DERMA SCIENCES, INC.
Form 10-K/A
April 02, 2012

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K/A

(Amendment No. 1)

x Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 2011

¨ 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)

Pennsylvania	23-2328753
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

214 Carnegie Center, Suite 300, Princeton, New Jersey	08540
(Address of principal executive offices)	(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. x

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

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, 2011, was approximately $55,127,459.

The number of shares outstanding of the issuer's common equity as of March 26, 2012 was 10,630,865.

Documents Incorporated by Reference

Portions of the Registrant’s definitive proxy statement for its 2012 annual meeting of shareholders are incorporated by reference in Part III of this report.

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Explanatory Note

This Amendment No. 1 on Form 10-K/A (this "Amendment") is being filed to amend our Annual Report on Form 10-K for the year ended December 31, 2011, as filed with the Securities and Exchange Commission (the "SEC") on March 28, 2011 (the "Form 10-K"). The purpose of this Amendment is to include certain regulatory disclosures that were inadvertently excluded from the Form 10-K.

This Amendment makes no other changes to the Form 10-K as filed with the SEC. This Amendment does not reflect events occurring after the original filing of the Form 10-K, or modify or update those disclosures that may be affected by subsequent events. Accordingly, this Amendment should be read in conjunction with the Form 10-K and our other filings with the SEC.

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. and Derma Sciences Europe LTD 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 and, on June 3, 1996, changed its state of domicile to Pennsylvania.

Derma Sciences is a medical technology company focused on three segments of the wound care marketplace: pharmaceutical wound care, advanced wound care and traditional wound care products. The Company has one pharmaceutical wound care product candidate that has completed a Phase 2 study and is working towards initiation of a Phase 3 study in 2012. The Company maintains manufacturing facilities in Toronto, Canada and Nantong, China and a well-established network of third party suppliers for its products. The majority of our products are sold through distributors to various health care providers such as wound care centers, extended care facilities, acute care facilities, home health care agencies and physicians' offices. Some of our products are sold through retail channels. The Company markets its products principally through direct sales representatives in the United States (the "U.S."), Canada and the United Kingdom (the "U.K."), and through independent distributors within other select international markets.

Products

Advanced Wound Care

Our advanced 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.

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.

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 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 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. TCC has been shown in multiple randomized controlled studies to achieve 89% heal rates. However, traditional TCC is utilized in less than 2% of otherwise indicated cases 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* 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.

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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.

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

On March 27, 2012, the Company entered into a definitive Agreement and Plan of Merger (the "Agreement") to acquire the stock of Medefficiency, Inc. ("Medefficiency"), a company engaged in the development, manufacturing and marketing of medical devices for treating chronic wounds and lower extremity injuries. Medefficiency specializes in total contact casting ("TCC") products. The TCC-EZ total contact cast system is Medefficiency's lead product, in addition to a line of traditional and specialized contact casts and related equipment. TCC-EZ represents the next generation of total contact casting and was developed to provide equivalent off-loading to a traditional total contact cast: yet it is much faster and easier to apply.

The Company has distributed Medefficiency's products since 2008 under an exclusive distribution agreement. Having the rights to these products and integrating them into our existing advanced wound care marketing and sales infrastructure will allow the Company to realize the benefit of these product's significant growth potential and higher margins. The growing body of clinical evidence of TCC-EZ's efficacy fits well with the Company's evidenced-based sales approach. The acquisition is subject to customary closing conditions and is anticipated to be completed by April 30, 2012.

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

We manufacture private label wound care and adhesive bandages for a number of United States and international customers.

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.

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.

Pharmaceutical Wound Care

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 1 study on healthy patients and a Phase 2 study on patients with diabetic foot ulcers. Topline results of this study were reported in February and May 2011. Full results of the study are currently under peer review at a major international advanced wound care journal.

DSC127 is a patented, topically applied novel angiotensin analog that targets receptors that are up-regulated upon injury to tissue. The drug candidate has been shown to improve epithelialization, granulation and vascularization, accelerating wound healing in a variety of normal and diabetic animal models. These findings suggest that DSC127 produces different actions at the wound site during various stages of healing. There were no safety concerns observed in the preclinical and Phase 1 and Phase 2 trials of DSC127.

When a New Drug Application (“NDA”) has been approved by FDA for commercial distribution of DSC127, 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.

In June of 2011, we raised approximately $26.3 million in order to fund the Phase 3 pivotal studies and associated activities. Since that time, we have put together a consulting team comprised of senior regulatory, medical, clinical, chemistry, manufacturing and controls, bioanalytical and non-clinical executives. We have had one meeting with the FDA to discuss the results of our Phase 2 study and the design of our Phase 3 studies. The Company intends to hold another meeting with the FDA to discuss the Phase 3 protocols for the pivotal studies, and a separate meeting to discuss the Chemistry, Manufacturing and Controls (“CMC”) portion of the program. The Company is intending to initiate the Phase 3 pivotal studies in the second half of 2012.

Sales and Marketing

In 2011, the United States accounted for 66%, Canada for 25% and the rest of the world for 9% of our total sales.

United States

In the United States, we employ a direct sales force and have relationships with 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 vice president of advanced wound care–sales, a vice president of advanced wound care—corporate accounts, four regional managers, 38 direct territory representatives, a sales administrator and four clinical resource specialists. We also employ a vice president of distribution—sales whose primary responsibility is to support our traditional wound care business. Our sales employees receive a base salary together with commissions based upon sales achievement within their area of responsibility.

Canada

In Canada, we employ a sales manager and three direct sales representatives and one manufacturer's representative covering the major population centers. Our direct sales representatives receive a base salary together with commissions based upon territory sales. 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 one to five 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 Centres (CCAC) agencies.

In May 2005, we entered into an agreement with a Canadian company, our only customer in Canada, to serve as the exclusive distributor of our products in Canada. The distribution agreement has been amended from time to time, the latest being January 2011. The amended agreement expires in April 2016. The distributor maintains strategically located distribution centers and over 50 sales representatives throughout Canada. We believe the agreement provides us with the means to supplement our direct sales force and better serve our customers throughout Canada.

For the years ended December 31, 2011 and 2010, our Canadian distributor accounted for 24% and 25% of the Company's consolidated net sales, respectively.

Other Foreign Markets

We have a direct selling organization in the United Kingdom consisting of five sales representatives and a sales administrator. This staff is managed by the general manager of this business unit. The general manager is also responsible for managing distributor relationships within the rest of the European Union, the Middle East and Africa. Throughout the rest of the world, we sell our products under various licensing and distribution agreements.

Competition

In the United States, our traditional wound care products compete in a commodity oriented marketplace with Covidien, Medline, Medical Action and a number of others. In the advanced wound care products marketplace, we compete principally with Convatec, Smith & Nephew, Molnlycke and Systagenix. Our adhesive bandage and related first aid products compete with Medline, ASO and Dynerex in the medical market, Medline and ASO in the industrial market, ASO, Medline and Liberty in the private label market and Johnson & Johnson, 3M and Medline in the retail market. 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 traditional 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. Internationally, we compete with global and local multinationals and domestic advanced wound care 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 products 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 and 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 the United States, China and other countries.

Our manufacturing facilities and the two contract manufacturers are monitored by our management and quality control teams who oversee production activity. Most of the equipment in these facilities is owned and used exclusively by us.

In our Toronto facility, we manufacture advanced and traditional wound care products. This facility has the capability of liquid packaging, blister/vacuum packaging, impregnation, die-cutting and steam sterilization. We also have a research and development laboratory on site. The Toronto facility is ISO 13485:2003, ISO 9001:2008, and Directive 93/42/EEC certified and SGS registered.

In our Nantong facility, we manufacture principally traditional and some advanced wound care products. This facility is primarily designed for production of low volume and specialty products. The quality control team at Nantong has the responsibility to oversee and inspect all products produced in China (including third party suppliers) for us. The Nantong facility is ISO 9001:2008 certified and TUV registered.

In both our Mexico and China contract manufacturing facilities we have adhesive bandages and related first aid products manufactured on our behalf. The Mexico facility is ISO 9001:2008 and ISO 13485:2004 certified and Aenor IQNET registered. The China facility is ISO 13485:2003 certified and NQA registered.

A number of traditional and advanced wound care products are sourced in semi-finished and finished form directly from suppliers. Derma 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 a number of trademarks covering the Company and its products. In addition, we own or license over 50 United States patents, corresponding foreign patents and patent applications. Most of our patents relating to our DSC127 technology are held under license agreements of indefinite duration. The license agreement relative to our *Bioguard* technology expires in June 2014. In 2010, we entered into an agreement extending our *Medihoney* license in perpetuity. Subject to meeting minimum royalty and other specified conditions, we expect to maintain these licenses indefinitely. 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.

Government Regulation

United States — Scope of Regulation

The manufacture, distribution and advertising of our products are subject to regulation by numerous federal and state governmental agencies in the United States. The 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.

The FDA regulates and imposes substantial requirements upon the research, development, pre-clinical and clinical testing, labeling, manufacture, quality control, storage, approval, advertising, promotion, marketing, distribution and export of pharmaceutical products, as well as significant reporting and record-keeping obligations. State governments may also impose obligations in these areas. The process required by the FDA before prescription drugs may be marketed in the U.S. generally involves the following:

- pre-clinical laboratory evaluations, including formulation and stability testing, and animal tests performed under the FDA's Good Laboratory Practices regulations to assess pharmacological activity and toxicity potential;

- submission and approval of an Investigational New Drug Application, ("IND"), including results of pre-clinical tests, manufacturing information, and protocols for clinical tests, which must become effective before clinical trials may begin in the U.S.;
- obtaining approval of Institutional Review Boards ("IRBs") to administer the products to human subjects in clinical trials;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the product for the product's intended use;
- development of manufacturing processes which conform to FDA current Good Manufacturing Practices ("cGMPs"), as confirmed by FDA inspection;
- submission of results for pre-clinical and clinical studies, and chemistry, manufacture and controls information on the product to the FDA in an NDA; and
- FDA review and approval of an NDA, prior to any commercial sale or shipment of a product.

The testing and approval process requires substantial time, effort, and financial resources, and it is not certain that any approval will be granted on a timely basis, if at all.

The results of the pre-clinical studies, together with initial specified manufacturing information, the proposed clinical trial protocol, and information about the participating investigators are submitted to the FDA as part of an IND, which must become effective before human clinical trials are initiated in the U.S. Additionally, an independent IRB must review and approve each study protocol and oversee conduct of the trial. An IND becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day period, raises concerns or questions about the conduct of the trials as outlined in the IND and imposes a clinical hold. If the FDA imposes a clinical hold, the IND sponsor must resolve the FDA's concerns before clinical trials can begin. Pre-clinical tests and studies can take several years to complete, and there is no guarantee that an IND submitted based on such tests and studies will become effective within any specific time period, if at all.

Human clinical trials are typically conducted in three sequential phases that may overlap.

- *Phase I:* The drug is initially introduced into healthy human subjects or patients and tested for safety and dosage tolerance. Absorption, metabolism, distribution, and excretion testing is generally performed at this stage.

- *Phase II:* The drug is studied in controlled, exploratory therapeutic trials in a limited number of subjects with the disease or medical condition for which the new drug is intended to be used in order to identify possible adverse effects and safety risks, to determine the preliminary or potential efficacy of the product for specific targeted diseases or medical conditions, and to determine dosage tolerance and the optimal effective dose.

- *Phase III:* When Phase II studies demonstrate that a specific dosage range of the drug is likely to be effective and the drug has an acceptable safety profile, controlled, large-scale therapeutic Phase III trials are undertaken at multiple study sites to demonstrate clinical efficacy and to further test for safety in an expanded patient population.

The FDA, the IRB or we may suspend or terminate clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Results of pre-clinical studies and clinical trials, as well as detailed information about the manufacturing process, quality control methods, and product composition, among other things, are submitted to the FDA as part of an NDA seeking approval to market and commercially distribute the product on the basis of a determination that the product is safe and effective for its intended use. Before approving an NDA, the FDA will inspect the facilities at which the product is manufactured and will not approve the product unless cGMP compliance is satisfactory. If applicable regulatory criteria are not satisfied, the FDA may deny the NDA or require additional testing or information. As a condition of approval, the FDA also may require post-marketing testing or surveillance to monitor the product's safety or efficacy. Even after an NDA is approved, the FDA may impose additional obligations or restrictions (such as labeling changes), or even suspend or withdraw a product approval on the basis of data that arise after the product reaches the market, or if compliance with regulatory standards is not maintained. We cannot be certain that any NDA we submit will be approved by the FDA on a timely basis, if at all. Also, any such approval may limit the indicated uses for which the product may be marketed. Any refusal to approve, delay in approval, suspension or withdrawal of approval, or restrictions on indicated uses could have a material adverse impact on our business prospects.

Each NDA must be accompanied by a user fee, pursuant to the requirements of the Prescription Drug User Fee Act ("PDUFA"), and its amendments. According to the FDA's fee schedule, effective on October 1, 2010 for the fiscal year 2011, the user fee for an application requiring clinical data, such as an NDA, is $1,542,000. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual product fee for prescription drugs ($86,520), and an annual establishment fee ($497,200) on facilities used to manufacture prescription drugs. A written request can be submitted for a waiver for the application fee for the first human drug application that is filed by a small business, but there are no waivers for product or establishment fees. We are not at the stage of development with our products where we are subject to these fees, but they are significant expenditures that may be incurred in the future and must be

paid at the time of application submissions to FDA.

Satisfaction of FDA requirements typically takes several years. The actual time required varies substantially, based upon the type, complexity, and novelty of the pharmaceutical product, among other things. Government regulation imposes costly and time-consuming requirements and restrictions throughout the product life cycle and may delay product marketing for a considerable period of time, limit product marketing, or prevent marketing altogether. Success in pre-clinical or early stage clinical trials does not ensure success in later stage clinical trials. Data obtained from pre-clinical and clinical activities are not always conclusive and may be susceptible to varying interpretations that could delay, limit, or prevent marketing approval. Even if a product receives marketing approval, the approval is limited to specific clinical indications. Further, even after marketing approval is obtained, the discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market.

After product approval, there are continuing significant regulatory requirements imposed by the FDA, including record-keeping requirements, obligations to report adverse side effects in patients using the products, and restrictions on advertising and promotional activities. Quality control and manufacturing procedures must continue to conform to cGMPs, and the FDA periodically inspects facilities to assess cGMP compliance. Additionally, post-approval changes in ingredient composition, manufacturing processes or facilities, product labeling, or other areas may require submission of a NDA Supplement to the FDA for review and approval. New indications will require additional clinical studies and submission of a NDA Supplement. Failure to comply with FDA regulatory requirements may result in an enforcement action by the FDA, including Warning Letters, product recalls, suspension or revocation of product approval, seizure of product to prevent distribution, impositions of injunctions prohibiting product manufacture or distribution, and civil and criminal penalties. Maintaining compliance is costly and time-consuming. We cannot be certain that we, or our present or future suppliers or third-party manufacturers, will be able to comply with all FDA regulatory requirements, and potential consequences of noncompliance could have a material adverse impact on our business prospects.

The FDA's policies may change, and additional governmental regulations may be enacted that could delay, limit, or prevent regulatory approval of our products or affect our ability to manufacture, market, or distribute our products after approval. Moreover, increased attention to the containment of healthcare costs in the U.S. and in foreign markets could result in new government regulations that could have a material adverse effect on our business. Our failure to obtain coverage, an adequate level of reimbursement, or acceptable prices for our future products could diminish any revenues we may be able to generate. Our ability to commercialize future products will depend in part on the extent to which coverage and reimbursement for the products will be available from government and health administration authorities, private health insurers, and other third-party payers. European Union member states and U.S. government and other third-party payers increasingly are attempting to contain healthcare costs by consideration of new laws and regulations limiting both coverage and the level of reimbursement for new drugs. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad.

Under the Drug Price Competition and Patent Term Restoration Act of 1984, a sponsor may obtain marketing exclusivity for a period of time following FDA approval of certain drug applications, regardless of patent status, if the drug is a new chemical entity or if new clinical studies were required to support the marketing application for the drug. This marketing exclusivity prevents a third party from obtaining FDA approval for an identical or nearly identical drug under an Abbreviated New Drug Application or a "505(b)(2) New Drug Application." The statute also allows a patent owner to obtain an extension of applicable patent terms for a period equal to one-half the period of time elapsed between the filing of an IND and the filing of the corresponding NDA plus the period of time between the filing of the NDA and FDA approval, with a five year maximum patent extension. We cannot be certain that we will be able to take advantage of either the patent term extension or marketing exclusivity provisions of these laws.

Our activities also may be subject to state laws and regulations that affect our ability to develop and sell our products. We are also subject to numerous federal, state, and local laws relating to such matters as safe working conditions, clinical, laboratory, and manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future, and the failure to comply may have a material adverse impact on our business prospects.

Canada — Scope of Regulation

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 sold in Canada.

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 September 2011, which occasioned the renewal and subsequent annual renewal of its Drug Establishment License.

Other Foreign Regulatory Authorities – Scope of Regulation

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.

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.

We believe that the Company is in compliance with all such laws, regulations and standards currently in effect and that the cost of continued 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.

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 had 212 full-time and two part-time employees at December 31, 2011. Of these employees, 92 are located in the United States, 76 in Canada, 40 in China and 6 in Europe. We consider our employee relations to be satisfactory.

Item 1A. Risk Factors

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

We incurred losses of $4,340,411 in 2011 and $2,448,864 in 2010, and additional losses in previous years. At December 31, 2011, we had an accumulated deficit of $28,136,327. 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 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 line 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 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 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 international operations 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 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. 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 where 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 unprofitable for healthcare providers or less profitable than alternative treatments.

There have been federal and state legislation changes which has subjected the pricing of healthcare goods and services to government control and made other changes to the United States 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 Congress and state legislatures 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 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.

Medical excise tax enacted into law becomes effective in 2013.

President Obama has signed into law the Patient Protection and Affordable Care Act which imposes, among other things, an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States beginning in 2013. Under these provisions, the Congressional Research Service predicts that the total cost to the medical device industry may be up to $20 billion over the next decade. We expect to be subject to this excise tax in the future on our sales of certain medical devices we manufacture, produce or import. We anticipate that all of our sales of medical devices in the United States will be subject to this 2.3% excise tax. The financial impact of this tax on our business is unclear and there can be no assurance that our business will not be materially adversely affected by it.

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 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.

The results of preclinical studies and completed clinical trials are not necessarily predictive of future results, and our current drug candidates may not have favorable results in later studies or trials.

Preclinical studies and Phase I and Phase II clinical trials are not primarily designed to test the efficacy of a drug candidate, but rather to test safety, to study pharmacokinetics and pharmacodynamics, and to understand the drug candidate's side effects at various doses and schedules. Favorable results in early studies or trials may not be repeated in later studies or trials, including continuing preclinical studies and large-scale Phase III clinical trials, and our drug candidates in later-stage trials may fail to show desired safety and efficacy despite having progressed through earlier-stage trials. Unfavorable results from ongoing preclinical studies or clinical trials could result in delays, modifications or abandonment of ongoing or future clinical trials, or abandonment of a clinical program. Preclinical and clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals or commercialization. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be delayed, repeated or terminated, or a clinical program to be abandoned.

We rely on third parties to conduct our clinical trials and many of our preclinical studies. If those parties do not successfully carry out their contractual duties or meet expected deadlines, our drug candidates may not advance in a timely manner or at all.

In the course of our preclinical testing and clinical trials, we rely on third parties, including laboratories, investigators, clinical contract research organizations ("CROs"), and manufacturers, to perform critical services for us. For example, we rely on third parties to conduct our clinical trials and many of our preclinical studies. CROs are responsible for many aspects of the trials, including finding and enrolling subjects for testing and administering the trials. Although we rely on these third parties to conduct our clinical trials, we are responsible for ensuring that each of our clinical trials is conducted in accordance with its investigational plan and protocol. Moreover, the FDA and foreign regulatory

authorities require us to comply with regulations and standards, commonly referred to as good clinical practices, or GCPs, for conducting, monitoring, recording, and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. Our reliance on third parties does not relieve us of these responsibilities and requirements. These third parties may not be available when we need them or, if they are available, may not comply with all regulatory and contractual requirements or may not otherwise perform their services in a timely or acceptable manner, and we may need to enter into new arrangements with alternative third parties and our clinical trials may be extended, delayed or terminated. These independent third parties may also have relationships with other commercial entities, some of which may compete with us. In addition, if such third parties fail to perform their obligations in compliance with our clinical trial protocols or GCPs, our clinical trials may not meet regulatory requirements or may need to be repeated. As a result of our dependence on third parties, we may face delays or failures outside of our direct control. These risks also apply to the development activities of collaborators, and we do not control their research and development, clinical trial or regulatory activities.

Approximately 40 percent of our products are sourced from third parties.

Approximately 40 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 10 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.

Approximately 68 percent 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 ™ total contact casts. The licensing agreements that we have with the owners of these technologies are of limited duration (with the exception of *Medihoney,* which is in perpetuity) 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/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 technology to become obsolete.

The wound and skin care sectors of the medical products industry are 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 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. 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.

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 4,773,217 shares of our common stock were potentially issuable at December 31, 2011 upon the conversion, exercise or vesting of outstanding convertible preferred stock, warrants, options and restricted stock units ("dilutive securities"). The shares of common stock potentially issuable upon conversion, exercise or vesting of dilutive securities are substantial compared to the 10,577,632 shares of common stock outstanding at December 31, 2011.

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 stock prices for the years 2007 through 2011 are set forth in the table below:

Derma Sciences, Inc.
Trading Range – Common Stock

Year	Low	High
2007	$4.64	$11.20
2008	$1.60	$10.80
2009	$1.92	$6.80
2010	$4.40	$9.00
2011	$4.50	$12.72

Events that may affect our common stock price include:

- Outcome of DSC 127 development;
- 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 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; and
- The loss of a major customer.

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.

If members of our management and their affiliates were to exercise all warrants and options held by them, members of management and their affiliates could influence matters that require shareholder approval.

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. Depending upon the warrants and options exercised by outside investors, if directors, executive officers and affiliates were to exercise their options and warrants, 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.

Part IV

Item 15. Exhibits, Financial Statement Schedules

(b) Exhibits

Exhibit Number	Description
31.1	± Certification of the Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley act of 2002.
31.2	± Certification of the Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley act of 2002.

± Filed herewith.

SIGNATURES

In accordance with Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

DERMA SCIENCES, INC.

April 2, 2012 By: /s/ Edward J. Quilty
Edward J. Quilty
Chairman, President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities indicated on April 2, 2012.

Signatures:	Title:
/s/ Edward J. Quilty Edward J. Quilty	President, Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)
/s/ John E. Yetter John E. Yetter, CPA	Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)
/s/ Srini Conjeevaram Srini Conjeevaram	Director
/s/ Stephen T. Wills Stephen T. Wills, CPA, MST	Director
/s/ James T. O'Brien James T. O'Brien	Director
/s/ C. Richard Stafford, Esq. C. Richard Stafford, Esq.	Director
/s/ Richard J. Keim Richard J. Keim	Director

/s/ Robert G. Moussa Robert G. Moussa	Director
/s/ Bruce F. Wesson Bruce F. Wesson	Director
/s/ Brett Hewlett Brett Hewlett	Director

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