DERMA SCIENCES, INC.
Form 10KSB
April 01, 2008

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-KSB

[X] Annual Report under Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 2007

[ ] Transition Report under 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 small business 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	Boston Stock Exchange

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

Title of Class

Common Stock, $.01 par value

Check whether the issuer is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act.[ ]

Check whether the Registrant: (1) filed all reports required to be filed by Sections 13 or 15(d) of the Exchange Act during the past 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 past 90 days.
Yes X No

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained in this form, and no disclosure will be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB. [ ]

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act.
Yes No X

Issuer s revenues for its most recent fiscal year were $34,135,401.

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 February 28, 2008, was approximately $21,153,856.

The number of shares outstanding of the issuer s common equity as of February 28, 2008 was 34,040,743.

Documents incorporated by reference: None

Part I

Item 1. Description of Business

Overview

Derma Sciences, Inc. (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 Derma Sciences acquired Genetic Laboratories Wound Care, Inc. (Genetic Labs) by means of a tax-free reorganization whereby Genetic Labs became a wholly-owned subsidiary of Derma Sciences. 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.

In November, 1998 Derma Sciences purchased the stock of Sunshine Products, Inc. (Sunshine Products) in a cash transaction. As a result of the stock purchase, Sunshine Products became a wholly-owned subsidiary of Derma Sciences.

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

In January 2004, Derma Sciences purchased substantially all the assets of the Kimberly-Clark Corporation s wound care segment. These assets have been integrated into the Company s existing wound care and wound closure and specialty securement device product lines.

In April 2006, Derma Sciences purchased 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 the Company s existing wound care product line.

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

Derma Sciences and its subsidiaries Sunshine Products, Derma Canada and Derma First Aid Products, Inc. are referred to collectively as the Company. The Company s executive offices are located at 214 Carnegie Center, Suite 300, Princeton, New Jersey.

The Company engages in the manufacture, marketing and sale of three dermatological related product lines: wound care, wound closure and specialty securement devices and skin care. In addition, the Company has leveraged its expanding manufacturing capabilities by building a growing private label/original equipment manufacture (OEM) business. The Company s customers consist of various health care agencies and institutions such as nursing homes, hospitals, home healthcare agencies, physician s offices and retail and closed door pharmacies. The Company sells its products principally through distributors servicing these markets in the United States, Canada and select international markets. The Company s principal distribution facilities are located in St. Louis, Missouri, and Toronto, Canada. The Company s principal manufacturing facility is located in Toronto, Canada. The Company, through Derma Canada, also maintains a light manufacturing facility in Nantong, China producing labor intensive wound care products. With the FAD acquisition the Company temporarily manufactures and distributes the adhesive strips and related first aid products at a Houston, Texas location. The manufacturing function is anticipated to be transferred to a third party by the second quarter of 2008 while the distribution function is anticipated to be integrated with the rest of the US distribution activities by the first quarter of 2009.

Company Products and Markets

Wound Care

The Company markets a line of wound care products to doctors, clinics, nursing homes, hospitals and other institutions. The Wound Care line consists of basic and advanced dressings, devices, ointments and sprays designed to manage and treat a wide range of skin conditions from basic burns, skin tears, abrasions and incontinence related skin impairment to chronic non-healing skin ulcerations such as pressure, diabetic and venous ulcers, surgical incisions and serious burns.

Wound Closure and Specialty Securement Devices

The Company markets a line of wound closure strips, nasal tube fasteners and a variety of catheter fasteners to doctors, clinics, nursing homes, hospitals and other institutions.

Private Label/OEM

The Company manufactures private label wound care and wound closure and specialty securement devices for a number of U.S. and international customers.

Skin Care

The Company markets general purpose and specialized skin care products to nursing homes, hospitals, home healthcare agencies and other institutions. These products include bath sponges, antibacterial skin cleansers, soaps, hair and body washes, lotions, body oil and moisturizers.

The Company has built a base business through sales of its own brand and private label brand commodity products. Prospectively, the Company is focusing its resources on the marketing, sale and distribution of novel higher margined advanced wound care products.

Product Pipeline

The company currently has two development stage products. The first is GUARDION™ Barrier Dressings with a novel antimicrobial that the Company has licensed from QuickMed Technologies, Inc. The patented polymer technology known as NIMBUS (novel intrinsically micro-biocidal utility substrate) was licensed from QuickMed in April, 2007, for use in a range of gauze and other traditional wound care dressings. The product is currently under review by the FDA for marketing clearance. The second is DSC127, a novel angiotensin analog, licensed from the University of Southern California in November, 2007, for use in wound healing and scar reduction. The compound has shown activity in these areas in pre-clinical animal model testing. The compound has successfully completed a phase I human trial, and is expected to enter into a phase II human trial in the third quarter of 2008.

Sales Resources

United States

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

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

Canada

In Canada, the Company employs a sales manager, one direct sales representative in Ontario, the most densely populated province, and a manufacturer s representative located in British Colombia. Company sales employees receive a base salary together with commissions based upon sales achievement within their areas of responsibility. The majority of the Company s Canadian sales are to hospitals pursuant to tender contracts with national, provincial and local buying groups. These institutional contracts are generally exclusive in nature and are awarded for a term of 1 to 5 years. Nursing home, home healthcare, physician office and retail sales are for the most part made through local dealers and government sponsored Community Care Access Centre s (CCAC) agencies.

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

Other Foreign Markets

The Company s products are sold throughout the rest of the world through various licensing and distribution agreements. Foreign sales are made principally to Europe and Latin America. Sales made to other foreign markets totaled $1,692,130 in 2007 and $1,225,515 in 2006.

Competition

The wound and skin care sectors of the medical products industry are characterized by rapidly evolving technology and intense competition. Many suppliers of competing products are considerably larger and have much greater resources than the Company. 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 those of the Company. Academic institutions, government agencies and other public and private research organizations are also conducting research activities and may commercialize wound and skin care products on their own or through joint ventures.

In the United States, the Company s 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, the Company competes principally with Bristol-Myers Squibb Convatec, Smith & Nephew and Johnson & Johnson. The market for wound closure strips and catheter fasteners is characterized by a wide range of generic competition. The most dominant competitor in the suture strip market is 3M. The Company s skin care products compete in a commodity oriented marketplace with Provon, Chester Laboratories and a number of others.

In Canada, the Company s 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, the Company competes principally with the same competitors as it competes with in the United States together with a number of domestic generic companies.

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

Product Sourcing

The Company maintains manufacturing facilities in Toronto, Canada, and Nantong, China. The Toronto and Nantong facilities manufacture the Company s line of basic and advanced wound care and its wound closure-specialty securement device products. With the FAD acquisition, the Company temporarily manufactures the adhesive strips and related first aid products at a Houston, Texas, location. The adhesive strip and related first aid products manufacturing is anticipated to be transferred to a third party by the second quarter of 2008. The Derma line of wound and skin care products and the patient bathing sponge are outsourced. 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.

The Company maintains a long-standing network of suppliers for its outsourced products. The majority of the Company s 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 the Company s policy regarding maintenance of adequate safety stock levels, the Company does not believe that a temporary interruption in supply or loss of one or more of its suppliers would have a long-term detrimental impact on its operations.

The Nantong facility is ISO 9002 certified. The Toronto facility is ISO 9001:2000/ISO 13485:2003 certified. The Company requires that all of its 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, Proprietary and Non-Proprietary Technology

The Company has a trademark on the name Derma Sciences in the United States and Dumex in the United States and Canada. A significant number of the Company s products in the United States are trademarked. The Company possesses a number of patented and non-patented formulations and process technologies that provide competitive advantages in the marketplace.

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

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

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

Government Regulation

United States Scope of Regulation

Agencies

The manufacture, distribution and advertising of the Company and its products are subject to regulation by numerous federal and state governmental agencies in the United States. The United States Food and Drug Administration (FDA) is responsible for enforcement of the Federal Food, Drug and Cosmetic Act, as amended, (FDC Act) which regulates drugs and devices manufactured and distributed in interstate commerce. Many of the Company s 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 analagous to the FDC Act and the FTC Act.

Medical Devices

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

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

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

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

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

All of the devices currently marketed by the Company, 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. ALGICELL™ Ag Absorbent Gelling Dressings with antimicrobial silver and MEDIHONEY™ Wound & Burn Dressings with Active *Leptospermum* Honey are unclassified.

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. Management believes all of the OTC products currently marketed by the Company have been deemed to be generally recognized as safe and effective and not misbranded.

Canada Scope of Regulation

Medical Devices

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

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

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

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

Drugs

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

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

Registration and Status of Derma Canada Products Sold in United States

Derma Canada has passed inspection by the United States Food and Drug Administration.

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, the Company is 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.

The Company is also subject to federal, state and foreign laws and regulations adopted for the protection of the environment and the health and safety of employees. Management believes that 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 the Company.

U.S. Third Party Reimbursement

In the United States, the Company sells its 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 the Company s products are purchased often are covered by medical insurance. Accordingly, the Company s customers routinely seek reimbursement for the cost of the Company s 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 the Company s 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 the Company s 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 the Company s products will continue to be available.

Employees

The Company maintained 155 full-time and 33 part-time employees at December 31, 2007. Of these employees, 74 are located in the United States, 70 in Canada and 44 in China. The Company considers its employee relations to be satisfactory.

Item 2. Description of Property

The Company s headquarter offices are located in Princeton, New Jersey. In February, 2008 the Company completed an expansion and renovation of the offices increasing its square footage to 8,024. The amended lease s monthly payment is $19,726 and the lease expires in August 2012. The Company also leases a 42,400 square foot warehouse in Fenton, Missouri, at a rate of $20,727 per month, under a lease that expires in March 2009. The Fenton, Missouri, facility serves as the United States distribution center for the Company s products.

Derma Canada leases 45,640 feet of office and manufacturing space, at a rate of $31,885 per month, under a lease that expires in August, 2012 and leases a 20,400 square foot distribution facility, at a rate of $11,300 per month, under a lease that expires in August, 2009. The 20,400 square foot facility formerly served as Derma Canada s distribution facility, a function outsourced commencing in June 2005. This facility is being sublet under a lease that expires in June 2008. In December 2006, the Company leased an additional 15,499 square feet of space adjacent to its Toronto office and manufacturing space, at a rate of $10,600 per month, for additional manufacturing and warehouse space. Simultaneously, the Company, in agreement with the landlord, was released from its lease on 6,068 square feet of non-adjacent property. A subsidiary of Derma Canada also leases 11,400 square feet of office and manufacturing space in Nantong, China, at a rate of $1,040 per month, under a lease that expires in June, 2008.

In November 2007, the Company entered into a lease for $18,750 per month for approximately 50,000 square feet of manufacturing and distribution space at the former NutraMax facility in Houston, Texas through May 2008. The Company is presently negotiating to extend the lease or secure suitable space elsewhere in the area through the first quarter 2009.

Management believes that the Company s facilities are adequate to meet its office, manufacturing and distribution requirements for the foreseeable future.

Item 3. Legal Proceedings

The Company is not a party to any material litigation.

Item 4. Submission of Matters to a Vote of Security Holders

A special meeting of shareholders of the Company was held on December 28, 2007. At the special meeting, the following matter was submitted to a vote of the Company s security holders with the results indicated:

Increase in Authorized Common Stock

Shareholders approved an amendment of the Company s articles of incorporation to increase the number of shares of common stock the Company is authorized to issue from 50,000,000 to 150,000,000. Details concerning the vote on the amendment are set forth below:

In favor	18,156,044
Against	1,027,662
Abstentions	45,397
Broker non-votes	0

The Company solicited proxies relative to the amendment. No proxies were solicited in opposition to the amendment.

Part II

Item 5. Market for Common Equity, Related Shareholder Matters and Small Business Issuer Purchases of Equity Securities

The Common Stock of the Company is traded on the OTC Bulletin Board under the symbol DSCI.OB. The Common Stock is listed on the Boston Stock Exchange under the symbol DMS. The Company s Common Stock commenced trading on May 13, 1994. The following table sets forth the high and low bid prices for the Company s Common Stock at the end of the indicated calendar quarters:

Quarter Ended	High	Low
2007		
March 31, 2007	$0.87	$0.66
June 30, 2007	$1.10	$0.59
September 30, 2007	$0.97	$0.60
December 31, 2007	$1.40	$0.58
2006		
March 31, 2006	$0.84	$0.45
June 30, 2006	$0.90	$0.75
September 30, 2006	$0.87	$0.59
December 31, 2006	$0.90	$0.66

The stock prices reflect inter-dealer prices without retail mark-up, mark-down or commission and may not necessarily represent actual transactions. There is no public market for the Company s preferred stock. As of the close of business on February 28, 2008 there were 1,264 holders of record of the Common Stock. The Company has paid no cash dividends in respect of its Common Stock and does not intend to pay cash dividends in the near future.

Item 6. Management's Discussion and Analysis of Financial Condition or Plan of Operations

Reference to Consolidated Financial Statements

Management s Discussion and Analysis or Plan of Operations should be read in conjunction with the Company s consolidated financial statements and notes to consolidated financial statements set forth in Item 7.

Overview of Consolidated Operating Results

The following table highlights the year ended December 31, 2007 versus 2006 operating results:

	Year Ended December 31,			
	2007	2006	Variance	
Gross Sales	$ 42,712,304	$ 33,973,676	$ 8,738,628	25.7%
Sales adjustments	(8,576,903)	(6,086,285)	(2,490,618)	40.9%
Net sales	34,135,401	27,887,391	6,248,010	22.4%
Cost of sales	22,530,986	18,235,003	4,295,983	23.6%
Gross profit	11,604,415	9,652,388	1,952,027	20.2%
Gross profit percentage	34.0%	34.6%		
Operating expenses	12,878,437	8,539,227	4,339,210	50.8%
Interest expense	413,992	374,079	39,913	10.7%
Loss on debt extinguishment	256,628		256,628	
Other expense/(income), net	77,929	(47,998)	125,927	
Total expenses	13,626,986	8,865,308	4,761,678	53.7%
(Loss) income before income taxes	(2,022,571)	787,080	(2,809,651)	
Provision for income taxes	262,034	118,341	143,693	
Net (loss) income	$ (2,284,605)	$ 668,739	$ (2,953,344)	

Gross to Net Sales Adjustments

Gross sales are adjusted for trade rebates, distribution fees (in Canada), sales incentives, Medicaid rebates, returns and allowances and cash discounts to derive net sales. Trade rebates are trued-up monthly based upon an analysis of historical sales subject to rebate and actual rebates received from distributors. The normal rebate cycle is one month. Non-exclusive distributors generally carry one months inventory. The Company s exclusive distributor in Canada normally carries three to four months inventory. As distributor inventory is depleted via sales, it is replenished via purchases from the Company. Rebates are processed and submitted for credit on a timely basis consistent with distributor sales. If the normal rebate cycle were one-half month less than estimated at December 31, 2007, the trade rebate reserve would be overstated by approximately $270,000. If the normal rebate cycle were one month greater than estimated at December 31, 2007, the trade rebate reserve would be understated by approximately $540,000. To minimize its cash outflow invested in rebates, distributors generally strive to optimize the rebate credit submission process.

Given the nature of the Company s products and business, there is no external information available to further validate the reasonableness of the trade rebate accrual balance. Historical trends of sales subject to rebate and rebates received are evaluated monthly, by distributor, on a 3 month, 6 month and 12 month rolling basis to update the continued reasonableness of the assumptions used to quantify the trade rebate accrual balance. Deviations in the

trends resulting, among other causes, from distributors not submitting their rebates on a timely basis are analyzed and factored in determining the required accrual balance.

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

Sales incentives are credits granted to specific customers based upon attainment of pre-determined sales objectives. The agreements are generally for a period of one year.

Medicaid rebates are accrued monthly based upon recent historical activity and reconciled quarterly based upon receipt of rebate reports from participating state agencies. Returns and allowances and cash discounts are accrued monthly based on recent historical activity.

Gross to net sales adjustments comprise the following:

	Year Ended December 31,	
	2007	2006
Gross Sales	$ 42,712,304	$ 33,973,676
Trade rebates	(6,629,106)	(4,637,960)
Distribution fees	(1,135,072)	(979,776)
Sales incentives	(225,386)	(149,831)
Medicaid rebates	(7,196)	(11,486)
Returns and allowances	(300,042)	(87,101)
Cash discounts	(280,101)	(220,131)
Total adjustments	(8,576,903)	(6,086,285)
Net sales	$ 34,135,401	$ 27,887,391

Trade rebates increased significantly in 2007 versus 2006 due to higher rebate intensive Canadian sales coupled with an increase in the overall rebate percentage due to renewal of buying group contracts at lower selling prices and continuing growth of rebate intensive U.S. private label sales. The increase in distribution fee expense is commensurate with the increase in Canadian net sales upon which it is based. The increase in sales incentive expense principally relates to the acquisition of the Western Medical business in April 2006, which utilizes sales incentives to a greater degree than in the Company s other product lines. An increased reliance on sales incentives in other areas of the Company s business, also contributed. A continuing trend towards lower levels of Medicaid reimbursed sales is responsible for the lower level of Medicaid rebates. Sales returns and allowances increased in 2007 due to the higher level of sales and an overall higher level of returns; however, the Company s returns and allowances continue to represent less than 1% of gross sales. Cash discounts increased commensurate with the sales increase and as a result of a slight increase in the percentage of cash discounts to sales, as a larger portion of the sales growth continues to come from customers that have historically taken advantage of the Company s discount terms.

Rebate Reserve Roll Forward

A roll forward of the trade rebate accruals at December 31, 2007 and 2006 is outlined below:

	Year Ended December 31,	
	2007	2006

Beginning balance - January 1	$ 1,817,558	$ 1,566,590
Rebates paid	(6,041,803)	(4,386,992)
Rebates accrued	6,629,106	4,637,960
Ending balance - December 31	$ 2,404,861	$ 1,817,558

The $587,303 increase in the 2007 trade rebate reserve ending balance principally reflects an increase in the Canadian rebate reserve due to higher sales and an increase in the exclusive distributor s inventory level commensurate with the sales and to build its safety stock to improve customer service. An increase in the overall rebate percentage in Canada due to renewal of buying group contracts at lower selling prices, also contributed. This increase was partially offset by diminishing non private label U.S. rebate laden sales. There has been no other discernable change in the nature of the Company s business as it relates to the accrual and subsequent payment of rebates. The $250,968 increase in the 2006 trade rebate reserve principally reflects an increase in the Canadian reserve due to higher sales, partially offset by diminishing non private label U.S. rebate laden sales and the discontinuation of extended payment terms with a large customer.

Net Sales and Gross Margin

The following table highlights 2007 versus 2006 product line net sales and gross profit:

	Year Ended December 31, 2007	2006	Variance	
Product Line Net Sales				
Wound care	$ 30,983,191	$ 24,450,557	$ 6,532,634	26.7%
Wound closure-specialty securement devices	2,260,735	2,308,452	(47,717)	(2.1%)
Skin care	891,475	1,128,382	(236,907)	(21.0%)
Total	$ 34,135,401	$ 27,887,391	$ 6,248,010	22.4%
Product Line Gross Profit				
Wound care	$ 10,043,756	$ 8,377,522	$ 1,666,234	19.9%
Wound closure-specialty securement devices	1,318,148	1,111,452	206,696	18.6%
Skin care	242,511	163,414	79,097	48.4%
Total	$ 11,604,415	$ 9,652,388	$ 1,952,027	20.2%

Consolidated net sales increased $6,248,010, or 22.4%, to $34,135,401 in 2007 from $27,887,391 in 2006. Canadian net sales increased $1,643,472, or 15.4% (9.0% excluding foreign exchange), to $12,324,111 in 2007 from $10,680,639 in 2006. This increase was driven by growth of $961,592 and favorable exchange of $681,880 associated with a 6.0% strengthening of the Canadian dollar. The increase was principally attributable to higher sales to the Company s exclusive Canadian distributor to meet demand and to rebalance its inventory, partially offset by price erosion associated with the renewal of bid contracts at lower overall selling prices and lower private label sales to the

distributor. Real growth as measured by sales of the Company s products reported by the distributor, unadjusted for foreign exchange, approximated 8.4%. U.S. net sales increased $4,604,538, or 26.8%, to $21,811,290 in 2007 from $17,206,752 in 2006. The increase was driven by the addition of incremental FAD sales of $1,823,526 and Western Medical sales of $1,841,653, continued private label growth and new product (Medihoney and silver alginate) sales growth of $785,816 partially offset by continued sales decline in the skin care, specialty securement devices and the Derma line of products. Excluding FAD and Western Medical sales, U.S. sales increased $939,359, or 7.7%.

Consolidated gross profit increased $1,952,027, or 20.2%, to $11,604,415 in 2007 from $9,652,388 in 2006. Company gross profit margin percentage decreased to 34.0% in 2007 from 34.6% in 2006. Canadian gross profit increased $444,051, or 12.3%, to $4,051,810 in 2007 from $3,607,759 in 2006. Canadian gross profit margin percentage decreased to 32.9% in 2007 from 33.8% in 2006. The improvement in Canadian 2007 gross profit dollars reflects the higher sales and favorable foreign exchange impact partially offset by margin erosion. The margin erosion

principally reflects ongoing price erosion in the Canadian traditional wound care market, higher cost third party supplied traditional wound care products and lower volume throughput that adversely impacted fixed overhead absorption in the Company s Canadian manufacturing facility. U.S. gross profit increased $1,507,976, or 25.0%, to $7,552,605 in 2007 from $6,044,629 in 2006. Gross profit margin percentage decreased to 34.6% in 2007 from 35.1% in 2006. The improvement in U.S. gross profit margin dollars reflects the impact of higher sales. The decrease in gross profit margin percentage is principally attributable to unfavorable product mix. The addition of the lower margined FAD business in the fourth quarter 2007 and continued growth of the lower margined private label business partially offset by higher margined new product sales are the primary contributors to the decrease in gross profit margin percentage. Excluding FAD and Western Medical, gross profit increased $400,326, or 10.1%, and the gross profit margin percentage would have been 33.0%.

Wound care sales consisting of traditional and advanced wound care products increased $6,532,634, or 26.7%, in 2007 versus 2006. Traditional wound care sales increased $4,410,535, or 26.7%. This increase was driven by an increase in Canadian basic wound care sales of $1,643,472 together with a U.S. sales increase of $2,767,063. The Canadian sales growth was driven principally by higher sales to the Company s exclusive Canadian distributor due to improving demand and the distributor s rebalancing of its inventory earlier in the year, partially offset by price erosion and lower private label sales to the distributor. The U.S. sales performance reflects incremental FAD and Western Medical sales of approximately $2,860,000 coupled with a modest decrease for the balance of the basic wound care line. Advanced wound care sales increased $2,122,099 or 26.7%. This increase was principally driven by U.S. private label and new product sales growth, partially offset by lower demand for the Derma line of products. Sales in 2007 of the Company s new silver alginate product launched in November 2006 and Medihoney launched in October 2007 were $666,375 and $119,441, respectively.

Wound care gross profit increased $1,666,234, or 19.9%, in 2007 versus 2006. Gross profit margin percentage decreased to 32.4% in 2007 from 34.3% in 2006. The gross profit margin dollar increase reflects the sales increase and margin decrease. The margin percentage decrease is principally attributable to unfavorable product mix.

Wound closure-specialty securement device sales decreased $47,717, or (2.1%), in 2007 versus 2006. The decrease is principally due to the discontinuation of a private label supply agreement partially offset by a prior year backorder fulfillment in the first quarter 2007.

Wound closure-specialty securement device gross profit increased $206,696, or 18.6%, in 2007 versus 2006. Gross profit margin percentage increased to 58.3% in 2007 from 48.1% in 2006. The increase in gross profit margin dollars reflects the improved gross profit margin percentage. The gross profit margin percentage improvement is due to the flow through of lower product costs associated with bringing the manufacture of these products in-house in the second half of 2006.

Skin care sales decreased $236,907, or 21.0%, in 2007 versus 2006 due to continuing competitive pressure. Skin care gross profit improved $79,097 to $242,511 in 2007 from $163,414 in 2006. The main driver for the gross profit dollar improvement was the expiration of the lease on the former skin care manufacturing facility.

Operating Expenses

The following table highlights 2007 versus 2006 operating expenses by type:

	Year Ended December 31, 2007