DERMA SCIENCES, INC.
Form 10-K
March 15, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

x Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 2015

.. Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the transition period from _____ to _____

Commission file number: 1-31070

DERMA SCIENCES, INC.

(Name of Issuer in Its Charter)

Delaware (State or other jurisdiction of incorporation or organization)	23-2328753 (I.R.S. Employer Identification No.)
214 Carnegie Center, Suite 300, Princeton, New Jersey (Address of principal executive offices)	08540 (Zip code)

Registrant's telephone number: (609) 514-4744

Securities registered under Section 12(b) of the Exchange Act:

Title of each class	Name of each exchange on which registered
Common Stock, $.01 par value	The NASDAQ Stock Market LLC

Securities registered under Section 12(g) of the Exchange Act:

None.

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ¨ No x

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes ¨ No x

Indicate by checkmark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes x No ¨

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files).

Yes x No ¨

Indicate by checkmark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

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 ¨	Accelerated filer x
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Yes ¨ No x

The aggregate market value of the common equity stock held by non-affiliates, computed by reference to the average bid and asked prices of such stock as of June 30, 2015, was approximately $174,229,000.

The number of shares outstanding of the issuer's common equity as of March 14, 2016 was 25,884,797.

Documents Incorporated by Reference

Portions of the Registrant's definitive proxy statement for its 2016 annual meeting of stockholders are incorporated by reference in Part III of this report.

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Cautionary Statement Regarding Forward-Looking Statements

This annual report on Form 10-K includes certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, statements about the confidence, strategies, plans, expectations, intentions, objectives, technologies, opportunities, market demand or acceptance of new or existing products of the Company, and other statements contained in this annual report that are not historical facts. Forward-looking statements in this annual report or hereafter included in other publicly available documents filed with the Securities and Exchange Commission reports to our stockholders and other publicly available statements issued or released by us involve known and unknown risks, uncertainties and other factors that could cause our actual results, performance (financial or operating) or achievements to differ from the future results, performance (financial or operating) or achievements expressed or implied by such forward-looking statements. Such future results are based upon management's best estimates, current conditions and the most recent results of operations. When used in this annual report, the words "expect," "anticipate," "intend," "plan," "believe," "seek," "estimate" and similar expressions are generally intended to identify forward-looking statements, because these forward-looking statements involve risks and uncertainties. There are important factors that could cause actual results to differ materially from those expressed or implied by these forward-looking statements, including our plans, objectives, expectations and intentions, changes in political, economic, business, competitive, market and regulatory factors and other factors that are discussed under the section in this annual report entitled "Risk Factors." Neither we nor any other person assume responsibility for the accuracy or completeness of these forward-looking statements. We are under no duty to update any of the forward-looking statements after the date of this annual report to conform these statements to actual results.

Part I

Item 1. Business

Overview

Derma Sciences, Inc. ("Derma Sciences") and its subsidiaries Sunshine Products, Inc., Derma Sciences Canada Inc., Derma First Aid Products, Inc., MedEfficiency, Inc., Derma Sciences Europe, Ltd., and Derma Sciences Nantong Incorporation are referred to collectively as "we," "our," "us" and the "Company." Our executive offices are located at 214 Carnegie Center, Suite 300, Princeton, New Jersey 08540. Derma Sciences was incorporated under the laws of Colorado on September 10, 1984. On June 3, 1996, we changed our state of domicile to Pennsylvania and on September 14, 2012, we changed our state of domicile to Delaware.

Derma Sciences, Inc. is a global medical device company focused on two segments of the wound care marketplace: advanced wound care ("AWC") and traditional wound care ("TWC"). Each segment is managed separately as each involves different technology, along with different marketing and sales strategies and resources. AWC products principally consist of both novel and otherwise differentiated dressings, bandages and skin substitutes designed to promote wound covering and protection, wound closure and wound healing and/or prevent infection. TWC products principally consist of branded and private label commodity related dressings, ointments, gauze bandages, adhesive bandages, specialty fixation and skin care products. We market our products globally to acute care, extended care, home health care, wound and burn care clinics and physician offices, principally through direct sales representatives in the United States ("US"), Canada and the United Kingdom ("UK") and through independent distributors within other select international markets. A smaller portion of the Company's sales are sold directly to care givers and through retail. In addition to the US, sales offices are maintained in Canada and in the UK for the Europe, Middle East and Africa ("EMEA") markets. Our Asia, Pacific and Latin America ("APLA") markets are managed out of the US. We source our products both internally through manufacturing facilities in Canada and China and through a global network of third party suppliers in accordance with regulatory guidelines governing their manufacture. Our products are distributed in the US principally through our own distribution network and through third party distribution throughout the rest of the world.

Effective November 2015, management of the Company approved a plan to terminate the Company's Phase 3 (DSC127) clinical program for diabetic foot ulcer healing. The decision to end the program followed the recommendation by the independent Data Monitoring Committee to stop the program based on its interim assessment. Based on this recommendation, we initiated an orderly termination of all our existing pharmaceutical development programs comprised of the diabetic foot healing program and two other programs utilizing the DSC127 compound for other therapeutic indications. As a result of these actions, the Company's pharmaceutical development activities have been reported as discontinued operations in the Company's Consolidated Financial Statements. Amounts previously reported in the Pharmaceutical Wound Care segment have been reclassified to conform to this presentation to allow for meaningful comparison of continuing operations.

Products

Advanced Wound Care

Our advanced wound care product line consists of the following:

MEDIHONEY offers a line of patented dressings, comprised of Active *Leptospermum* Honey. *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.

TCC-EZ is a patented market leading off-loading system for patients with diabetic foot ulcers. Total contact casting ("TCC") has been shown in multiple randomized controlled studies to achieve 89% healing rates. However, traditional TCC is utilized in a small percentage of cases (< 5%) due to various factors, 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. *TCC-EZ* allows for a much more simplified process, so application errors are less common, and the cast itself is significantly lighter than a traditional TCC cast, due to its open weave pattern.

AMNIOEXCEL and *AMNIOMATRIX* represent our entry into the $300 million skin substitute market. AMNIOEXCEL is an amniotic extracellular membrane product that is a sterile, room-temperature stable, re-absorbable tissue allograft derived from human amnion, providing a natural scaffold for tissue repair, reconstruction and replacement. AMNIOMATRIX is a cryopreserved liquid allograft derived from human placenta tissue used as a wound covering in the treatment of localized tissue defects. The addressable skin substitute market includes traumatic injuries, burns, surgical wounds, complex chronic and acute wounds and other soft-tissue defects.

XTRASORB provides a novel, proprietary line of dressings that utilizes super-absorbent polymer technologies. While other absorbing dressings currently on the market use open cell structures to capture fluid, *XTRASORB* dressings convert fluid within the dressings to a gel, thus locking the exudates into the dressings. *XTRASORB* dressings have a distinct advantage over alternative products due to their ability to absorb more fluid and segregate the fluid from the wound, thus avoiding further wound deterioration. Studies have shown these dressings are able to reduce wound exposure to harmful and damaging matrix metalloproteinases ("MMP's"). These dressings can absorb excess wound fluid and compare favorably to the market leading dressings at a cost effective price point.

BIOGUARD is a line of patented primary and secondary dressings containing an active antimicrobial compound. This compound, a cationic biocide, is intrinsically bound to the dressing through a proprietary process that results 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, especially for burns. The dressings have been shown to kill 99.9% of virulent bacteria such as methicillin resistant *staphylococcus aureus* (MRSA) in less than one minute.

Other advanced wound care products include *ALGICELL AG,* a proprietary antimicrobial dressing with ionic silver as its active ingredient; and a range of moist, occlusive dressings such as hydrocolloids, foams, hydrogels, alginates, additional silver antimicrobial dressings, cleansers and our proprietary *DERMAGRAN* products.

Our advanced wound care products are the main focus of our sales and marketing resources. Our promoted advanced wound care products are differentiated in the marketplace and carry higher gross profit margins. MEDIHONEY and TCC-EZ are our two largest selling products. These products, together with our AMNIO products, represent our major growth opportunities. We continue to evaluate synergistic products and technologies within the advanced wound care market for consideration in the expansion of our advanced wound care product line.

Traditional Wound Care

Our traditional wound care product line consists of the following:

A broad line of branded gauze sponges and bandages, non-adherent impregnated dressings, retention devices, paste bandages and other compression devices for the medical markets;

A broad line of branded and private-label adhesive bandages and related first aid products for the medical, industrial, private label and retail markets;

Private-label wound care products utilizing our manufacturing capabilities for a number of U.S. and international health care companies;

A line of rigid and proprietary flexible wound closure strips, nasal tube fasteners and a variety of catheter fasteners for the medical markets; and

A line of general purpose and specialized skin care products for the institutional medical market.

Our traditional wound care products are generally not differentiated in the marketplace and carry lower gross profit margins. We sell these products principally through distributors or, in the case of private label products, directly to customers on the basis of quality, price and customer service. At times, we have the opportunity to bundle these products with the sale of our advanced wound care products. As such, this product line does not require a significant investment in sales and marketing resources to sustain it. To the extent opportunities for growth are available, we will invest accordingly.

A breakdown of net sales between Advanced Wound Care and Traditional Wound Care are outlined below ($'s 000's):

	% of Total		% of Total		% of Total

	2015		2014		2013	
Advanced Wound Care	$41,782	49.5 %	$38,111	45.5 %	$33,929	42.6 %
Traditional Wound Care	42,692	50.5 %	45,635	54.5 %	45,782	57.4 %
Total	$84,474		$83,746		$79,711	

Net sales by location of entity are outlined below ($'s 000's):

	2015	2014	2013
United States	$70,345	$67,458	$65,348
Canada	9,408	11,616	10,812
Rest of World	4,721	4,672	3,551
Total	$84,474	$83,746	$79,711

Rest of World is broken down and separately managed between EMEA and APLA.

For detailed financial information regarding each segment, see Part II, Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations, and Note 13 to the Consolidated Financial Statements.

Sales and Marketing

Our sales and marketing infrastructure is divided into two groups, Advanced Wound Care and Traditional Wound Care. The Advanced Wound Care group is comprised of the Group President and the sales and marketing infrastructure that supports the global sale of our advanced wound care products. This infrastructure includes the Company's global advanced wound care marketing, clinical, product development and sales organizations. The Advanced Wound Care group's principal objective is to create care giver demand for our products. The Traditional Wound Care group is comprised of the Group President and the global marketing and sales infrastructure that support the global sale of our traditional wound care products. The Group President is directly responsible for managing our U.S. distribution and global private label traditional wound care relationships. This infrastructure includes the global commodity wound care, first aid products and contract manufacturing marketing and sales organizations, together with the corporate accounts team that supports both groups. The Traditional Wound Care group's principal objective is to create distributor and private label demand for our products.

Marketing

Our Advanced Wound Care global marketing team is comprised of a senior vice president, three product managers, two graphic artists, and three administrative support personnel at corporate headquarters. While the majority of this teams' time is spent supporting the U.S. market, they are also responsible for supporting our rest of world marketing efforts by working closely with local management.

Our Traditional Wound Care marketing efforts consist principally of direct expenses in support of the business. These efforts are for the most part managed by sales personnel. As needed, the advanced wound care team will assist with creative marketing requirements.

Clinical

Our Advanced Wound Care global clinical team is located in the U.S. and is comprised of a director, three clinicians and a clinical project manager. The director and project manager are located at corporate headquarters, while the clinicians are field based. All team members contribute to the development of clinical evidence in support of our advanced would care products, the process of which is managed by the project manager. While the majority of this teams' time is spent supporting the U.S. market, they are also responsible for supporting clinical efforts throughout the rest of the world by working closely with local management.

Product Development

A product development manager is responsible for oversight and coordination of our product development efforts, working closely with our operations team, manufacturers, external consultants and product/technology licensors.

Sales

Our advanced wound care global sales team is comprised of a senior vice president and two sales administrators at corporate headquarters. In the U.S., our field sales force consists of four regions, consisting of four regional managers and 38 territory managers. Our EMEA sales team is comprised of a general manager and a sales administrator headquartered in the U.K. The general manager is responsible for managing a direct sales force of six in the U.K.

consisting of a sales manager and five territory managers, together with distributor relationships throughout the rest of EMEA. Our APLA sales team is led by a vice president at corporate headquarters who is responsible for managing distributor relationships throughout APLA. In 2014, we added regional in-market sales support in South America and the Far East to further develop these markets.

Our traditional wound care sales team is comprised of a vice president of first aid products and a vice president of corporate accounts located at corporate headquarters. The vice president of first aid products, working with a number of independent brokers, is responsible for managing our branded and private label first aid business. The vice president of corporate accounts, working with one field director, a sales operations manager and three sales operations specialists, is responsible for managing our relationship with group purchasing organizations in the U.S., as well as providing sales analytics for sales management, commission and third party fee payment, and administrative support. Our Canada sales team reports directly to the Group President and is responsible for supporting both our advanced and traditional lines of products. The team is comprised of a sales manager and a sales administrator located in our Toronto sales office, together with four territory managers covering the major population centers.

Competition

Many of our competitors are larger and have greater resources than we do. The advanced wound care sector of the global medical device marketplace is characterized by evolving technology and intense competition. We believe that we have assembled a broad range of proprietary advanced wound care products capable of effectively competing in the marketplace. We are recognized for both our entrepreneurial culture that cost effectively incubates product development and our ability to commercialize new advanced wound care products offering superior value. Our traditional wound care products compete in a very intense commodity oriented global marketplace. We offer a broad range of traditional wound care products, some of which have a degree of product differentiation. While our competitors sell products that are in many respects comparable to ours, we have been successful in this environment selling our traditional wound care products on the basis of quality, price and customer service.

Product Sourcing

Our Operations team headquartered in Toronto, Canada manages our global supply chain function which consists of internal product manufacturing, third party supply of product, regulatory, distribution and inventory management. Our main manufacturing facility is located in Toronto and manufactures a broad range of advanced and traditional wound care products. We have a small facility in Nantong, China which we use principally for low volume and labor intensive traditional wound care gauze products. We have a contract manufacturing relationship with a supplier in China for adhesive bandages and related first aid products and one in Mexico for paste bandages. All of these facilities are FDA registered and ISO certified.

A significant portion of our products are sourced directly from a long standing global network of third party suppliers. We require that all suppliers conform to the standards set forth in the Good Manufacturing Practice regulations promulgated by the FDA and local health agencies. The majority of these products are manufactured using readily available components. Accordingly, there are numerous companies capable of manufacturing these products to applicable specifications and regulatory standards.

We obtain the bulk honey used in our MEDIHONEY products exclusively from the product licensor, although we have the right to source our requirements elsewhere. Although both parties endeavor to effectively manage demand versus capacity on a continuous basis and maintain adequate safety stock levels to guard against any interruption in supply, the availability of medicinal honey meeting our exacting specifications for purity and quality is not guaranteed, as it is a natural product that must be harvested on an annual basis. While we have not yet qualified any other sources of bulk honey, other sources of bulk honey do exist.

We are contractually obligated to source a key component of our TCC-EZ product exclusively from the product licensor. Both parties effectively manage demand versus capacity on a continuous basis and we maintain a reasonable level of safety stock to guard against interruption in supply.

We are contractually obligated to source AMNIOEXCEL and AMNIOMATRIX products exclusively from the product licensor. Both parties effectively manage demand versus capacity on a continuous basis and maintain adequate safety stock levels to guard against any interruption in supply. The licensor has agreed to qualify and maintain a qualified back up supplier for these products to protect against a long term interruption in supply.

Given the oversight of our manufacturing facilities and our third party suppliers, the availability of other suppliers and our inventory management policy concerning safety stock levels, we do not believe that a temporary interruption of supply or the loss of one or more suppliers would have a long-term detrimental impact on our supply chain operations.

Derma Sciences is registered with the FDA and Health Canada. We hold the following ISO certifications: ISO 13485:2003, ISO9001:2008 and Directive 93/42/EEC. Derma Toronto and Nantong China have been recently inspected by the FDA and no violations were noted. The Company has also been inspected by various international regulatory agencies and customer audits and has consistently achieved very high compliance ratings.

Patents, Trademarks, Proprietary and Non-Proprietary Technology

We own or license a number of trademarks covering the Company and its products. In addition, we own or license over 50 U.S. patents, corresponding foreign patents and patent applications. The patents relating to the MEDIHONEY, BIOGUARD, AMNIOEXCEL and AMNIOMATRIX technologies are held under license agreements of indefinite duration. We also have a number of non-patented formulations and process technologies that, together with the aforementioned patents, provide competitive advantages in the marketplace.

Government Regulation

The manufacture, distribution and advertising of our products are subject to various U.S. and foreign agencies. In addition, we are subject to regulation regarding occupational safety, laboratory practices, environmental protection and hazardous substance control and may be subject to other present and future U.S. and foreign regulations. We believe we are in compliance with all such laws, regulations and standards currently in effect and that the cost of continued compliance will not have a material adverse effect on us.

Employees

Derma Sciences had 260 full-time and 3 part-time employees at December 31, 2015. Of these employees, 118 are located in the U.S., 103 in Canada, 29 in China, twelve in Europe and one in South Korea. The Company considers employee relations to be satisfactory.

Available Information

We file reports with the Securities and Exchange Commission (the “SEC”), including our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished to the SEC pursuant to the requirements of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). The general public may read and copy any materials that we file with the SEC at the SEC’s Public Reference Room located at 100 F Street N.E., Washington, DC 20549. The public may also obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an internet site, www.sec.gov, which contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

You may also obtain copies of our annual reports on our website at www.dermasciences.com under the heading "Investor Relations." The information disclosed on our website is not incorporated by this reference and is not a part of this Annual Report on Form 10-K. We make available on our website, free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to these reports, as soon as reasonably practicable after we electronically file with or furnish the reports to the SEC. The following corporate governance related documents are also available free on our website: Code of Ethics, Board Independency Guidelines, Audit Committee Charter, Compensation Committee Charter, and Nominating and Corporate Governance Committee Charter.

Item 1A. Risk Factors

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

We incurred net losses from continuing operations of $20,366,663, $20,844,615 and $12,529,496 in 2015, 2014 and 2013, respectively, and additional losses in previous years. At December 31, 2015, we had an accumulated deficit of $142,049,846. We cannot offer any assurance that we will be able to generate sustained or future earnings.

Our liquidity may be dependent upon 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 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 next twelve months. However, in the event our cash flow from operating activities is insufficient to meet our requirements, we may be forced either to secure a line of credit or seek additional equity financing. The sale of additional securities could result in additional dilution to our stockholders. 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 financial condition would be adversely impacted if our goodwill becomes impaired.

As a result of acquisition accounting for our various acquisitions, we have accumulated $13,457,693 of goodwill as of December 31, 2015 of which $6,337,967 related to our Advanced Wound Care segment and $7,119,726 related to our Traditional Wound Care segment. Our goodwill is not amortized, but is tested for impairment at least annually or when events or changes in circumstances indicate the carrying value of each segment, and collectively the Company taken as a whole, might exceed its fair value. The impairment test requires us to compare the fair value of each segment to their carrying value, including goodwill. In addition, we evaluate the fair value of our outstanding common stock to determine whether it exceeds our overall carrying value. The fair value of each segment is determined using the "income approach," where we use a discounted cash flow model to evaluate our goodwill impairment assessment or in combination with other generally acceptable valuation methodologies such as "market approaches", which utilize comparable company multiples and merger and acquisitions. We predominantly use the income approach because we believe the income approach most appropriately measures our income producing assets. If our goodwill were to become impaired, we would need to recognize a non-cash impairment charge, which could have a material adverse effect on our consolidated balance sheet, results of operations and potentially, our common stock price.

The results of the annual impairment test performed as of December 31, 2015 indicated the fair value of each segment exceeded its carrying value and the fair value of our outstanding common stock exceeded the carrying value of the Company taken as a whole.

The market price of the Company's common stock has been subject to volatility over the past several months due to overall market conditions and Company events that have taken place. In November 2015, the Company terminated its pharmaceutical development operations (see Note 3 to the Company's consolidated financial statements) and in December 2015, it announced the implementation of a restructuring plan and the departure of its Chief Executive Officer (see Note 4 to the Company's consolidated financial statements). As of December 31, 2015, the Company's carrying value was $98.4 million, or $3.80 per share of outstanding common stock and the Company's market value was $118.3 million, or $4.57 per share of outstanding common stock based on the closing trading price on such date. Since January 7, 2016 through March 14, 2016, the market price of the Company's common stock has declined and has traded in a range of $2.85 to $3.91, and has generally been below our carrying value of $3.80 as of December 31, 2015, and as such, is indicative of a possible impairment. Consequently, if our stock price remains at such levels or decreases further our goodwill may be determined to be impaired and the Company would need to recognize a non-cash impairment charge, which could have a material adverse effect on our consolidated balance sheet, results of operations, and potentially the Company's stock price.

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 international operations and our ability to maintain a continuous supply of wound care products from our international operations and suppliers. While we do not envision any adverse change to our international operations or suppliers, adverse changes to these operations, as a result of political, governmental, regulatory, economic, exchange rate, labor, logistical or other factors, could have a material 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 and other global government authorities. 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, which requires clinical data and the level of reimbursement, particularly for new therapeutic products or where fiduciary parties, including third party payors perceive 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 administratively burdensome or unprofitable for healthcare providers or less profitable than alternative treatments. In addition, reimbursement from Medicare, Medicaid and other third-party payors may be subject to periodic adjustments as a result of legislative, regulatory and policy changes as well as budgetary pressures. Possible reductions in, or eliminations of, coverage or reimbursement by third-party payors, or denial of, or provision of uneconomical reimbursement for new products, as a result of these changes may affect our customers' revenue and ability to purchase our products. Any changes in the healthcare regulatory, payment or enforcement landscape relative to our customers' healthcare services has the potential to significantly affect our operations and revenue.

There have been federal and state legislation changes which have subjected the pricing of healthcare goods and services to government control and made other changes to the U.S. healthcare system. While we cannot predict the outcome of current or future legislation, we anticipate, particularly given the recent enactment of healthcare reform legislation that governmental authorities will continue to 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 legislation, whether domestic or abroad, will be adopted that might affect our products. It is also uncertain what actions government including federal and/or 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 clearance/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 U.S. 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 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 develop, manufacture, and market products.

Government regulation by the U.S. FDA 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 times consuming and expensive and may involve delays or actions adversely impacting the marketing and sale of our current or future products.

A significant portion of our products are sourced from third parties.

A significant portion of our products are sourced in raw, semi-finished and finished form directly from third party suppliers. None of these sourced products presently account for more than 10% of our sales with the exception of *MEDIHONEY* and *TCC-EZ*. We maintain good relations with our third party suppliers. With the exception of *MEDIHONEY, TCC-EZ* and our AMNIO Products 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 various technologies utilized in many of our advanced wound care products are licensed from third parties and one or more could become unavailable.

A significant percentage 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, *TCC-EZ* total contact casts and our AMNIO Products. The licensing agreements that we have with the owner of the *TCC-EZ* technology is of limited duration and renewal of the agreement is at the discretion of the licensor. In addition, in some instances, the maintenance of the license agreements requires that we meet various minimum sales and/or 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 technologies to become obsolete.

The wound care sector of the medical products industry is characterized by rapidly evolving technology and intense competition. Our competitors currently manufacture and distribute a variety of products that are in many respects comparable to our products. Many suppliers of competing products are considerably larger and have much greater resources than we do. In addition, many specialized products companies have formed collaborations with large, established companies to support research, development and commercialization of wound 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 care products on their own or through joint ventures. While we have 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. Also, defending against a claim could be time consuming and costly. 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.

We are subject to stringent medical device regulation and any adverse regulatory action may materially affect our financial condition and business operations.

Fraud, Abuse and False Claims

We are directly and indirectly subject to various federal and state laws governing relationships with healthcare providers and pertaining to healthcare fraud and abuse, including anti-kickback laws. In particular, the federal healthcare program Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for or recommending a good or service for which payment may be made in whole or part under federal healthcare programs, such as the Medicare and Medicaid programs. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. In implementing the statute, the Office of Inspector General of the U.S. Department of Health and Human Services ("OIG") has issued a series of regulations, known as the "safe harbors." These safe harbors set forth provisions that, if all their applicable requirements are met, will assure healthcare providers and other parties that they will not be prosecuted under the Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable element of a safe harbor may result in increased scrutiny by government enforcement authorities, such as the OIG. Many states have laws similar to the federal law.

The Federal False Claims Act ("FCA") imposes civil liability on any person or entity that submits, or causes the submission of, a false or fraudulent claim to the U.S. Government. Damages under the FCA can be significant and consist of the imposition of fines and penalties. The FCA also allows a private individual or entity with knowledge of past or present fraud against the federal government to sue on behalf of the government to recover the civil penalties and treble damages. The U.S. Department of Justice ("DOJ") on behalf of the government has previously alleged that the marketing and promotional practices of pharmaceutical and medical device manufacturers including the off-label promotion of products or the payment of prohibited kickbacks to doctors violated the FCA resulting in the submission of improper claims to federal and state healthcare entitlement programs such as Medicaid. In certain cases, manufacturers have entered into criminal and civil settlements with the federal government under which they entered into plea agreements, paid substantial monetary amounts and entered into corporate integrity agreements that require, among other things, substantial reporting and remedial actions going forward.

The FDA has been increasing its scrutiny of the medical device industry and the government is expected to continue to scrutinize the industry closely with inspections, and possibly enforcement actions, by the FDA or other agencies. Additionally, the FDA may restrict manufacturing and impose other operating restrictions, enjoin and restrain certain violations of applicable law pertaining to medical devices, and assess civil or criminal penalties against our officers, employees, or us. The FDA may also recommend prosecution to the DOJ. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively manufacturing, marketing and selling our products. In addition, negative publicity and product liability claims resulting from any adverse regulatory action could have a material adverse effect on our financial condition and results of operations.

Tissue Product Regulations

Our AMNIOEXCEL® and AMNIOMATRIX® products are derived from human tissue. The FDA has specific regulations governing human cells, tissues and cellular and tissue-based products ("HCT/Ps"). An HCT/P is a product containing or consisting of human cells or tissue intended for transplantation into a human patient. HCT/Ps that meet the criteria for regulation solely under Section 361 of the Public Health Service Act (so-called "361 HCT/Ps") are not subject to any premarket clearance or approval requirements and are subject to less stringent post-market regulatory requirements. There can be no assurance that the FDA will not, at some future point, take the position that our current or any future tissue products do not qualify for regulation as 361 HCT/Ps. Any regulatory reclassification could have adverse consequences for us and make it more difficult or expensive for us to conduct our business by requiring premarket clearance or approval and compliance with additional post-market regulatory requirements with respect to those products. Moreover, increased regulatory scrutiny could lead to increased regulation of HCT/Ps, including 361 HCT/Ps. We also cannot guarantee that the FDA will not impose more stringent definitions with respect to products that qualify as 361 HCT/Ps or interpret existing regulations in a manner that will require submission of a Biologics License Application for some or all of our HCT/P products. For example, two of the regulatory criteria that must be met in order for a product to be regulated solely as an HCT/P are that the HCT/P be "minimally manipulated" and that it be "intended for homologous use only". The FDA has recently issued two separate draft guidance documents interpreting these requirements, each of which are scheduled to be the subject of a public hearing to be held by the FDA at an as yet to be announced date later in 2016.

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 4,332,954 shares of our common stock were potentially issuable at December 31, 2015 upon the conversion, exercise or vesting of outstanding convertible preferred stock, warrants, options and restricted stock units. The shares of common stock potentially issuable upon conversion, exercise or vesting of these securities are substantial compared to the 25,876,870 shares of common stock outstanding at December 31, 2015.

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 bid prices for the years 2011 through 2015 are set forth in the table below:

Derma Sciences, Inc.
Trading Range – Common Stock

Year	Low	High
2011	$4.50	$12.72
2012	$6.94	$11.89
2013	$9.93	$15.45
2014	$7.88	$15.51
2015	$3.85	$9.89

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, exchange rates or other general economic conditions;
- Changes in market conditions in the wound care industry;
- 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;
- Additions or departures of key personnel;
- Changes in third party reimbursement policies;
- The introduction of new products either by us or by our competitors;
- The loss of a major customer; and
- Our termination of pharmaceutical development activities.

Although 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.

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.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our headquarters are located in Princeton, New Jersey. In addition to the lease relative to our headquarters, we have entered into leases for office, manufacturing, and distribution facilities. Our facilities, locations, size, monthly rent and lease expirations are set forth in the table below:

Location	Use	Segment	Square Footage	Base Monthly Rent	Lease Expiration
Princeton, New Jersey	Corporate Headquarters	Other	15,065	$41,532	November 2018
Fenton, Missouri	Distribution	Advanced and Traditional Wound Care	42,400	$15,911	March 2021
Houston, Texas	Distribution	Traditional Wound Care	52,300	$19,872	March 2020
Toronto, Canada	Manufacturing, Distribution & Offices	Advanced and Traditional Wound Care and Other	91,060	$43,181	August 2017
Maidenhead, U.K.	Offices	Advanced and Traditional Wound Care	450	$1,370	July 2019
Nantong, China	Manufacturing & Offices	Traditional Wound Care	11,388	$2,065	December 2018

We believe that our facilities are adequate to meet our office, manufacturing and distribution requirements for the foreseeable future.

Item 3. Legal Proceedings

None.

Item 4. Mine Safety Disclosures

Not applicable.

Part II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common stock is traded on the NASDAQ Capital Market under the symbol "DSCI." The following table sets forth the high and low bid prices for our common stock during each of the indicated calendar quarters:

Quarter Ended	High	Low
March 31, 2015	$9.89	$7.27
June 30, 2015	$8.81	$6.39
September 30, 2015	$7.37	$4.57
December 31, 2015	$5.99	$3.85
March 31, 2014	$15.51	$10.71
June 30, 2014	$13.02	$8.45
September 30, 2014	$12.02	$7.88
December 31, 2014	$9.45	$8.10

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.

Holders of common stock. As of the close of business on March 14, 2016 there were approximately 696 holders of record of our common stock. We believe that the number of beneficial holders of our common stock is substantially greater. On March 14, 2016, the closing sales price of our common stock as reported on the NASDAQ Capital Market was $3.13.

Dividends and dividend policy. We have never paid any cash dividends on our common 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.

Securities authorized for issuance under equity compensation plans. The information called for by this item is incorporated by reference to our definitive proxy statement relating to our 2016 annual meeting of stockholders, which we will file with the Securities and Exchange Commission within 120 days after December 31, 2015.

Recent sales of unregistered securities. All prior sales of unregistered securities have been previously reported on a quarterly report on Form 10-Q or a current report on Form 8-K.

Item 6. Selected Financial Data

The selected consolidated financial data presented below has been derived from our Consolidated Financial Statements for each of the periods indicated. The data set forth below is qualified by reference to and should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our Consolidated Financial Statements included as Items 7 and 8, respectively, in this Annual Report.

	Year Ended December 31,				
	2015	2014	2013	2012	2011
Statement of Operations Data:					
Net sales	$84,474,284	$83,745,680	$79,710,980	$72,648,198	$62,630,247
Cost of sales	51,740,109	53,635,745	50,320,506	47,507,349	44,218,300
Gross profit	32,734,175	30,109,935	29,390,474	25,140,849	18,411,947
Selling, general and administrative	51,430,091	50,846,895	41,945,599	32,485,368	21,173,884
Research and development	807,128	440,246	-	-	-
Restructuring and other charges	2,458,555	-	-	-	-
Other expense (income), net	649,779	(181,543)	(185,740)	(26,729)	451,842
Income tax (benefit) provision	(2,244,715)	(151,048)	160,111	(2,370,482)	69,538
Net loss from continuing operations	(20,366,663)	(20,844,615)	(12,529,496)	(4,947,308)	(3,283,317)
Loss from discontinued operations, net of taxes	(17,740,817)	(18,926,940)	(11,434,557)	(7,123,123)	(1,057,094)
Net loss	$(38,107,480)	$(39,771,555)	$(23,964,053)	$(12,070,431)	$(4,340,411)
Basic and diluted loss per share of common stock					
Continuing operations	$(0.79)	$(0.85)	$(0.73)	$(0.40)	$(0.37)
Discontinued operations	(0.69)	(0.77)	(0.67)	(0.57)	(0.12)
Total basic and diluted loss per share of common stock	$(1.48)	$(1.62)	$(1.40)	$(0.97)	$(0.49)
Shares used in computing basic and diluted loss per share of common stock	25,734,474	24,584,071	17,056,632	12,488,263	8,780,981

	At December 31,				
	2015	2014	2013	2012	2011
Balance Sheet Data:					
Cash, cash equivalents and short term investments	$40,818,195	$75,392,845	$21,979,586	$45,346,657	$22,335,350
Working capital	$57,568,491	$89,332,503	$40,040,002	$61,185,368	$34,855,480
Total assets	$114,780,155	$139,290,466	$88,576,353	$103,842,630	$58,623,892
Stockholders' equity	$98,425,855	$125,564,664	$77,148,148	$93,711,193	$50,847,534

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Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion provides an analysis of the results for each or our segments, an overview of our liquidity and capital resources and other items related to our business for the years ended December 31, 2015, 2014 and 2013. It contains forward-looking statements about our future revenue, operating results and expectations. See "Cautionary Statement Regarding Forward-Looking Statements" and the section in this annual report entitled "Risk Factors" for a discussion of the risks, assumptions and uncertainties affecting these statements. This discussion and analysis should be read in conjunction with Part I of this annual report as well as our consolidated financial statements and notes thereto included in this annual report.

Year Ended December 31, 2015 Compared to Year Ended December 31, 2014

Overview

The following table highlights the year ended December 31, 2015 versus 2014 operating results:

	Year Ended December 31,		Variance	
	2015	2014		
Gross sales	$95,407,219	$94,008,003	$1,399,216	1.5%
Sales adjustments	(10,932,935)	(10,262,323)	(670,612)	6.5
Net sales	84,474,284	83,745,680	728,604	0.9
Cost of sales	51,740,109	53,635,745	(1,895,636)	(3.5)
Gross profit	32,734,175	30,109,935	2,624,240	8.7
Selling, general and administrative expense	51,430,091	50,846,895	583,196	1.1
Research and development expense	807,128	440,246	366,882	83.3
Restructuring and other charges	2,458,555	-	2,458,555	*
Other expense (income), net	649,779	(181,543)	831,322	*
Total expenses	55,345,553	51,105,598	4,239,955	8.3
Loss from continuing operations before income taxes	(22,611,378)	(20,995,663)	(1,615,715)	7.7
Income tax benefit	(2,244,715)	(151,048)	(2,093,667)	*
Net loss from continuing operations	(20,366,663)	(20,844,615)	477,952	(2.3)
Loss from discontinued operations, net of taxes	(17,740,817)	(18,926,940)	1,186,123	(6.3)
Net Loss	$(38,107,480)	$(39,771,555)	$1,664,075	(4.2%)

***** *not meaningful*

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Gross to Net Sales Adjustments

Gross to net sales adjustments are comprised of the following:

	Year Ended December 31,	
	2015	2014
Gross sales	$95,407,219	$94,008,003
Trade rebates	(7,565,281)	(7,050,638)
Distributor fees	(876,117)	(1,083,584)
Sales incentives	(1,248,464)	(929,196)
Returns and allowances	(476,534)	(534,523)
Cash discounts	(766,539)	(664,382)
Total adjustments	(10,932,935)	(10,262,323)
Net sales	$84,474,284	$83,745,680

Trade rebates increased in 2015 versus 2014 principally due to an increase in sales subject to rebate and the rebate percentage as a result of product mix towards higher rebated products. The decrease in distributor fees is commensurate with the decrease in sales upon which the fees are based. The increase in sales incentives reflects higher sales subject to incentives. Sales returns and allowances decreased in 2015 due to quality control issues affecting 2014 sales that did not reoccur in 2015. The increase in cash discounts principally relates to an increase in sales subject to cash discount.

Rebate Reserve Roll-Forward

A roll-forward of the trade rebate accruals for the years ended December 31, 2015 and 2014 were as follows:

	2015	2014
Beginning balance – January 1	$1,880,525	$1,746,993
Rebates paid	(7,809,367)	(6,917,106)
Rebates accrued	7,565,281	7,050,638
Ending balance – December 31	$1,636,439	$1,880,525

The $244,086 decrease in the trade rebate reserve balance at December 31, 2015 from December 31, 2014 principally reflects the timing of rebate payments partially offset by increases in sales subject to rebate and rebate percentage. There was no other significant change in the nature of our business in 2015 as it relates to our rebate program.

	2015			2014		
	Gross Sales	Sales Adj.	Net Sales	Gross Sales	Sales Adj.	Net Sales
By Entity						
US	$75,915,980	$(5,570,898)	$70,345,082	$71,445,103	$(3,986,572)	$67,458,531
Canada	14,764,408	(5,356,083)	9,408,325	17,890,528	(6,274,984)	11,615,544
International	4,726,831	(5,954)	4,720,877	4,672,372	(767)	4,671,605
Total	$95,407,219	$(10,932,935)	$84,474,284	$94,008,003	$(10,262,323)	$83,745,680

U.S. sales adjustments increased due to higher trade rebates, sales incentives and cash discounts partially offset by lower sales returns and allowances. U.S. rebates, sales incentives and cash discounts increased due to increased sales upon which the fees are based. The U.S. rebate percentage also increased as a result of increased sales of higher rebated products. Sales returns and allowances in the U.S. decreased in 2015 due to quality control issues affecting 2014 sales that did not reoccur in 2015. Sales adjustments in Canada were less in 2015 than 2014 due to lower trade rebates and distribution fees. The decrease in Canadian sales rebates and distributor fees is commensurate with the decrease in Canadian sales upon which the fees are based. The Canadian rebate percentage increased due to increased sales of higher rebated products.

	2015			2014		
	Gross Sales	Sales Adj.	Net Sales	Gross Sales	Sales Adj.	Net Sales
By Segment						
Advanced wound care	$45,298,535	$				