.

The cash generating unit level or reporting unit at which we test goodwill for impairment is the operating segment level as that term is used in FASB accounting guidance relating to segment reporting. We have three operating segments: wound care, wound closure—specialty securement devices and skin care. Products are allocated to each segment based on the nature and intended use of the product. All of our goodwill has been allocated to the wound care segment as the business acquisitions which gave rise to the goodwill were wound care businesses.

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For 2008 and 2007 and consistent with prior periods, we estimated the fair value of our wound care segment, using the income approach, where we use a discounted cash flow model (DCF) in preparing our goodwill impairment assessment. This approach calculates fair value by estimating the after-tax cash flows attributable to a reporting unit and then discounting these after-tax cash flows to a present value using a risk-adjusted discount rate. We selected this method as being the most meaningful in preparing our goodwill assessments because we believe the income approach most appropriately measures our income producing assets.

Significant estimates used in the fair value calculation include: (i) estimates of future revenue and expense growth, (ii) future estimated effective tax rates, (iii) future estimated capital expenditures, (iv) future required investments in working capital, (v) average cost of capital, and (vi) the terminal value of the reporting unit.

The amount and timing of future cash flows within our DCF analysis is based on our five year forecast. Beyond our five year forecast we assumed a terminal value to calculate the value of cash flows beyond the last projected period in our DCF analysis. Annual revenue growth rates in our DCF model reflect expected growth in our advanced wound care products as well as growth in the products which we gained access to when we acquired FAD in November of 2007 as we introduce these products across our existing customer base. The weighted average cost of capital used to discount cash flows for the annual 2008 goodwill impairment test was estimated to be 17%.

Over time, our wound care segment has become an increasingly significant portion of our overall business. For the year ended December 31, 2008, our wound care segment accounted for approximately 95% of our consolidated revenue which is consistent with the results we are experiencing in 2009. Given the significance of this segment to our overall results, we also look to our publicly traded market value, which we may adjust in consideration of an appropriate control premium, as an indicator of the fair value of our wound care segment and the reasonableness of our DCF model.

There have been no substantial changes to the methodology employed, significant assumptions or calculations applied in the first step of the goodwill impairment test over the past several years.

#### Inventory

The Company writes down the value of inventory by the estimate of the difference between the cost of the inventory and its net realizable value. The estimate takes into account projected sales of the inventory on hand and the age of the inventory in stock. If actual future demand or market conditions are less favorable than those projected by management, additional inventory write-downs may be required. The provision for the write-down of inventory is recorded in cost of sales.

#### **Stock-Based Compensation**

We record compensation expense associated with stock options and other equity-based compensation in accordance with the provisions of ASC Topic 718, Stock Compensation (formerly SFAS 123R) which requires that share-based payment transactions with employees, such as grants of stock options and restricted stock, be recognized in the financial statements based on their fair value at the grant date and recognized as compensation expense over their vesting periods. We estimate the fair value of stock options as of the date of grant using the Black-Scholes or binomial/lattice pricing model (as applicable) and restricted stock based on the quoted market price. ASC Topic 718 requires significant judgment and the use of estimates to value equity-based compensation, particularly surrounding Black-Scholes or binomial/lattice pricing model assumptions such as stock price volatility and expected option lives, as well as expected option forfeiture rates.

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# Year Ended December 31, 2008 Compared to Year Ended December 31, 2007

## **Results of Operations**

#### **Consolidated Operating Results**

The following table highlights the year ended December 31, 2008 versus 2007 operating results:

	Year Ended De	cember 31,	Variance		
	2008	2007	v arrance		
Gross Sales	\$60,431,835	\$42,712,304	\$17,719,531	41.5	%
Sales adjustments	(10,232,407)	(8,576,903)	(1,655,504)	19.3	%
Net sales	50,199,428	34,135,401	16,064,027	47.1	%
Cost of sales	35,289,684	22,530,986	12,758,698	56.6	%
Gross profit	14,909,744	11,604,415	3,305,329	28.5	%
Selling, general and administrative expense	17,196,863	11,885,368	5,311,495	44.7	%
Research and development expense	653,326	653,326 993,069		(34.2%	6)
Interest expense	940,148	413,992	526,156	127.1	%
Loss on debt extinguishment		256,628	(256,628)		
Other expense, net	22,529	77,929	(55,400)	(71.1%	6)
Total expenses	18,812,866	13,626,986	5,185,880	38.1	%
(Loss) income before income taxes	(3,903,122)	(2,022,571)	(1,880,551)	93.0	%
Provision for income taxes	58,815	262,034	203,219	(77.6%	6)
Net loss	\$(3,961,937)	\$(2,284,605)	\$(1,677,332)	73.4	%

#### **Gross to Net Sales Adjustments**

Gross sales are adjusted for trade rebates, distributor fees (in Canada), sales incentives, returns and allowances and cash discounts to derive net sales. Trade rebates are trued-up monthly based upon an analysis of historical sales subject to rebate and actual rebates received from distributors. The normal rebate cycle is one month. Non-exclusive distributors generally carry one month s inventory. Our exclusive distributor in Canada normally carries three to four months inventory. As distributor inventory is depleted via sales, it is replenished via purchases from us. Rebates are processed and submitted for credit on a timely basis consistent with distributor sales. If the normal rebate cycle were one-half month less than estimated at December 31, 2008, the trade rebate reserve would be overstated by approximately \$240,000. If the normal rebate cycle were one month greater than estimated at December 31, 2008, the trade rebate reserve would be understated by approximately \$480,000. To minimize their cash outflow invested in rebates, distributors generally strive to optimize the rebate credit submission process.

Given the nature of our products and business, there is no external information available to further validate the reasonableness of the trade rebate accrual balance. Historical trends of sales subject to rebate and rebates received are evaluated monthly, by distributor, on a 3 month, 6 month and 12 month rolling basis to update the continued reasonableness of the assumptions used to quantify the trade rebate accrual balance. Deviations in the trends resulting, among other causes, from distributors not submitting their rebates on a timely basis are analyzed and factored in determining the required accrual balance.

We currently pay our exclusive Canadian distributor a fixed fee of 10% on net sales subject to the fee (as defined) for distribution services in Canada. The distributor fee is accrued each month based on net sales to the distributor times the ratio of estimated percentage of distributor fee expense to net sales based on past history. The percentage of distributor fee expense to net sales is re-evaluated quarterly for reasonableness.

Sales incentives are credits granted to specific customers based upon attainment of pre-determined sales objectives.

The agreements are generally for a period of one year.

Returns and allowances and cash discounts are accrued monthly based on recent historical activity.

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Gross to net sales adjustments comprise the following:

	Year Ended De	Year Ended December 31,			
	2008	2007			
Gross Sales	\$60,431,835	\$42,712,304			
Trade rebates	(7,446,780)	(6,636,302)			
Distributor fees	(1,135,901)	(1,135,072)			
Sales incentives	(481,803)	(225,386)			
Returns and allowances	(694,765 )	(300,042)			
Cash discounts	(473,158)	(280,101)			
Total adjustments	(10,232,407)	(8,576,903)			
Net sales	\$50,199,428	\$34,135,401			

Trade rebates increased in 2008 versus 2007 due principally to an increase in the overall Canadian rebate percentage due to renewal of buying group contracts at lower selling prices and continuing growth of rebate intensive U.S. private label sales. The change in distribution fee expense is commensurate with the change in Canadian net sales upon which it is based. The increase in sales incentive expense relates principally to a full year of FAD incentives. The sales returns and allowances increase is due principally to a full year of FAD sales and a higher level of FAD returns and allowances associated with the integration of this business during 2008 coupled with a large private label return, partially offset by lower Canadian returns. Cash discounts increased commensurate with an increase in the U.S. sales subject to discount.

#### **Rebate Reserve Roll Forward**

A twelve month roll forward of the trade rebate accruals at December 31, 2008 and 2007 is outlined below:

	Year Ended December 31,			
	2008	2007		
Beginning balance January 1	\$2,407,709	\$1,819,558		
Rebates paid	(7,194,403)	(6,048,151)		
Rebates accrued	7,446,780	6,636,302		
Ending balance December 31	\$2,660,086	\$2,407,709		

The \$252,377 increase in the trade rebate reserve balance in 2008 reflects continued growth of the rebate intensive U.S. private label business coupled with a timing related delay in the payment of the corresponding rebates together with an increase in the Canadian rebate reserve (in local currency) due to higher sales, an increase in the overall rebate percentage due to renewal of buying group contracts at lower selling prices coupled with an increase in the exclusive distributor s inventory level. These increases were partially offset by an overall reduction in the Canadian reserve due to the weakening of the Canadian dollar in the fourth quarter of 2008. There has been no other discernable change in the nature of our business as it relates to the accrual and subsequent payment of rebates.

#### **Net Sales and Gross Margin**

The following table highlights the December 31, 2008 versus 2007 product line net sales and gross profit:

Year Ended	Variance	
2008	2007	v arrance

Net Sales	\$50,199,428	3	\$34,135,40	1	\$16,064,027	47.1%
Cost of sales	35,289,684	ļ	22,530,98	6	12,758,698	56.6%
Gross Profit	\$14,909,744	ļ	\$11,604,41	5	\$3,305,329	28.5%
Gross Profit %	29.7	%	34.0	%		

Consolidated net sales increased \$16,064,027, or 47.1%, in 2008 versus 2007. Canadian net sales decreased \$232,253, or 1.9%, to \$12,091,858 in 2008 from \$12,324,111 in 2007. This decrease was driven by lower sales of \$228,888 and unfavorable exchange of \$3,365. Price erosion and some softness in demand in the fourth quarter, partially offset by a modest distributor inventory build and gross *Medihoney* sales of \$152,267 are principally responsible for the sales decrease. U.S. net sales increased \$16,296,280, or 74.7%, to \$38,107,570 in 2008 from \$21,811,290 in 2007. The increase was driven by the addition of incremental FAD sales of \$15,654,910 coupled with higher advanced wound care sales of \$1,546,584, offset by lower traditional wound care, private label, specialty fixation device and skin care sales. The higher advanced wound care sales reflect continued growth of *Medihoney* together with the balance of the line in response to increased sales and marketing support. Gross U.S. *Medihoney* sales in 2008 were \$1,361,624. The decrease in private label sales reflects softening demand from several customers partially offset by strengthened demand from others. Specialty fixation device sales declined due to the discontinuation of a private label agreement in 2007. Excluding FAD sales, U.S. sales increased \$641,368, or 3.2%.

Consolidated gross profit increased \$3,305,329, or 28.5%, in 2008 versus 2007. The consolidated gross profit margin percentage decreased to 29.7% in 2008 from 34.0% in 2007. Canadian gross profit decreased \$104,625, or 2.6%, to \$3,947,185 in 2008 from \$4,051,810 in 2007. The Canadian gross profit margin percentage decreased to 32.6% in 2008 from 32.9% in 2007. The decrease in Canadian 2008 gross profit dollars reflects the lower gross profit margin percentage. The decline in Canadian gross profit margin percentage principally reflects the adverse impact of lower production volumes on overhead absorption and unfavorable labor efficiency (smaller than normal production runs) together with unfavorable purchase price variances in the fourth quarter associated with higher China product costs. U.S. gross profit increased \$3,409,954, or 45.2%, to \$10,962,559 in 2008 from \$7,552,605 in 2007. The U.S. gross profit margin percentage decreased to 28.8% in 2008 from 34.6% in 2007. The increase in U.S. gross profit dollars reflects higher sales, partially offset by the decline in gross profit margin percentage. The decrease in gross profit margin percentage is principally attributable to the addition of lower margined FAD sales. FAD gross profit margin percentage in 2008 was lower than normal due principally to the need to continue higher cost domestic manufacturing to meet customer demand. Excluding FAD, U.S. gross profit decreased \$118,246, or 1.6%, and the gross profit margin percentage would have been 34.0%, versus 35.2% in 2007. The decrease in the U.S. gross profit margin dollars (excluding FAD), reflects the lower gross profit margin percentage. The decrease in the U.S. gross profit margin percentage (excluding FAD) is attributable to the loss of the higher margined specialty fixation private label agreement in 2007, unfavorable product sales mix and higher transportation and product costs.

#### **Selling, General and Administrative Expenses**

The following table highlights December 31, 2008 versus 2007 operating expenses by type:

	Year Ended D	December 31,	Variance		
	2008	2007	variance		
Distribution	\$1,893,146	\$1,062,766	\$830,380	78.1	%
Marketing	1,781,128	1,512,338	268,790	17.8	%
Sales	5,714,899	3,088,052	2,626,847	85.1	%
General administrative	7,807,690	6,222,212	1,585,478	25.5	%
Total	\$17,196,863	\$11.885.368	\$5.311.495	44.7	%

Selling, general and administrative expenses increased \$5,311,495, or 44.7%, in 2008 versus 2007, including a decrease of \$2,542 in Canadian selling, general and administrative expenses attributable to exchange.

Distribution expense increased \$830,830, or 78.1%, in 2008 versus 2007. Expenses in Canada decreased \$41,127 (including a \$1,168 benefit related to exchange) while expenses in the U.S increased \$871,507. The decrease in

Canada relates to lower utility and maintenance expense, partially offset by lease settlement costs associated with our former Canadian distribution center. The U.S. increase was driven by the addition of

incremental FAD expense of \$822,852 (including one-time transition related costs that are not expected to recur) coupled with incremental personnel and operating costs in St. Louis in support of the non-FAD business.

Marketing expense increased \$268,790, or 17.8%, in 2008 versus 2007. The increase is principally attributable to U.S. increases of \$234,779 to \$1,649,044 in 2008 from \$1,414,264 in 2007. These increases related to \$74,856 in clinical personnel, trade show and promotion expense principally in support of our advanced wound care growth initiatives, partially offset by the absence of any bonus payout in 2008 and \$159,924 in incremental FAD expenses reflecting a full year of activity and the addition of a graphic artist. Canada expense increased \$34,010 (including a \$2,032 benefit related to exchange), or 34.7%, reflecting a higher level of advanced wound care marketing effort, principally for *Medihoney*.

Sales expense increased \$2,626,847, or 85.1%, in 2008 versus 2007. Expenses in Canada increased \$160,220 (including a \$4,099 benefit related to exchange) while expenses in the U.S. increased \$2,466,627. Expenses in Canada increased principally due to consulting costs related to the sale of *Medihoney*, higher travel costs, higher buying group administrative fees (sales volume related) and implementation of a distributor sales incentive program, partially offset by the absence of any bonus payout in 2008. The U.S. increase was principally attributable to an expansion of the sales force to support our advanced wound care products, starting in June 2007, from two representatives to one national sales director and ten sales representatives and the inclusion of the FAD sales force. The sales force expansion involved incremental costs of \$1,338,170 from \$1,954,933 in 2007 to \$3,293,103 in 2008, partially offset by the absence of any bonus payout in 2008. Incremental FAD sales expenses of \$1,002,817 reflect a full year of activity. Higher customer service costs of \$125,640 to support the expanded business, also contributed.

General administrative expense increased \$1,585,478, or 25.5%, in 2008 versus 2007. Expenses in Canada decreased \$96,797 (including \$4,757 of expense related to exchange) while expenses in the U.S. increased \$1,682,275. The decrease in Canada reflects lower bonus and Sarbanes-Oxley consulting expenses (more extensive and costly first year testing in 2007 not repeated in 2008) partially offset by normal year-to-year compensation and benefit increases and one new materials management position (transferred from U.S.). The U.S. increase principally reflects incremental intangible amortization expense of \$767,811 related to the FAD acquisition, higher finance and IT employee costs of \$266,251 associated with new hires in the second half of 2007 and in 2008 to support the growth in the business and expanding regulatory requirements, higher bad debt expense of \$267,047 principally attributable to integration of the FAD business, higher rent of \$98,881 and depreciation of \$58,713 associated with the expansion of the headquarters office in February 2008, higher investor relations costs of \$107,381 due to expanded efforts in this area, higher equity based compensation costs of \$124,683, higher legal costs of \$85,381 related to patent infringement defense, debt covenant compliance and finalization of the Nutramax settlement, higher accounting fees of \$73,468 associated with an expansion of scope due to the addition of FAD and an expanding regulatory environment, higher insurance costs of \$62,071 associated with the addition of FAD, higher IT operating costs of \$36,641 principally in support of the FAD acquisition, recruiting costs of \$26,892, together with normal year-to-year compensation and benefit and other inflationary cost increases, partially offset by lower bonus of \$229,500, lower Sarbanes-Oxley consulting expenses of \$71,049 associated with a planned reduction in scope for the second year of testing and the transfer of one materials management position to Canada.

#### **Research and Development Expense**

Research and development costs of \$653,326 for the year ended December 31, 2008 relate to ongoing development, consulting and legal expenses of DSC 127 that was initiated in the first quarter 2008. The 2007 expense consists of \$868,069 associated with the licensing of the DSC 127 technology in November 2007 and \$125,000 associated with the license of certain anti-microbial technology in March 2007.

#### **Interest Expense**

Interest expense increased \$526,156 to \$940,148 in 2008 from \$413,992 in 2007. Interest expense in Canada decreased \$29,556 while interest expense in the U.S. increased \$555,713. The decrease in Canada reflects the payoff of all Canadian debt in September 2007. The 2007 interest amount included a \$93,821 non-cash charge related to the issuance of common stock warrants in connection with a private placement of securities in November 2007. Interest charges related to the common stock warrants ceased in December 2007

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upon approval of an increase in authorized common shares. The \$649,534 (adjusted for the 2007 non-cash charge) increase in 2008 U.S interest expense is due to the financing associated with the FAD acquisition in November 2007, partially offset by higher interest income of \$37,119.

#### **Loss on Debt Extinguishment**

In connection with the FAD acquisition in November 2007, we incurred a \$200,000 credit facility early termination fee with our former U.S. lender. In addition, we wrote-off \$56,628 in un-amortized deferred financing costs associated with the facility. The total loss on debt extinguishment of \$256,628 has been recorded as a separate line item on the consolidated statement of operations.

#### **Other Expense**

Other expense decreased \$55,400 to \$22,529 in 2008 from \$77,929 in 2007. The main drivers for the decrease in 2008 were higher royalty and other miscellaneous income, partially offset by higher foreign exchange expense.

#### **Income Taxes**

We recorded a \$63,823 current foreign tax provision and a \$5,008 deferred foreign tax benefit in 2008 based on our Canadian subsidiary s operating results. No provision was made for our U.S. operations in 2008 due to a net operating loss coupled with available net operating loss carry forwards. We recorded a \$262,034 deferred foreign tax provision in 2007 related to our Canadian subsidiary s operating results.

Due to uncertainties surrounding our ability to use our U.S. net operating loss carry forwards and net deferred tax assets, a full valuation allowance for the U.S. net deferred tax assets has been provided.

#### **Net Loss**

We generated a net loss of \$3,961,937, or \$0.82 per share (basic and diluted), in 2008 compared to a net loss of \$2,284,605, or \$0.69 per share (basic and diluted), in 2007.

#### Liquidity and Capital Resources

#### **Operational Overview**

Net sales increased 47.1% (1.4% excluding FAD) in 2008 over 2007. This growth was driven by a sales increase in the U.S. of 74.7% (3.5% excluding FAD), together with a decrease in Canadian sales of 1.9%. Sales growth in the U.S. was driven by incremental sales associated with the FAD business (acquired November 8, 2007) of \$15,763,189 coupled with growth of the advanced wound care line. FAD sales continue to represent a growth opportunity for us. Gross U.S. sales of our new *Medihoney* product launched in October 2007 were \$1,361,624 in 2008 versus \$113,394 for three months in 2007. Gross U.S. sales of our silver alginate product were \$1,103,409 in 2008 versus \$683,462 in 2007. In the fourth quarter 2008, we launched the MedEfficiency line of Total Contact Cast systems and *Xtrasorb*. In February 2009, we received clearance from the Food and Drug Administration for the marketing and sale of *Bioguard*, our new novel infection control product. The launch and approval of these promising new products bodes well for the future growth of our higher-margin advanced wound care product line. Private label sales are expected to grow by virtue of anticipated increases in core product demand and the realization of new business opportunities. Skin care sales continue to deteriorate in the face of competitive pressure and a reduction of resources allocated to support the line. Sales for the specialty fixation and closure device line, while experiencing some fluctuation over the past several

quarters, are expected to be relatively stable going forward. Adjusted for exchange, Canada sales to our exclusive distributor were off slightly in 2008. Measured in local currency, sales of our products reported by the Canadian distributor continued to grow, albeit modestly. Expanded marketing and sales efforts, a continued focus on contract compliance, exploring opportunities in other market segments (other than our traditional strength in the acute care segment) and working closely with our exclusive Canadian distributor to capitalize on sales growth opportunities are expected to generate positive results going forward. With gross sales of \$152,267 in 2008 our new *Medihoney* product has started to gain traction in Canada. We are actively pursuing distributors in numerous countries to increase our international sales. A number of our advanced wound care products have recently earned CE mark status and we anticipate that during 2009 we will establish agreements with distributors in Europe and the Middle East.

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We have realized significant product cost improvement over the last several years as a result of our manufacturing and sourcing initiatives. The savings generated by these initiatives have helped partially mitigate the adverse impact of price erosion and foreign exchange on a large portion of our business and served to sustain or improve our gross profit dollars. This trend will become increasingly difficult to perpetuate. Product cost savings associated with implementation of China and other sourcing initiatives have been another contributor to our cost reduction success. Current market conditions in China and other markets portend increasing product and transportation costs that will put pressure on our margins. We will continue to seek opportunities both internally and externally to lower our transportation and product costs and raise selling prices wherever possible in an effort to offset the adverse impact of these higher costs.

At the time of the FAD acquisition in November 2007, the seller was in the process of transferring its domestic production to China and decommissioning most of its U.S. manufacturing infrastructure and overhead. Completion of this initiative will allow the FAD business to reduce its existing product costs thereby allowing it to better compete. Since the acquisition, we have had to continue manufacturing a portion of our adhesive strip requirements in our U.S. facility at higher cost while working to complete the transfer of products to China and evaluating other cost effective sources of supply. U.S. production was discontinued in October 2008 at which time we began to realize the significant savings associated therewith.

Selling, general and administrative expenses increased 44.7% in 2008 over 2007 in line with expectations. The increase is attributable to incremental FAD expenses (intangible asset amortization, planned sales and marketing expenses), planned increases in distribution, marketing and sales expenses in support of our growth initiatives and higher professional service fees as a result of increasing regulatory requirements, bad debt expenses related to the FAD integration and increased corporate office rent to accommodate growth and FAD assimilation. Excluding these expenses, growth in the balance of operating expenses is in line with inflation and continues to be closely monitored.

In November 2007, we made a significant investment in research and development via the licensing of certain angiotensin analog technology. The initial evaluation of the market potential and probability of obtaining approval for sale of products employing this technology was determined to be favorable. Products employing this technology entered the phase II portion of product development trials in the first quarter 2008. Completion of the phase II study is expected by the second quarter of 2010. Presently, we plan to take the product through phase II at an estimated cost of \$1,600,000, including the \$653,326 spent on research and development in 2008. Upon completion of the phase II study in 2010, we will reevaluate the market potential of the product and the probability of its ultimately being approved for sale to determine the best future course of action to take with this product.

In November 2007, in connection with the FAD acquisition, we entered into a new five-year credit and security agreement comprised of an \$8,000,000 revolver and a \$6,000,000 term loan. Given the significant increase in debt, interest expense has become a larger component of our overall cost structure going forward.

We reported a loss of \$3,961,937, albeit at a diminishing quarterly rate in 2008. While sales and gross profit dollars increased, overall performance was adversely impacted by a deteriorating gross profit margin percentage associated with a combination of unfavorable sales mix and higher transportation and product costs. A delay in the planned leveraging of incremental growth oriented sales and marketing investment, incremental research and development costs, a significant increase in borrowing costs and incremental costs required to remain compliant with increasingly stringent regulatory requirements, were also contributing factors. In response to these conditions, we initiated steps in the fourth quarter 2008 to improve performance and liquidity. While not losing sight of our advanced wound care growth objectives, plans were scaled back to more affordable levels resulting in a reduction of selling, general and administrative expenses going forward. Discontinuing U.S. production of FAD products has resulted in a significant reduction in product costs. In addition, steps were taken to identify and eliminate all other non-essential operating

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costs. We anticipate we will continue to operate at a loss in the near term as we implement this new strategy, but we fully expect to significantly improve upon our 2008 performance.

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#### **Cash Flow and Working Capital**

At December 31, 2008 and December 31, 2007, we had cash and cash equivalents on hand of \$391,038 and \$577,096, respectively. The \$186,058 decrease in cash reflects net cash used in operating activities of \$4,743,967 and cash used as a result of exchange rate changes of \$401,684, less cash provided by financing activities of \$4,358,248 and net cash provided in investing activities of \$601,346.

Net cash used in operating activities of \$4,743,967 stems from \$494,076 cash provided from operations (net loss plus non-cash items), together with \$5,238,043 cash used from the net change in operating assets and liabilities. The increase in cash provided from operations reflects the non-cash items, partially offset by the operating loss incurred. Funding of higher receivable and inventory levels coupled with reductions in accrued expenses were the main drivers behind the net change in ongoing operating assets and liabilities. The change in receivables relates to the increase in sales and a deterioration in receivable aging associated principally with the integration of FAD. The increase in inventory principally reflects the build-up of FAD inventory to better meet customer service requirements during the integration process. The decrease in accrued expenses and other current liabilities principally reflects payment of the 2007 USC license fees of \$839,348, accrued bonus (no bonus was accrued in 2008) and timing related changes in Canadian reserves.

Net cash provided by investing activities of \$601,346 reflects receipt of \$1,193,187 cash from the final settlement of the FAD acquisition purchase price in June 2008. Offsetting the cash provided by this settlement were \$120,484 expended for ongoing acquisition related costs and \$471,357 in capital expenditures. The capital expenditures consisted of purchases of manufacturing equipment, trade show booth upgrades, leasehold improvements and furniture at corporate headquarters and new computer equipment.

Net cash provided by financing activities of \$4,358,248 reflects cash received of \$5,728,246 from the sale of common stock and the exercise of common stock warrants and options, net of expenses, increased line of credit borrowings of \$2,227,408, less regularly scheduled debt payments of \$1,313,749, deferred financing costs of \$269,235 principally related to the amendment of our bank covenants in March 2008 and the transfer of \$2,014,422 of cash including \$14,422 in earned interest, into a restricted account the use of which is subject to the approval of the lender.

Working capital increased \$1,370,613, or 25.5%, at December 31, 2008 to \$6,739,651 from \$5,369,038 at December 31, 2007. This increase is principally due to the balance of funds raised from the private equity syndication in April 2008 together with the funds received in June 2008 from the final FAD acquisition settlement that have not been set aside in the blocked control account (restricted cash) or expended. Working capital of this magnitude is considered sufficient to support ongoing operations.

#### **Financing Arrangements**

In August 2008, we and our lender modified the terms of our five-year revolving credit and security agreement. The modified terms amend the existing minimum EBITDA, fixed charge coverage, senior debt coverage and total debt coverage covenants. Amendment of the covenants was predicated on our depositing \$2,000,000 in a blocked account controlled by our lender. Our maximum revolver borrowing capacity remained unchanged at the lesser of (a) the revolver loan commitment (\$8,000,000) or (b) the borrowing base (as defined), less \$1,500,000.

With the cash on hand at December 31, 2008, together with available revolver capacity of \$2,045,800, we have \$2,436,838 of available liquidity at December 31, 2008.

# **DESCRIPTION OF BUSINESS**

#### **Overview**

We are a specialty medical device/pharmaceutical company with a primary focus on wound care. We engage in the manufacture, marketing and sale of three proprietary dermatological related product lines: (1) wound care, (2) wound closure and specialty securement devices, and (3) skin care. In addition, we have leveraged our expanding manufacturing capabilities by building a growing private label/original equipment manufacture (OEM) business. Our customers consist of various health care agencies and institutions such as wound care centers, long-term care facilities, hospitals, home healthcare agencies, physicians offices and closed door pharmacies. We also sell our products through retail channels such as retail pharmacies, other retail outlets and first-aid kit manufacturers. While we have our own direct selling organization, our products are principally sold through medical products supply distributors. We currently sell our products in the United States, Canada and select international markets. Our principal U.S. distribution facilities are located in St. Louis, Missouri, and Houston, Texas. In Canada, our products are distributed exclusively by a third party distributor. Our principal manufacturing facility is located in Toronto, Canada. We, through our subsidiary Derma Sciences Canada, have a light manufacturing facility in Nantong, China producing low volume and/or labor intensive wound care products.

The markets we serve are large and growing. Our mission is to enhance shareholder value by servicing a significant portion of these markets as a fully integrated wound care product provider.

#### **Business Strategy**

Our strategic objective is to in-license, develop and launch novel higher margined advanced wound care products while utilizing revenues from our core business (to the extent possible) to fund this objective. A major component of this strategy is the expansion of our *Medihoney* product line. We have an exclusive five-year agreement expiring October, 2012 for the *Medihoney* line of products in the territory of North and South America and we seek to establish our *Medihoney* product line throughout the world as a leading therapy for treating a broad range of chronic and non-chronic wounds. To this end, we plan to utilize a portion of the proceeds of this offering to purchase the exclusive world-wide patent rights, know-how and trademarks for the *Medihoney* line of products and establish international management and distribution of the *Medihoney* brands.

In addition to our *Medihoney* strategy, we will continue to evaluate external opportunities to leverage our core capabilities for growth. Our immediate objectives are to:

Successfully complete the phase II trial of DSC127 and evaluate future development and partnering opportunities. Expand our direct advanced wound care sales force in the United States in order to leverage the sales and profit potential of our current and pipeline products.

Expand our wound care line through internal development, product line extensions and in-licensing.

Establish FAD as the leader in private label adhesive bandages.

Become an innovator in new dressings for the first-aid market.

Improve manufacturing and sourcing operations to lower costs and improve margins. Expand our international business using our novel advanced wound care products as the catalyst.

#### **Acquisitions**

In September, 1998 we acquired Genetic Laboratories Wound Care, Inc. (Genetic Labs) by means of a tax-free reorganization whereby Genetic Labs became our wholly-owned subsidiary. In December, 1999, pursuant to an

Agreement and Plan of Merger dated December 27, 1999, Genetic Labs was merged into Derma Sciences, Inc. by means of a tax-free reorganization whereby the separate corporate existence of Genetic Labs ceased. The Genetic Labs products constitute our wound closure specialty securement device product line.

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In November, 1998 we acquired the stock of Sunshine Products, Inc. (Sunshine Products) in a cash transaction. As a result of the stock purchase, Sunshine Products became our wholly-owned subsidiary. The Sunshine Products products constitute our skin care product line.

In September, 2002 we acquired the assets of Dumex Medical Inc., a leading manufacturer and distributor of wound care and related medical devices to the Canadian market. The acquisition was effected by our wholly-owned Canadian subsidiary, Derma Sciences Canada Inc. ( Derma Canada ) f/k/a Dumex Medical Canada Inc. The Dumex Medical products have been integrated into our wound care product line.

In January 2004, we acquired substantially all the assets of the Kimberly-Clark Corporation s wound care segment. These assets have been integrated into both our existing wound care and wound closure specialty securement device product lines.

In April 2006, we acquired certain assets and the business of Western Medical, Inc. (Western Medical), a manufacturer and marketer of a line of specialty medical textile compression, support and protective dressing products. These assets have been integrated into our existing wound care product line.

In November, 2007, we acquired certain assets and the business of Nutra Max Products, Inc. s first aid division. FAD is a leading manufacturer and marketer of branded and private label adhesive strips and related first aid products to the medical, industrial and retail markets. These assets have been integrated into our existing wound care product line.

#### **Markets**

#### **Market Data**

Our products are sold in the U.S., Canada and select international markets. There are roughly 500 million people over the age of 65 worldwide. This figure is expected to grow to one billion by the year 2030 (Dobriansky et al. 2008). In the United States, there are 37.1 million people over age 65. This figure is expected to grow to 71.5 million by 2030 (Sondik et al. March, 2008). The global market size for advanced/active wound care products is estimated to be \$4.9 billion and growing at a 10% rate annually. The United States accounts for 39% of this market. Europe accounts for 41% and the rest of the world accounts for the remaining 20% (Tibballs, J. 2009).

There are an estimated six million chronic wounds treated in the United States every year (Crandall 2008). The average cost to treat these wounds ranges from \$5,000 to \$25,000 and the ancillary costs to the healthcare system and society are considerably greater (Advanced Wound Care Biologics August, 2002). The chronic wound market is growing at a rate of 10% annually due to a growing aging population and higher incidences of diabetes (Dobriansky et al. 2008).

There are 246 million people with diabetes worldwide. This figure is expected to reach 380 million by the year 2025. In the United States, there are 16.6 million people afflicted with diabetes. This figure has doubled since 1997 (Diabetes Atlas 2006). In the United States, an estimated 2.4 million patients with diabetes will develop chronic foot ulcers during their lifetimes (Diabetes in North America June, 2005). Ulcers are responsible for 20% of all diabetes-related hospitalizations (Frykberg et al. 2000). Diabetic ulcers, if not treated, can become infected and lead to below the knee amputations (O Brien et al. 1998).

Roughly 250 people die every day in the United States from complications arising from hospital acquired infections, many of which are surgical site infections (Klevens et al. March-April, 2007). These 90,000 deaths per year exceed AIDS related deaths as well as virtually all major cancer types with the exception of lung cancer (Centers for Disease

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Control and Prevention). In a 2006 study, it was estimated that the average cost for hospitalization in which a patient acquired an infection was \$53,915, compared to \$8,311 when the patient does not (Hospital-Acquired Infections in Pennsylvania January, 2009). Hospital acquired infections result in adding \$28 to \$30 billion each year to United States healthcare costs (McCaughey 2008).

Currently, the global market for antimicrobial dressings is estimated to be \$250 million (Global Top Ten Medical Device Technologies July, 2009). This market is mostly comprised of silver and iodine-based dressings, both of which are noted to have toxic side effects which are deleterious to wound healing. We, through several of our product offerings including *Medihoney* and *Bioguard*, meet the global need for non-toxic yet effective topical antimicrobials.

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#### **Products**

#### **Advanced/Active Wound Care**

Our advanced/active wound care products include the following:

Medihoney is a line of novel, patented dressings, comprised of a high percentage of Active Leptospermum Honey.

This unique type of honey has been shown to result in durable antimicrobial, anti-inflammatory and immunomodulatory activities. Medihoney dressings are ideal for the management of non-chronic and hard-to-heal wounds including chronic ulcers, burns and post-operative wounds. The dressings are non-toxic and have been shown in a large scale randomized controlled study to promote healing.

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Bioguard is a line of novel, patented barrier dressings that contain an active antimicrobial compound. This compound, a cationic biocide, is intrinsically bound to the dressing through a proprietary process resulting in the inability for the compound to separate from the dressing. These dressings are ideal for prophylactic use in the prevention of hospital or community acquired infections through wound sites. The dressings have been shown to kill 99.9% of virulent bacteria such as methicillin resistant *staphylococcus aureus* (MRSA) in less than 1 minute, and 99.999% of MRSA in less than 1 hour. Bioguard s patented polymer technology known as NIMBUS (novel intrinsically micro-biocidal utility substrate) was licensed from QuickMed Technologies, Inc. in April, 2007.

Algicell Ag is a proprietary antimicrobial dressing utilizing ionic silver as its active ingredient. The dressing can absorb up to 20 times its weight in wound fluid. These dressings compare favorably to the market leading dressings at a cost-effective price point.

*Xtrasorb* is a novel, proprietary dressing that utilizes a super absorbent polymer. While other absorbing dressings currently on the market use open cell structures to capture fluid, *Xtrasorb* dressings convert fluid within the dressing to a gel thus locking the exudates into the dressing. *Xtrasorb* dressings have a distinct advantage over competitive dressings in that they absorb more fluid and hold the fluid away from the wound thus avoiding further deterioration of the wound.

TCC-EZ is a novel, patented advanced dressing system for the management of diabetic foot ulcers. It is considered a next generation total contact casting (TCC) system. TTC have been shown in multiple randomized controlled studies to achieve 89% heal rates. However, utilization of TTC is less than 2% due to various challenging issues such as long application times, frequency of application error and patient dissatisfaction as a result of the heavy nature of the cast. TCC-EZ virtually eliminates these issues as it can be applied in less than one third the time of a traditional TCC, is a one-step process so application errors are uncommon and the cast itself is significantly lighter due to its open weave pattern than a traditional TCC.

Other advanced wound care products include a range of moist, occlusive dressings such as hydrocolloids, foams, hydrogels, alginates, additional silver antimicrobial dressings, cleansers and our proprietary *Dermagran* products.

#### **Traditional Wound Care and Skin Care**

Our traditional wound care line consists of gauze sponges and bandages, non-adherent impregnated dressings, retention devices, paste bandages and other compression devices.

We market general purpose and specialized skin care products to nursing homes, hospitals, home healthcare agencies and other institutions. These products include barrier creams and ointments, antibacterial cleansing foams and sprays, shampoos and body washes, hand sanitizers, bath additives, body oils and moisturizers.

#### **Wound Closure and Specialty Securement Devices**

We market a line of wound closure strips, nasal tube fasteners and a variety of catheter fasteners to doctors, clinics, nursing homes, hospitals and other institutions. Our specialty securement and closure device products incorporate our proprietary polyamide fabrics in combination with a pressure sensitive skin-friendly adhesive. These product combinations result in an ideal balance between elasticity and adherence, making the products unique in their ability to safely hold devices in place on the skin while assisting with the closure of sensitive areas of the skin where a good cosmetic outcome is a priority. We also market a line of traditional rigid wound closure strips.

#### Private Label/OEM

We manufacture private label wound care and wound closure and specialty securement devices for a number of United States and international customers.

#### **Product Pipeline**

We are currently developing DSC127, an angiotensin analog licensed from the University of Southern California in November, 2007, for use in wound healing and scar reduction. The compound has shown activity in these areas in pre-clinical animal model testing. The compound has successfully completed a phase I human trial and is presently undergoing phase II human trials. This trial will assess safety and efficacy of DSC127 on non-healing diabetic ulcers. We expect to receive the results of the phase II trials in the third quarter, 2010. If the results are favorable, we will ascertain whether it is in our best interests to conduct phase III trials or license the rights to the product.

The potential markets for DSC127 include: (1) the \$10 billion chronic wound market, (2) the \$8 billion scar prevention/reduction market, (3) the \$6 billion burn market, and (4) the \$6 billion radiation and other wound markets. The markets we enter will depend on the results of the DSC127 clinical trials.

We continue to evaluate certain products and technologies within the advanced/active wound care market. Once products and technologies are located, we may enter into licensing agreements or joint venture relationships with owners of the products and technologies.

We have several ongoing product development programs involving line-extensions of our key brands including *Medihoney*, *Bioguard* and *Xtrasorb*. We anticipate new line extensions to begin coming to market in the first quarter, 2010 and continuing through the third quarter, 2011.

#### Sales and Marketing

Sales in the United States and Canada account for approximately 70% and 25%, respectively, of our total sales with sales to Europe and Latin America comprising the balance of 5%.

#### **United States**

In the United States, we employ a direct sales force and a number of national, regional and local distributors (with their own sales forces) to sell our products. The majority of our sales are made to distributors and large institutional customers who sell the products to end users. Direct sales to end users are not a significant part of our business.

Our direct sales force consists of an executive vice president—sales, a national director—sales, ten direct territory representatives and one clinical resource specialist. Our sales employees receive a base salary together with commissions based upon sales and gross profit achievement within their area of responsibility.

#### Canada

In Canada, we employ a sales manager, one direct sales representative in Ontario and a manufacturer s representative located in British Colombia. Our sales representative receives a base salary together with commissions based upon territory sales achievement. Our manufacturer s representative is paid commission based upon territory sales achievement and is reimbursed for expenses. The majority of our Canadian sales are to hospitals pursuant to tender contracts with national, provincial and local buying groups. These institutional contracts are generally exclusive in nature and are awarded for a term of 1 to 5 years. Nursing home, home healthcare, physician office and retail sales are for the most part made through local dealers and government sponsored Community Care Access Centre s (CCAC) agencies.

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In May 2005, we entered into a five year agreement with a Canadian company to serve as the exclusive distributor of our products in Canada. The distributor maintains strategically located distribution centers and over 40 sales representatives throughout Canada. We believe the agreement provides better service to our customers throughout Canada and greater opportunity for sales growth.

## **Other Foreign Markets**

Our products are sold throughout the rest of the world through various licensing and distribution agreements. Foreign sales are made principally to Europe and Latin America. Sales made to other foreign markets totaled \$2,743,388 in 2008 and \$1,692,130 in 2007.

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#### Competition

The wound and skin care sectors of the medical products industry are characterized by rapidly evolving technology and intense competition. Many suppliers of competing products are considerably larger and have much greater resources than us. In addition, many specialized products companies have formed collaborations with large, established companies to support research, development and commercialization of wound and skin care products which may be competitive with ours. Academic institutions, government agencies and other public and private research organizations are also conducting research activities and may commercialize wound and skin care products on their own or through joint ventures.

In the United States, our basic wound care products compete in a commodity oriented marketplace with Covidien, Medical Action and a number of others. In the advanced wound care products marketplace, we compete principally with Convatec, Smith & Nephew, MoInlycke and Systagenix (formerly Johnson & Johnson s wound care division) and Johnson & Johnson. The market for wound closure strips and catheter fasteners is characterized by a wide range of generic competition. The most dominant competitor in the suture strip market is 3M. Our skin care products compete in a commodity oriented marketplace with Medline, Provon and a number of others.

In Canada, our basic wound care products compete in a commodity-oriented marketplace with Covidien, Medicom, Medical Mart, and a number of others. In the advanced wound care products marketplace, we compete principally with the same competitors as we compete with in the United States together with a number of domestic generic companies.

Our ability to remain competitive is based on our ability to provide our customers with a broad range of quality products at a competitive price with superior customer service. The prospective ability to develop cost effectively and/or acquire and commercialize new products that provide superior value is an integral component of our ability to stay competitive. We believe that the breadth and quality of our existing product lines, the infrastructure in place to cost effectively source and market our products and the skill and dedication of our employees will allow us to successfully compete.

#### **Product Sourcing**

We lease manufacturing and warehousing facilities in Toronto, Canada, and Nantong, China, and employ contract manufacturers in Mexico City, Mexico, and ZhongShan, China. Approximately 60% of our products are manufactured at these four locations. The remaining 40% of our products are manufactured by third party manufacturers in China and other countries.

Our four manufacturing facilities are monitored and controlled by our management and quality control teams. These teams oversee product production. Most of the equipment in these facilities is owned by us and used exclusively by

Our 76,399 square foot facility in Toronto manufactures our line of basic and advanced wound care and wound closure-specialty securement device products. This facility has the capability of liquid packaging, blister/vacuum packaging, impregnation, die-cutting and steam sterilization. We also have research and development laboratories on site. The Toronto facility is ISO 13485:2003, ISO 9001:2000, and Directive 93/42/EEC certified and SGS registered.

Our 11,388 square foot facility in Nantong manufactures our line of basic and some advanced wound care products. This facility is primarily designed for production of high-quality and specialty products. The quality control team at Nantong has the responsibility to oversee and inspect all products produced in China for us. The Nantong facility is

ISO 9002 certified and TUV registered.

Both our Mexico City and ZhongShan facilities manufacture adhesive bandages and related first aid products. The Mexico City facility is ISO 9001:2000 and ISO 13485:2004 certified and Aenor IQNET registered. The ZhongShan facility is ISO 13485:2003 certified and NQA registered.

A number of basic and advanced wound care products are sourced in semi-finished and finished form directly from suppliers. Derma Sciences Canada also serves in a distributor capacity (sourcing finished products directly from suppliers) for a number of medical device products in Canada.

We maintain a long-standing network of suppliers for our outsourced products. The majority of our outsourced products utilize readily available components. Accordingly, there are numerous companies capable of manufacturing these products to applicable regulatory standards. Given the availability of other suppliers, as well as our policy regarding maintenance of adequate safety stock levels, we do not believe that a temporary interruption in supply or loss of one or more of our suppliers would have a long-term detrimental impact on our operations.

We require that all of our suppliers conform to the standards set forth in the Good Manufacturing Practice (GMP) regulations promulgated by the United States FDA and local health agencies.

#### Patents, Trademarks, Proprietary and Non-Proprietary Technology

We own or license the following trademarks: *Derma Sciences*, *Dermagran*, *American White Cross*, *Dumex*, *Medihoney*, *Algicell*, *Xtrasorb*, *TCC-EZ*, *Mobility1* and *Bioguard*. In addition, we own or license over fifty United States patents, corresponding foreign patents and patent applications. Our patents expire between 2018 and 2020. Most of our patents relate to our DSC127 technology and are held under a license agreement of indefinite duration. License agreements relative to our *Bioguard* and *Medihoney* technologies currently expire in June, 2014 and October, 2012, respectively. However, we expect that these license agreements will be renewed. We also have a number of non-patented formulations and process technologies that, together with the aforementioned patents, provide competitive advantages in the marketplace.

We believe our patents, proprietary and non-proprietary technology afford us reasonable protection against the unauthorized copying of the technology embodied in the subject products. However, the specific means whereby these products promote wound healing and skin care are unknown and the chemical and biological processes bearing upon wound healing and skin care are highly complex and subject to a wide variety of influences and stimuli. As such, it is possible that competitors will develop products equal, or superior, to ours without infringing upon our intellectual property.

Patent law relating to the scope of claims with respect to wound care products is still evolving and our patent rights are subject to uncertainty. Furthermore, the existence of patent rights does not provide absolute assurance against infringement of these rights. The prosecution and defense of patent claims is both costly and time consuming, regardless of the outcome.

An important component of our growth strategy is to acquire, by purchase or license, both proprietary and non-proprietary wound and skin care technology. There can be no assurance that we will be able to obtain such technology on acceptable terms, if at all. Future inability to acquire or license wound and skin care technology could have a material adverse effect on our business.

#### **Government Regulation**

#### United States Scope of Regulation

#### Agencies

The manufacture, distribution and advertising of our products are subject to regulation by numerous federal and state governmental agencies in the United States. The United States Food and Drug Administration (FDA) is responsible for enforcement of the Federal Food, Drug and Cosmetic Act, as amended, (FDC Act) which regulates drugs and devices manufactured and distributed in interstate commerce. Many of our products are classified either as over-the-counter drugs or medical devices pursuant to the FDC Act. The Federal Trade Commission (FTC)

administers the Federal Trade Commission Act (FTC Act) which regulates the advertising of products including over-the-counter drugs and devices. All states have individual laws analogous to the FDC Act and the FTC Act.

#### **Medical Devices**

The FDC Act requires that all devices for human use marketed in the United States prior to May 28, 1976 (Pre-amendment Devices) be classified by the FDA, based on recommendations of expert panels, into one of three regulatory classes. Class I products are subject only to the general controls which apply to all devices, irrespective of class. General controls include the registration of manufacturers, record-keeping requirements, labeling requirements, and Good Manufacturing Practice (GMP) regulations.

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Class II devices are those for which general controls are not sufficient to ensure safety and effectiveness, and for which enough information exists to develop a standard. These devices are required to meet performance standards established by the FDA. Performance standards may specify materials, construction components, ingredients, labeling and other properties of the device. A standard may also provide for the testing of devices to ensure that different lots of individual products conform to the requirements.

The most restrictive controls are applied to devices placed in Class III. Class III devices are required to have FDA approval for safety and effectiveness before they can be marketed unless the FDA determines that pre-market approval is not necessary. Pre-market approval necessitates the compilation of extensive safety and effectiveness data which is normally expensive to compile. Approval of Class III devices may require several years.

Devices marketed after May 28, 1976 are considered to be one of two kinds: those that are and those that are not substantially the same as a Pre-amendment Device. Those that are substantially equivalent to a Pre-amendment Device are given the same classification as the equivalent Pre-amendment Device. New devices which are not substantially equivalent to Pre-amendment Devices are automatically placed in Class III thereby requiring pre-market approval.

All manufacturers are required to give the FDA ninety days notice before they can introduce a device on the market. During the ninety-day period, the FDA will determine whether the device is or is not substantially equivalent to a Pre-amendment Device. If the FDA determines that the device is not substantially equivalent to a Pre-amendment Device, it is automatically placed in Class III and the manufacturer will have to provide the FDA with a Premarket Approval Application (PMA) containing evidence that the device is safe and effective before the device may be commercially distributed to the public. However, the manufacturer may request that the FDA reclassify the device by filing a reclassification petition.

All of the devices currently marketed by us, with the exceptions of Sterile Water and Sterile Saline, have been found by the FDA to be substantially equivalent to a Pre-amendment Device and are, therefore, classified in Class I. Sterile Water and Sterile Saline are classified in Class II and meet the performance standards established by the FDA. Algicell Ag Dressings with antimicrobial silver and Medihoney Wound & Burn Dressings with Active Leptospermum Honey are unclassified. We and our principal suppliers with respect to products sold to us operate in accordance with GMP.

#### **Over-the-Counter Drugs**

Prescription drugs may be dispensed only on the prescription of a licensed practitioner and must be labeled: Caution: Federal law prohibits dispensing without prescription. In general, a drug is restricted to the prescription class if it is not safe for use except under professional supervision. All drugs having characteristics that do not require prescription dispensing are considered to be over-the-counter (OTC) drugs.

In 1972, the FDA began a comprehensive review of the safety, efficacy and labeling of all OTC drugs for the purpose of establishing the conditions under which such drugs could be generally recognized as safe, effective and not misbranded. To facilitate the review, these drug products were grouped into therapeutic classes and advisory panels were established to review each class. The panels completed their review in 1983 and it remains for the FDA to complete the rulemaking process.

On the basis of the recommendations submitted by the panels, the FDA issues monographs setting forth the conditions under which OTC drugs in each class are deemed to be generally recognized as safe, effective and not misbranded. Generally, the administrative process includes the publication of a Preliminary, Tentative Final and Final Monograph.

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During the rulemaking process, products are placed into one of three categories describing whether a drug is deemed to be generally recognized as safe and effective and not misbranded (Category I), to be not generally recognized as safe and effective or misbranded (Category II) or to lack sufficient data for categorization (Category III). Products that do not comply with general OTC regulations or an applicable Final Monograph are subject to regulatory action. Any OTC drug not in compliance with the content and labeling requirements of a Final Monograph is subject to regulatory action unless it is the subject of an approved new drug application. The FDA has issued a Compliance Policy Guide in which it determined that it would not pursue regulatory action against OTC drugs prior to the adoption of a

final regulation unless failure to do so presents a potential public health hazard. We believe all of the OTC products currently marketed by us have been deemed to be generally recognized as safe and effective and not misbranded.

#### Canada Scope of Regulation

#### **Medical Devices**

The Medical Devices Regulations have been established under the authority of the Food and Drugs Act and apply to all medical devices imported and sold in Canada. The Medical Devices Bureau of the Therapeutic Products Directorate is the national authority that monitors and evaluates the safety, effectiveness and quality of diagnostic and therapeutic medical devices in Canada.

On July 1, 1998 the Medical Devices Regulations set forth the requirements governing the sale, importation and advertisement of medical devices in Canada. Regulatory scrutiny is applied in these areas based on risk management principles that classify medical devices into four classes, with Class I representing the lowest risk and Class IV the highest.

Every medical device imported or sold in Canada, with the exception of Class I medical devices, is required to be licensed prior to being imported or sold. A device license will be issued to the manufacturer of a device if it is determined that the device meets applicable safety and effectiveness requirements. Although Class I devices do not require a license, they are monitored through Establishment Licenses. An Establishment License permits importers, distributors and manufacturers of Class I devices to operate in Canada without using a licensed importer.

As of January 1, 2003, manufacturers of Class II, III and IV devices are required to have a quality system registered to ISO 13485 or ISO 13488 by a registrar recognized by Health Canada. Proof of registration must be submitted with any new license application after January 1, 2003 and with the renewal of existing licenses after November 1, 2003.

#### **Drugs**

The Health Products and Food Branch Inspectorate of Health Canada regulates drugs and the processes used to manufacture drugs. A Drug Establishment License is required for activities such as fabrication, packaging/labeling, importation, distribution, wholesale and testing. Derma Canada last underwent an inspection by the Health Products and Food Branch Inspectorate in August 2007 which occasioned the renewal and subsequent annual renewal of its Drug Establishment License.

Once a drug has been approved, the Therapeutic Products Directorate issues a DIN (Drug Identification Number) which permits the manufacturer to market the drug in Canada. A DIN lets the user know that the product has undergone and passed a review of its formulation, labeling and instructions for use.

#### Registration and Status of Derma Canada Products Sold in United States

Derma Canada has passed inspection by the FDA.

#### Other Foreign Regulatory Authorities

Whether or not FDA approval has been obtained, approval of medical drugs and devices by regulatory authorities in foreign countries must be obtained prior to marketing drugs and devices in such countries. The requirements governing the conduct of clinical trials and product approval vary widely from country to country and the time

required for approval may be longer or shorter than that required for FDA approval. Although there are procedures for unified filings for certain European countries, most countries currently maintain their own product approval procedures and requirements.

## **Other Regulatory Requirements**

In addition to the regulatory framework for product approvals, we are subject to regulation under state and federal law, including requirements regarding occupational safety, laboratory practices, environmental protection and hazardous substance control, and may be subject to other present and future local, state, federal and foreign regulation.

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We are also subject to federal, state and foreign laws and regulations adopted for the protection of the environment and the health and safety of employees. Management believes that we are in compliance with all such laws, regulations and standards currently in effect and that the cost of compliance with such laws, regulations and standards will not have a material adverse effect on us.

#### Third Party Reimbursement in the United States

In the United States, we sell our wound care products to nursing homes, hospitals, home healthcare agencies, retail and closed door pharmacies and similar institutions. The patients at these institutions for whose care our products are purchased often are covered by medical insurance. Accordingly, our customers routinely seek reimbursement for the cost of our wound care products from third party payors such as Medicare, Medicaid, health maintenance organizations and private insurers. The availability of reimbursement from such third party payors is a factor in our sales of wound care products.

Medicaid is a federally funded program administered by the states. Medicaid insurance is available to individuals who have no Medicare or private health insurance or to individuals who have exhausted their Medicare benefits. Included in the Medicaid insurance coverage are in-patient stays in long term care facilities, hospitalization and drugs.

Medicare is a federally funded program administered by private insurance companies. Medicare insurance generally is available to individuals who have paid social security taxes and are over the age of 65 years. Several of our wound care and fixation products are eligible for Medicare reimbursement.

Federal and state governments, as well as private insurers, will continue their pursuit of programs designed to control or reduce the cost of health care. These cost cutting measures may include reductions in reimbursements and/or increases in mandatory rebates for wound care products. As such, there is uncertainty as to whether, and to what extent, reimbursements for our products will continue to be available.

#### **Employees**

We maintained 161 full-time and 13 part-time employees at September 30, 2009. Of these employees, 65 are located in the United States, 69 in Canada and 40 in China. We consider our employee relations to be satisfactory.

## DESCRIPTION OF PROPERTY

Our headquarters are located in Princeton, New Jersey. In addition to the lease relative to our headquarters, we have entered into leases for manufacturing