DERMA SCIENCES, INC.
Form 10-K
March 29, 2011

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, 2010

¨ 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:

Title of Class

Common Stock, $.01 par value

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

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¨ Nox

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.
Yesx 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¨ 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¨ Nox

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, 2010, was approximately $16,829,509.

The number of shares outstanding of the issuer's common equity as of February 28, 2011 was 6,647,745.

Documents Incorporated by Reference

Portions of the Registrant’s definitive proxy statement for its 2011 annual meeting of shareholders are incorporated by reference in Part III of this report.

Item 1. Description of Business

Overview

Derma Sciences, Inc. (“Derma Sciences”) and its subsidiaries Sunshine Products, Inc., Derma Sciences Canada Inc. (“Derma Canada”), Derma First Aid Products, Inc. and Derma Sciences Europe, Ltd. are referred to collectively as "We” and “Company.” Our executive offices are located at 214 Carnegie Center, Suite 300, Princeton, New Jersey.

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

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

Derma Sciences was incorporated under the laws of Colorado on September 10, 1984. On June 3, 1996 Derma Sciences changed its state of domicile to Pennsylvania.

In September 1998, we acquired Genetic Laboratories Wound Care, Inc. (“Genetic Labs”) by means of a tax-free reorganization whereby Genetic Labs became our wholly-owned subsidiary. In December 1999, pursuant to an Agreement and Plan of Merger dated December 27, 1999, Genetic Labs was merged into Derma Sciences by means of a tax-free reorganization whereby the separate corporate existence of Genetic Labs ceased. The Genetic Labs products constitute our wound closure and specialty securement device product line.

In November 1998, we acquired the stock of Sunshine Products, Inc. (“Sunshine Products”) in a cash transaction. As a result of the stock purchase, Sunshine Products became our wholly-owned subsidiary. The product offering obtained from this acquisition constitutes our skin care product line.

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

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

In April 2006, we acquired certain assets and the business of Western Medical, Inc. (“Western Medical”), a manufacturer and marketer of a line of specialty medical textile compression, support and protective dressing

products. These assets have been integrated into our existing wound care product line.

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

In May 2010, we incorporated Derma Sciences Europe Ltd. to operate our Europe, Middle East and Africa business interests.

Products

Advanced/Active Wound Care

Our advanced/active wound care products include the following:

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

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

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

Xtrasorb is a novel, proprietary 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 and 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, is a one-step process – so application errors are uncommon – and the cast itself is significantly lighter – due to its open weave pattern – than a traditional TCC.

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

Traditional Wound Care

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.

Private Label/OEM

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

Wound Closure and Specialty Securement Devices

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

Skin Care

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

Product Development

We are currently developing DSC127, an angiotensin analog licensed from the University of Southern California in November 2007, for use in wound healing and scar reduction. The compound has shown activity in these areas in pre-clinical animal model testing. The compound has successfully completed a Phase I human trial and has completed the efficacy portion of a Phase II human trial on diabetic foot ulcers. Efficacy results of this study were reported in February 2011.

DSC127 is a patented, topically applied novel angiotensin analog that targets receptors that are up-regulated upon injury to tissue. The drug has been shown to improve epithelialization, granulation and vascularization, accelerating wound healing in a variety of normal and diabetic animal models. This finding suggests 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 I trial 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.

We are in the process of determining our strategic alternatives with DSC127, given the successful Phase II study. Considerations include partnering the drug, either globally or exclusively outside the United States, and either comprehensively (all indications) or indications outside of wound healing (which could include, but are not limited to, scar prevention/reduction).

The durability portion of the Phase II study is scheduled to end in the first quarter of 2011. In the following months, a full report on all the study data will be prepared and sent to the United States Food and Drug Administration (“FDA”). At that time, we will announce all of the key endpoint data. Also, at or around that time, we will make a request for an End-of-Phase II meeting with the FDA.

We continue to evaluate certain products and technologies within the advanced/active 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.

We have several ongoing product development programs involving line-extensions of our key brands including Medihoney, Bioguard and Xtrasorb. We anticipate new line extensions coming to market throughout 2011.

Sales and Marketing

In 2010 the United States accounted for 68%, Canada 26% and rest of world 6% 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 national director – sales, 20 direct territory representatives, a sales administrator and two clinical resource specialists. Our sales employees receive a base salary together with commissions based upon sales and gross profit achievement within their area of responsibility.

Canada

In Canada, we employ a sales manager, one direct sales representative in Ontario, a manufacturer's representative in British Colombia, and an advanced wound care consultant covering Ontario and the Maritimes. Our direct sales representative receives 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 advanced wound care consultant is paid on a per assignment basis. 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 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 a means to better serve our customers throughout Canada and greater opportunity for sales growth than we could provide utilizing our own resources.

Other Foreign Markets

We have a direct selling organization in the United Kingdom consisting of four 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 and for placing direct sales representatives in countries where appropriate. Throughout the rest of the world, we sell our products through various licensing and distribution agreements. Currently, our foreign sales are made principally to Europe and Latin America. Sales made to all foreign markets totaled $3,691,733 in 2010 and $2,448,342 in 2009.

Competition

In the United States, our basic wound care products compete in a commodity oriented marketplace with Covidien, Medical Action and a number of others. In the advanced wound care products marketplace, we compete principally with Convatec, Smith & Nephew, Molnlycke and Systagenix (formerly Johnson & Johnson's wound care division). 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 basic wound care products compete in a commodity-oriented marketplace with Covidien, Medicom, Medical Mart and a number of others. In the advanced wound care products marketplace, we compete principally with the same competitors as we compete with in the United States, together with a number of domestic generic companies. 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 City, Mexico, and ZhongShan, China. Approximately 60% of our products are manufactured at these four locations. The remaining 40% of our products are manufactured by third party manufacturers in the United States, China and other countries.

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

In our 76,399 square foot Toronto facility we manufacture our line of basic and advanced wound care and wound closure and specialty securement device 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 11,388 square foot Nantong facility we manufacture our line of basic 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 for us. The Nantong facility is ISO 9001:2008 certified and TUV registered.

In both our Mexico City and ZhongShan facilities we manufacture adhesive bandages and related first aid products. The Mexico City facility is ISO 9001:2008 and ISO 13485:2004 certified and Aenor IQNET registered. The ZhongShan facility is ISO 13485:2003 certified and NQA registered.

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

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

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

Patents, Trademarks, Proprietary and Non-Proprietary Technology

We own or license the following trademarks: Derma Sciences, Dermagran, American White Cross, Dumex, Medihoney, Algicell, Xtrasorb, TCC-EZ and Bioguard. In addition, we own or license over 50 United States patents, corresponding foreign patents and patent applications. Most of our patents relate to our DSC127 technology are held

under license agreements of indefinite duration. The license agreement relative to our Bioguard technology expires in June 2014. We recently 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

Agencies

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

Medical Devices

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

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

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

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

All manufacturers are required to give the FDA 90 days notice before they can introduce a device on the market. During the 90-day period, the FDA will determine whether the device is or is not substantially equivalent to a Pre-amendment Device. If the FDA determines that the device is not substantially equivalent to a Pre-amendment Device, it is automatically placed in Class III and the manufacturer will have to provide the FDA with a Premarket Approval Application ("PMA") containing evidence that the device is safe and effective before the device may be commercially distributed to the public. However, the manufacturer may request that the FDA reclassify the device by filing a reclassification petition.

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

Over-the-Counter Drugs

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

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

On the basis of the recommendations submitted by the panels, the FDA issues monographs setting forth the conditions under which OTC drugs in each class are deemed to be generally recognized as safe, effective and not misbranded. Generally, the administrative process includes the publication of a "Preliminary," "Tentative Final" and "Final Monograph." During the rulemaking process, products are placed into one of three categories describing whether a drug is deemed to be generally recognized as safe and effective and not misbranded (Category I), to be not generally recognized as safe and effective or misbranded (Category II) or to lack sufficient data for categorization (Category III). Products that do not comply with general OTC regulations or an applicable Final Monograph are subject to regulatory action. Any OTC drug not in compliance with the content and labeling requirements of a Final Monograph is subject to regulatory action unless it is the subject of an approved new drug application. The FDA has issued a Compliance Policy Guide in which it determined that it would not pursue regulatory action against OTC drugs prior to the adoption of a final regulation unless failure to do so presents a potential public health hazard. We believe all of the OTC products currently marketed by us have been deemed to be generally recognized as safe and effective and not misbranded.

Canada — Scope of Regulation

Medical Devices

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

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

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

As of January 1, 2003, manufacturers of Class II, III and IV devices are required to have a quality system registered to ISO 13485 or ISO 13488 by a registrar recognized by Health Canada. Proof of registration must be submitted with

any new license application after January 1, 2003, and with the renewal of existing licenses after November 1, 2003.

Drugs

The Health Products and Food Branch Inspectorate of Health Canada regulates drugs and the processes used to manufacture drugs. A Drug Establishment License is required for activities such as fabrication, packaging/labeling, importation, distribution, wholesale and testing. Derma Canada last underwent an inspection by the Health Products and Food Branch Inspectorate in August 2009, which occasioned the renewal and subsequent annual renewal of its Drug Establishment License.

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

Registration and Status of Derma Canada Products Sold in United States

Derma Canada has passed inspection by the FDA.

Other Foreign Regulatory Authorities

Whether or not FDA approval has been obtained, approval of medical drugs and devices by regulatory authorities in foreign countries must be obtained prior to marketing drugs and devices in such countries. The requirements governing the conduct of clinical trials and product approval vary widely from country to country and the time required for approval may be longer or shorter than that required for FDA approval. Although there are procedures for unified filings for certain European countries, most countries currently maintain their own product approval procedures and requirements.

Other Regulatory Requirements

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

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 compliance with such laws, regulations and standards will not have a material adverse effect on us.

Third Party Reimbursement in the United States

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

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

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

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

extent, reimbursements for our products will continue to be available.

Employees

We maintained 195 employees at December 31, 2010. Of these employees, 79 are located in the United States, 70 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 $2,448,864 in 2010, and $1,282,725 in 2009, and additional losses in previous years. At December 31, 2010, we had an accumulated deficit of $23,795,916. We cannot offer any assurance that we will be able to generate sustained or significant future earnings.

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

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

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

Our future operations and earnings will depend to a large extent on the results of our 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.

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.

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.

Many of our advanced wound care products utilize technology that we license on an exclusive basis from third parties. These products include Medihoney dressings, Bioguard dressings and MedEfficiency TM 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.

11

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 3,035,382 shares of our common stock are potentially issuable at March 29, 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 6,724,894 shares of common stock outstanding at March 29, 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 2006 through 2010 are set forth in the table below:

Derma Sciences, Inc.
Trading Range – Common Stock

Year	Low	High
2006	$ 3.60	$ 7.20
2007	$ 4.64	$ 11.20

2008	$ 1.60	$ 10.80
2009	$ 1.92	$ 6.80
2010	$ 4.40	$ 9.00

Events that may affect our common stock price include: