TRANSDERM LABORATORIES CORP
Form 10KSB
April 18, 2007

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-KSB

(Mark One)

x ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2006

o TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number: 000-27642

TRANSDERM LABORATORIES CORPORATION
(Name of small business issuer in its charter)

Delaware	13-3518345
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
101 Sinking Springs Lane, Emigsville, PA	17318
(Address of principal executive offices)	(Zip code)

Issuer's telephone number, including area code: 717-764-1191

Securities registered under Section 12(b) of the Exchange Act: None

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

Common Stock, $.001 Par Value
(Title of class)

Check whether the issuer (1) filed all reports required to be filed by Section 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 the past 90 days. o 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. x

State the issuer's revenues for its most recent fiscal year: $5,940,000

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was sold, or the average bid and asked price of such common

equity, as of a specified date within the past 60 days. (See definition of affiliate in Rule 12b-2 of the Exchange Act.): Not applicable.

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

State the number of shares outstanding of each of the issuer's classes of common equity, as of the latest practicable date: 40,000,000 as of March 30, 2007.

DOCUMENTS INCORPORATED BY REFERENCE

None.

Transitional Small Business Disclosure Format (Check one): o Yes x No

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-KSB for the year ended December 31, 2006 ("Annual Report") contains forward-looking statements. We have based these forward-looking statements on our current expectations and projections about future events. These statements include, but are not limited to:

- statements relating to our ability to restructure our outstanding past due liabilities;
- statements as to the development of new products and the commercialization of products;
- statements as to the anticipated timing of clinical tests and other business developments;
- expectations as to the adequacy of our cash balances to support our operations for specified periods of time and as to the nature and level of cash expenditures; and
- expectations as to the market opportunities for our products, as well as our ability to take advantage of those opportunities.

These statements may be found in the sections of this Annual Report entitled “Description of Business”, “Risk Factors”, and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” as well as in this Annual Report generally. Actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including all the risks discussed in “Risk Factors” and elsewhere in this Annual Report.

In addition, statements that use the terms “can,” “continue,” “could,” “may,” “potential,” “predicts,” “should,” “will,” “believe,” “plan,” “intend,” “estimate,” “anticipate,” “scheduled” and similar expressions are intended to identify forward-looking statements. All forward-looking statements in this Annual Report reflect our current views about future events and are based on assumptions and are subject to risks and uncertainties that could cause our actual results to differ materially from future results expressed or implied by the forward-looking statements. Many of these factors are beyond our ability to control or predict. Forward-looking statements do not guarantee future performance and involve risks and uncertainties. Actual results will differ, and may differ materially, from projected results as a result of certain risks and uncertainties. The risks and uncertainties include, without limitation, those described under “Risk Factors” and those detailed from time to time in our filings with the Securities and Exchange Commission, and include, among others, the following:

- our ability to restructure outstanding liabilities and continue as a going concern;
- our ability to successfully develop and commercialize new products;
- a lengthy approval process and the uncertainty of the Food and Drug Administration and other government regulatory requirements;
- the degree and nature of our competition;
- our continued ability to obtain certain raw materials from which we manufacture our products;
- our ability to employ and retain qualified employees; and

- the other factors referenced in this Annual Report, including, without limitation, under the section entitled “Risk Factors”, “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and “Description of Business.”

These risks are not exhaustive. Other sections of this Annual Report may include additional factors that could adversely impact our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Given these risks and uncertainties, investors should not place undue reliance on forward-looking statements as a prediction of actual results. These forward-looking statements are made only as of the date of this Annual Report. Except for our ongoing obligation to disclose material information as required by federal securities laws, we do not intend to update you concerning any future revisions to any forward-looking statements to reflect events or circumstances occurring after the date of this Annual Report.

INTRODUCTORY NOTE

In January 2007, Transderm Laboratories Corporation (“Transderm”) filed an Annual Report on Form 10-KSB for the years ended December 31, 2003 and 2004 (the “2004 Annual Report”). Prior to filing the 2004 Annual Report, Transderm had not filed any annual or quarterly reports with the Securities and Exchange Commission since it filed an annual report for the year ended December 31, 1998 in November 1999 and quarterly reports for the first three quarters of 1999. In March 2007, Transderm filed an Annual Report on Form 10-KSB for the year ended December 31, 2005. This Annual Report covers the year ended December 31, 2006 and includes audited financial statements for the year then ended. Transderm does not plan to file any quarterly reports for the 2006 fiscal year unless so requested by the Securities and Exchange Commission and expects to file all periodic reports required by the Securities Exchange Act of 1934, as amended, during the 2007 fiscal year.

PART I

ITEM 1. DESCRIPTION OF BUSINESS

Overview.

Transderm Laboratories Corporation (“Transderm”, the “Company”, “we”, “us”, or like terms) is a Delaware corporation that conducts its business primarily through its subsidiary, Hercon Laboratories Corporation ("Hercon"). Unless the context otherwise requires, the terms “we”, “us”, the “Company” or similar terminology, includes Transderm Laboratories Corporation and Hercon, of which Transderm owns 98.5%. Transderm is a 90%-owned subsidiary of Health-Chem Corporation ("Health-Chem" which, together with Transderm, Hercon and Health-Chem’s other subsidiaries, may be referred to as the “Group”).

We develop, manufacture and market transdermal drug delivery systems. A transdermal drug delivery system is an adhesive patch containing medication which is released through the skin into the bloodstream at a controlled rate over an extended period of time. Transdermal delivery can significantly enhance the therapeutic benefit of certain drugs, through improved efficacy, safety and patient compliance, when compared to conventional methods of drug administration, such as oral or parenteral (drugs that are delivered other than by the digestive tract, such as subcutaneous or intramuscular injection, or intravenously) delivery. Over the last several years, our sole product and continuing source of revenue has been a transdermal nitroglycerin patch for the relief of the vascular and cardiovascular symptoms related to angina pectoris (chest pain). We manufacture our nitroglycerin patch both on a contract basis for specific clients and for sale to distributors and wholesalers for distribution in the United States. We manufacture our products in accordance with Good Manufacturing Practices, or GMP’s, prescribed by the United States Food and Drug Administration, or FDA, at our facility in Emigsville, Pennsylvania.

Transderm has developed a base of technology in the design of transdermal systems by applying its expertise in the area of skin biology, pharmaceutical and polymer chemistry, drug diffusion, adhesive technology, pharmacokinetics and clinical protocol design. We believe that the integration of our technology and manufacturing experience gives us a competitive advantage by providing us with the capability to custom design and produce individual, cost-effective transdermal delivery systems for specific drugs. As a result, over the last several years, we have been engaged by third parties to conduct feasibility studies and development and related activities with respect to new pharmaceutical products that may be amenable to transdermal delivery and, in some cases, to manufacture such products for them on a commercial basis if they reach the market.

Current Financial Condition of Transderm.

Transderm continues its efforts to recover from the operational and financial adversity it has experienced since 1997, the basis for which is more fully described in the 2004 Annual Report. While net sales had increased during the period 2001 through 2004 (the financial information for the years 2001 and 2002 is unaudited), net revenues decreased significantly during each of 2005 and 2006 as a result of a decline in orders in each such year by one of our principal customers, as described elsewhere in this Report. Transderm has posted significant operating losses in each year since 1997, and as of December 31, 2006 had an accumulated deficit of $35.6 million and a working capital deficiency of approximately $26 million.

At December 31, 2006, the Company had total liabilities of $41.3 million, which included approximately (i) $7.3 million due under the terms of a license acquired from Key Pharmaceuticals, Inc. to utilize certain technology in its current generation transdermal patch (the "Key License"), which represents royalty payments owed over the last seven years (the "Key Royalty"), and (ii) $30.5 million owed to Health Chem, including $14.1 million related to redeemable preferred stock under which Transderm is currently in default, $7.2 million related to a subordinated promissory note under which Transderm is currently in default, and $9.2 million related to a long-term payable (each of which items is more fully described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in the notes to the Financial Statements, and which are herein collectively referred to as the "Intercompany Obligations").

Transderm's current financial condition negatively impacts its day-to-day operations and undermines its ability to grow its business. In addition, at December 31, 2006, Health-Chem, Transderm's parent corporation, had total outstanding liabilities of approximately $22.4 million, including $11.5 million of principal and interest due under certain debentures under which it has been in default since April 1999, and had a working capital deficiency of approximately $16.2 million, which conditions also bear on Transderm's current and future prospects. Transderm's ability to return to profitability from the precarious financial condition which it has experienced over the last several years is predicated on a number of factors, including the Group's ability to reach agreements with its largest creditors, its ability to reduce operating expenses as a percentage of revenues, its ability to obtain financing and its ability to identify and bring new products to market.

Transderm's and the Group's fragile financial condition leaves them vulnerable because:

- existing creditors of either company could seek the immediate collection of amounts due them which could cause either company to seek protection under federal bankruptcy laws;

- their obligations and liabilities, as well as their respective stockholders' deficiencies, do not allow them to obtain financing for operations;

- their working capital deficiencies prevent the Group from diversifying operations by developing new products and reducing reliance on revenues generated from sales of a single product;

- the extraordinary conditions make it difficult to endure business cycles resulting from general economic conditions or the effects of competition, among other things, as they occur;

- the condition prevents them from taking advantage of business opportunities as they may arise; and

- the condition does not allow them to retain senior management who have experience in the pharmaceutical industry or in any business in which they may become involved in the future.

Transdermal Delivery Systems.

A transdermal drug delivery system, known as a transdermal patch or skin patch, is a medicated adhesive patch that is placed on the skin to deliver a time released dose of medication through the skin and into the bloodstream. These systems utilize a special membrane to control the rate at which the liquid drug contained in the patch can pass through the skin and into the bloodstream. Transdermal drug delivery involves the inherent challenge of overcoming the skin barrier. Skin protects the body from the environment very effectively and generally is only permeable to small molecule, lipophilic (oil soluble) drugs which require only limited dose sizes. Transdermal delivery systems, therefore, not only have to provide drug to the skin under stable conditions in controlled dosages and in a format convenient to the patient, but also serve to locally increase the permeability of skin to larger, charged, or hydrophilic (easily dissolved in water) drug molecules while minimizing irritation.

The first transdermal patch was approved by the FDA in 1979. It contained the drug scopolamine used to prevent the nausea and vomiting associated with motion sickness. In 1981, the FDA approved a patch for nitroglycerin and as of 2003 patches have been approved to deliver 15 molecules spanning 35 different drugs, including combination patches utilized for, among other purposes, contraception and hormone replacement.

The first transdermal systems consisted of plastic dipped into a drug that was dissolved in alcohol. The plastic had an adhesive around the edges. These patches created a significant number of skin reactions and frequently became dislodged from the skin. Second, third and fourth generation patches have been developed which have significantly advanced adhesion properties, delivery control and skin permeability. There are four major types of transdermal drug delivery systems in use today: single layer drug-in-adhesive systems, multi-layer drug-in-adhesive systems, reservoir transdermal systems and matrix systems. The basic components of current transdermal delivery systems include the drug(s) either incorporated directly into the adhesive or dissolved or dispersed in a reservoir or inert polymer matrix; an outer backing film of paper, plastic, or foil; and a pressure-sensitive adhesive that anchors the patch to the skin. Developments and improvements to transdermal systems are being made rapidly.

Transdermal drug delivery has numerous advantages over conventional drug delivery methods. In contrast to orally delivered drugs, compounds entering the body through the skin escape first-pass metabolism in the liver (which may destroy the drug), often resulting in higher bioavailability of the drug. Transdermal delivery is effective for use in patients who experience nausea from the medication because there are few or no gastrointestinal effects from the drug itself and is useful for those drugs that have poor oral uptake, need frequent administration or that interact with stomach acid and allows effective use of drugs with short half-lives that otherwise require large initial doses (bolus dosing) to achieve desired drug levels, such as nitroglycerin. As a result, the side effects, or variability in therapeutic effect due to peaks and troughs in plasma concentration, that are seen with bolus administration are minimized. In contrast to intravenous drug delivery, transdermal administration is noninvasive and poses little risk of infection. It is also relatively easy for patients to apply and remove a transdermal system.

Our Nitroglycerin Transdermal Patch.

In 1986, we introduced the first FDA-approved generic transdermal nitroglycerin patch into the United States market. Nitroglycerin, also known as glycerin trinitrate, provides relief from vascular and cardiovascular symptoms related to angina pectoris or angina. Angina pectoris, or "heart pain," is the chest discomfort that occurs when the blood oxygen supply to an area of the heart muscle does not meet the demand. Nitroglycerin corrects the imbalance between the flow of blood and oxygen to the heart and relieves the work that the heart must do by dilating the arteries and veins in the body. Dilation of the veins reduces the amount of blood that returns to the heart that must be pumped. Dilation of the arteries lowers the pressure in the arteries against which the heart must pump. As a consequence, the heart works less and requires less blood and oxygen. Additionally, nitroglycerin preferentially dilates blood vessels that supply the areas of the heart where there is not enough oxygen, thereby delivering oxygen to the heart tissue that needs it most.

Since no one holds a valid patent covering nitroglycerin, which would grant to the patent holder the exclusive right to sell the drug while the patent is in effect and which is intended to protect the holder’s development investment, others can seek to obtain FDA approval to sell nitroglycerin-based products, assuming the proposed product meets certain specific criteria, by submitting an Abbreviated New Drug Application, or ANDA. The ANDA approval process can be substantially quicker and significantly less expensive than the new drug approval process because the applicant can rely on results collected from clinical trials conducted by the original drug developer.

Our nitroglycerin transdermal patch comprises a multi-layer drug-in-adhesive system wherein the medication and all the excipients (the inert substances used as a diluents or vehicles for a drug) are incorporated into a membrane between two distinct drug-in-adhesive layers under a single backing film. Our patch is comprised of three layers; a transparent outer backing layer composed of a composition plastic film and printed with the name of the drug and strength; nitroglycerin in a acrylic-based polymer adhesive with a cross-linking agent; and a protective, translucent peelable liner which covers the second layer and must be removed prior to use. Our nitroglycerin transdermal patch is AB2 rated, which means it is considered bioequivalent to Novartis’ NitroDerm™ product based on clinical trial data. Our patch is a one-day use patch and is sold in shelf cartons, with each shelf carton containing thirty patches. Our patch is produced in three different dosage sizes, with each size delivering different milligrams per hour (mg/hr) amounts of nitroglycerin to the patient. The three sizes are: 0.2mg/hr, 0.4mg/hr and 0.6mg/hr.

Our second generation transdermal patch technology developed during the mid 1990’s incorporates certain technology which, unbeknownst to us at the time of development, was the subject of a patent held by Key Pharmaceuticals, Inc., or Key, a subsidiary of Schering-Plough Corporation. In December 1997, Key obtained a court order enjoining us from manufacturing or selling transdermal nitroglycerin patches that have been found to infringe Key's patent before the expiration of Key's patent on February 16, 2010. In March 2000, we acquired a non-exclusive license from Key to manufacture, use, import, sell and offer for sale any drug-in-adhesive transdermal nitroglycerin patch product developed by the Company either before or during the term of the license which provided for the payment of a royalty per unit sold in amounts ranging from $2 to $3, based upon the dosage delivered. The license extends to February 16, 2010, the expiration of Key’s patents. We are in breach of the Key License for not having made royalty payments under the Key License since its execution and as of December 31, 2006 we owed aggregate royalties to Key of approximately $7,321,000. We recently entered into discussions with Key with respect to payment of past due royalties. If we are unable to negotiate an agreement with Key with respect to the royalties due and are prevented from utilizing the Key technology, we would have to discontinue selling our transdermal patches unless we could develop our own technology to replace that covered by the Key License or otherwise locate and obtain a license for similar technology which can be incorporated into our manufacturing process, of which we can give no assurance. Moreover, our failure to negotiate a repayment agreement with Key on terms favorable to us could have a material negative impact on our Company. See “BUSINESS-Risk Factors” and “Management’s Discussion and Analysis of Financial Statements and Results of Operations.”

Research and Development.

Our research and development efforts are severely constrained by our lack of cash, as described elsewhere in this Annual Report, and other than activities currently being undertaken for third parties as described below, we are not engaging in any research and development on our own behalf.

If and when we possess the financial resources to resume proprietary research and development activities, we expect that our primary strategy will be to identify generic drugs which can be delivered transdermally, which correspond with our technical and manufacturing capabilities and which we believe have substantial market potential or for which a product niche may exist. We may also explore developing transdermal products that use FDA-approved drugs that currently are being delivered to patients through means other than transdermal delivery. In addition, we may seek to supplement our research and development efforts by entering into research and development agreements, joint ventures and other collaborative arrangements with other companies.

By focusing on bringing new products to market based upon unprotected, generic drugs that are then being delivered transdermally, we will not have to bear the same level of research and development costs and other expenses associated with bringing a new drug formulation to market. Thus, we believe that we would be able to charge significantly less for a product, a decided competitive advantage in our industry, given that managed care organizations typically favor generic products over brand name drugs, and governments encourage, or under some circumstances, mandate generic drugs.

We currently are developing transdermal products for two companies, one of which has engaged us to assist in the development of two drug formulations to be delivered transdermally. In all cases, we act as an independent contractor for the party that engaged us and said party owns all intellectual property which may emanate from the projects we are retained to complete or the services which we render.

In February 2001, Hercon entered into a series of agreements with Ranbaxy Pharmaceuticals Inc. under which we:

- granted a worldwide, non-exclusive, royalty-free license to Ranbaxy to use certain intellectual property we developed relating to the transdermal delivery of a certain generic pharmaceutical compound;

- acquired a license from Ranbaxy to use certain intellectual property it had developed in connection with the pharmaceutical compound and were retained by Ranbaxy to assist in the development of commercial products to deliver the pharmaceutical compound transdermally; and

- agreed to supply the products which may be developed and approved by the FDA exclusively to Ranbaxy which agreed to purchase from us all of its requirements for such products from us on an exclusive basis.

We recently completed certain milestones under these agreements, including producing a supply of the pharmaceutical compound which permitted Ranbaxy to complete pilot bioequivalence study results which were filed by Ranbaxy with the FDA as part of the ANDA filed in connection with this compound.

We have undertaken to provide certain services, including, completing the development of the initial formulation of the pharmaceutical compound for transdermal delivery, demonstrating that our production techniques can be scaled-up to meet anticipated production runs of the transdermal patch, providing all laboratory data relating to the utilization of our patch technology for this pharmaceutical compound, completing documentation necessary for GMP production of the product, providing dosage forms for the pilot and bioequivalence studies, conducting the pilot and other studies and providing underlying documentation required for Ranbaxy to gain regulatory approval for the product and support Ranbaxy's ANDA filing. We are performing under this agreement as requested by Ranbaxy.

Ranbaxy granted us a license to utilize certain intellectual property we will require for the manufacture of the products which are the subject of the agreement and we have agreed to supply Ranbaxy with such product in the strengths and amounts as Ranbaxy may require for its bioequivalence studies. Thereafter, assuming Ranbaxy's ANDA for this product is approved by the FDA, of which neither we nor Ranbaxy can be certain, we will manufacture and supply Ranbaxy with all of its commercial requirements of the product, subject to its right to acquire the product elsewhere if we are unable to furnish the supplies it requires, under the circumstances provided in the agreement. We have agreed to sell the product exclusively to Ranbaxy. We also have agreed to conform to GMP's in connection with the manufacture of the product and otherwise supply product in conformity with Ranbaxy's specifications as enumerated in the agreement which relate to quality control, packaging and labeling, among other things. Ranbaxy will pay us fixed prices for the products of various dosages and a royalty in excess of the per product price in the event it achieves certain net sales milestones. The agreement has a ten-year term from the date of the first commercial sale of the products. We have agreed to indemnify Ranbaxy for damages resulting from, among other things, our formulation or manufacturing of the product and Ranbaxy has agreed to indemnify us for damages relating to regulatory improprieties.

In June 2004, we entered into a Development, Manufacturing and Supply Agreement with Ranbaxy relating to a generic pharmaceutical compound subject to transdermal delivery. Under the agreement, we have been engaged to manufacture and supply products for use both in connection with Ranbaxy's regulatory approval requirements and ANDA application and thereafter, if FDA approval is granted for the product, of which neither we nor Ranbaxy can be certain, on an ongoing basis to meet its requirements. In furtherance of our efforts, Ranbaxy extended a loan to us in the amount of $166,664 to purchase certain equipment required in connection with our obligations under the agreement which is repayable by offsetting amounts payable for product which may eventually be purchased from us, agreed to pay for the active pharmaceutical ingredient incorporated into the product during the trial phases and to pay for a contract research organization to conduct bioequivalence studies of the proposed product. Our obligations under this agreement are similar to those in our agreement with Ranbaxy described above. For example, we have agreed to conform to GMP's in connection with the manufacture of the product and otherwise supply product in conformity with Ranbaxy's specifications as enumerated in the agreement which relate to quality control, packaging and labeling, among other things, and in accordance with all applicable laws. The successful completion of the development portion of the agreement could yield us an aggregate of $678,800 of gross revenues, payable in tranches upon achieving certain milestones. Ranbaxy will purchase products from us at prices calculated in relation to the price we pay for the underlying active pharmaceutical ingredient and in the event that the price for said ingredient exceeds the maximum amount set forth in the agreement, Ranbaxy may terminate the agreement as to that specific product. We have agreed to indemnify Ranbaxy for damages resulting from, among other things, our development and related obligations under the agreement and Ranbaxy has agreed to indemnify us for damages relating to regulatory improprieties.

In April 2006, we entered into a Development, Manufacturing and Supply Agreement with Cure Therapeutics, Inc., or CTI, relating to the development of a transdermal patch which delivers a generic pharmaceutical compound which will be utilized for new indications (that is, the treatment of conditions not covered by the original FDA approval) for such drugs. Under the agreement, CTI engaged us to undertake all processing of the pharmaceutical compound for the purpose of filing a new drug application, or NDA, with the FDA and to manufacture and supply sufficient quantities of the compound required for obtaining approval of the NDA. Our engagement is divided into three stages: technology transfer, formulation optimization, and scale-up; FDA phase 2 clinical trial batch manufacturing; and FDA phase 3 clinical trial batch manufacturing. Our obligations under the agreement include all manner of analyzing, testing, optimizing the formulation of our process by which clinical trial products are made, creation of dedicated tooling, scaling-up our manufacturing facility to produce commercial quantities of product, finishing, packaging, inspecting, labeling and preparing product for shipment, all as required under applicable law. In addition, we are required to maintain data and records with respect to all aspects of the foregoing for the specific purpose of filing same with the FDA with respect to the NDA and to report to CTI with respect to each phase of the process. CTI pays us fees upon our successful completion of milestones enumerated in the agreement. We are currently working on the second stage under the agreement. CTI has agreed, at its own cost and expense, to engage a contract research organization to conduct safety and efficacy studies of the clinical trial products we manufacture and, in the event that such studies fail to demonstrate the safety or efficacy of such products, CTI may terminate the agreement. We have agreed to conform to GMP's in connection with the manufacture of the product and otherwise supply product in conformity with CTI's specifications as enumerated in the agreement which relate to quality control, packaging and labeling, among other things, and in accordance with all applicable laws. We have agreed to indemnify CTI for damages resulting from, among other things, our performance of or failure to perform our obligations under the agreement and CTI has agreed to indemnify us for damages relating to regulatory improprieties. Each party has agreed to maintain the confidentiality of the other's confidential information. The agreement has a term of two years but is subject to prior termination by either party in the event of a material breach by the other party and by CTI for any reason at any time upon written notice. The parties recognize the possibility that no commercial product may arise from their efforts.

We are also conducting a number of feasibility studies on transdermal products on behalf of client companies and are pursuing additional contract manufacturing opportunities. We do not undertake clinical studies. As a contract manufacturer for developing products, it would be the responsibility of our client to undertake and bear the cost of these clinical studies, including preparing and filing all documents required by the FDA. We would, however, perform routine chemical analysis of these products to determine if they meet proposed product specifications.

For the years ended December 31, 2006 and 2005, we spent $491,000 and $438,000, respectively, for research and development activities. Our research and development expense may vary significantly from quarter to quarter and year to year depending on, among other things, product development cycles and whether we or a third party are funding development. These variations in research and development spending may not be accurately anticipated and may have a material effect on our results of operations. Currently, research and development personnel engage in assisting with technical transfers of existing formulation and test methodology to our production facility. In addition, our personnel perform small scale development work on behalf of clients, including producing hand-cut transdermal patches on a research laminator for analytical testing or performing permeation studies to demonstrate how drug formulations penetrate a skin layer. Our personnel also work on improving test methods that may impact day to day testing requirements for commercial products. We periodically outsource analytical testing either because we do not possess the appropriate equipment or outsourcing such testing is more economically efficient.

The time necessary to complete clinical trials and the regulatory process to obtain marketing approval varies significantly. We cannot be certain that we will have the financial resources necessary to complete products which we propose to develop, that those projects to which we dedicate resources will be successfully completed, that we will be able to obtain regulatory approval for any such product, or that any approved product may be produced in commercial quantities, at reasonable costs, and be successfully marketed. Similarly, we cannot assure that our competitors, most of which have greater resources than we do, will not develop and introduce products that will adversely affect our business and results of operations.

Manufacturing.

We conduct our manufacturing operations in a single facility comprised of an approximately 61,000 square foot building located on approximately 3.5 acres in Emigsville, Pennsylvania. Our products are manufactured in accordance with GMPs prescribed by the FDA. The FDA visited our facilities in November 2003 and June 2006 and issued establishment inspection reports. The reports indicated that there were no objectionable conditions or practices noted during their reviews. The FDA did not issue a Form FDA 483 (Inspectional Observations) report to us during either of these two visits. The FDA uses the Form FDA 483 report to communicate all observations of objectionable conditions noted during their inspection process. This facility has also been licensed by the United States Drug Enforcement Administration ("DEA") to conduct research and manufacture products containing Schedule II controlled substances. To bring new products to market as quickly as possible, we will seek to have the manufacturing capacity to produce the new product prior to obtaining FDA approval.

Our products are manufactured according to current GMPs as specified by federal regulations which require us to maintain and update procedures and specifications as provided under federal law. We must maintain records that demonstrate the application of raw materials from receipt to use in a finished product. In addition, any complaints received must be documented and investigated. We are obligated to submit to the FDA reports covering our marketed products that include both chemistry information and adverse event information on an annual basis. If we do not adhere to current GMPs, the FDA could seek an injunction barring commercial distribution of our products.

The manufacture of advanced transdermal drug delivery systems requires specialized skills in several areas, as well as specialized manufacturing equipment. Our process development and design engineers work closely with the research and development department starting early in the product design stage, which renders the manufacturing development process more efficient. All scale-up work (spanning the gamut of initial research on a potential product to large-scale manufacturing for clinical and stability work), commencing with initial product development trials, is conducted on full-size, completely functional manufacturing equipment, reducing delays in the development and approval process and smoothing the transition to commercial production. Some of this equipment is manufactured in-house; the balance is fabricated by outside manufacturers to our specifications. We believe that this equipment provides a decided advantage in the manufacture of the complex multi-layer systems necessary for successful transdermal drug delivery. We currently have assembly packaging equipment in place having a single shift capacity of over 24 million patches annually. We believe that our current manufacturing facility is adequate for our intended purposes and will be sufficient for product expansion for the foreseeable future.

As part of the manufacturing process, we have developed and perform appropriate quality control procedures including testing of all raw materials and finish