

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

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2009

OR

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: 000-52998

Transdel Pharmaceuticals, Inc.

(Name of Registrant in Its Charter)

Delaware

(State or Other Jurisdiction of Incorporation or Organization)

45-0567010

(I.R.S. Employer Identification No.)

4225 Executive Square, Suite 485
La Jolla, CA

(Address of Principal Executive Offices)

92037

(Zip Code)

Registrant's telephone number, including area code: (858) 457-5300

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

None

Securities registered pursuant to Section 12(g) of the Act:

Title of Each Class

Common Stock, \$0.001 par value per share

Name of Each Exchange on Which Registered

None

Indicate by check mark if the registrant is a well-known seasoned filer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. Yes No

Indicate by check mark whether the registrant (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 and Regulations 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 check mark if disclosure of delinquent filers in response to Item 405 of Regulation S-K (§229.405 of this chapter), is not contained herein, and will not 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-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of "accelerated filer," "large accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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

The aggregate market value of the Common Stock of the registrant (the "Common Stock") held by non-affiliates of the registrant, based on the last sale price of the Common Stock on June 30, 2009 (the last business day of the registrant's most recently completed second fiscal quarter) of \$1.40 per share as reported by the OTC Bulletin Board, was approximately \$13,518,100. Shares of Common Stock held by each officer and director and by each person who is known by the registrant to own 5% or more of the outstanding Common Stock, if any, have been excluded in that such persons may be deemed to be affiliates of the registrant. Share ownership information of certain persons known by the registrant to own greater than 5% of the outstanding common stock for purposes of the preceding calculation is based solely on information on Schedules 13D and 13G, if any, filed with the Securities and Exchange Commission and is as of June 30, 2009. This determination of affiliate status is not necessarily a conclusive determination for any other purposes.

As of March 23, 2010, there were 15,652,061 shares of our Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain of the statements included in this Form 10-K, including information incorporated by reference, are “forward-looking statements.” Forward-looking statements include, without limitation, any statement that may predict, forecast, indicate, or imply future results, performance or achievements, and may contain the words “estimate,” “project,” “intend,” “forecast,” “anticipate,” “plan,” “planning,” “expect,” “believe,” “will,” “shall,” “will likely,” “should,” “could,” “would,” “may” or words or expressions of similar meaning, including when used in the negative. Forward-looking statements, include, but are not limited to: statements regarding our research and development programs; proposed marketing and sales; patents and regulatory approvals; the effect of competition and proprietary rights of third parties; our interpretation of the results of the Phase 3 clinical trial for Ketotransdel®; whether the results from the clinical trial, along with the other clinical trials that may be required by the FDA, will be sufficient to support a 505(b)(2) New Drug Approval (NDA) submission; the potential indications for use for Ketotransdel®; the market opportunity for our products; and our ability to complete additional development activities for products utilizing our proprietary transdermal delivery platform, the need for and availability of additional financing and our access to capital; the trading of our common stock, licensing, distribution, collaboration and marketing arrangements with pharmaceutical companies; and the period of time for which our existing cash will enable us to fund our operations. In addition to the items described in this report under the heading “Risk Factors,” many important factors, risks and uncertainties affect our ability to achieve our stated objectives and to successfully develop and commercialize any product candidates, including, among other things, our ability to: the outcome of the final analyses of the data from the Phase 3 clinical trial may vary from our initial conclusions; the FDA may not agree with our interpretation of such results or may challenge the adequacy of our clinical trial design or the execution of the clinical trial; the FDA may require us to complete more than one additional clinical trial for Ketotransdel® before we can submit a 505(b)(2) NDA application; the results of any future clinical trials may not be favorable and we may never receive regulatory approval for Ketotransdel®; the third parties upon whom we rely to conduct our clinical trials may not perform as expected; obtain substantial additional funds to support our operations; obtain and maintain all necessary patents or licenses; demonstrate the safety and efficacy of product candidates at each stage of development; meet applicable regulatory standards and receive required regulatory approvals; and compete successfully against other products and to market products in a profitable manner. Therefore, prospective investors are cautioned that the forward-looking statements included in this report may prove to be inaccurate. In light of the significant uncertainties inherent to the forward-looking statements included herein, the inclusion of such information should not be regarded as a representation or warranty by us or any other person that our objectives and plans will be achieved in any specified time frame, if at all. Except to the extent required by applicable laws or rules, we do not undertake any obligation to update any forward-looking statements or to announce revisions to any of the forward-looking statements, whether to reflect events or circumstances after the date initially filed or published, to reflect the occurrence of unanticipated events or otherwise.

PART I

ITEM 1. DESCRIPTION OF BUSINESS

Company Overview

Transdel Pharmaceuticals, Inc. (“Transdel” or the “Company”) is a specialty pharmaceutical company developing non-invasive, topically delivered products. Our innovative patented Transdel™ cream formulation technology is designed to facilitate the effective penetration of a variety of products through the tough skin barrier. Ketotransdel®, our lead pain product, utilizes the Transdel™ platform technology to deliver the active drug, ketoprofen, a non-steroidal anti-inflammatory drug (“NSAID”), through the skin directly into the underlying tissues where the drug exerts its well-known anti-inflammatory and analgesic effects.

We intend to leverage the Transdel™ platform technology to expand and create a portfolio of topical products for a variety of indications. Our patent on the Transdel™ proprietary cream formulation covers our novel transdermal formulation with over 500 different drugs in over 60 therapeutic areas, including both approved and established drugs.

Corporate History

On September 17, 2007, we entered into an Agreement of Merger and Plan of Reorganization (the “Merger Agreement”) with, Transdel Pharmaceuticals Holdings, Inc., a privately held Nevada corporation (“Transdel Holdings”), and Trans-Pharma Acquisition Corp., our newly formed, wholly-owned Delaware subsidiary (“Acquisition Sub”). Upon closing of the merger transaction contemplated under the Merger Agreement (the “Merger”), Acquisition Sub merged with and into Transdel Holdings, and Transdel Holdings, as the surviving corporation, became our wholly-owned subsidiary.

On each of September 17, 2007, and October 10, 2007, we completed private placements to selected institutional and individual investors in which we issued shares of our common stock and warrants to purchase shares of our common stock. In connection with the private placements, we raised approximately \$3.8 million (net of placement fees and other costs aggregating \$342,105 of which \$36,229 was paid in fiscal year 2008) from the issuance of 2,071,834 shares of common stock and detachable redeemable five-year warrants to purchase 517,958 shares of our common stock at a cash exercise price of \$4.00 per share and a cashless exercise price of \$5.00 per share. In addition, we issued redeemable three-year warrants to purchase 33,750 shares of common stock to placement agents in connection with the September 2007 and October 2007 private placements.

Also, on May 12, 2008, we sold 1,818,180 shares of common stock for gross proceeds of approximately \$4.0 million (net of legal and accounting costs of \$22,470) through a follow-on private placement (the “Follow-on Private Placement”) to accredited investors. In addition, the investors received warrants to purchase 227,272 shares of common stock, exercisable for a period of five years at a cash and cashless exercise price of \$4.40 and \$5.50 per share, respectively.

Our common stock has been quoted on the OTC Bulletin Board since October 1, 2007 under the symbol TDLPOB. Prior to that date, there was no active market for our common stock. On March 23, 2010, the closing price of our common stock was \$1.00 per share.

Our executive offices are located at 4225 Executive Square, Suite 485, La Jolla, California 92037 and our telephone number at such office is (858) 457-5300. Our website address is www.transdelpharma.com.

Ketotransdel®

Ketotransdel® is comprised of a transdermal formulation of ketoprofen, a non-steroidal anti-inflammatory drug (“NSAID”), and our proprietary Transdel™ drug delivery system and is being developed for the treatment of acute pain. Ketotransdel® penetrates the skin barrier to reach the targeted underlying tissues where it exerts its localized anti-inflammatory and analgesic effect. The topical delivery of the drug may minimize systemic exposure, therefore, resulting in fewer concerns pertaining to gastrointestinal, hepatic, cardiovascular and other adverse systemic effects, which are associated with orally administered NSAIDs. We believe that this product may be considered for patients with site specific localized pain and who also (i) have a history of gastrointestinal, cardiovascular, kidney or liver problems, (ii) are geriatric or pediatric patients and/or (iii) are patients at risk for drug interactions.

We selected ketoprofen as the active ingredient for Ketotransdel® based on its efficacy and safety track record when administered topically.

Clinical Program for Ketotransdel®

Ketotransdel® was tested in a double blind, placebo-controlled Phase 1/2 clinical study. The study tested the efficacy and safety of topical Ketotransdel® for the treatment of acute pain and soreness in a delayed-onset muscle soreness model placebo versus active. We also measured the level of systemic absorption of topical Ketotransdel®. This clinical study for acute pain and muscle soreness demonstrated a significant medical benefit from Ketotransdel® in terms of relief of pain and muscle soreness. Also, approximately 1/100th of the blood levels of ketoprofen were found in the circulatory system as compared to a comparable dose of commercially available oral ketoprofen.

In June 2008, we initiated a Phase 3 clinical study designed as a randomized, double-blind, placebo-controlled, multi-center Phase 3 study that enrolled a total of 364 patients with acute soft tissue injuries of the upper or lower extremities in 26 centers in the United States. The primary efficacy endpoint was the difference between Ketotransdel® and placebo in the change from baseline in pain intensity as measured by the 100 mm Visual Analogue Scale (VAS) during daily activities over the past 24 hours on the Day 3 visit.

As we reported in October 2009, the top-line results showed that the study demonstrated statistical significance in its primary endpoint in the per protocol analysis and was favorable for Ketotransdel® in the Intent-To Treat (ITT) Analysis. Ketotransdel® also demonstrated an excellent safety and tolerability profile. In particular, there were no Ketotransdel® treatment related gastrointestinal, cardiovascular, hepatic or other clinically relevant adverse events reported. Furthermore, Ketotransdel® was well absorbed through the skin and in support of the safety and tolerability only minimal blood concentrations of ketoprofen were detected in a subset of patients who underwent blood sampling for pharmacokinetic (PK) analyses following repeated topical applications. These PK results are consistent with our previous clinical study findings and support the excellent safety profile.

In January 2010, we reported on further in-depth analyses of the ITT data from the Ketotransdel® Phase 3 study. For the modified ITT analysis we identified 35 patients who did not meet study entry criteria at the time of randomization. Excluding the data from these patients who should not have been randomized into the study based on information that was not known at the time of enrollment, the study demonstrated statistical significance ($p < 0.038$) on the primary efficacy endpoint. This analysis was confirmed by an independent statistical expert.

The weight of evidence of a treatment effect in this study is further strengthened by a key secondary endpoint (pain intensity recorded 3 times daily on patient diary cards) that supports the primary endpoint. The pain curves over time show consistent separation between treatment groups reaching statistical significance in favor of Ketotransdel®; using both the original and modified ITT population.

Based on discussions with the FDA at least two adequate and well-controlled Phase 3 studies are required in order to obtain regulatory approval to market Ketotransdel®. We believe that the first Phase 3 trial will qualify as one adequate and well-controlled trial because there is statistical significance on the primary endpoint in an objectively defined modified ITT population, and statistical significance on secondary endpoints. We are in the process of determining the design of the second Phase 3 trial. There is no assurance that the FDA will accept our conclusion of the modified ITT data from the first Phase 3 study as sufficient as part of the requirements for regulatory approval.

As part of a routine requirement to provide safety information in the NDA submission we have to perform studies such as to assess the allergenicity potential and absorption of ketoprofen during concurrent exercise and heat exposure with Ketotransdel®. These additional supportive trials will be conducted in healthy subjects. The timing of the second Phase 3 trial and the other supportive studies will be dependent on obtaining adequate financing to support the execution of these activities and for other working capital expenditures.

We expect that Ketotransdel®, if and when approved by the FDA, could become the first topical NSAID cream product available by prescription in the United States for acute pain management. We are seeking a commercial partner for Ketotransdel®, and are actively pursuing discussions with U.S. and foreign based potential partners with sales and marketing infrastructures.

Cosmeceutical/Cosmetic Product Development Program

We have expanded our product development programs to include cosmetic/cosmeceutical products, which utilize our patented transdermal delivery system technology, Transdel™. Our lead product is an anti-cellulite formulation, for which we have initial clinical information supporting the beneficial effects of this key cosmetic/cosmeceutical product on skin appearance. Our potential pipeline of cosmetic/cosmeceutical products includes hyperpigmentation and anti-aging formulations. We are pursuing discussions with potential sales and marketing partners for these cosmetic/cosmeceutical products.

On May 20, 2009, we entered into a license agreement with JH Direct, LLC ("JH Direct") providing JH Direct with the exclusive worldwide rights to our anti-cellulite cosmeceutical product. Under the terms of the agreement, JH Direct will pay us initial royalty advances if the product is marketed and a continuing licensing royalty on the worldwide sales of the anti-cellulite product. We

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retained the exclusive rights to seek pharmaceutical/dermatological partners for the anti-cellulite product for an initial period of one year following the launch of the product, thereafter JH Direct will be allowed to expand in this channel. We anticipate that JH Direct will launch the anti-cellulite product through a direct response television campaign during the second half of 2010.

Other Product Development Programs

We believe that the clinical success of Ketotransdel® will facilitate the use of the Transdel™ delivery technology in other products. We have identified co-development opportunities for potential products in pain management and other therapeutic areas utilizing the Transdel™ platform technology and we are exploring potential partnerships for these identified products. In addition to others, some of these identified co-development areas include hormone based products, antiemetic and dermatological products using our Transdel delivery system. We are also looking to out-license our Transdel™ drug delivery technology for the development and commercialization of additional innovative drug products. There can be no assurance that any of the activities associated with our product development programs will lead to definitive agreements.

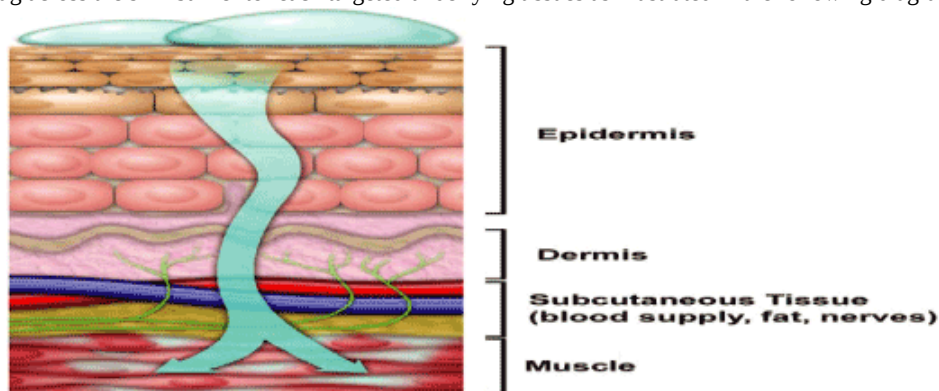
Market and Opportunity

The market for NSAIDs and COX-2 inhibitors in the United States may exceed \$8 billion. Since the withdrawal of major COX-2 inhibitors in 2005, oral NSAIDs have captured a share of the multibillion retail market for COX-2 inhibitors. Oral NSAIDs remain one of the most prescribed classes of drugs in the pain management market. Over 30 million people worldwide use prescription and over-the-counter NSAIDs daily.

We believe that there is a significant unmet medical need for topical pain management products that minimize systemic absorption of NSAIDs such as Ketotransdel® due to the recognition of cardiovascular, gastrointestinal and other risks associated with orally administered NSAIDs.

The Transdel™ Technology

Transdel™ is our proprietary transdermal cream drug delivery platform. It consists of a cream that enables transdermal penetration of drugs avoiding first pass metabolism by the liver and minimizing systemic exposure. The Transdel™ drug delivery system facilitates the effective dissolution and delivery of a drug across the skin barrier to reach targeted underlying tissues as illustrated in the following diagram:



Transdel™ has the following properties that make it a highly versatile vehicle for topical drug administration:

- Maximizes solubilization of drugs and components (lipophilic, hydrophilic and amphiphilic);
- Uses synergistic mechanisms to enhance penetration so that more effective concentrations of the beneficial drug or substances reach the dermal and subcutaneous tissue layers of the skin;
- Compatible with a broad range of drugs and molecular sizes;
- Biocompatible — Components generally regarded as safe (GRAS);
- Thermodynamically stable, insensitive to moisture and resistant to microbial contamination;
- Clinical data collected to date supports safety and efficacy;
- Potentially result in decreased safety concerns which are associated with oral drugs, such as stomach irritation;

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- Not associated with limitations of transdermal patches;
- The patent for Transdel™ specifically lists over 500 different drugs in over 60 therapeutic areas, including both approved and established drugs;
- Ease of application, aesthetically acceptable and odorless; and
- Potentially produces patentable new products when combined with established drugs or new drugs.

Competition

The pharmaceutical industry is highly competitive. There are competitors in the United States that are currently selling FDA -approved products that our products would compete with if and when approved by the FDA. Also, we are aware of companies developing patch products and other pain formulations.

In addition to product safety, development and efficacy, other competitive factors in the pharmaceutical market include product quality and price, reputation, service and access to scientific and technical information. It is possible that developments by our competitors will make our products or technologies uncompetitive or obsolete. In addition, the intensely competitive environment of the pain management products requires an ongoing, extensive search for medical and technological innovations and the ability to market products effectively, including the ability to communicate the effectiveness, safety and value of branded products for their intended uses to healthcare professionals in private practice, group practices and managed care organizations. Because we are smaller than our competitors, we may lack the financial and other resources needed to develop, produce, distribute, market and commercialize any of our drug candidates or compete for market share in the pain management sector.

Third Party Service Agreements

We contract with various third parties to provide certain critical services including conducting and managing clinical and non-clinical studies, manufacturing, certain research and development activities, medical affairs and certain regulatory activities and financial functions. Our failure to maintain our relationships with these third party contractors may have a material adverse effect on our business, financial condition and results of operations.

Governmental Regulation

Our ongoing product development activities are subject to extensive and rigorous regulation at both the federal and state levels. Post development, the manufacture, testing, packaging, labeling, distribution, sales and marketing of our products is also subject to extensive regulation. The Federal Food, Drug and Cosmetic Act of 1983, as amended, and other federal and state statutes and regulations govern or influence the testing, manufacture, safety, packaging, labeling, storage, record keeping, approval, advertising, promotion, sale and distribution of pharmaceutical products. Noncompliance with applicable requirements can result in fines, recall or seizure of products, total or partial suspension of production and/or distribution, refusal of the government to approve New Drug Applications, or NDAs, civil sanctions and criminal prosecution.

FDA approval is typically required before each dosage form or strength of any new drug can be marketed. Applications for FDA approval must contain information relating to efficacy, safety, toxicity, pharmacokinetics, product formulation, raw material suppliers, stability, manufacturing processes, packaging, labeling, and quality control. The FDA also has the authority to revoke previously granted drug approvals. Product development and approval within this regulatory framework requires a number of years and involves the expenditure of substantial resources.

Current FDA standards for approving new pharmaceutical products are more stringent than those that were applied in the past. As a result, labeling revisions, formulation or manufacturing changes and/or product modifications may be necessary. For example, due to an increased understanding of the cardiovascular and gastrointestinal risks associated with NSAIDs, the FDA approved new rules requiring that professional labeling for all prescription and over-the-counter NSAIDs include information on such risks. We cannot determine what effect changes in regulations or legal interpretations, when and if promulgated, may have on our business in the future. Changes could, among other things, require expanded or different labeling, the recall or discontinuance of certain products, additional record keeping and expanded documentation of the properties of certain products and scientific substantiation. Such regulatory changes, or new legislation, could have a material adverse effect on our business, financial condition and results of operations. The evolving and complex nature of regulatory requirements, the broad authority and discretion of the FDA and the generally high level of regulatory oversight results in a continuing possibility that from time to time, we will be adversely affected by regulatory actions despite ongoing efforts and commitment to achieve and maintain full compliance with all regulatory requirements.

FDA Approval Process

To obtain approval of a new product from the FDA, we must, among other requirements, submit data supporting safety and efficacy, as well as detailed information on the manufacture and composition of the product and proposed labeling. The testing and collection of data and the preparation of necessary applications are expensive and time-consuming. The FDA may not act quickly or favorably in reviewing these applications, and we may encounter significant difficulties or costs in our efforts to obtain FDA approvals that could delay or preclude us from marketing our products.

The process required by the FDA before a new drug may be marketed in the U.S. generally involves the following: (i) completion of nonclinical laboratory and animal testing in compliance with FDA regulations; (ii) submission of an investigational new drug application, which must become effective before human clinical trials may begin; (iii) performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use; and (iv) submission and approval of an NDA by the FDA.

The sponsor typically conducts human clinical trials in three sequential phases, but the phases may overlap

- Phase 1 clinical studies frequently begin with the initial introduction of the compound into healthy human subjects prior to introduction into patients, involves testing the product for safety, adverse effects, dosage, tolerance, absorption, metabolism, excretion and other elements of clinical pharmacology.
- Phase 2 clinical studies typically involve studies in a small sample of the intended patient population to assess the efficacy of the compound for a specific indication, to determine dose tolerance and the optimal dose range as well as to gather additional information relating to safety and potential adverse effects.
- Phase 3 clinical studies are undertaken to further evaluate clinical safety and efficacy in an expanded patient population at typically dispersed study sites, in order to determine the overall risk-benefit ratio of the compound and to provide an adequate basis for product labeling.

As a product candidate moves through the clinical phases, manufacturing processes are further defined, refined, controlled and validated. The level of control and validation required by the FDA in the conduct of clinical trials increases as clinical studies progress.

Clinical trials must be conducted in accordance with the FDA's good clinical practices requirements. The FDA may order the temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. An institutional review board, or IRB, generally must approve the clinical trial design and patient informed consent at each clinical site and may also require the clinical trial at that site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

The applicant must submit to the FDA the results of the nonclinical studies and clinical trials, together with, among other things, detailed information on the manufacture and composition of the product and proposed labeling, in the form of an NDA, including payment of a user fee, unless waived. The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the Prescription Drug User Fee Act, or PDUFA, the FDA ordinarily has 10 months in which to complete its initial review of the NDA and respond to the applicant. However, the PDUFA goal dates are not legal mandates and the FDA response often occurs several months beyond the original PDUFA goal date. The review process and the target response date under PDUFA may be extended if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the NDA submission. Following completion of the FDA's initial review of the NDA and the clinical and manufacturing procedures and facilities, the FDA will issue a complete response or action letter, which will either include an approval authorizing commercial marketing of the drug for certain indications or contain the conditions that must be met in order to secure final approval of the NDA. If the FDA's evaluation of the NDA submission and the clinical and manufacturing procedures and facilities is not favorable, the FDA may refuse to approve the NDA.

Section 505(b)(2) New Drug Applications

Since the active pharmaceutical ingredient, in Ketotransdel® is Ketoprofen which has already been approved by the FDA, we are able to file a NDA under section 505(b)(2) of the Hatch-Waxman Act of 1984 for this product as well as other products that we may develop including approved active pharmaceutical ingredients. This is an alternate path to FDA approval for new formulations of previously approved products. Section 505(b)(2) was enacted as part of the Drug Price Competition and

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Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The Hatch-Waxman Act permits the applicant to rely upon certain published nonclinical or clinical studies conducted for an approved product or the FDA's conclusions from prior review of such studies. The FDA may also require companies to perform additional studies or measurements to support any changes from the approved product. The FDA may then approve the new product for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant. While references to nonclinical and clinical data not generated by the applicant or for which the applicant does not have a right of reference are allowed, all development, process, stability, qualification and validation data related to the manufacturing and quality of the new product must be included in an NDA submitted under Section 505(b)(2).

Each study is conducted in accordance with certain standards under protocols that detail the objectives of the study, the parameters to be used to monitor safety, and efficacy criteria to be evaluated. Each protocol must be submitted to the FDA. In some cases, the FDA allows a company to rely on data developed in foreign countries or previously published data, which eliminates the need to independently repeat some or all of the studies.

To the extent that the Section 505(b)(2) applicant is relying on the FDA's conclusions regarding studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book publication. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid is called a paragraph IV certification. If the applicant does not challenge the listed patents, the Section 505(b)(2) application will not be approved until all the listed patents claiming the referenced product have expired. The Section 505(b)(2) application also will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired.

As a condition of approval, the FDA or other regulatory authorities may require further studies, including Phase IV post-marketing studies to provide additional data. Other post-marketing studies may be required to gain approval for the use of a product as a treatment for clinical indications other than those for which the product was initially tested. Also, the FDA or other regulatory authorities require post-marketing reporting to monitor the adverse effects of the drug. Results of post-marketing programs may limit or expand the further marketing of the products.

The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available drugs for uses that are not described in the drug's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label use.

In 2005, the FDA asked the manufacturer of Celebrex, as well as all manufacturers of prescription and over-the-counter NSAIDs, to revise the labeling for their products. Manufacturers of NSAIDs are being asked to revise their labeling to provide specific information about the potential risk of cardiovascular events and gastrointestinal risks of their individual products. We are continuing to analyze how this pronouncement will affect the labeling of Ketotransdel®.

Quality Assurance Requirements

The FDA enforces regulations to ensure that the methods used in, and facilities and controls used for, the manufacture, processing, packing and holding of drugs conform to current good manufacturing practices, or cGMP. The cGMP regulations the FDA enforces are comprehensive and cover all aspects of operations, from receipt of raw materials to finished product distribution, insofar as they bear upon whether drugs meet all the identity, strength, quality, purity and safety characteristics required of them. To assure compliance requires a continuous commitment of time, money and effort in all operational areas.

The FDA conducts pre-approval inspections of facilities engaged in the development, manufacture, processing, packing, testing and holding of the drugs subject to NDAs. If the FDA concludes that the facilities to be used do not meet cGMP, good laboratory practices or good clinical practices requirements, it will not approve the NDA. Corrective actions to remedy the deficiencies must be performed and verified in a subsequent inspection. In addition, manufacturers of both pharmaceutical products and active pharmaceutical ingredients used to formulate the drug also ordinarily undergo a pre-approval inspection, although the inspection can be waived when the manufacturer has had a passing cGMP inspection in the immediate past. Failure of any facility to

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pass a pre-approval inspection will result in delayed approval and would have a material adverse effect on our business, results of operations and financial condition.

The FDA also conducts periodic inspections of facilities to assess their cGMP status. If the FDA were to find serious cGMP non-compliance during such an inspection, it could take regulatory actions that could adversely affect our business, results of operations and financial condition. The FDA could initiate product seizures, request product recalls and seek to enjoin a product's manufacture and distribution. In certain circumstances, violations could lead to civil penalties and criminal prosecutions. In addition, if the FDA concludes that a company is not in compliance with cGMP requirements, sanctions may be imposed that include preventing the company from receiving the necessary licenses to export its products and classifying the company as an "unacceptable supplier," thereby disqualifying the company from selling products to federal agencies. Imported active pharmaceutical ingredients and other components needed to manufacture our products could be rejected by United States Customs.

We believe that we and our suppliers and outside manufacturers are currently in compliance with all FDA requirements.

Other FDA Matters

If there are any modifications to an approved drug, including changes in indication, manufacturing process or labeling or a change in a manufacturing facility, an applicant must notify the FDA, and in many cases, approval for such changes must be submitted to the FDA or other regulatory authority. Additionally, the FDA regulates post-approval promotional labeling and advertising activities to assure that such activities are being conducted in conformity with statutory and regulatory requirements. Failure to adhere to such requirements can result in regulatory actions that could have a material adverse effect on our business, results of operations and financial condition.

Intellectual Property

We obtained a patent from the United States Patent and Trademark Office on our Transdel™ technology in 1998, which affords protection of Transdel™ through 2016 in the United States. This patent specifically lists over 500 different drugs in over 60 therapeutic areas, including both approved and established drugs. The Transdel™ technology may also have an application to deliver drugs not listed in its patent, including novel drugs. Also, it covers composition of matter, methods of use and methods of manufacture. In regard to this U.S. patent, we will be pursuing patent strategies that will potentially allow us to extend the life of the patent beyond 2016.

Summary of Recent Events

The Board of Directors (the "Board") accepted the resignation of Dr. Juliet Singh as our Chief Executive Officer and as a director on the Board, effective February 17, 2010. The Board appointed Jeffrey J. Abrams, M.D. as Chairman of the Board. The Board also appointed John T. Lomoro, our current Chief Financial Officer, as acting Chief Executive Officer. Mr. Lomoro will also serve as our principal executive officer. In addition, in February 2010, we appointed Terry Nida as our Chief Business Officer.

In connection with her resignation, we entered into a consulting agreement with Dr. Singh, which provides that she will provide consulting services to us at request and the direction of the Board.

Employees

As of March 23, 2009, we employ four full-time individuals, responsible for financial accounting and investor relations, business and corporate development, research and development management, and general administration. Our employees are not unionized and we believe that our relationship with our employees is good.

SEC Filings; Internet Address

We file our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports with the SEC and make such filings available, free of charge, on www.transdelpharma.com, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The information found on our web-site shall not be deemed incorporated by reference by any general statement incorporating by reference this report into any filing under the Securities Act of 1933 or under the Securities Exchange Act of 1934, except to the extent we specifically incorporate the information found on our web-site by reference, and shall not otherwise be deemed filed under such Acts.

Our filings are also available through the SEC Web-site, www.sec.gov, and at the SEC Public Reference Room at 100 F Street, NE Washington DC 20549. For more information about the SEC Public Reference Room, you can call the SEC at 1-800-SEC-0330.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. Before investing in our common stock you should carefully consider the following risks, together with the financial and other information contained in this Form 10-K. If any of the following risks actually occurs, our business, prospects, financial condition and results of operations could be adversely affected. In that case, the trading price of our common stock would likely decline and you may lose all or a part of your investment.

Risks Relating to Our Business

We have incurred losses in the research and development of Ketotransdel® and our Transdel™ technology since inception. No assurance can be given that we will ever generate revenue or become profitable.

Since inception we have recorded operating losses. From Inception through December 31, 2009, we have a deficit accumulated during the development stage of approximately \$14.9 million, and for the year ended December 31, 2009, we experienced a net loss of approximately \$4.6 million. In addition, we expect to incur increasing operating losses for the foreseeable future as we continue to incur costs for research and development and clinical trials, and in other development activities. Our ability to generate revenue and achieve profitability depends upon our ability, alone or with others, to complete the development of our proposed products, obtain the required regulatory approvals and manufacture, market and sell our proposed products. Development is costly and requires significant investment. In addition, we may choose to in-license rights to particular drugs or active ingredients for use in cosmetic/cosmeceutical products. The license fees for such drugs or active ingredients may increase our costs.

As we continue to engage in the development of Ketotransdel® and develop other products, including cosmetic/cosmeceutical products, there can be no assurance that we will ever be able to achieve or sustain market acceptance, profitability or positive cash flow. Our ultimate success will depend on many factors, including whether Ketotransdel® receives FDA approval. We cannot be certain that we will receive FDA approval for Ketotransdel®, or that we will reach the level of sales and revenues necessary to achieve and sustain profitability. Unless we raise additional capital, we will not be able to execute our business plan or fund business operations. Furthermore, we will be forced to reduce our expenses and cash expenditures to a material extent, which would impair or delay our ability to execute our business plan.

The report of our independent registered public accounting firm on our 2009 consolidated financial statements contains a going concern modification, and we will need additional financing to execute our business plan, fund our operations and to continue as a going concern, which additional financing may not be available on a timely basis, or at all.

We have limited remaining funds to support our operations. We have prepared our consolidated financial statements in this Form 10-K on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. We will not be able to execute our current business plan, fund our business operations or continue as a going concern long enough to achieve profitability unless we are able to secure additional funds. As of December 31, 2009, with our current cash and cash equivalents position, we have forecasted and anticipate having adequate resources in order to execute a portion of our operating plan into the second quarter of 2010, which would include the final payments for the Phase 3 clinical trial completed in 2009 and general and administrative expenses. The Report of Independent Registered Public Accounting Firm on our December 31, 2009 consolidated financial statements includes an explanatory paragraph stating that the recurring losses incurred from operations and a working capital deficiency raise substantial doubt about our ability to continue as a going concern. However, in order to meet the FDA's requirement for two adequate and well controlled Phase 3 clinical trials in order to obtain regulatory approval to market Ketotransdel®, we will need to secure additional funds. If adequate financing is not available, we will not be able to meet the FDA's requirements to obtain regulatory approval to market Ketotransdel®. In addition, if one or more of the risks discussed in these risk factors occur or our expenses exceed our expectations, we may be required to raise further additional funds sooner than anticipated.

We will be required to pursue sources of additional capital to fund our operations through various means, including equity or debt financing, funding from a corporate partnership or licensing arrangement or any similar financing. Future financings through equity investments are likely to be dilutive to existing stockholders. Also, the terms of securities we may issue in future capital transactions may be more favorable for our new investors. Newly issued securities may include preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have additional dilutive effects. In addition, if we raise additional funds through collaboration and licensing arrangements, we may be required to relinquish potentially valuable rights to our product candidates or proprietary technologies, or grant licenses on terms that are not favorable to us. Further, we may incur substantial costs in pursuing future capital and/or financing, including investment banking fees, legal fees, accounting fees, printing and distribution expenses and other costs. We may also be required to recognize non-cash expenses in connection with certain securities we may issue, such as convertible notes and warrants, which will adversely impact our financial results.

The significant downturn in the overall economy and the ongoing disruption in the capital markets has reduced investor confidence and negatively affected investments generally and specifically in the pharmaceutical industry. In addition, the fact that we are not profitable and will need significant additional funds to meet the FDA's requirement for two adequate and well controlled Phase 3 clinical trials in order to obtain regulatory approval to market Ketotransdel® and any other clinical trials we would want to

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commence for other products, could further impact the availability or cost of future financings. As a result, there can be no assurance that additional funds will be available when needed from any source or, if available, will be available on terms that are acceptable to us. If we are unable to raise funds to satisfy our capital needs on a timely basis, we may be required to cease operations.

We may not be able to correctly estimate our future operating expenses, which could lead to cash shortfalls.

Our operating expenses may fluctuate significantly in the future as a result of a variety of factors, many of which are outside of our control. These factors include:

- the time and resources required to develop, conduct clinical trials and obtain regulatory approvals for our drug candidates;
- the costs to attract and retain personnel with the skills required for effective operations; and
- the costs of preparing, filing, prosecuting, defending and enforcing patent claims and other patent related costs, including litigation costs and the results of such litigation.

Timing and results of clinical trials to demonstrate the safety and efficacy of products as well as FDA approval of products are uncertain.

We are subject to extensive government regulations. The process of obtaining FDA approval is costly, time consuming, uncertain and subject to unanticipated delays. Before obtaining regulatory approvals for the sale of any of our products, we must demonstrate through preclinical studies and clinical trials that the product is safe and effective for each intended use. Preclinical and clinical studies may fail to demonstrate the safety and effectiveness of a product. Even promising results from preclinical and early clinical studies do not always accurately predict results in later, large scale trials. A failure to demonstrate safety and efficacy would result in our failure to obtain regulatory approvals. Moreover, if the FDA grants regulatory approval of a product, the approval may be limited to specific indications or limited with respect to its distribution, which could limit revenues.

We cannot assure you that the FDA or other regulatory agencies will approve any products developed by us, on a timely basis, if at all, or, if granted, that such approval will not subject the marketing of our products to certain limits on indicated use. In particular, the outcome of the final analyses of the data from the Phase 3 clinical trial for Ketotransdel® may vary from our initial conclusions or the FDA may not agree with our interpretation of such results or may challenge the adequacy of our clinical trial design or the execution of the clinical trial, including our modified ITT analysis for our Phase 3 clinical trial of Ketotransdel®. The FDA is requiring two adequate and well controlled Phase 3 clinical trials for Ketotransdel® before we can submit a 505(b) (2) New Drug Application. In addition, the results of any future clinical trials may not be favorable and we may never receive regulatory approval for Ketotransdel®. Any limitation on use imposed by the FDA or delay in or failure to obtain FDA approvals of products developed by us would adversely affect the marketing of these products and our ability to generate product revenue, as well as adversely affect the price of our common stock.

If we fail to comply with continuing federal, state and foreign regulations, we could lose our approvals to market drugs and our business would be seriously harmed.

Following initial regulatory approval of any drugs we may develop, we will be subject to continuing regulatory review, including review of adverse drug experiences and clinical results that are reported after our drug products become commercially available. This would include results from any post-marketing tests or continued actions required as a condition of approval. The manufacturer and manufacturing facilities we use to make any of our drug candidates will be subject to periodic review and inspection by the FDA. If a previously unknown problem or problems with a product or a manufacturing and laboratory facility used by us is discovered, the FDA or foreign regulatory agency may impose restrictions on that product or on the manufacturing facility, including requiring us to withdraw the product from the market. Any changes to an approved product, including the way it is manufactured or promoted, often requires FDA approval before the product, as modified, can be marketed. In addition, we and our contract manufacturers will be subject to ongoing FDA requirements for submission of safety and other post-market information. If we or our contract manufacturers fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw our regulatory approval;
- suspend or terminate any of our ongoing clinical trials;

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- refuse to approve pending applications or supplements to approved applications filed by us;
- impose restrictions on our operations;
- close the facilities of our contract manufacturers; or
- seize or detain products or require a product recall.

Additionally, regulatory review covers a company's activities in the promotion of its drugs, with significant potential penalties and restrictions for promotion of drugs for an unapproved use. Sales and marketing programs are under scrutiny for compliance with various mandated requirements, such as illegal promotions to health care professionals. We are also required to submit information on our open and completed clinical trials to public registries and databases. Failure to comply with these requirements could expose us to negative publicity, fines and penalties that could harm our business.

If we violate regulatory requirements at any stage, whether before or after marketing approval is obtained, we may be fined, be forced to remove a product from the market or experience other adverse consequences, including delay, which would materially harm our financial results. Additionally, we may not be able to obtain the labeling claims necessary or desirable for product promotion.

Delays in the conduct or completion of our clinical and non-clinical trials or the analysis of the data from our clinical or non-clinical trials may result in delays in our planned filings for regulatory approvals, and may adversely affect our business.

We cannot predict whether we will encounter problems with any of our completed or planned clinical or non-clinical studies that will cause us or regulatory authorities to delay or suspend planned clinical and non-clinical studies. Any of the following could delay the completion of our planned clinical studies:

- failure of the FDA to approve the scope or design of our clinical or non-clinical trials or manufacturing plans;
- delays in enrolling volunteers in clinical trials;
- insufficient supply or deficient quality of materials necessary for the performance of clinical or non-clinical trials;
- negative results of clinical or non-clinical studies; and
- adverse side effects experienced by study participants in clinical trials relating to a specific product.

There may be other circumstances other than the ones described above, over which we may have no control that could materially delay the successful completion of our clinical and non-clinical studies.

None of our pharmaceutical product candidates, other than Ketotransdel[®], have commenced clinical trials.

None of our pharmaceutical product candidates, other than Ketotransdel[®], have commenced any clinical trials and there are a number of FDA requirements that we must satisfy in order to commence clinical trials. These requirements will require substantial time, effort and financial resources. We cannot assure you that we will ever satisfy these requirements. In addition, prior to commencing any trials of a drug candidate, we must evaluate whether a market exists for the drug candidate. This is costly and time consuming and no assurance can be given that our market studies will be accurate. We may expend significant capital and other resources on a drug candidate and find that no commercial market exists for the drug. Even if we do commence clinical trials of our other drug candidates, such drug candidates may never be approved by the FDA.

Once approved, there is no guarantee that the market will accept our products, and regulatory requirements could limit the commercial usage of our products.

Even if we obtain regulatory approvals, uncertainty exists as to whether the market will accept our products or if the market for our products is as large as we anticipate. A number of factors may limit the market acceptance of our products, including the timing of regulatory approvals and market entry relative to competitive products, the availability of alternative products, the price of our products relative to alternative products, the availability of third party reimbursement and the extent of marketing efforts by third party distributors or agents that we retain. We cannot assure you that our products will receive market acceptance in a commercially viable period of time, if at all. We cannot be certain that any investment made in developing products will be recovered, even if we are

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successful in commercialization. To the extent that we expend significant resources on research and development efforts and are not able, ultimately, to introduce successful new products as a result of those efforts, our business, financial position and results of operations may be materially adversely affected, and the market value of our common stock could decline.

We may be subject to product liability claims.

The development, manufacture, and sale of pharmaceutical and cosmetic/cosmeceutical products expose us to the risk of significant losses resulting from product liability claims. Although we have obtained and intend to maintain product liability insurance to offset some of this risk, we may be unable to maintain such insurance or it may not cover certain potential claims against us.

In the future, we may not be able to afford to obtain insurance due to rising costs in insurance premiums in recent years. Currently we have been able to secure insurance coverage, however, we may be faced with a successful claim against us in excess of our product liability coverage that could result in a material adverse impact on our business. If insurance coverage is too expensive or is unavailable to us in the future, we may be forced to self-insure against product-related claims. Without insurance coverage, a successful claim against us and any defense costs incurred in defending ourselves may have a material adverse impact on our operations.

If our patents are determined to be unenforceable, or if we are unable to obtain new patents based on current patent applications or for future inventions, we may not be able to prevent others from using our intellectual property.

Our success will depend in part on our ability to:

- obtain and maintain patent protection with respect to our products;
- prevent third parties from infringing upon our proprietary rights;
- maintain trade secrets;
- operate without infringing upon the patents and proprietary rights of others; and
- obtain appropriate licenses to patents or proprietary rights held by third parties if infringement would otherwise occur, both in the U.S. and in foreign countries.

We obtained a patent from the United States Patent and Trademark Office on our Transdel™ technology in 1998, which affords protection of Transdel™ through 2016 in the United States. We may not be successful in our efforts to extend the date of our patent protection beyond 2016.

The patent and intellectual property positions of specialty pharmaceutical companies, including ours, are uncertain and involve complex legal and factual questions. There is no guarantee that we have or will develop or obtain the rights to products or processes that are patentable, that patents will issue from any pending applications or that claims allowed will be sufficient to protect the technology we develop or have developed or that is used by us, our contract manufacturing organizations or our other service providers. In addition, we cannot be certain that patents issued to us will not be challenged, invalidated, infringed or circumvented, including by our competitors, or that the rights granted thereunder will provide competitive advantages to us.

Furthermore, patent applications in the U.S. are confidential for a period of time until they are published, and publication of discoveries in scientific or patent literature typically lags actual discoveries by several months. As a result, we cannot be certain that the inventors listed in any patent or patent application owned by us were the first to conceive of the inventions covered by such patents and patent applications or that such inventors were the first to file patent applications for such inventions.

We also may rely on unpatented trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with employees, consultants, collaborators and others. We also have invention or patent assignment agreements with our employees and certain consultants. There can be no assurance, however, that binding agreements will not be breached, that we will have adequate remedies for any breach, or that trade secrets will not otherwise become known or be independently discovered by competitors. In addition, there can be no assurance that inventions relevant to us will not be developed by a person not bound by an invention assignment agreement with us.

The use of our technologies could potentially conflict with the rights of others.

The manufacture, use or sale of our proprietary products may infringe on the patent rights of others. If we are unable to avoid infringement of the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming and may divert management's attention and our resources. We may not have sufficient resources to bring these actions to a successful conclusion. In such case, we may be required to alter our products, pay licensing fees or cease activities. If our products conflict with patent rights of others, third parties could bring legal actions against us claiming damages and seeking to enjoin manufacturing and marketing of affected products. If these legal

actions are successful, in addition to any potential liability for damages, we could be required to obtain a license in order to continue to manufacture or market the affected products. We may not prevail in any legal action and a required license under the patent may not be available on acceptable terms, if at all.

We will be dependent on outside manufacturers in the event that we successfully develop our product candidates into commercial products; therefore, we will have limited control of the manufacturing process, access to raw materials, timing for delivery of finished products and costs. One manufacturer may constitute the sole source of one or more of our products.

Third party manufacturers will manufacture all of our products, in the event that we successfully develop our product candidates into commercial products. Currently, certain of our contract manufacturers constitute the sole source of one or more of our products. If any of our existing or future manufacturers cease to manufacture or are otherwise unable to deliver any of our products or any of the components of our products, we may need to engage additional manufacturing partners. Because of contractual restraints and the lead-time necessary to obtain FDA approval of a new manufacturer, replacement of any of these manufacturers may be expensive and time consuming and may disrupt or delay our ability to supply our products and reduce our revenues.

Because all of our products, in the event that we successfully develop our product candidates into commercial products, will be manufactured by third parties, we have a limited ability to control the manufacturing process, access to raw materials, the timing for delivery of finished products or costs related to this process. There can be no assurance that our contract manufacturers will be able to produce finished products in quantities that are sufficient to meet demand or at all, in a timely manner, which could result in decreased revenues and loss of market share. There may be delays in the manufacturing process over which we will have no control, including shortages of raw materials, labor disputes, backlog and failure to meet FDA standards. Increases in the prices we pay our manufacturers, interruptions in our supply of products or lapses in quality could adversely impact our margins, profitability and cash flows. We are reliant on our third-party manufacturers to maintain their manufacturing facilities in compliance with FDA and other federal, state and/or local regulations including health, safety and environmental standards. If they fail to maintain compliance with FDA or other critical regulations, they could be ordered to curtail operations, which would have a material adverse impact on our business, results of operations and financial condition.

We also rely on our outside manufacturers to assist us in the acquisition of key documents such as drug master files and other relevant documents that are required by the FDA as part of the drug approval process and post-approval oversight. Failure by our outside manufacturers to properly prepare and retain these documents could cause delays in obtaining FDA approval of our drug candidates.

We are dependent on third parties to conduct clinical trials and non-clinical studies of our drug candidates and to provide services for certain core aspects of our business. Any interruption or failure by these third parties to meet their obligations pursuant to various agreements with us could have a material adverse effect on our business, results of operations and financial condition.

We do not employ personnel or possess the facilities necessary to conduct many of the activities associated with our programs. We engage consultants, advisors, contract research organizations (CROs) and others to design, conduct, analyze and interpret the results of studies in connection with the research and development of our product candidates. As a result, many important aspects of our product candidates' development are outside our direct control. There can be no assurance that such third parties will perform all of their obligations under arrangements with us or will perform those obligations satisfactorily.

The CROs with which we contract for execution of our clinical studies play a significant role in the conduct of the studies and subsequent collection and analysis of data, and we will likely depend on these and other CROs and clinical investigators to conduct any future clinical studies or assist with our analysis of completed studies and to develop corresponding regulatory strategies. Individuals working at the CROs with which we contract, as well as investigators at the sites at which our studies are conducted, are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. If these CROs fail to devote sufficient time and resources to our studies, or if their performance is substandard, it will delay the approval of our applications to regulatory agencies and the introduction of our products. Failure of these CROs to meet their obligations could adversely affect development of our product candidates and as a result could have a material adverse effect on our business, financial condition and results of operations. Moreover, these CROs may have relationships with other commercial entities, some of which may compete with us. If they assist our competitors at our expense, it could harm our competitive position.

Our cosmetic/cosmeceutical product development program may not be successful.

We recently expanded our product development program to include cosmetic/cosmeceutical products, which utilize our patented transdermal delivery system technology, Transdel™. Because our primary focus will remain on seeking FDA approval for Ketotransdel, we plan to use limited resources on our cosmetic/cosmeceutical development program and, as a result, we will need to partner with third parties to perform formulation, clinical research, manufacturing, sales and marketing activities. We have initial clinical information supporting the beneficial effects of our anti-cellulite product on skin appearance, and to supplement the license agreement entered into for this product, we are pursuing discussions with potential sales and marketing partners for this product. We

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cannot assure you that the results of any further studies that may be required before these products can be commercialized will be successful, that we will enter into commercial agreements (in addition to the license agreement entered into in the second quarter 2009 with JH Direct, LLC) with third parties for these products on acceptable terms, or at all, or that these products will be successfully commercialized. Even if we are not required to obtain FDA pre-market approval for these products, we will still be subject to a number of federal and state regulations, including regulation by the FDA and the Federal Trade Commission on any marketing claims we make about our products. There is no assurance that we will be successful in developing any other cosmetic/cosmeceutical products, including products for hyperpigmentation and anti-aging. Any products we develop may cause undesirable side effects that could limit their use, require their removal from the market and subject us to adverse regulatory action and product liability claims. Further, the market for cosmetic/cosmeceutical products is highly competitive, and there is no assurance that our products will be able to compete against the many products and treatments currently being offered or under development by other established, well-known and well-financed cosmetic, health care and pharmaceutical companies.

We currently have no internal sales and marketing resources and may have to rely on third parties in the event that we successfully commercialize our product.

In order to market any of our products in the United States or elsewhere, we must develop internally or obtain access to sales and marketing forces with technical expertise and with supporting distribution capability in the relevant geographic territory. We may not be able to enter into marketing and distribution arrangements or find a corporate partner to market our drug candidates, and we currently do not have the resources or expertise to market and distribute our products ourselves. If we are not able to enter into marketing or distribution arrangements or find a corporate partner who can provide support for commercialization of our products, we may not be able to successfully commercialize our products. Moreover, any new marketer or distributor or corporate partner for our specific combinations, with whom we choose to contract may not establish adequate sales and distribution capabilities or gain market acceptance for our products.

If we are unable to retain our key personnel or attract additional professional staff, we may be unable to maintain or expand our business.

Because of the specialized scientific nature of our business, our ability to develop products and to compete will remain highly dependent, in large part, upon our ability to attract and retain qualified scientific, technical and commercial personnel. The loss of key scientific, technical and commercial personnel or the failure to recruit additional key scientific, technical and commercial personnel could have a material adverse effect on our business. While we have consulting agreements with certain key institutions, we cannot assure you that we will succeed in retaining personnel or their services under existing agreements. There is intense competition for qualified personnel in the pharmaceutical industry, and we cannot assure you that we will be able to continue to attract and retain the qualified personnel necessary for the development of our business.

Risks Relating to Our Industry

If we are unable to compete with other companies that develop rival products to our products, then we may never gain market share or achieve profitability.

The pharmaceutical industry is intensely competitive, and we face competition across the full range of our activities. If we fail to compete successfully, our business, results of operations and financial condition could be adversely affected. Our competitors include brand name and generic manufacturers of pharmaceuticals specializing in transdermal drug delivery, especially those doing business in the United States. In the market for pain management products, our competitors include manufacturers of over-the-counter and prescription pain relievers. Because we are smaller than many of our national competitors, we may lack the financial and other resources needed to compete for market share in the pain management sector. Our other potential drug candidates will also face intense competition from larger and better established pharmaceutical and biotechnology companies. Many of these competitors have significantly greater financial, technical and scientific resources than we do. In addition to product safety, development and efficacy, other competitive factors in the pharmaceutical market include product quality and price, reputation, service and access to scientific and technical information. If our products are unable to compete with the products of our competitors, we may never gain market share or achieve profitability.

We may not be able to keep up with the rapid technological change in the biotechnology and pharmaceutical industries, which could make our products obsolete and reduce our potential revenues.

Biotechnology and related pharmaceutical technologies have undergone and continue to be subject to rapid and significant change. Our future will depend in large part on our ability to maintain a competitive position with respect to these technologies. It is possible that developments by our competitors will render our products and technologies obsolete or unable to compete. Any products that we develop may become obsolete before we recover expenses incurred in developing those products, which may require that we raise additional funds to continue our operations.

Our ability to generate revenues will be diminished if we fail to obtain acceptable prices or an adequate level of reimbursement from third-party payors.

If we succeed in bringing a specific product to market, we cannot be certain that the products will be considered cost effective and that reimbursement from insurance companies and other third-party payors will be available or, if available, will be sufficient to allow us to sell the products on a competitive basis.

Significant uncertainty exists as to the reimbursement status of newly approved health care products. Third-party payors, including Medicare, are challenging the prices charged for medical products and services. Government and other third-party payors increasingly are attempting to contain health care costs by limiting both coverage and the level of reimbursement for new drugs and by refusing, in some cases, to provide coverage for uses of approved products for disease indications for which the FDA has not granted labeling approval. Third-party insurance coverage may not be available to patients for any products we discover and develop, alone or with collaborators. If government and other third-party payors do not provide adequate coverage and reimbursement levels for our products, the market acceptance of these products may be reduced.

Changes in the healthcare industry that are beyond our control may be detrimental to our business.

The healthcare industry is changing rapidly as the public, governments, medical professionals and the pharmaceutical industry examine ways to broaden medical coverage while controlling the increase in healthcare costs. Potential changes could put pressure on the prices of prescription pharmaceutical products and reduce our business or prospects. We cannot predict when, if any, proposed healthcare reforms will be implemented or their affect on our business.

Risks Relating to the Common Stock

We are subject to financial reporting and other requirements for which our accounting and other management systems and resources may not be adequately prepared.

We are subject to reporting and other obligations under the Securities Exchange Act of 1934, as amended, (the "Exchange Act") including the requirements of Section 404 of the Sarbanes-Oxley Act. Section 404 requires us to conduct an annual management assessment of the effectiveness of our internal controls over financial reporting for the annual report on Form 10-K. Also, we will be required to obtain a report by our independent registered public accounting firm addressing these assessments commencing with our annual report on Form 10-K for the fiscal year ending December 31, 2010. These reporting and other obligations will place significant demands on our management, administrative, operational, and accounting resources. We anticipate that we may need to upgrade our systems; implement additional financial and management controls, reporting systems and procedures; implement or outsource an internal audit function; and hire additional accounting and finance staff. If we are unable to accomplish these objectives in a timely and effective fashion, our ability to comply with our financial reporting requirements and other rules that apply to reporting companies could be impaired and we may not be able to obtain the independent registered public accounting firm opinion required by Section 404. Any failure to maintain effective internal controls could have a negative impact on our ability to manage our business and on our stock price.

If we fail to maintain an effective system of internal control, we may not be able to report our financial results accurately or to prevent fraud. Any inability to report and file our financial results accurately and timely could harm our business and adversely impact the trading price of our common stock.

Effective internal control is necessary for us to provide reliable financial reports and prevent fraud. If we cannot provide reliable financial reports or prevent fraud, we will not be able to manage our business as effectively, and our business and reputation with investors would be harmed. Any such inability to establish effective controls or loss of confidence would have an adverse affect on our financial condition, results of operation and access to capital. We have not performed an in-depth analysis to determine if past failures of internal controls exist, and may in the future discover areas of our internal control that need improvement.

Public company compliance may make it more difficult to attract and retain officers and directors.

The Sarbanes-Oxley Act and new rules subsequently implemented by the Securities and Exchange Commission ("SEC") have required changes in corporate governance practices of public companies. As a public company, we expect these new rules and regulations to increase our compliance costs and to make certain activities more time consuming and costly. We also expect that these new rules and regulations may make it more difficult and expensive for us to obtain director and officer liability insurance in the future and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our board of directors or as executive officers.

Our stock price may be volatile.

The market price of our common stock is likely to be highly volatile and could fluctuate widely in price in response to various factors, many of which are beyond our control, including the following:

- changes in the pharmaceutical industry and markets;
- competitive pricing pressures;
- our ability to obtain working capital financing;
- new competitors in our market;
- additions or departures of key personnel;
- limited “public float” in the hands of a small number of persons whose sales or lack of sales could result in positive or negative pricing pressure on the market price for our common stock;
- sales of our common stock;
- our ability to execute our business plan;
- operating results that fall below expectations;
- loss of any strategic relationship with our contract manufacturers and clinical and non-clinical research organizations;
- industry or regulatory developments;
- economic and other external factors; and
- period-to-period fluctuations in our financial results.

In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of our common stock.

We have not paid dividends in the past and do not expect to pay dividends in the future. Any return on investment may be limited to the value of our common stock.

We have never paid cash dividends on our common stock and do not anticipate doing so in the foreseeable future. The payment of dividends on our common stock will depend on earnings, financial condition and other business and economic factors affecting us at such time as our board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on your investment will only occur if our stock price appreciates.

Our common stock is classified as a “penny stock”, which makes it more difficult for our investors to sell their shares.

Our common stock is currently subject to the “penny stock” rules adopted under Section 15(g) of the Exchange Act. The penny stock rules apply to companies whose common stock is not listed on The Nasdaq Stock Market or other national securities exchange and trades at less than \$4.00 per share or that have tangible net worth of less than \$5,000,000 (\$2,000,000 if the company has been operating for three or more years). These rules require, among other things, that brokers who trade penny stock to persons other than “established customers” complete certain documentation, make suitability inquiries of investors and provide investors with certain information concerning trading in the security, including a risk disclosure document and quote information under certain circumstances. Many brokers have decided not to trade penny stocks because of the requirements of the penny stock rules and, as a result, the number of broker-dealers willing to act as market makers in such securities is limited. If we remain subject to the penny stock rules for any significant period, it could have an adverse effect on the market, if any, for our securities. If our securities are subject to the penny stock rules, investors will find it more difficult to dispose of our securities.

Furthermore, for companies whose securities are traded in the OTC Bulletin Board, it is more difficult (1) to obtain accurate quotations, (2) to obtain coverage for significant news events because major wire services generally do not publish press releases about such companies and (3) to obtain needed capital.

Offers or availability for sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

The sale by our stockholders of substantial amounts of our common stock in the public market or upon the expiration of any statutory holding period, under Rule 144, or upon expiration of lock-up periods applicable to outstanding shares, or issued upon the exercise of outstanding options or warrants, could create a circumstance commonly referred to as an “overhang” and in anticipation of which the market price of our common stock could fall. The existence of an overhang, whether or not sales have occurred or are occurring, also could make more difficult our ability to raise additional financing through the sale of equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate.

ITEM 2. PROPERTIES

Facilities

We lease approximately 1,681 square feet of office space in La Jolla, California. The current lease term expires on March 31, 2010 at which time we anticipate to renew the lease for a period of time sufficient to allow us to operate our business uninterrupted. This facility serves as our corporate headquarters.

We believe our current facility is adequate for our immediate and near-term needs. Additional space may be required as we expand our activities. We do not currently foresee any significant difficulties in obtaining any required additional facilities.

ITEM 3. LEGAL PROCEEDINGS

None.

ITEM 4. RESERVED

PART II**ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY****Market Information**

Our common stock has been quoted on the OTC Bulletin Board since October 1, 2007 under the symbol TDLP.OB. Prior to that date, there was no active market for our common stock. The OTC Bulletin Board is a regulated quotation service that displays real-time quotes, last-bid prices and volume information in over-the-counter equity securities. The OTC Bulletin Board securities are traded by a community of market makers that enter quotes and trade reports. This market is extremely limited and any prices quoted may not be a reliable indication of the value of our common stock. The closing price of our common stock on March 23, 2010 was \$1.00 per share.

The following table sets forth the high and low last-bid prices for our common stock for the periods indicated, as reported by the OTC Bulletin Board. The quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission, and may not represent actual transactions.

Fiscal Year 2009	High	Low
First Quarter	\$1.10	\$0.60
Second Quarter	\$1.70	\$0.65
Third Quarter	\$1.99	\$0.80
Fourth Quarter	\$4.00	\$1.06
Fiscal Year 2008	High	Low
First Quarter	\$2.94	\$1.05
Second Quarter	\$1.98	\$1.10
Third Quarter	\$1.75	\$1.00
Fourth Quarter	\$1.39	\$0.55

Holders

As of March 12, 2010 we had approximately 73 stockholders of record (excluding an indeterminate number of stockholders whose shares are held in street or "nominee" name) of our common stock.

Dividends

We have not paid any dividends on our common stock since our inception and do not expect to pay dividends on our common stock in the foreseeable future.

Recent Sales of Unregistered Securities

None.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This report contains "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. For this purpose, any statements contained herein regarding our strategy, future operations, financial position, future revenues, projected costs and expenses, prospects, plans and objectives of management, other than statements of historical facts, are forward-looking statements. The words "anticipate," "believes," "estimates," "intends," "may," "plans," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such statements reflect our current views with respect to future events. We cannot guarantee that we actually will achieve the plans, intentions, or expectations disclosed in our forward-looking statements. There are a number of important factors that could cause actual results or events to differ materially from those disclosed in the expressed or implied forward-looking statements we make. These important factors include our "critical accounting policies and estimates" and the risk factors set forth above in Part I, Item 1A — Risk Factors. Although we may elect to update forward-looking statements in the future, we specifically disclaim any obligation to do so, even if our estimates change. Readers should not rely on those forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report.

Overview

We are a specialty pharmaceutical company developing non-invasive, topically delivered products. Our innovative patented Transdel™ cream formulation technology is designed to facilitate the effective penetration of a variety of products through the tough skin barrier. Ketotransdel®, our lead pain product, utilizes the Transdel™ platform technology to deliver the active drug, ketoprofen, a non-steroidal anti-inflammatory drug ("NSAID"), through the skin directly into the underlying tissues where the drug exerts its well-known anti-inflammatory and analgesic effects. We intend to leverage the Transdel™ platform technology to expand and create a portfolio of topical products for a variety of indications.

On September 17, 2007, we entered into an Agreement of Merger and Plan of Reorganization (the "Merger Agreement") with Transdel Pharmaceuticals Holdings, Inc., a privately held Nevada corporation ("Transdel Holdings"), and Trans-Pharma Acquisition Corp., our newly formed, wholly-owned Delaware subsidiary ("Acquisition Sub"). Upon closing of the merger transaction contemplated under the Merger Agreement (the "Merger"), Acquisition Sub merged with and into Transdel Holdings, and Transdel Holdings, as the surviving corporation, became our wholly-owned subsidiary.

As is discussed further in the Liquidity and Capital Resources section below, we have limited funds to support our operations. Our continuation as a going concern subsequent to the second quarter of 2010 is dependent on our ability to obtain additional financing to fund the continued operation of our business model for a long enough period to achieve profitable operations.

Plan of Operations

For the next twelve months, our current operating plan is focused on the development of our lead drug, Ketotransdel® for the indication of acute pain, inflammation and swelling associated with soft tissue injuries, development of cosmetic/cosmeceutical products and co-development opportunities in other therapeutic areas utilizing our Transdel™ platform technology.

Clinical Program for Ketotransdel®

In June 2008, we initiated a Phase 3 clinical study designed as a randomized, double-blind, placebo-controlled, multi-center Phase 3 study that enrolled a total of 364 patients with acute soft tissue injuries of the upper or lower extremities in 26 centers in the United States. The primary efficacy endpoint was the difference between Ketotransdel® and placebo in the change from baseline in pain intensity as measured by the 100 mm Visual Analogue Scale (VAS) during daily activities over the past 24 hours on the Day 3 visit.

As we reported in October 2009, the top-line results showed that the study demonstrated statistical significance in its primary endpoint in the per protocol analysis and was favorable for Ketotransdel® in the Intent-To Treat (ITT) Analysis. Ketotransdel® also demonstrated an excellent safety and tolerability profile. In particular, there were no Ketotransdel® treatment related gastrointestinal, cardiovascular, hepatic or other clinically relevant adverse events reported. Furthermore, Ketotransdel® was well absorbed through the skin and in support of the safety and tolerability only minimal blood concentrations of ketoprofen were detected in a subset of patients who underwent blood sampling for pharmacokinetic (PK) analyses following repeated topical applications. These PK results are consistent with our previous clinical study findings and support the excellent safety profile.

In January 2010, we reported on further in-depth analyses of the ITT data from the Ketotransdel® Phase 3 study. For the modified ITT analysis we identified 35 patients who did not meet study entry criteria at the time of randomization. Excluding the data from these patients who should not have been randomized into the study based on information that was not known at the time of enrollment, the study demonstrated statistical significance ($p < 0.038$) on the primary efficacy endpoint. This analysis was confirmed by an independent statistical expert.

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The weight of evidence of a treatment effect in this study is further strengthened by a key secondary endpoint (pain intensity recorded 3 times daily on patient diary cards) that supports the primary endpoint. The pain curves over time show consistent separation between treatment groups reaching statistical significance in favor of Ketotransdel®; using both the original and modified ITT population.

Based on discussions with the FDA at least two adequate and well-controlled Phase 3 studies are required in order to obtain regulatory approval to market Ketotransdel®. We believe that the first Phase 3 trial will qualify as one adequate and well-controlled trial because there is statistical significance on the primary endpoint in an objectively defined modified ITT population, and statistical significance on secondary endpoints. We are in the process of determining the design of the second Phase 3 trial. There is no assurance that the FDA will accept our conclusion of the modified ITT data from the first Phase 3 study as sufficient as part of the requirements for regulatory approval.

As part of a routine requirement to provide safety information in the NDA submission we have to perform studies such as to assess the allergenicity potential and absorption of ketoprofen during concurrent exercise and heat exposure with Ketotransdel®. These additional supportive trials will be conducted in healthy subjects. The timing of the second Phase 3 trial and the other supportive studies will be dependent on obtaining adequate financing to support the execution of these activities and for other working capital expenditures.

We expect that Ketotransdel®, if and when approved by the FDA, could become the first topical NSAID cream product available by prescription in the United States for acute pain management. We are seeking a commercial partner for Ketotransdel®, and are actively pursuing discussions with U.S. and foreign based potential partners with sales and marketing infrastructures.

Cosmeceutical/Cosmetic Product Development Program

We have expanded our product development programs to include cosmetic/cosmeceutical products, which utilize our patented transdermal delivery system technology, Transdel™. Our lead product is an anti-cellulite formulation, for which we have initial clinical information supporting the beneficial effects of this key cosmetic/cosmeceutical product on skin appearance. Our potential pipeline of cosmetic/cosmeceutical products includes hyperpigmentation and anti-aging formulations. We are pursuing discussions with potential sales and marketing partners for these cosmetic/cosmeceutical products.

On May 20, 2009, we entered into a license agreement with JH Direct, LLC (“JH Direct”) providing JH Direct with the exclusive worldwide rights to our anti-cellulite cosmeceutical product. Under the terms of the agreement, JH Direct will pay us initial royalty advances if the product is marketed and a continuing licensing royalty on the worldwide sales of the anti-cellulite product. We retained the exclusive rights to seek pharmaceutical/dermatological partners for the anti-cellulite product for an initial period of one year following the launch of the product, thereafter JH Direct will be allowed to expand in this channel. We anticipate that JH Direct will launch the anti-cellulite product through a direct response television campaign during the second half of 2010.

Other Product Development Programs

We believe that the clinical success of Ketotransdel® will facilitate the use of the Transdel™ delivery technology in other products. We have identified co-development opportunities for potential products in pain management and other therapeutic areas utilizing the Transdel™ platform technology and we are exploring potential partnerships for these identified products. In addition to others, some of these identified co-development areas include hormone based products, antiemetic and dermatological products using our Transdel delivery system. We are also looking to out-license our Transdel™ drug delivery technology for the development and commercialization of additional innovative drug products. There can be no assurance that any of the activities associated with our product development programs will lead to definitive agreements.

We believe that our current staff is sufficient to carry out our business plan in the coming twelve months, however, if our operations in the future require it, we will consider the employment of additional staff or the use of consultants. Upon the resignation of our Chief Executive Officer, effective February 17, 2010, our Board of Directors initiated a search for a new Chief Executive Officer. Until then, our Chief Financial Officer, John Lomoro, will serve as the acting Chief Executive Officer.

Results of Operations

Comparisons of Years Ended December 31, 2009 and 2008

Selling, General and Administrative Expenses

Our selling, general and administrative expenses include personnel costs including wages and stock-based compensation, corporate facility expenses, investor relations, consulting, insurance, legal and accounting expenses.

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The table below provides information regarding selling, general and administrative expenses:

	Year ended December 31,		\$ Variance
	2009	2008	
Selling, general and administrative	<u>\$ 1,598,369</u>	<u>\$ 1,755,731</u>	\$ (157,362)

For the year ended December 31, 2009, the decrease of \$157,362 in selling, general and administrative expense, as compared to the year ended December 31, 2008, was primarily related to the decrease in investor relations and legal expenses, partially offset by increased expenses for personnel, consulting and insurance costs. Further explanations for these variances are as follows:

- The primary reason for the decrease in investor relations expense was due to the lower amount of amortization, approximately \$260,000, related to the value of stock-based compensation for stock and warrants previously issued to investor relations firms. The decrease in legal fees of approximately \$100,000 is due to a lower amount of legal activity and related expense during the current period in comparison to the same period last year. Also, travel and entertainment expenses decreased by approximately \$20,000.
- The increase in personnel expenses of approximately \$110,000 is due to an increase in wages (as of July 1, 2008) and additional stock-based compensation granted to employees and board members in the second and fourth quarters of 2008 and during the second quarter of 2009. Consulting expenses increased by approximately \$70,000 primarily related to stock-based compensation and monthly fees for business development consulting services. Insurance costs increased by approximately \$30,000 from two product liability policies that we obtained in the latter part of the second quarter 2008 and in the fourth quarter of 2008 for our Phase 3 clinical trial and our cosmeceutical products as well as other incremental insurance costs.

Research and Development Expenses

Our research and development expenses primarily include costs for the Ketotransdel clinical program. These costs are comprised of expenses for our current Phase 3 study, including costs for our contract research organization and investigator payments to the clinical sites participating in the study. Other expenses are personnel costs including wages and stock-based compensation, contract manufacturing, non-clinical studies, consulting and other costs related to the clinical program.

The table below provides information regarding research and development expenses:

	Year ended December 31,		\$ Variance
	2009	2008	
Research and development	<u>\$ 2,965,707</u>	<u>\$ 1,990,665</u>	\$ 975,042

For the year ended December 31, 2009, the increase of \$975,042 in research and development expense, as compared to the year ended December 31, 2008, was primarily related to the increase of expenses for the current Phase 3 study, partially offset by decreased expenses related to personnel, contract manufacturing and non-clinical studies. Further explanations for these variances are as follows:

- During the current period, we recognized an increase of approximately \$1.5 million of expenses related to the current Phase 3 study, primarily related to the investigator payments owed to the clinical sites for the patients they enrolled in the study and the fees incurred by our contract research organization for their services provided in conducting the study. Also, we recognized an increase of approximately \$200,000 for consulting services related to the management of the Phase 3 trial and data analysis on the Phase 3 results.
- The decrease in personnel expenses of approximately \$350,000 was primarily related to stock-based compensation and wages of former employees recognized in the prior year, partially offset by such expenses for our chief medical officer who joined us in October 2009. Also, during the same period in the prior year, we recognized approximately \$410,000 of expenses related to contract manufacturing activities and non-clinical studies for the Phase 3 clinical program which were not incurred in the current period.

Interest Income

Interest income was \$10,440 and \$67,008, for the years ended December 31, 2009 and 2008, respectively. The decrease was due to a lower average cash balance and lower interest rates during fiscal year 2009 as compared to fiscal year 2008.

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Gain on Settlement

In 2008, we recognized a gain of \$375,000 after fees paid to our counsel and an executive and director of the Company as result of a settlement agreement with a law firm previously retained by us.

Liquidity and Capital Resources

Since inception through December 31, 2009, we have incurred losses of approximately \$14.9 million. These losses are primarily due to selling, general and administrative and research and development expenses incurred in connection with developing and seeking regulatory approval for our lead drug, Ketotransdel®. Historically, our operations have been financed through capital contributions and debt and equity financings.

As of December 31, 2009, we had approximately \$1.6 million in cash and cash equivalents. In May 2008, we completed a private placement to accredited investors, where we raised gross proceeds of approximately \$4.0 million (net of legal fees aggregating \$22,470) from the issuance of 1,818,180 shares of common stock and detachable warrants to purchase 227,272 shares of our common stock at a cash exercise price of \$4.40 per share and a cashless exercise price of \$5.50 per share.

We have limited funds to support our operations. We have prepared our consolidated financial statements in this Form 10-K on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Our continuation as a going concern subsequent to the second quarter of 2010 is dependent on our ability to obtain additional financing to fund the continued operation of our business model for a long enough period to achieve profitable operations. As of December 31, 2009, with our current cash and cash equivalents position, we have forecasted and anticipate having adequate resources in order to execute a portion of our operating plan into the second quarter of 2010, which would include final payments for the Phase 3 clinical study completed in 2009 and general and administrative expenses. However, in order to conduct the second Phase 3 trial and the other routine supportive safety studies that are required in order to obtain regulatory approval to market Ketotransdel®, we will need to secure additional funds. We intend to seek additional financing to fund the clinical requirements for Ketotransdel® as well as to continue our cosmetic/cosmeceutical program and to explore co-development opportunities. If adequate financing is not available, we will not be able to meet the FDA's requirements to obtain regulatory approval to market Ketotransdel®.

We will be required to pursue sources of additional capital to fund our operations through various means, including equity or debt financing, funding from a corporate partnership or licensing arrangement or any similar financing. Future financings through equity investments are likely to be dilutive to existing stockholders. Also, the terms of securities we may issue in future capital transactions may be more favorable for our new investors. Newly issued securities may include preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have additional dilutive effects. In addition, if we raise additional funds through collaboration and licensing arrangements, we may be required to relinquish potentially valuable rights to our product candidates or proprietary technologies, or grant licenses on terms that are not favorable to us. Further, we may incur substantial costs in pursuing future capital and/or financing, including investment banking fees, legal fees, accounting fees, printing and distribution expenses and other costs. We may also be required to recognize non-cash expenses in connection with certain securities we may issue, such as convertible notes and warrants, which will adversely impact our financial results.

The significant downturn in the overall economy and the ongoing disruption in the capital markets has reduced investor confidence and negatively affected investments, generally and specifically, in the pharmaceutical industry. In addition, the fact that we are not profitable and need significant additional funds to complete our clinical trials, could further impact the availability or cost of future financings. As a result, there can be no assurance that additional funds will be available when needed from any source or, if available, will be available on terms that are acceptable to us. If we are unable to raise funds to satisfy our capital needs on a timely basis, we may be required to cease operations.

As reported in the Report of Independent Registered Public Accounting Firm on our December 31, 2009 consolidated financial statements, we have incurred recurring losses from operations and have an accumulated deficit that raises substantial doubt about our ability to continue as a going concern. In addition, since we do not have adequate cash resources, as of the date of the Report, to support our operating plan for the next twelve to fifteen months, this too factored into our public accounting firm's doubt we will continue as a going concern.

Critical Accounting Policies

We rely on the use of estimates and make assumptions that impact our financial condition and results. These estimates and assumptions are based on historical results and trends as well as our forecasts as to how results and trends might change in the future. Although we believe that the estimates we use are reasonable, actual results could differ from those estimates.

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We believe that the accounting policies described below are critical to understanding our business, results of operations and financial condition because they involve more significant judgments and estimates used in the preparation of our consolidated financial statements. An accounting policy is deemed to be critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made, and any changes in the different estimates that could have been used in the accounting estimates that are reasonably likely to occur periodically could materially impact our consolidated financial statements.

Our most critical accounting policies and estimates that may materially impact our results of operations include:

Stock-Based Compensation. All share-based payments to employees, including grants of employee stock options and restricted stock grants, to be recognized in the financial statements based upon their fair values. We use the Black-Scholes option pricing model to estimate the grant-date fair value of share-based awards. Fair value is determined at the date of grant. The financial statement effect of forfeitures is estimated at the time of grant and revised, if necessary, if the actual effect differs from those estimates.

Our accounting policy for equity instruments issued to consultants and vendors in exchange for goods and services follows Financial Accounting Standards Board (“FASB”) guidance. As such, the value of the applicable stock-based compensation is periodically remeasured and income or expense is recognized during the vesting terms. The measurement date for the fair value of the equity instruments issued is determined at the earlier of (i) the date at which a commitment for performance by the consultant or vendor is reached or (ii) the date at which the consultant or vendor’s performance is complete. In the case of equity instruments issued to consultants, the fair value of the equity instrument is recognized over the term of the consulting agreement. An asset acquired in exchange for the issuance of fully vested, nonforfeitable equity instruments should not be presented or classified as an offset to equity on the grantor’s balance sheet once the equity instrument is granted for accounting purposes. Accordingly, we record the fair value of nonforfeitable equity instruments issued for future consulting services as prepaid consulting fees in our consolidated balance sheets.

Off-Balance Sheet Arrangements

Since our inception, except for standard operating leases, we have not engaged in any off-balance sheet arrangements, including the use of structured finance, special purpose entities or variable interest entities.

Recent Accounting Pronouncements

In the third quarter of 2009, the FASB issued the FASB Accounting Standards Codification (the “Codification”). The Codification is the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in preparation of financial statements in conformity with generally accepted accounting principles in the United States. All accounting guidance that is not included in the Codification will be considered to be non-authoritative. The FASB will issue Accounting Standard Updates, or ASUs, which will serve only to update the Codification, provide background information about the guidance and provide the basis for conclusions on changes in the Codification. ASUs are not authoritative in their own right. The Codification does not change GAAP and did not have an effect on our financial position or results of operations.

Other recent accounting pronouncements issued by the FASB did not or are not believed by management to have a material impact on our present or future consolidated financial statements.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements and supplementary data required by this item are included in Part IV, Item 15 of this Report.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURES

None.

Item 9A (T). CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed with the Commission is recorded, processed, summarized and reported within the time periods specified in the Commission’s rules and forms and that such information is accumulated and communicated to our management, including our acting chief executive officer and chief financial officer, as appropriate, to allow for timely decisions regarding required disclosure. In

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designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Commission Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our acting chief executive officer and the chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the year covered by this annual report on Form 10-K. Based on the foregoing, our acting chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed by, or under the supervision of, the acting chief executive officer and chief financial officer and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Our evaluation of internal control over financial reporting includes using the framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"), an integrated framework for the evaluation of internal controls issued by COSO, to identify the risks and control objectives related to the evaluation of our control environment.

Based on our evaluation under the frameworks described above, our management has concluded that our internal control over financial reporting was effective as of December 31, 2009.

This annual report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation requirements by our independent registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit us to provide only management's report in this annual report.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management, including our acting chief executive officer and our chief financial officer, do not expect that our disclosure controls or our internal control over financial reporting will prevent or detect all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of controls effectiveness to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

ITEM 9B. OTHER INFORMATION

None.

PART III**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE****Executive Officers and Directors**

The following table sets forth information regarding our executive officers and directors as of March 15, 2010:

<u>Name</u>	<u>Age</u>	<u>Position</u>
John T. Lomoro	40	Acting Chief Executive Officer and Chief Financial Officer
Joachim Schupp, M.D.	57	Chief Medical Officer
Terry Nida	61	Chief Business Officer
Jeffrey J. Abrams, M.D.	62	Chairman of the Board
Anthony S. Thornley	63	Director
Lynn C. Swann	57	Director

Our directors hold office for one-year terms until the earlier of their death, resignation or removal or until their successors have been elected and qualified. Our officers are elected annually by the board of directors and serve at the discretion of the board. In addition to the information presented below regarding each director's specific experience, qualifications, attributes and skills that led our Board to the conclusion that he should serve as a director, we also believe that all of our directors and director nominees have a reputation for integrity, honesty and adherence to high ethical standards. They each have demonstrated business acumen and an ability to exercise sound judgment, as well as a commitment of service to our company and our Board.

Biographies

John T. Lomoro has been our acting chief executive officer since February 2010 and our chief financial officer since the merger with Transdel Pharmaceuticals Holdings, Inc. on September 17, 2007 and the chief financial officer of Transdel Pharmaceuticals Holdings, Inc. since September 2007. From 2004 to 2007, Mr. Lomoro was the director of North American accounting for Carl Zeiss Vision Inc., a privately held international optical lens manufacturing and distribution company. From 2003 to 2004, Mr. Lomoro was the manager of financial reporting and planning for dj Orthopedics, Inc., a publicly traded medical device manufacturing company. From 2002 to 2003, Mr. Lomoro was a corporate accounting manager at Wireless Knowledge, Inc. Mr. Lomoro's experience also includes approximately five years in public accounting as an audit manager at Ernst & Young LLP. Mr. Lomoro received a B.S. degree in accounting from St. Cloud State University of Minnesota and is a certified public accountant.

Joachim Schupp, M.D. has been the chief medical officer of Transdel since October 2009. Dr. Schupp has almost 25 years of leadership experience in the pharmaceutical industry. Prior to Transdel, Dr. Schupp was the Vice President of Medical Affairs at Adventrx Pharmaceuticals and Vice President of Clinical Data Services at ProSano Corporation. For almost two decades, Dr. Schupp held various leadership positions in clinical development and global project management with Novartis Pharmaceuticals (and former Ciba-Geigy AG) in Switzerland. He provided medical support for the life-cycle management of Ciba-Geigy's lead product Voltaren® (diclofenac) and his international cross-functional project team leadership role in multiple therapeutic areas is credited for the development and market approval of several drugs, including Femara®, Apligraf®, and Exjade®. Dr. Schupp received his M.D. from the Free University of Berlin in Germany and he served on the faculty at the University of Pretoria, South Africa in Internal Medicine and Rheumatology.

Terry Nida has been the Chief Business Officer of Transdel since February 2010. He has over 30 years of pharmaceutical industry experience and has developed an established and successful track record in negotiating and closing global and regional joint development, licensing, distribution, sales and marketing partnerships and supply agreements with multiple pharmaceutical companies. Prior to Transdel, Mr. Nida worked as an Executive Consultant for pharmaceutical and biotechnology companies, including such responsibilities as business development. From 2006 to 2008, Mr. Nida held positions as Chief Operating Officer at Urogen Pharmaceuticals and from 1995 to 2006 was the Vice President Corporate Development, Marketing and Sales at VIVUS, Inc. Prior to VIVUS, Mr. Nida held senior management positions with Carrington Laboratories, Centocor and started his career with Bristol Myers. Mr. Nida received his B.S. and M.A. degrees from Wichita State University.

Jeffrey J. Abrams, M.D., MPH, has been the Chairman of the Board since February 2010 and a director since the merger with Transdel Pharmaceuticals Holdings, Inc. on September 17, 2007. Dr. Abrams has been a director of Transdel Pharmaceuticals Holdings, Inc. since 1998. Prior to joining Transdel Pharmaceuticals Holdings, Inc., Dr. Abrams was a practicing primary care clinician for over twenty years. Dr. Abrams received a B.A. from the State University of New York at Buffalo, an M.D. from the Albert Einstein College of Medicine and an M.P.H. from San Diego State University. Dr. Abrams was one of the co-founders of our company, and we believe that his qualifications to sit on our Board include his scientific and technical knowledge of our Transdel™ technology and our lead product candidate, Ketotransdel® and his years of experience as a practicing primary care clinician.

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Anthony S. Thornley has been a director since November 2007. Mr. Thornley currently serves on the Board of Directors at Callaway Golf Incorporated, Cavium Networks Inc. and Airvana Inc. From February 2002 to June 2005, he served as President and Chief Operating Officer of QUALCOMM Incorporated, a wireless communication technology and integrated circuit company. From July 2001 to February 2002 he served as Chief Financial Officer and Chief Operating Officer of QUALCOMM, and from March 1994 to February 2002, he was the Chief Financial Officer of QUALCOMM. Prior to joining QUALCOMM, Mr. Thornley was with Nortel Networks, a telecommunications equipment manufacturer, for sixteen years in various financial and information systems management positions, including Vice President Finance and IS, Public Networks, Vice President Finance NT World Trade and Corporate Controller Nortel Limited. He has also worked for Coopers and Lybrand in public accounting. Mr. Thornley received his BS degree in Chemistry from the University of Manchester, England. We believe Mr. Thornley's qualifications to sit on our Board include his years of experience as an executive officer with leading national companies, including his service as President, Chief Operating Officer and Chief Financial Officer of QUALCOMM, his service on other public company boards and committees, and his status as a financial expert under Sarbanes-Oxley.

Lynn C. Swann has been a director since November 2008. He is president of Swann, Inc., a consulting firm specializing in marketing and communications and managing director of Diamond Edge Capital Partners, LLC, a New York-based finance company. Mr. Swann currently serves on the Board of Directors of H.J. Heinz Company, Hershey Entertainment and Resorts Company, Harrah's Entertainment, Inc. and Empower Software. He was also chairman of the President's Council on Physical Fitness and Sports from 2002-2005. A former all-pro wide receiver for the Pittsburgh Steelers and 2001 Hall of Famer, he spent twenty-nine years with ABC Sports as a sports analyst and broadcaster before retiring in 2006. Active in community affairs, Mr. Swann is a spokesman, former board president and current director of Big Brothers Big Sisters of America, and former director of the Pittsburgh Ballet Theatre. Mr. Swann holds a B.A. degree in public relations from the University of Southern California. We believe Mr. Swann's qualifications to sit on our Board include his years of experience as a business consultant, his expertise in marketing and communications, investment banking and financial advisory services and his service on other public company boards and committees.

There are no family relationships among our directors and executive officers.

Section 16(a) Beneficial Ownership Reporting Compliance

No person who, during the fiscal year ended December 31, 2009, was one of our directors or officers, or beneficial owner of more than ten percent of our Common Stock (which is the only class of securities registered under Section 12 of the Exchange Act), failed to file on a timely basis reports required by Section 16 of the Exchange Act during such fiscal year. The foregoing is based solely upon our review of Forms 3 and 4 relating to the most recent fiscal year as furnished to us under Rule 16a-3(d) under the Exchange Act, and Forms 5 and amendments thereto furnished to us with respect to our most recent fiscal year, and any representation received by us from any reporting person that no Form 5 is required.

Code of Ethics

On December 6, 2007, we adopted an amended and restated code of ethics and business conduct that applies to our principal executive officer, principal financial officer, or persons performing similar functions and all other employees. A copy of the amended and restated code of ethics and business conduct can be found on our website at www.transdelpharma.com.

Director Independence

We believe that all of our directors are each an "independent director," as that term is defined by applicable listing standards of The Nasdaq Stock Market and Securities and Exchange Commission rules, including the rules relating to the independence standards of an audit committee and the non-employee director definition of Rule 16b-3 promulgated under the Exchange Act.

Board Committees

Our Board currently performs the functions and duties generally performed by separately constituted audit, compensation and nominating and corporate governance committees. We intend to recruit additional directors to serve on our Board, and at such time, the Board will form separate Board committees. We intend that a majority of our directors will be independent directors, and that our Board and Board committees will meet the corporate governance requirements imposed by the Nasdaq Stock Market although we are not required to comply with such requirements until we seek listing on the Nasdaq Stock Market. Additionally, the Board will direct each committee to adopt a charter to govern its duties and actions.

Our Board does not have a policy regarding the separation of the roles of Chief Executive Officer and Chairman of the Board as the Board believes it is in the best interest of the Company to make that determination based on the position and direction of the Company and the membership of the Board. The Board has determined that having an independent director serve as Chairman is in the best interests of the Company and its stockholders at this time. This structure ensures a greater role for the independent directors in the oversight of the company and active participation of the independent directors in setting agendas and establishing Board priority

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and procedures, while allowing our acting Chief Executive Officer to focus on the management of the Company's day-to-day operations.

Audit Review. Our Board is responsible for assuring the integrity of our financial control, audit and reporting functions and reviews with our management and our independent auditors the effectiveness of our financial controls and accounting and reporting practices and procedures. In addition, our Board reviews the qualifications of our independent auditors, is responsible for their appointment, compensation, retention and oversight and reviews the scope, fees and results of activities related to audit and non-audit services. Our board has determined that Mr. Thornley is an audit committee financial expert.

Executive Compensation. Our Board reviews and sets our general compensation policies and executive compensation, including officer salary levels, incentive compensation programs and share-based compensation. Our Board also has the exclusive authority to administer our 2007 Incentive Stock and Awards Plan. Juliet Singh, our former Chairman, President and Chief Executive Officer, abstained from any board discussions with respect to her compensation during the time she served as an executive of our company.

Nominating and Corporate Governance. Our Board is responsible for identifying and selecting potential candidates for our Board. Our Board reviews the credentials of proposed members of the Board, either in connection with filling vacancies or the election of directors at each annual meeting of stockholders. The Board will consider qualified nominees recommended by stockholders. The Board intends to periodically assess how well it is performing, and make recommendations regarding corporate governance matters and practices. Nominees for director are selected on the basis of their depth and breadth of experience, integrity, ability to make independent analytical inquiries, understanding our business environment and willingness to devote adequate time to their board duties.

We do not have a formal policy with regard to the consideration of diversity in identifying director nominees, but the Board strives to nominate directors with a variety of complementary skills so that, as a group, the Board will possess the appropriate talent, skills and expertise to oversee the Company's business.

There has been no change to the procedures by which security holders may recommend nominees to our Board of Directors.

Risk Oversight. The Board's role in the Company's risk oversight process includes receiving regular reports from members of management on areas of material risk to the Company, including operational, financial, legal and regulatory. The Board receives these reports from the appropriate "risk owner" within the organization to enable it to understand our risk identification, risk management and risk mitigation strategies. The Board encourages management to promote a corporate culture that incorporates risk management into the Company's day-to-day business operations.

ITEM 11. EXECUTIVE COMPENSATION

The following table sets forth for the periods presented certain information concerning all compensation earned by or awarded or paid to our named executive officers serving as of December 31, 2009.

Summary Compensation Table

Name	Year	Salary (\$)	Stock Awards (\$)	Option Awards (\$)(1)	Total (\$)
Juliet Singh, Ph.D., (2) President and Chief Executive Officer	2009	225,000	—	210,361	435,361
	2008	210,000	—	140,167	350,167
John T. Lomoro, Chief Financial Officer	2009	170,000	—	105,181	275,181
	2008	160,000	—	70,083	230,083
Joachim P.H. Schupp, M.D. (3) Chief Medical Officer	2009	40,269	—	220,404	260,673

- (1) Reflects the dollar amount of the grant date fair value of awards granted during the respective fiscal years, measured in accordance with guidance from the Financial Accounting Standards Board ("FASB"). As a result of changes to the rules relating to these disclosures, the fiscal year 2008 amounts have been revised from the amounts reported in our previous Form 10-K to reflect the grant date fair value of the options granted, rather than the expense recognized for financial reporting purposes. The assumptions used in the calculations for these amounts are described in Note 7 to our consolidated financial statements included herein.

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- (2) Effective February 17, 2010, the Board of Directors of the Company accepted the resignation of Dr. Juliet Singh as Chief Executive Officer and as a director on the Board.
- (3) On October 12, 2009, Joachim P.H. Schupp, M.D. was appointed as our Chief Medical Officer. In association with his appointment, Dr. Schupp was awarded an option for 215,000 shares of common stock at an exercise price of \$1.70, which vests quarterly over a three year period. Prior to his appointment, Dr. Schupp was retained by the company as a consultant in April 2009. Not included above is the compensation earned by Dr. Schupp as a consultant for the company which included a monthly cash retainer and an option for 85,000 shares of common stock at an exercise price of \$1.60 that was awarded to him in June 2009. This option vests over a one-year period and had a grant date fair value of approximately \$97,000 (as adjusted for modifications made to this award upon appointment as our Chief Medical Officer).

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth certain information concerning outstanding stock awards held by our named executive officers as of December 31, 2009.

Name	Option Awards (1)		Option Exercise Price (\$)	Option Expiration Date
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable		
Juliet Singh, Ph.D. (2)	33,333	166,667	1.60	6/18/2019
	100,000	100,000	2.00	4/23/2018
	10,000	—	2.00	9/16/2017
	150,000	50,000	2.00	9/16/2017
John T. Lomoro	16,667	83,333	1.60	6/18/2019
	50,000	50,000	2.00	4/23/2018
	112,500	37,500	2.00	9/16/2017
Joachim P.H. Schupp, M.D.	—	215,000	1.70	10/14/2019
	55,000	30,000	1.60	6/18/2019

(1) — All options vest on a quarterly basis over their respective vesting term.

(2) — As noted below, as of February 17, 2010, in accordance with the separation agreement entered into with Dr. Singh, 300,000 stock options that were unvested as of the resignation date became fully vested.

Employment Agreement

We entered into an employment agreement with Juliet Singh, Ph.D. to serve as our chief executive officer. Pursuant to this employment agreement, Dr. Singh was entitled to receive an annual base salary of \$195,000, subject to annual reviews by our board of directors. Dr. Singh was also entitled to a performance-based bonus to be comprised of cash and/or equity compensation. Subject to the terms of Dr. Singh's employment agreement, the Board of Directors increased Dr. Singh's salary to \$225,000 effective July 1, 2008 and granted a stock option for 200,000 shares of common stock at an exercise price of \$2.00.

Effective February 17, 2010, the Board of Directors accepted the resignation of Dr. Juliet Singh as Chief Executive Officer and as a director on the Board. In connection with Dr. Singh's resignation, we entered into a separation agreement that provides her with one year of continued salary in accordance with the terms of her existing employment agreement as well as the accelerated vesting of 300,000 stock options previously granted. In addition, Dr. Singh will have three years from the date of her resignation to exercise her vested options. We also entered into a consulting agreement with Dr. Singh, which provides that she has agreed to provide consulting services to us at the request and the direction of the Board. Dr. Singh will be entitled to \$5,000 per month for her consulting services.

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2007 Incentive Stock and Awards Plan

On September 17, 2007, our board of directors and stockholders adopted the 2007 Incentive Stock and Awards Plan (the “2007 Plan”). The purpose of the 2007 Plan is to provide an incentive to attract and retain directors, officers, consultants, advisors and employees whose services are considered valuable, to encourage a sense of proprietorship and to stimulate an active interest of such persons into our development and financial success. Under the 2007 Plan, we are authorized to issue incentive stock options intended to qualify under Section 422 of the Internal Revenue Code of 1986, as amended, non-qualified stock options, stock appreciation rights, performance shares, restricted stock and long term incentive awards. The 2007 Plan will be administered by our board of directors until such time as such authority has been delegated to a committee of the board of directors. Effective November 5, 2008, the shareholders approved an amendment to the 2007 Plan to increase the number of authorized shares to 3,000,000 from 1,500,000.

As of March 15, 2010, there were outstanding options to purchase 1,905,000 shares of our common stock, 220,313 shares of restricted stock outstanding under the 2007 Plan, and 774,687 shares of our common stock available for issuance under the 2007 Plan.

Director Compensation

The following table sets forth for the periods presented certain information concerning all compensation earned by or awarded or paid to the members of our board of directors serving on December 31, 2009.

Name	Year	Fees Earned or Paid in Cash (\$)	Stock Awards \$(1)(6)	Option Awards \$(2)(6)	Total (\$)
Juliet Singh, Ph.D.	2009	\$ —	\$ —	\$ —	\$ —
	2008	\$ —	\$ —	\$ —	\$ —
Jeffrey J. Abrams, M.D. (3)	2009	\$ —	\$ —	\$ —	\$ —
	2008	\$ —	\$ —	\$ 37,300	\$ 37,300
Anthony S. Thornley (4)	2009	\$ —	\$ —	\$ —	\$ —
	2008	\$ —	\$ —	\$ 37,300	\$ 37,300
Lynn C. Swann (5)	2009	\$ —	\$ —	\$ —	\$ —
	2008	\$ —	\$ 17,500	\$ 48,288	\$ 65,788

- (1) In November 2008, the Company awarded 25,000 shares of its restricted common stock to Mr. Swann upon his appointment to the Board of Directors.
- (2) In November 2008, each member of the Board of Directors, except Dr. Singh, was awarded an option for 80,000 shares of common stock at an exercise price of \$0.70, which vests quarterly over a five year period. Also, in November 2008, upon his appointment, the Board of Directors granted Mr. Swann an option to purchase 25,000 shares of common stock at an exercise price of \$0.70, which vested quarterly over a 1 year period.
- (3) As of December 31, 2009, Dr. Abrams held 90,000 stock options, of which 26,000 were vested.
- (4) As of December 31, 2009, Mr. Thornley held 90,000 stock options, of which 26,000 were vested.
- (5) As of December 31, 2009, Mr. Swann held 105,000 stock options and 25,000 shares of restricted common stock, of which 41,000 and 25,000 were vested, respectively.
- (6) Reflects the dollar amount of the grant date fair value of awards granted during the respective fiscal years, measured in accordance with FASB guidance. As a result of changes to the rules relating to these disclosures, the fiscal year 2008 amounts have been revised from the amounts reported in our previous Form 10-K to reflect the grant date fair value of the options or stock granted, rather than the expense recognized for financial reporting purposes. The assumptions used in the calculations for these amounts are described in Note 7 to our consolidated financial statements included herein.

[Table of Contents](#)**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The following table sets forth certain information as of March 15, 2010, regarding the beneficial ownership of our common stock by (i) each person or entity who, to our knowledge, owns more than 5% of our common stock; (ii) our named executive officers; (iii) each director; and (iv) all of our executive officers and directors as a group. Unless otherwise indicated in the footnotes to the following table, each person named in the table has sole voting and investment power with respect to shares of common stock and the address for the current officers and directors is c/o Transdel Pharmaceuticals, Inc. 4225 Executive Square, Suite 485, La Jolla, California 92037. Shares of common stock subject to options, warrants, or other rights currently exercisable or exercisable within 60 days of March 15, 2010, are deemed to be beneficially owned and outstanding for computing the share ownership and percentage of the stockholder holding such options, warrants or other rights, but are not deemed outstanding for computing the percentage of any other stockholder.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage Beneficially Owned (1)
Juliet Singh, Ph.D.	2,564,125(6)	15.8%
Jeffrey J. Abrams, M.D.	1,592,500(2)	10.2%
The Abrams Family Trust	1,562,500(3)	—
Anthony S. Thornley	103,400(4)	*
Lynn C. Swann	70,000(5)	*
John T. Lomoro	216,667(7)	1.4%
Joachim Schupp, M.D.	105,833(7)	*
Terry Nida	—	—
Joseph Grasela(8)	1,171,875	7.5%
John C. Grasela(8)	1,171,875	7.5%
All executive officers and directors as a group (5 persons)	2,088,400	13.0%

* less than 1%

- (1) Based on 15,652,061 shares of our common stock issued and outstanding as of March 15, 2010.
- (2) Jeffrey J. Abrams, M.D., a director, is a trustee of the Abrams Family Trust. Dr. Abrams has sole voting and investment control with respect to the shares of common stock owned by the Abrams Family Trust. Includes 30,000 shares of common stock issuable upon the exercise of stock options.
- (3) Dr. Abrams is a trustee of the Abrams Family Trust, which owns 1,562,500 shares of our common stock.
- (4) Includes 12,500 and 30,000 shares of common stock issuable upon the exercise of warrants and stock options, respectively.
- (5) Includes 45,000 shares of common stock issuable upon the exercise of stock options and 25,000 shares of restricted stock.
- (6) Includes 610,000 shares of common stock issuable upon the exercise of stock options.
- (7) Total amount includes shares of common stock issuable upon the exercise of stock options.
- (8) Joseph Grasela and John C. Grasela are adult siblings living in separate households.

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The following table summarizes our compensation plans under which our equity securities are authorized for issuance as of December 31, 2009:

EQUITY COMPENSATION PLAN INFORMATION (1)

	Number of Shares to be Issued Upon Exercise of Outstanding Stock Options	Weighted- Average Exercise Price of Outstanding Stock Options	Number of Shares Remaining Available for Future Issuance Under Equity Compensation Plans
Equity compensation plans approved by security holders	1,605,000	\$ 1.64	1,074,687
Equity compensation plans not approved by security holders	5,000	2.00	—
Total	1,610,000	\$ 1.64	1,074,687

(1) See footnote 7 in the consolidated financial statements included herein for information related to the equity compensation plans.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

Except for those noted below, we have not engaged in any transaction since January 1, 2008 in which the amount involved exceeds the lesser of \$120,000 or 1% of the average of our total assets at year end for fiscal 2008 and 2009 and in which any of our directors, named executive officers or any holder of more than 5% of our common stock, or any member of the immediate family of any of these persons or entities controlled by any of them, had or will have a direct or indirect material interest.

In February 2007, prior to the Merger, our Board of Directors approved a payment of 12.5% of any proceeds we may receive from an action we had initiated against a prior law firm, not to exceed \$100,000, to be paid each to Drs. Singh and Abrams for their monetary contributions and uncompensated time commitment over a period of approximately four years related to pursuing this matter and other amounts paid on our behalf. On February 5, 2008, as a result of mediation, we reached a settlement agreement with the law firm. Although the law firm did not admit to any liability or wrongdoing, they desired to resolve the dispute and therefore, agreed to pay us \$750,000. In exchange for the settlement, the law firm, any other parties involved in the mediation and us released and waived any future claims against each other, whether known or unknown at the time of the settlement. In accordance with our February 2007 board approved payments, \$93,750 was paid to Global Strategic Medical Consulting Inc. of which the sole shareholder of this entity is our former Chief Executive Officer, Dr. Juliet Singh, and \$93,750 was paid to The Abrams Family Trust of which our director, Jeffrey Abrams, M.D., is the trustee, from our settlement with the law firm.

Director and Officer Indemnification Agreements

In addition to the indemnification provisions contained in our charter documents, we generally enter into separate indemnification agreements with our directors and officers. These agreements require us, among other things, to indemnify the director or officer against specified expenses and liabilities, such as attorneys' fees, judgments, fines and settlements, paid by the individual in connection with any action, suit or proceeding arising out of the individual's status or service as our director or officer, other than liabilities arising from willful misconduct or conduct that is knowingly fraudulent or deliberately dishonest, and to advance expenses incurred by the individual in connection with any proceeding against the individual with respect to which the individual may be entitled to indemnification by us.

Executive and Director Compensation

Please see the sections titled "Executive Compensation" and "Director Compensation" for information regarding the compensation paid to our executive officers and directors.

Separation Agreement and General Release

Effective February 17, 2010, the Board of Directors accepted the resignation of Dr. Juliet Singh as Chief Executive Officer and as a director on the Board. In connection with Dr. Singh's resignation, we entered into a separation agreement that provides her with one year of continued salary in accordance with the terms of her existing employment agreement as well as the accelerated vesting of 300,000 stock options previously granted. In addition, Dr. Singh will have three years from the date of her resignation to exercise her vested options. We also entered into a consulting agreement with Dr. Singh, which provides that she has agreed to provide consulting services to us at the direction of the Board. Dr. Singh will be entitled to \$5,000 per month for her consulting services.

Company Policy Regarding Related Party Transactions

It is our policy that the disinterested members of our Board of Directors approve or ratify transactions involving directors, executive officers or principal stockholders or members of their immediate families or entities controlled by any of them in which they have a substantial ownership interest in which the amount involved may exceed the lesser of \$120,000 or 1% of the average of our total assets at year end and that are otherwise reportable under SEC disclosure rules. Such transactions include employment of immediate family members of any director or executive officer. Management advises the Board of Directors on a regular basis of any such transaction that is proposed to be entered into or continued and seeks approval.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Aggregate fees for professional services rendered to the company by KMJ Corbin & Company LLP for the years ended December 31, 2009 and 2008, were:

Audit Fees	<u>2009</u>	<u>2008</u>
	\$ 74,250	\$ 98,750

The *Audit Fees* for the years ended December 31, 2009 and 2008 were for professional services rendered for audits and quarterly reviews of our consolidated financial statements, and assistance with reviews of registration statements and documents filed with the SEC. There were no Audit-Related Fees, Tax Fees or All Other Fees billed by or paid to our principal accountant during the years ended December 31, 2009 and 2008.

Our Board of Directors pre-approves all services to be provided by KMJ Corbin & Company LLP. KMJ Corbin & Company LLP performed no services, and no fees were incurred or paid, relating to financial information systems design and implementation. All fees paid to KMJ Corbin & Company LLP for fiscal 2009 and 2008 were pre-approved by our Board of Directors.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

- (a) List of the following documents filed as part of the report:
- (1) See the index to our consolidated financial statements on page F-1 for a list of the financial statements being filed herein.
 - (2) All financial statement schedules are omitted because they are not applicable or the required information is shown in the consolidated financial statements or other notes thereto.
 - (3) See the Exhibits under Item 15(b) below for all Exhibits being filed or incorporated by reference herein.
- (b) Exhibits:

<u>Exhibit No.</u>	<u>Description</u>
2.1	Agreement and Plan of Merger, dated as of September 17, 2007, by and among Transdel Pharmaceuticals, Inc., Transdel Pharmaceuticals Holdings, Inc. and Trans-Pharma Acquisition Corp. Incorporation (incorporated herein by reference to Exhibit 2.1 the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on September 21, 2007)
3.1	Amended and Restated Certificate of Incorporation (incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission September 13, 2007)
3.2	Amended and Restated Bylaws (incorporated herein by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission September 13, 2007)

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<u>Exhibit No.</u>	<u>Description</u>
10.1	Form of September 2007 and October 2007 Private Offering Subscription Agreement (incorporated herein by reference to Exhibit 10.1 the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on September 21, 2007)
10.2	Form of Warrant to purchase Common Stock (incorporated herein by reference to Exhibit 10.2 the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on September 21, 2007)
10.3	Registration Rights Agreement dated October 10, 2007, by and between Transdel Pharmaceuticals, Inc. and each of the investors signatory thereto (incorporated herein by reference to Exhibit 10.3 the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on September 21, 2007)
10.4	Placement Agent Agreement, dated September 17, 2007, between Transdel Pharmaceuticals Holdings, Inc. and Granite Financial Group, LLC (incorporated herein by reference to Exhibit 10.5 the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on September 21, 2007)
10.5	Placement Agent Agreement, dated September 17, 2007, between Transdel Pharmaceuticals Holdings, Inc. and WFG Investments, Inc. (incorporated herein by reference to Exhibit 10.6 the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on September 21, 2007)
10.6	Placement Agent Agreement, dated September 17, 2007, by and between Transdel Pharmaceuticals Holdings, Inc. and Palladium Capital Advisors, LLC (incorporated herein by reference to Exhibit 10.7 the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on September 21, 2007)
10.7	Form of Directors and Officers Indemnification Agreement (incorporated herein by reference to Exhibit 10.8 the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on September 21, 2007)
10.8	Assignment of Employment Agreement, dated September 17, by and among Transdel Pharmaceuticals Holdings, Inc., Transdel Pharmaceuticals, Inc. and Juliet Singh, Ph.D. (incorporated herein by reference to Exhibit 10.9 the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on September 21, 2007)
10.9	Employment Agreement, dated June 27, 2007, by and between Transdel Pharmaceuticals Holdings, Inc. and Juliet Singh, Ph.D. (incorporated herein by reference to Exhibit 10.10 the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on September 21, 2007)
10.10	Transdel Pharmaceuticals, Inc. 2007 Incentive Stock and Awards Plan (incorporated herein by reference to Exhibit 10.11 the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on September 21, 2007)
10.11	Form of 2007 Incentive Stock Option Agreement (incorporated herein by reference to Exhibit 10.12 the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on September 21, 2007)
10.12	Form of 2007 Non-Qualified Stock Option Agreement (incorporated herein by reference to Exhibit 10.13 the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on September 21, 2007)
10.13	Stock Purchase Agreement, dated as of September 17, 2007, by and between Transdel Pharmaceuticals, Inc. and Rolf Harms. (incorporated herein by reference to Exhibit 10.14 to the Registration Statement on Form SB-2 of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on December 7, 2007)
10.14	Agreement of Conveyance, Transfer and Assignment of Assets and Assumption of Obligations, dated as of September 17, 2007, by and between Transdel Pharmaceuticals, Inc. and Bywater Resources Holdings Inc. (incorporated herein by reference to Exhibit 10.15 to the Registration Statement on Form SB-2 of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on December 7, 2007)
10.15	Form of Lock-Up Agreement (incorporated herein by reference to Exhibit 10.4 to the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on September 21, 2007)

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<u>Exhibit No.</u>	<u>Description</u>
10.16	Research and Development Services Agreement, dated October 11, 2007, by and between DPT Laboratories, Ltd. And Transdel Pharmaceuticals Holdings, Inc. (incorporated herein by reference to Exhibit 10.17 to the Registration Statement on Form SB-2 of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on December 7, 2007) (portions of this exhibit have been omitted pursuant to a request for confidential treatment)
10.17	Project Scope Document, effective May 30, 2007, by and between DPT Laboratories, Ltd. and Transdel Pharmaceuticals Holdings, Inc. (incorporated herein by reference to Exhibit 10.18 to the Registration Statement on Form SB-2 of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on December 27, 2007) (portions of this exhibit have been omitted pursuant to a request for confidential treatment)
10.18	Form of May 2008 Private Offering Subscription Agreement (incorporated herein by reference to Exhibit 10.1 the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on May 15, 2008)
10.19	Form of Warrant to purchase Common Stock (incorporated herein by reference to Exhibit 10.2 the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on May 15, 2008)
10.20	Clinical Trial Services Agreement by and between Transdel Pharmaceuticals, Inc. and Cato Research Ltd. (incorporated herein by reference to Exhibit 10.1 in the Quarterly Report on Form 10-Q of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on August 11, 2008)
10.21	Separation Agreement and General Release between Juliet Singh and Transdel Pharmaceuticals, Inc. dated February 17, 2010
14	Amended and Restated Code of Ethics and Business Conduct (incorporated herein by reference to Exhibit 14 to the Registration Statement on Form SB-2 of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on December 7, 2007)
21	List of Subsidiaries (incorporated herein by reference to Exhibit 21 the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on September 21, 2007)
23.1	Consent of KMJ Corbin & Company LLP
31.1	Section 302 Certification of Principal Executive Officer and Principal Financial Officer
32	Section 906 Certification of Principal Executive Officer and Principal Financial Officer
(c)	Financial Statement Schedules

All financial statement schedules are omitted because they are not applicable or the required information is shown in the consolidated financial statements or other notes hereto.

SIGNATURES

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

TRANSDel PHARMACEUTICALS, INC.

By: /s/ John Lomoro
Name: John Lomoro
Title: Acting Chief Executive Officer and
Chief Financial Officer
Date: March 31, 2010

In accordance with the requirements of the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ John T. Lomoro</u> John T. Lomoro	Acting Chief Executive Officer and Chief Financial Officer (Principal Executive Officer and Principal Accounting and Financial Officer)	March 31, 2010
<u>/s/ Jeffrey J. Abrams</u> Jeffrey J. Abrams, M.D.	Chairman of the Board	March 31, 2010
<u>/s/ Anthony S. Thornley</u> Anthony S. Thornley	Director	March 31, 2010
<u>/s/ Lynn C. Swann</u> Lynn C. Swann	Director	March 31, 2010

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(A Development Stage Company)
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Transdel Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Transdel Pharmaceuticals, Inc. and subsidiaries (a development stage company) (the "Company") as of December 31, 2009 and 2008, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2009 and for the period from July 24, 1998 (date of inception) through December 31, 2009. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit on its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Transdel Pharmaceuticals, Inc. and subsidiaries as of December 31, 2009 and 2008, and the consolidated results of their operations and their cash flows for each of the two years in the period ended December 31, 2009 and for the period from July 24, 1998 (date of inception) through December 31, 2009 in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As more fully described in Note 4 to the consolidated financial statements, the Company has incurred significant operating losses, had negative cash flows from operations and has not recognized any revenues since inception and has a deficit accumulated during the development stage. These items raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 4. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amount and classification of liabilities that may result from the outcome of this uncertainty.

/s/ KMJ Corbin & Company LLP
KMJ Corbin & Company LLP

Costa Mesa, California
March 31, 2010

TRANSDel PHARMACEUTICALS, INC.
(A Development Stage Company)
CONSOLIDATED BALANCE SHEETS

	December 31,	
	2009	2008
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 1,589,773	\$ 5,111,031
Prepaid consulting fees	—	29,048
Prepaid expenses and other current assets	80,917	193,306
Total current assets	1,670,690	5,333,385
Computer equipment, net	1,394	2,450
Total assets	<u>\$ 1,672,084</u>	<u>\$ 5,335,835</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 681,014	\$ 556,390
Accrued Phase 3 expenses	343,633	141,952
Accrued expenses and payroll liabilities	70,226	65,651
Total current liabilities	<u>1,094,873</u>	<u>763,993</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized, none outstanding	—	—
Common stock, \$0.001 par value; 50,000,000 shares authorized, 15,652,061 and 15,556,283 shares outstanding as of December 31, 2009 and 2008, respectively	15,652	15,556
Additional paid-in capital	15,497,128	14,938,219
Deficit accumulated during the development stage	(14,935,569)	(10,381,933)
Total stockholders' equity	577,211	4,571,842
Total liabilities and stockholders' equity	<u>\$ 1,672,084</u>	<u>\$ 5,335,835</u>

See accompanying notes to these consolidated financial statements.

TRANSDel PHARMACEUTICALS, INC.
(A Development Stage Company)
CONSOLIDATED STATEMENTS OF OPERATIONS

	<u>Year Ended December 31,</u>		For the Period
	<u>2009</u>	<u>2008</u>	From July 24,
			1998 (Inception)
			Through
			December 31,
			2009
Operating expenses:			
Selling, general and administrative	\$ 1,598,369	\$ 1,755,731	\$ 6,437,681
Research and development	2,965,707	1,990,665	7,514,116
Operating loss	<u>4,564,076</u>	<u>3,746,396</u>	<u>13,951,797</u>
Other income (expense):			
Interest expense	—	—	(1,575,755)
Interest income	10,440	67,008	127,069
Gain on settlement	—	375,000	375,000
Gain on forgiveness of liabilities	—	—	89,914
Total other income (expense), net	<u>10,440</u>	<u>442,008</u>	<u>(983,772)</u>
Net loss	<u>\$ (4,553,636)</u>	<u>\$ (3,304,388)</u>	<u>\$ (14,935,569)</u>
Basic and diluted loss per common share	<u>\$ (0.29)</u>	<u>\$ (0.22)</u>	
Weighted average common shares outstanding, basic and diluted	<u>15,612,993</u>	<u>14,822,062</u>	

See accompanying notes to these consolidated financial statements.

TRANSDel PHARMACEUTICALS, INC.
(A Development Stage Company)
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2009 AND 2008 AND FOR THE PERIOD FROM JULY 24, 1998
(INCEPTION) THROUGH DECEMBER 31, 2009

	<u>Common Stock</u>		<u>Additional Paid-in Capital</u>	<u>Deficit Accumulated During the Development Stage</u>	<u>Total Stockholders' Equity (Deficit)</u>
	<u>Shares</u>	<u>Amount</u>			
Balance as of July 24, 1998 (Inception)	—	\$ —	\$ —	\$ —	\$ —
Estimated fair value of services contributed by stockholders	—	—	100,000	—	100,000
Net loss	—	—	—	(100,000)	(100,000)
Balance December 31, 1998	—	—	100,000	(100,000)	—
Estimated fair value of services contributed by stockholders	—	—	200,000	—	200,000
Net loss	—	—	—	(204,000)	(204,000)
Balance December 31, 1999	—	—	300,000	(304,000)	(4,000)
Issuance of common stock at \$0.006 per share in May and June 2000	937,500	937	5,063	—	6,000
Estimated fair value of services contributed by stockholders	—	—	200,000	—	200,000
Net loss	—	—	—	(213,092)	(213,092)
Balance December 31, 2000	937,500	937	505,063	(517,092)	(11,092)
Estimated fair value of services contributed by stockholders	—	—	200,000	—	200,000
Net loss	—	—	—	(208,420)	(208,420)
Balance December 31, 2001	937,500	937	705,063	(725,512)	(19,512)
Estimated fair value of services contributed by stockholders	—	—	200,000	—	200,000
Net loss	—	—	—	(228,217)	(228,217)
Balance December 31, 2002	937,500	937	905,063	(953,729)	(47,729)
Estimated fair value of services contributed by stockholders	—	—	200,000	—	200,000
Net loss	—	—	—	(207,196)	(207,196)
Balance December 31, 2003	937,500	937	1,105,063	(1,160,925)	(54,925)
Estimated fair value of services contributed by stockholders	—	—	400,000	—	400,000
Net loss	—	—	—	(508,226)	(508,226)
Balance December 31, 2004	937,500	937	1,505,063	(1,669,151)	(163,151)
Capital contributions	—	—	14,200	—	14,200
Issuance of common stock at \$0.006 per share in August 2005	2,453,125	2,453	13,247	—	15,700
Exercise of stock options at \$0.006 per share in August 2005	15,625	16	84	—	100
Estimated fair value of services contributed by stockholders	—	—	400,000	—	400,000

TRANSDel PHARMACEUTICALS, INC.
(A Development Stage Company)
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2009 AND 2008 AND FOR THE PERIOD FROM JULY 24, 1998
(INCEPTION) THROUGH DECEMBER 31, 2009

Net loss	—	—	—	(539,622)	(539,622)
Balance December 31, 2005	3,406,250	3,406	1,932,594	(2,208,773)	(272,773)
Capital contributions	—	—	48,600	—	48,600
Exercise of stock options at \$0.006 per share in June and July 2006	375,000	375	2,025	—	2,400
Estimated fair value of services contributed by stockholders	—	—	400,000	—	400,000
Net loss	—	—	—	(584,232)	(584,232)
Balance as of December 31, 2006	3,781,250	3,781	2,383,219	(2,793,005)	(406,005)
Issuance of common stock at \$0.006 per share during January through March 2007	3,984,374	3,985	21,515	—	25,500
Exercise of warrants and stock options at \$0.006 per share in April and August 2007	39,063	39	211	—	250
Capital contributions	—	—	105,907	—	105,907
Estimated fair value of services contributed by stockholders	—	—	175,000	—	175,000
Forgiveness of notes payable and interest	—	—	241,701	—	241,701
Issuance of restricted stock at a value of \$2.00 per share in August 2007	195,313	195	(195)	—	—
Issuance of common stock in connection with merger on September 17, 2007	1,849,993	1,850	(1,850)	—	—
Net proceeds from private placement offering issued at \$100,000 per unit in September and October 2007	2,071,834	2,072	3,835,719	—	3,837,791
Issuance of common stock related to conversion of Senior Convertible notes payable and accrued interest	1,530,177	1,530	1,528,647	—	1,530,177
Beneficial conversion feature upon conversion of Senior Convertible notes payable	—	—	1,530,177	—	1,530,177
Issuance of common stock and warrants for consulting services in September 2007 at a value of \$2.00 per share for stock transactions and \$100,000 per unit for stock and warrant transaction	275,000	275	549,725	—	550,000
Stock-based compensation	—	—	184,522	—	184,522
Net loss	—	—	—	(4,284,540)	(4,284,540)
Balance as of December 31, 2007	13,727,004	13,727	10,554,298	(7,077,545)	3,490,480
Net proceeds from private placement offering issued at \$110,000 per unit in May 2008 and final costs of 2007 private placement offering	1,818,180	1,818	3,939,483	—	3,941,301
Adjustment and issuance of common stock, warrant and stock options related to consulting services agreements	(13,901)	(14)	(117,979)	—	(117,993)
Issuance of restricted stock at a value of \$0.70 per share in November 2008	25,000	25	(25)	—	—
Stock-based compensation	—	—	562,442	—	562,442
Net loss	—	—	—	(3,304,388)	(3,304,388)
Balance as of December 31, 2008	15,556,283	15,556	14,938,219	(10,381,933)	4,571,842

See accompanying notes to these consolidated financial statements.

TRANSDel PHARMACEUTICALS, INC.
(A Development Stage Company)
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2009 AND 2008 AND FOR THE PERIOD FROM JULY 24, 1998
(INCEPTION) THROUGH DECEMBER 31, 2009

Issuance of common stock and stock options related to consulting services agreements	45,778	46	121,409	—	121,455
Exercise of stock options at \$0.99 per share in August 2009	50,000	50	49,450	—	49,500
Stock-based compensation	—	—	388,050	—	388,050
Net loss	—	—	—	(4,553,636)	(4,553,636)
Balance as of December 31, 2009	<u>15,652,061</u>	<u>\$ 15,652</u>	<u>\$15,497,128</u>	<u>\$(14,935,569)</u>	<u>\$ 577,211</u>

See accompanying notes to these consolidated financial statements.

TRANSDel PHARMACEUTICALS, INC.
(A Development Stage Company)
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,		For The Period From July 24, 1998 (Inception) Through December 31, 2009
	2009	2008	
Cash flows from operating activities:			
Net loss	\$ (4,553,636)	\$ (3,304,388)	\$ (14,935,569)
Adjustments to reconcile net loss to net cash used in operating activities:			
Estimated fair value of contributed services	—	—	2,475,000
Gain on forgiveness of liabilities	—	—	(89,914)
Amortization of prepaid consulting fees	29,048	341,708	572,008
Depreciation	1,056	704	1,760
Non-cash interest on notes payable	—	—	1,575,755
Stock-based compensation	509,505	562,442	1,256,468
Changes in operating assets and liabilities:			
Prepaid consulting costs	—	—	(140,000)
Prepaid expenses and other current assets	112,389	(147,702)	(80,917)
Accounts payable	124,624	(139,951)	770,928
Accrued Phase 3 expenses	201,681	141,952	343,633
Accrued expenses and payroll liabilities	4,575	11,750	70,226
Net cash used in operating activities	<u>(3,570,758)</u>	<u>(2,533,485)</u>	<u>(8,180,622)</u>
Cash flows from investing activities:			
Purchase of fixed assets	—	(3,154)	(3,154)
Net cash used in investing activities	<u>—</u>	<u>(3,154)</u>	<u>(3,154)</u>
Cash flows from financing activities:			
Proceeds from notes payable to stockholders	—	—	226,300
Proceeds from notes payable	—	—	1,500,000
Capital contributions	—	—	168,707
Net proceeds from purchase of common stock and exercise of warrants and stock options	49,500	—	99,450
Proceeds from Private Placements	—	3,941,301	7,779,092
Net cash provided by financing activities	<u>49,500</u>	<u>3,941,301</u>	<u>9,773,549</u>
Net change in cash and cash equivalents	(3,521,258)	1,404,662	1,589,773
Cash and cash equivalents, beginning of period	5,111,031	3,706,369	—
Cash and cash equivalents, end of period	<u>\$ 1,589,773</u>	<u>\$ 5,111,031</u>	<u>\$ 1,589,773</u>
Supplemental disclosure of cash flow information:			
Issuance of and adjustment to common stock and warrants to consulting firms for prepaid consulting fees	<u>\$ —</u>	<u>\$ 117,993</u>	<u>\$ 432,007</u>
Conversion of notes payable and accrued interest into common stock	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1,530,177</u>
Forgiveness of notes payable and accrued interest to shareholders	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 241,701</u>
Conversion of advances to notes payable to shareholders	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 196,300</u>

See accompanying notes to these consolidated financial statements.

TRANSDel PHARMACEUTICALS, INC.
(A Development Stage Company)
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Business Description

Transdel Pharmaceuticals, Inc. (“Transdel” or “Company”) is a specialty pharmaceutical company developing non-invasive, topically delivered products. The Company’s innovative patented Transdel™ cream formulation technology is designed to facilitate the effective penetration of a variety of products through the tough skin barrier. Ketotransdel®, the Company’s lead pain product, utilizes the Transdel™ platform technology to deliver the active drug, ketoprofen, a non-steroidal anti-inflammatory drug (“NSAID”), through the skin directly into the underlying tissues where the drug exerts its well-known anti-inflammatory and analgesic effects. The Company intends to leverage its Transdel™ platform technology to expand and create a portfolio of topical products for a variety of indications.

Note 2. Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (“GAAP”), and with the rules and regulations of the Securities and Exchange Commission (“SEC”) related to an annual report on Form 10-K. The consolidated financial statements include the accounts of Transdel Pharmaceuticals Inc. and its wholly-owned subsidiary, Transdel Pharmaceuticals Holdings, Inc. (collectively, the “Company”). All significant intercompany balances and transactions have been eliminated in consolidation. The Company has evaluated subsequent events through the filing date of this Form 10-K, and determined that no subsequent events have occurred that would require recognition in the consolidated financial statements or disclosure in the notes thereto other than as disclosed in the accompanying notes.

Note 3. Merger with Public Company and Reorganization

On September 17, 2007, Transdel entered into an Agreement of Merger and Plan of Reorganization (the “Merger Agreement”) by and among Transdel, Transdel Pharmaceuticals Holdings, Inc., a privately held Nevada corporation (“Transdel Holdings”), and Trans-Pharma Acquisition Corp., a newly formed, wholly-owned Delaware subsidiary of Transdel (“Acquisition Sub”). Upon closing of the merger transaction contemplated under the Merger Agreement (the “Merger”), Acquisition Sub merged with and into Transdel Holdings, and Transdel Holdings, as the surviving corporation, became a wholly-owned subsidiary of Transdel.

In connection with the merger, 1,849,993 of Transdel common shares remain outstanding and all other outstanding shares of Transdel were cancelled. Also, at the closing of the Merger, each share of Transdel Holdings common stock issued and outstanding immediately prior to the closing of the Merger was exchanged for the right to receive 0.15625 of one share of Transdel’s common stock. An aggregate of 8,000,000 shares of Transdel’s common stock, which includes 195,313 shares of restricted stock which were subject to forfeiture (see Note 7), were issued to the holders of Transdel Holdings’ common stock. As a result of the transaction, the former owners of Transdel Holdings became the controlling stockholders of Transdel. Accordingly, the merger of Transdel Holdings and Transdel is a reverse merger that has been accounted for as a recapitalization of Transdel Holdings.

Effective on September 17, 2007, and for all reporting periods thereafter, Transdel’s operating activities, including any prior comparative period, will include only those of Transdel Holdings. All references to shares and per share amounts in the accompanying consolidated financial statements and footnotes have been restated to reflect the aforementioned share exchange.

Note 4. Summary of Significant Accounting Policies

New Accounting Standard. In the third quarter of 2009, the Financial Accounting Standards Board (“FASB”) issued the FASB Accounting Standards Codification (the “Codification”). The Codification is the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in preparation of financial statements in conformity with generally accepted accounting principles in the United States. All accounting guidance that is not included in the Codification will be considered to be non-authoritative. The FASB will issue Accounting Standard Updates (“ASUs”), which will serve only to update the Codification, provide background information about the guidance and provide the basis for conclusions on changes in the Codification. ASUs are not authoritative in their own right. The Codification does not change GAAP and did not have an effect on the Company’s financial position or results of operations.

Going Concern. The accompanying consolidated financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred recurring operating losses, had negative operating cash flows and has not recognized any revenues since July 24, 1998 (Inception). In addition, the Company had a deficit accumulated during the development stage of \$14.9 million at December 31, 2009. These factors raise substantial doubt about the Company’s ability to continue as a going concern.

TRANSDel PHARMACEUTICALS, INC.
(A Development Stage Company)
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

Note 4. Summary of Significant Accounting Policies (continued)

The Company's continuation as a going concern is dependent on its ability to obtain additional financing to fund operations, implement its business model, and ultimately, to attain profitable operations. The Company intends to raise additional financing to fund its operations through various means, including equity or debt financing, funding from a corporate partnership or licensing arrangement or any similar financing. However, there is no assurance that sufficient financing will be available or, if available, on terms that would be acceptable to the Company.

The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

Development Stage Enterprise. The Company is a development stage company as defined under FASB guidance. The Company is devoting substantially all of its present efforts to establish a new business, and its planned principal operations have not yet commenced. All losses accumulated since inception have been considered as part of the Company's development stage activities.

These consolidated financial statements contemplate the realization of assets and the satisfaction of liabilities in the normal course of business. The Company is a development stage enterprise and has sustained significant losses since Inception and expects to continue to incur losses through 2010.

In order to execute the second Phase 3 clinical trial and other supportive safety studies for Ketotransdel[®], which are required by the U.S. Food and Drug Administration ("FDA") to obtain final regulatory approval for Ketotransdel[®], the Company will need to secure additional funds through various means, including equity and debt financing, funding from a corporate partnership or licensing arrangement or any similar financing. There can be no assurance that the Company will be able to obtain additional debt or equity financing, if and when needed, on terms acceptable to the Company. Any additional equity or debt financing may involve substantial dilution to the Company's stockholders, restrictive covenants or high interest costs. The failure to raise needed funds on sufficiently favorable terms could have a material adverse effect on the execution of the Company's business plan, operating results and financial condition. The Company's long term liquidity also depends upon its ability to generate revenues from the sale of its products and achieve profitability. The failure to achieve these goals could have a material adverse effect on the execution of the Company's business plan, operating results and financial condition.

Research and Development. Research and development costs are charged to expense and accordingly accrued when incurred.

Cash and Cash Equivalents. Cash equivalents consist of highly liquid investments with maturities of three months or less from the original purchase date.

Concentrations of Credit Risk. Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash and cash equivalents. The Company invests its excess cash balances (approximately \$701,000 as of December 31, 2009) in a combination of government issued and government backed securities. The remaining amount of cash is held in an operating account and in the form of multiple short term certificates of deposit, all of which (except for \$100,000 of the operating account) are insured by the Federal Deposit Insurance Corporation ("FDIC") as they are individually under the insured maximum of \$250,000.

Computer Equipment. Computer equipment is stated at cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful life of three years.

Fair Value of Financial Instruments. The fair values of the Company's cash and cash equivalents, accounts payable and accrued expenses approximate carrying values due to their short maturities.

Revenue Recognition. The Company will recognize revenues in accordance with FASB guidance, which requires that four basic criteria must be met before revenue can be recognized: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred; (3) the selling price is fixed and determinable; and (4) collectibility is reasonably assured. Determination of criteria (3) and (4) will be based on management's judgments regarding the fixed nature of the selling prices of the products delivered and the collectibility of those amounts. Provisions for discounts and rebates to customers, estimated returns and allowances, and other adjustments will be provided for in the same period the related sales are recorded. The Company will defer any revenue for which the product has not been delivered or for which services have not been rendered or are subject to refund until such time that the Company and the customer jointly determine that the product has been delivered or services have been rendered or no refund will be required.

TRANSDel PHARMACEUTICALS, INC.
(A Development Stage Company)
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

Note 4. Summary of Significant Accounting Policies (continued)

As of December 31, 2009, the Company had not generated any revenues and the Company does not anticipate that it will generate any revenues until one or more of its drug candidates are approved by the FDA or until the Company is able to commercialize one or more of its cosmetic products. Also, effective sales and marketing support must be in place for either the drug candidates or the cosmetic products in order to generate any revenues. The FDA approval process is highly uncertain and the Company cannot estimate when it will generate revenues at this time from sales of its products.

Stock-Based Compensation. Under FASB guidance all share-based payments to employees, including grants of stock options to employees, directors and consultants and restricted stock grants, are to be recognized in the financial statements based upon their fair values. The Company recorded total stock-based compensation for employees, directors and consultants of \$509,505, \$562,442 and \$1,256,468 for the years ended December 31, 2009 and 2008 and the period from Inception through December 31, 2009, respectively, for options and restricted stock granted and vested which is included in selling, general and administrative expenses and research and development expenses in the amount of \$431,826 and \$77,679, \$284,750 and \$277,692, and \$780,154 and \$476,314, respectively.

The Company's accounting policy for equity instruments issued to consultants and vendors in exchange for goods and services follows FASB guidance. As such, the value of the applicable stock-based compensation is periodically remeasured and income or expense is recognized during their vesting terms. The measurement date for the fair value of the equity instruments issued is determined at the earlier of (i) the date at which a commitment for performance by the consultant or vendor is reached or (ii) the date at which the consultant or vendor's performance is complete. In the case of equity instruments issued to consultants, the fair value of the equity instrument is primarily recognized over the term of the consulting agreement. In accordance with FASB guidance, an asset acquired in exchange for the issuance of fully vested, nonforfeitable equity instruments should not be presented or classified as an offset to equity on the grantor's balance sheet once the equity instrument is granted for accounting purposes. Accordingly, the Company recorded the fair value of nonforfeitable equity instruments issued for future consulting services as prepaid consulting fees in its consolidated balance sheets (see Note 6).

Basic and Diluted Loss per Common Share. Basic net loss per common share is computed by dividing net loss for the period by the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss for the period by the weighted average number of common and common equivalent shares, such as stock options and warrants outstanding during the period.

Basic and diluted net loss applicable to common stock per share is computed using the weighted average number of common shares outstanding during the period. Common stock equivalents (prior to application of the treasury stock, if converted method) from stock options and warrants were 2,407,730 and 1,887,730 for the years ended December 31, 2009 and 2008, respectively, are excluded from the calculation of diluted net loss per share for all periods presented because the effect is anti-dilutive.

Use of Estimates. The preparation of financial statements in conformity with GAAP requires management to make estimates and judgments that affect the reported amounts of assets, liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenues and expenses during the reporting periods. Significant estimates made by management are, among others, the valuation of contributed services, stock options, deferred taxes and stock-based compensation issued to employees and non-employees. Actual results could differ from those estimates.

Reclassification. To conform to the current year's presentation, the Company reclassified \$141,952 related to amounts previously classified as accounts payable as of December 31, 2008 to accrued Phase 3 expenses.

Note 5. Notes Payable

In August 2005, the Company issued seven convertible promissory notes in the aggregate amount of \$226,300 to various stockholders (collectively, the "Stockholders' Notes"). The Stockholders' Notes bore interest at 4% per annum and were to mature on August 25, 2010. In connection with the issuance of the Stockholders' Notes, the Company granted warrants that were exercisable into an aggregate 35,359 shares of the Company's common stock. The warrants were determined to have an insignificant fair value at the time of the grant.

In May 2007, the holders of the Stockholders' Notes and related warrants forgave the amounts due and forfeited the related warrants. In connection with the forgiveness, the Company recorded additional paid-in capital of \$241,701 equal to the value of the Stockholders' Notes and related accrued interest. Interest expense on the Stockholders' Notes was \$15,401 for the period from Inception through December 31, 2009.

TRANSDel PHARMACEUTICALS, INC.
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Note 5. Notes Payable (continued)

In May and June 2007, the Company issued convertible notes payable to various lenders for an aggregate amount of \$1,500,000 (collectively, the "2007 Notes"). Each of the 2007 Notes included interest at 7% per annum and were to mature on December 16, 2007 ("Maturity Date"). However, as a result of the Merger and Private Placement (see Note 6), the entire outstanding principal amount and accrued interest was converted into the Company's common stock at a conversion price equal to \$1.00 per share, which resulted in the issuance of 1,530,177 shares. Also, the Company recorded a debt discount of \$1,530,177, which was amortized immediately to interest expense upon the conversion of the 2007 Notes. Excluding the debt discount, interest expense on the 2007 Notes was \$30,177 for the period from Inception through December 31, 2008.

Note 6. Stockholders' Equity

Prior to the Merger during fiscal year 2007, the Company issued 3,984,374 shares of its common stock at a price of \$0.006 per share for proceeds of \$25,700, which includes the issuance of 31,250 shares upon the exercise of a warrant (see below). Also, prior to the Merger, the Company received capital contributions of \$105,907 from the Company's stockholders and recorded capital contributions of \$175,000 (the estimated fair value of the services contributed) in connection with services contributed by stockholders, which is recorded respectively in selling, general and administrative and research and development expenses in the accompanying statements of operations.

Concurrent with the Merger, the Company sold 2,071,834 shares of common stock for gross proceeds of \$4,143,667 through a private placement (the "Private Placement"). In addition, the investors received warrants to purchase 517,958 shares of common stock for a period of five years at a cash and cashless exercise price of \$4.00 and \$5.00 per share, respectively.

In connection with the Private Placement, the Company incurred placement agent fees and other related expenses totaling \$342,105 (of which \$36,229 was paid in fiscal year 2008) and issued warrants to purchase up to 33,750 shares of common stock for a period of three years at cash and cashless exercise price of \$4.00 and \$5.00 per share, respectively.

On May 12, 2008, the Company sold 1,818,180 shares of common stock for gross proceeds of \$4,000,000 through a follow-on private placement (the "Follow-on Private Placement") to accredited investors. In addition, the investors received warrants to purchase 227,272 shares of common stock for a period of five years at a cash and cashless exercise price of \$4.40 and \$5.50 per share, respectively. In connection with the Follow-On Private Placement, the Company incurred expenses of \$22,470, which was recorded as a reduction of additional paid-in capital.

In September 2007, the Company entered into three, one-year consulting agreements with three separate firms to provide services related to investor communications. The terms per one of the agreements, among other items, include monthly payments of \$7,500 plus expenses and for another agreement a non-refundable fee of \$140,000. Also, in the aggregate, 275,000 shares of common stock were issued in accordance with the terms of the agreements along with a warrant to purchase 18,750 shares of common stock for a period of five years at a cash and cashless exercise price of \$4.00 and \$5.00, respectively. The fair value of the stock and warrants were valued at \$550,000. The estimated costs of the consulting agreements, including the stock, warrants and non-refundable fee were amortized over the one-year terms.

In accordance with FASB guidance, 100,000 of the 275,000 shares of common stock were subject to remeasurement on a periodic basis as the performance condition for these shares was not satisfied until the end of the contract term. The remeasurement for the 100,000 shares was completed in two stages. First, in February 2008, the consulting agreement associated with these shares was terminated and as a condition of the termination, the firm retained 50,000 shares and transferred the remaining 50,000 shares to another firm. Therefore, since the performance obligation related to the 50,000 shares, retained by the terminated consulting firm, was complete they were revalued as of the February termination date to \$60,000. This was the fair market value of the shares on the February 2008 termination date of which approximately \$30,000 was recorded as an expense in each of the fiscal years 2008 and 2007. Due to the final valuation of these shares an adjustment of \$40,000 was recorded to decrease prepaid consulting costs and additional paid-in capital as the original value of these shares was \$100,000. Second, the remaining 50,000 shares that were transferred to the other firm were intended to be utilized for the payment of investor relation services. During fiscal year 2008, through quarterly revaluations of these shares, the Company recorded a net decrease of \$7,500 to prepaid consulting costs and additional paid-in capital. The Company originally estimated that these shares would be utilized and earned for investor relations services by the end of the one-year term, however, these 50,000 shares along with 32,568 (for an aggregate of 82,568) shares from the issuance of common stock to one of the other consulting firms were not earned as of the termination of the respective agreements.

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Note 6. Stockholders' Equity (continued)

As a result, the aggregate expense recognized to date for the 82,568 shares of approximately \$158,000 was reversed during fiscal year 2008 and since shares were considered not to be issued or outstanding, the same value was deducted (in the aggregate) from common stock and additional paid-in capital.

On October 27, 2008, the Company entered into an agreement with an investor relations firm ("IR Firm"), pursuant to which the IR Firm would provide certain investor relations and public relations services to the Company for a period of one year, beginning on November 1, 2008. In exchange for such services, the Company issued the 82,568 registered shares of its common stock, of which 68,667 shares were nonforfeitable (valued at \$85,834 and recorded as prepaid consulting fees in the accompanying consolidated balance sheet as of December 31, 2008) and 13,901 shares were forfeitable, to the IR Firm as a prepayment of services to be received. The Company terminated the agreement with the IR Firm effective March 31, 2009. Therefore, for the year ended December 31, 2009 the Company amortized the remaining portion of the nonforfeitable shares of \$28,612 (previously issued and recorded as prepaid consulting fees) and recognized the issuance of the 13,901 forfeitable shares in addition to the issuance of 31,877 (for an aggregate of 45,778) shares of the Company's common stock for services provided by the IR Firm. The fair market value of the shares issued during the first quarter of 2009 was \$50,356, which was included in selling, general and administrative expenses in the accompanying statement of operations and is included in the expenses disclosed in Note 4.

On April 24, 2008, the Company entered into a one-year consulting agreement with a firm to provide the Company with financial advisory services. As compensation for the services, the Company issued a three-year warrant to purchase 5,000 shares of the Company's common stock at a cash and cashless price of \$2.00 per share. The fair value of the warrant, determined based on the Black-Scholes pricing model, was valued at \$1,310, which was amortized over the one-year term ending in April 2009. For the year ended December 31, 2009, \$436 was amortized and included in selling, general and administrative expenses in the accompanying statement of operations.

For the year ended December 31, 2009 and 2008 and for the period from Inception through December 31, 2008, the Company amortized \$29,048, \$341,708 and \$572,008, respectively, of prepaid consulting fees which is included as part of selling, general and administrative expenses.

Other common stock and capital contributions:

- In fiscal year 1998, the Company recorded capital contributions of \$100,000 (the estimated fair value of the services contributed) in connection with services contributed by stockholders, which is recorded respectively in selling, general and administrative and research and development expenses in the accompanying consolidated statements of operations.
- In fiscal year 1999, the Company recorded capital contributions of \$200,000 (the estimated fair value of the services contributed) in connection with services contributed by stockholders, which is recorded respectively in selling, general and administrative and research and development expenses in the accompanying consolidated statements of operations.
- In fiscal year 2000, the Company issued 937,500 shares of common stock at a price of \$0.006 per share for proceeds of \$6,000. Also, recorded capital contributions of \$200,000 (the estimated fair value of the services contributed) in connection with services contributed by stockholders, which is recorded respectively in selling, general and administrative and research and development expenses in the accompanying consolidated statements of operations.
- In fiscal year 2001, the Company recorded capital contributions of \$200,000 (the estimated fair value of the services contributed) in connection with services contributed by stockholders, which is recorded respectively in selling, general and administrative and research and development expenses in the accompanying consolidated statements of operations.
- In fiscal year 2002, the Company recorded capital contributions of \$200,000 (the estimated fair value of the services contributed) in connection with services contributed by stockholders, which is recorded respectively in selling, general and administrative and research and development expenses in the accompanying consolidated statements of operations.
- In fiscal year 2003, the Company recorded capital contributions of \$200,000 (the estimated fair value of the services contributed) in connection with services contributed by stockholders, which is recorded respectively in selling, general and administrative and research and development expenses in the accompanying consolidated statements of operations.

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Note 6. Stockholders' Equity (continued)

- In fiscal year 2004, the Company recorded capital contributions of \$400,000 (the estimated fair value of the services contributed) in connection with services contributed by stockholders, which is recorded respectively in selling, general and administrative and research and development expenses in the accompanying consolidated statements of operations.
- In fiscal year 2005, the Company issued 2,468,750 shares of common stock at a price of \$0.006 per share for gross proceeds of \$15,800. The Company received additional capital contributions of \$14,200 from the Company's stockholders. Also, recorded capital contributions of \$400,000 (the estimated fair value of the services contributed) in connection with services contributed by stockholders, which is recorded respectively in selling, general and administrative and research and development expenses in the accompanying consolidated statements of operations.
- In fiscal year 2006, the Company issued 375,000 shares of common stock at a price of \$0.006 per share for gross proceeds of \$2,400. The Company received additional capital contributions of \$48,600 from the Company's stockholders. Also, recorded capital contributions of \$400,000 (the estimated fair value of the services contributed) in connection with services contributed by stockholders, which is recorded respectively in selling, general and administrative and research and development expenses in the accompanying consolidated statements of operations.

Note 7. Stock Option Plan

On September 17, 2007, the Company's Board of Directors and stockholders adopted the 2007 Incentive Stock and Awards Plan (the "Plan"), which provides for the issuance of a maximum of an aggregate of 3,000,000 (as amended on November 5, 2008) shares of Common Stock. The purpose of the Plan is to provide an incentive to attract and retain directors, officers, consultants, advisors and employees whose services are considered valuable, to encourage a sense of proprietorship and to stimulate an active interest of such persons into the Company's development and financial success. Under the Plan, the Company is authorized to issue incentive stock options intended to qualify under Section 422 of the Code, non-qualified stock options and restricted stock. The Plan will be administered by the Company's Board of Directors until such time as such authority has been delegated to a committee of the board of directors.

Pursuant to the terms of the Private Placement, the Company was restricted from issuing options to purchase shares of common stock at an exercise price below \$2.00 per share through September 17, 2008. On May 12, 2009, the Company filed a registration statement, covering the resale of any shares of common stock issued pursuant to the Plan.

A summary of the Plan for the year ended December 31, 2009 is as follows:

	<u>Number of Shares</u>	<u>Weighted Ave. Exercise Price</u>	<u>Weighted Ave. Remaining Contractual Life</u>	<u>Aggregate Intrinsic Value</u>
Outstanding – January 1, 2009	1,085,000	\$ 1.63		
Granted	620,000	1.63		
Exercised	(50,000)	0.99		
Cancelled	(50,000)	2.00		
Outstanding – December 31, 2009	<u>1,605,000</u>	<u>\$ 1.64</u>	<u>8.8</u>	<u>\$ 216,000</u>
Exercisable – December 31, 2009	<u>649,677</u>	<u>\$ 1.79</u>	<u>8.3</u>	<u>\$ 59,733</u>
Vested and expected to vest – December 31, 2009	<u>1,534,633</u>	<u>\$ 1.65</u>	<u>8.7</u>	<u>\$ 200,640</u>

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Note 7. Stock Option Plans (continued)

The aggregate intrinsic value in the table above represents the total pre-tax amount of the proceeds, net of exercise price, which would have been received by option holders if all option holders had exercised and immediately sold all options with an exercise price lower than the market price on December 31, 2009, based on the closing price of the Company's common stock of \$1.50 on that date. The intrinsic value of the options exercised during 2009 was approximately \$23,000.

Since the adoption of the Plan, options have been granted to the employees, directors and consultants at exercise prices that ranged from \$0.70 to \$2.62, the estimated fair market value of the common stock on the dates of issuance. All options granted to date expire on the ten year anniversary of the issuance date and vest on a quarterly basis over three months to five years. The Company uses the Black-Scholes option pricing model to estimate the grant-date fair value of share-based awards. The Black-Scholes model requires subjective assumptions regarding future stock price volatility and expected time to exercise, along with assumptions about the risk-free interest rate and expected dividends, which affect the estimated fair values of the Company's stock-based awards. The expected term of options granted was determined in accordance with the "simplified approach" as the Company has very limited historical data on employee exercises and post-vesting employment termination behavior. The expected volatility is based on the historical volatilities of the common stock of comparable publicly traded companies based on the Company's belief that it currently has limited historical data regarding the volatility of its stock price on which to base a meaningful estimate of expected volatility. The risk-free rate selected to value any particular grant is based on the U.S. Treasury rate that corresponds to the expected term of the grant effective as of the date of the grant. The Company used 0% as an expected dividend yield assumption. These factors could change in the future, affecting the determination of stock-based compensation expense in future periods. Utilizing these assumptions, the fair value is determined at the date of grant. The Company recorded total stock-based compensation for employees and directors of \$372,737, \$256,374 and \$721,117 for the years ended December 31, 2009 and 2008 and the period from Inception through December 31, 2009, respectively.

In accordance with FASB guidance, the financial statement effect of forfeitures is estimated at the time of grant and revised, if necessary, if the actual effect differs from those estimates. Starting with options granted in November 2008, the Company assigned a forfeiture factor of 10%, which was assigned to employee option grants during 2009 and continue to be assigned to future director and employee options. This percentage was determined based on consideration of actual forfeitures realized to date and estimated forfeitures to potentially occur in the future.

As of December 31, 2009, there was approximately \$825,000 of total unrecognized compensation expense related to unvested stock options under the Plan. That expense is expected to be recognized over the weighted-average period of 2.0 years.

Furthermore, in August 2007, the Company issued a restricted stock grant to an executive of the Company for 195,313 shares of the Company's common stock upon closing of the Merger (See Note 3). The restricted stock grant was scheduled to vest 100% on March 17, 2009 and valued at approximately \$391,000, which was being amortized over the 18 month period. However, on April 4, 2008, the Company's Board of Directors waived any restrictions or forfeiture conditions on the shares of restricted common stock in conjunction with the executive's resignation and a separation agreement entered into between the Company and the executive. Therefore, the remaining unrecognized expense of \$236,000 was fully amortized in the second quarter of 2008 as a result of the waiver of the restrictions and forfeiture conditions. For the year ended December 31, 2009 and 2008 and the period from Inception through December 31, 2009, the Company recorded stock-based compensation related to this restricted stock of \$0, \$298,110, and \$391,000, respectively.

Also, on November 21, 2008, the Company issued a restricted stock grant to a director of the Company for 25,000 shares of the Company's common stock. The restricted stock grant vested over a one-year period. The fair value of the grant was determined to be \$17,500 and was amortized to selling, general and administrative expenses on a straight line basis over the one-year vesting period. For the year ended December 31, 2009 and 2008 and the period from Inception through December 31, 2009, the Company recorded stock-based compensation related to this restricted stock of \$15,313, \$2,187, and \$17,500, respectively.

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Note 7. Stock Option Plan (continued)

The table below illustrates the fair value per share and Black-Scholes option pricing model with the following assumptions used for grants issued to employees and directors during the years ended December 31, 2009 and 2008:

	2009	2008
Weighted-average fair value of options granted	\$ 1.15	\$ 0.64
Expected term (in years)	6.0	6.1
Expected volatility	75-85%	85%
Risk-free interest rate	2.97%	2.73%
Dividend yield	—	—

On December 19, 2008, the Board of Directors approved and the Company entered into a consulting agreement with a firm to provide the Company with business development services. As part of the compensation for the services, the Company issued the firm a non-qualified stock option, under the Plan, to purchase up to 50,000 shares of common stock. The stock option vested in full on March 19, 2009 and was fully exercised during the third quarter of 2009. The option was granted with an exercise price of \$0.99. The option was revalued on an interim basis until the termination of the agreement and the final estimated fair value of the stock option, based on the Black-Scholes pricing model, was \$20,205. This option was amortized over the term of the agreement which was approximately four months as the consulting agreement was terminated effective April 16, 2009. For the year ended December 31, 2009 and 2008 and the period from Inception through December 31, 2009, the Company recorded stock-based compensation related to this stock option of \$14,434, \$5,771 and \$20,205, respectively.

In April 2009, the Company entered into a consulting agreement with a consultant to provide the Company with clinical management services. On June 18, 2009, as part of the compensation for the services, the Board of Directors approved and the Company issued the consultant a non-qualified stock option, under the Plan, to purchase up to 85,000 shares of common stock. Per the option agreement, a portion of the stock option (25,000 shares) became fully vested once the Company announced the results from the Phase 3 trial of Ketotransdel®, which occurred on October 6, 2009. Therefore, the final valuation of this portion of the option was determined at that time, which was \$36,658. The remainder of the stock option (60,000 shares) was scheduled to vest, on a quarterly basis, over a one-year term, if the consulting agreement was still effective and had not been terminated by either the Company or the consultant prior to the one-year vesting term. The option was granted with an exercise price of \$1.60 and has a ten year life. However, effective October 12, 2009, the consultant became an employee of the Company. Therefore, the original stock option agreement was amended and effectively removed the requirement for the consulting agreement to be in place for the remainder of term, but rather that the individual retains the employee status through the remaining vesting term that will end on June 1, 2010. Since this option effectively was transformed into an employee stock option agreement with the change in status, the final valuation of the option was determined. For the portion of the 60,000 options that vested prior to the change in status, the amount associated with those vested shares (\$20,006) was recorded as a consulting stock-based compensation expense. The expense related to the options that vest subsequent to the hire date, are recorded as employee stock-based compensation.

The table below illustrates the fair value per share and Black-Scholes option pricing model with the following assumptions used for the grants issued to the consulting firms during the years ended December 31, 2009 and 2008:

	2009	2008
Weighted-average fair value of options granted	\$ 1.40	\$ 0.69
Expected term (in years)	5.5	5.5
Expected volatility	75%	85%
Risk-free interest rate	2.71%	1.13%
Dividend yield	—	—

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Note 8. Stock Warrants

In addition to the warrants issued in conjunction with the Private Placement and the Follow-On Private Placement, the Company issued a warrant to purchase shares of its common stock to a firm in connection with a consulting agreement at an exercise price of \$2.00. The expiration of the outstanding warrants occurs through May 2013 at various periods (see Note 6).

A summary of the status of the warrants for the year ended December 31, 2009 is as follows:

	Number of Shares Subject to Warrants Outstanding	Weighted- Average Exercise Price
Warrants outstanding – January 1, 2009	802,730	\$ 4.10
Granted	—	—
Exercised	—	—
Expired	—	—
Warrants outstanding – December 31, 2009	<u>802,730</u>	<u>\$ 4.10</u>
Weighted average remaining contractual life of the outstanding warrants – December 31, 2009	<u>2.81 years</u>	

Note 9. Income Taxes

In accordance with FASB guidance, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has 50% or less likelihood of being sustained upon examination. Additionally, the FASB provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition.

The Company has evaluated the impact of this FASB guidance on its financial statements, which was effective beginning January 1, 2007. The evaluation of a tax position in accordance with this guidance is a two-step process. The first step is recognition: The enterprise determines whether it is more-likely-than-not that a tax position will be sustained upon examination, including resolution of any related appeals or litigation processes, based on the technical merits of the position. In evaluating whether a tax position has met the more-likely-than-not recognition threshold, the enterprise should presume that the position will be examined by the appropriate taxing authority that would have full knowledge of all relevant information. The second step is measurement: A tax position that meets the more-likely-than-not recognition threshold is measured to determine the amount of benefit to recognize in the financial statements. The tax position is measured at the largest amount of benefit that is greater than 50 percent likely of being realized upon ultimate settlement. Tax positions that previously failed to meet the more-likely-than-not recognition threshold should be recognized in the first subsequent financial reporting period in which that threshold is met. Previously recognized tax positions that no longer meet the more-likely-than-not recognition threshold should be derecognized in the first subsequent financial reporting period in which that threshold is no longer met. The Company believes that its income tax filing positions and deductions will be sustained on audit and does not anticipate any adjustments that will result in a material change to its financial position. Therefore, no reserves for uncertain income tax positions have been recorded pursuant to this FASB guidance. The cumulative effect, if any, of applying this guidance is to be reported as an adjustment to the opening balance of retained earnings in the year of adoption. The Company did not record a cumulative effect adjustment related to the adoption of this guidance.

The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrual for interest or penalties at December 31, 2009 and 2008, and has not recognized interest and/or penalties in the consolidated statements of operations for the years ended December 31, 2009 and 2008. The Company is subject to taxation in the United States and California. The Company's tax years for 2000 and forward are subject to examination by the United States and state tax authorities due to the carry forward of unutilized net operating losses.

At December 31, 2009 and 2008, the Company had deferred tax assets of \$4,735,888 and \$2,716,094, respectively. Due to uncertainties surrounding the Company's ability to generate future taxable income to realize these assets, a full valuation has been established to offset the net deferred tax asset. Additionally, the future utilization of the company's net operating loss to offset future

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Note 9. Income Taxes (continued)

taxable income may be subject to an annual limitation, pursuant to Internal Revenue Code Section 382, as a result of ownership changes that may have occurred previously or that could occur in the future. The Company has not performed a Section 382 analysis to determine the limitation of the net operating loss and research and development credit carry forwards.

As of December 31, 2009, the Company had federal and California net operating loss carryforwards of approximately \$9.9 million and \$9.7 million, respectively. The federal and California tax loss carry forwards will begin to expire in 2020 and 2015, respectively, unless previously utilized. The Company has federal and California research and development tax credit carryforwards of approximately \$286,000 and \$299,000, respectively, which begin to expire in 2027 unless previously utilized.

Significant components of the company's deferred tax assets are as follows:

	<u>2009</u>	<u>2008</u>
Deferred tax assets:		
Federal and state net operating loss carryforwards	\$ 3,928,340	\$ 2,295,402
Stock-based compensation	307,911	134,688
Tax credits	482,638	271,618
Other	16,999	14,386
Total deferred tax assets	4,735,888	2,716,094
Less valuation allowance	(4,735,888)	(2,716,094)
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

Realization of the deferred tax assets is dependent upon the generation of future taxable income, the amount and timing of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by approximately \$2.0 million and \$1.5 million in 2009 and 2008, respectively.

The provision for income taxes using the statutory federal income tax rate of 34% as compared to the company's effective tax rate is summarized as follows:

	<u>2009</u>	<u>2008</u>
Federal tax benefit at statutory rate	\$(1,548,236)	\$(1,123,492)
State tax benefit, net	(261,667)	(181,563)
Research and development credits	(211,019)	(271,618)
Employee stock-based compensation	—	56,929
Other differences	1,128	(10,124)
Increase in valuation allowance	2,019,794	1,529,868
Provision for income taxes	<u>\$ —</u>	<u>\$ —</u>

A portion of the net operating loss carry forwards as of December 31, 2009 and 2008 include amounts related to stock option deductions. Under FASB guidance, any excess tax benefits from share-based compensation are only realized when income taxes payable is reduced, with the corresponding credit posted to Additional Paid-in Capital.

Note 10. Recent Accounting Pronouncements

There were no recent accounting pronouncements that have not yet been adopted by the Company that are expected to have a material impact on the consolidated financial statements.

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Note 11. Commitments and Contingencies

Commitments

The Company leases its office facilities under a noncancelable operating lease, which expires in March 2010. The Company anticipates renewing the lease upon expiration. For fiscal year 2010, the Company's lease commitment is approximately \$15,000. Rent expense for the years ended December 31, 2009, 2008 and the period from Inception through December 31, 2009, was \$70,120, \$71,237 and \$170,835, respectively.

Indemnities and Guarantees

In addition to the indemnification provisions contained in the Company's charter documents, the Company will generally enter into separate indemnification agreements with the Company's directors and officers. These agreements require the Company, among other things, to indemnify the director or officer against specified expenses and liabilities, such as attorneys' fees, judgments, fines and settlements, paid by the individual in connection with any action, suit or proceeding arising out of the individual's status or service as the Company's director or officer, other than liabilities arising from willful misconduct or conduct that is knowingly fraudulent or deliberately dishonest, and to advance expenses incurred by the individual in connection with any proceeding against the individual with respect to which the individual may be entitled to indemnification by the Company. These guarantees and indemnities do not provide for any limitation of the maximum potential future payments the Company could be obligated to make. Historically, the Company has not been obligated nor incurred any payments for these obligations and, therefore, no liabilities have been recorded for these indemnities and guarantees in the accompanying consolidated balance sheets.

Cato Research Ltd. Agreement

In accordance with the Master Services Agreement, dated April 10, 2007, between the Company and Cato Research Ltd. ("Cato"), a contract research and development organization, the Company entered into a clinical trial services agreement ("Agreement") with Cato on June 10, 2008. Under the Agreement, Cato served as the Company's strategic partner and contract research organization in conducting the Company's Phase 3 clinical trial for Ketotransdel®. As of December 31, 2009, the Company incurred approximately \$3.2 million (original estimate of costs was \$3.3 million) related to Cato's fees as well as pass-through costs incurred by Cato or payable to the clinical sites for patients enrolled in the study. The Company does not anticipate incurring any additional costs related to this Agreement.

Cosmetic Products Consulting Agreement

On August 25, 2008, the Company entered into a consulting agreement with a firm to provide product and business development services for specific cosmetic/cosmeceutical products that would be developed by the Company. To the extent a specific cosmetic/cosmeceutical product, applicable to the consulting agreement, is successfully developed and a separate agreement is entered into between the Company and a third party for (including but not limited to) the out-license or distribution of a product, the firm will receive a percentage of the operating profits from the third party agreement as agreed upon in the consulting agreement.

Cosmeceutical License Agreement

On May 20, 2009, the Company and JH Direct, LLC ("JH Direct") entered into a licensing agreement providing JH Direct with the exclusive worldwide rights to the Company's anti-cellulite cosmeceutical product which utilizes the Company's patented transdermal delivery system technology, Transdel™. Under the terms of the agreement, JH Direct will pay the Company initial royalty advances and a continuing licensing royalty on the worldwide sales of the anti-cellulite product. The Company retained the exclusive rights to seek pharmaceutical/dermatological partners for the anti-cellulite product for an initial period of one year following the launch of the product, thereafter JH Direct will be allowed to expand in this channel. In accordance with the cosmetic products consulting agreement, the consulting firm will receive a percentage of the operating profits paid to the Company.

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Note 12. Related Party Transaction

Mediation Settlement

In February 2007, prior to the Merger, the Company's Board of Directors approved a payment of 12.5% of any proceeds the Company may receive from an action the Company had initiated against a prior law firm, not to exceed \$100,000, to be paid each to Drs. Singh and Abrams for their monetary contributions and uncompensated time commitment over a period of approximately four years related to pursuing this matter and other amounts paid on the Company's behalf. On February 5, 2008, as a result of mediation, the Company reached a settlement agreement with the law firm. Although the law firm did not admit to any liability or wrongdoing, they desired to resolve the dispute and therefore, agreed to pay the Company \$750,000. In exchange for the settlement, the law firm, any other parties involved in the mediation and the Company released and waived any future claims against each other, whether known or unknown at the time of the settlement. In accordance with the Company's February 2007 board approved payments, \$93,750 was paid to Global Strategic Medical Consulting Inc. of which the sole shareholder of this entity is the Company's former Chief Executive Officer, Dr. Juliet Singh, and \$93,750 was paid to The Abrams Family Trust of which the Company's director, Jeffrey Abrams, M.D., is the trustee, from the Company's settlement with the law firm.

Note 13. Subsequent Events

Management Reorganization

Effective February 17, 2010, the Board of Directors of the Company accepted the resignation of Dr. Juliet Singh as Chief Executive Officer of the Company and as a director on the Board. The Board appointed Jeffrey J. Abrams, M.D. as Chairman of the Board and appointed John T. Lomoro, the Company's current Chief Financial Officer, as acting Chief Executive Officer. Mr. Lomoro will also serve as the Company's principal executive officer.

In connection with Dr. Singh's resignation, the Company and Dr. Singh entered into a separation agreement that provides Dr. Singh with one year of continued salary in accordance with the terms of her existing employment agreement as well as the accelerated vesting of 300,000 stock options previously granted. In addition, Dr. Singh will have three years from the date of her resignation to exercise her vested options. The separation agreement also includes a mutual release of claims.

The Company and Dr. Singh also entered into a consulting agreement, which provides that Dr. Singh has agreed to provide consulting services to the Company at the request and direction of the Board. Dr. Singh will be entitled to \$5,000 per month for her consulting services.

Stock Option Grant

On February 26, 2010, the Company's Board of Directors granted 300,000 stock options to an executive officer of the Company under the Company's 2007 Incentive Stock and Awards Plan. All of the options were granted with an exercise price of \$0.90 and have a ten year life. Also, the options vest one-twelfth per quarter commencing on the first full quarter after the initial grant date of February 26, 2010.

TRANSDel PHARMACEUTICALS, INC.

SEPARATION AGREEMENT AND GENERAL RELEASE OF ALL CLAIMS

This Separation Agreement and General Release of All Claims ("Separation Agreement") is made by and between Transdel Pharmaceuticals, Inc. ("Company") and Juliet Singh, Ph.D. ("Employee") with respect to the following facts:

A. Employee is currently employed by Company as its Chief Executive Officer pursuant to an Employment Agreement dated June 27, 2007 ("Employment Agreement") and is currently a director on the Company's Board of Directors (the "Board"). Employee's employment will cease effective February 17, 2010 ("Separation Date"). Employee will receive the Severance benefit provided for in Section 9.3 of the Employment Agreement.

B. During Employee's employment, Employee has been granted options to purchase an aggregate of 610,000 shares of Company's common stock (the "Options") pursuant to the Company's 2007 Incentive Stock and Awards Plan (the "Plan"). As of Employee's Separation Date 310,000 of Employee's Option shares have vested, while 300,000 Option shares remain unvested.

C. The Company wishes to reach an amicable separation with Employee and assist Employee's transition to other employment. The parties desire to settle all claims and issues that have, or could have been raised by Employee, in relation to Employee's employment with Company and arising out of or in any way related to the acts, transactions or occurrences between Employee and Company to date, including, but not limited to, Employee's employment with Company or the termination of that employment, on the terms set forth below.

THEREFORE, in consideration of the promises and mutual agreements hereinafter set forth, it is agreed by and between the undersigned as follows:

1. Severance Package. Company agrees to provide Employee with the following benefits ("Severance Package") to which Employee is not otherwise entitled. Employee acknowledges and agrees that this Severance Package constitutes adequate legal consideration for the promises and representations made by Employee in this Agreement.

1.1 Voluntary Resignation of Employment and Director Position. In exchange for the promises set forth herein, Employee is voluntarily resigning her employment and all positions Employee holds with Company, including all officer positions and her position as a director on the Board, effective February 17, 2010 at 5:00 p.m. (Pacific). In order to facilitate her resignation, Employee agrees to execute the Resignation Notice, attached hereto as Exhibit A, concurrently with this Agreement. Company shall list on its Form 8-K and its press release that the reason for Employee's separation from employment with Company was a voluntary resignation.

1.2 Accelerated Severance Payment. Pursuant to Section 9.3 of the Employment Agreement, the Company shall pay Employee twelve (12) months of her continued base salary (the "Severance Payment"). The payment of the Severance Payment will be made in accordance with the Company's standard payroll practices (i.e., payments made twice monthly on the fifteenth and last day of each month), with the first payment due on February 28, 2010. Notwithstanding the foregoing, if the Company completes an equity financing in which it raises at least \$5 million through the issuance of its securities, the Company's duty to make the Severance Payment shall accelerate, and the Company shall pay any remaining balance of the Severance Payment within ten (10) days of the closing of the financing.

1.3 Acceleration of Vesting of Unvested Stock Options. Employee was previously granted, pursuant to the Company's Plan, options to purchase up to 610,000 shares of common stock (the "Options"). As of the Separation Date, 310,000 shares subject to the Options will be vested and exercisable. Notwithstanding anything in the Stock Option Agreements evidencing the Options (the "Stock Option Agreements") to the contrary, the Company agrees to accelerate the vesting of all of Employee's 300,000 unvested shares of common stock subject to the Options (the "Acceleration Shares"), such that Employee shall be vested in all of the shares subject to the Options as of the Separation Date (including the Acceleration Shares).

1.4 Extension of Exercise Period. The Company agrees to amend the terms of the Stock Option Agreements evidencing the Options to provide that Employee will have three years from the Separation Date in which to exercise all or a portion of the Options. Except as specifically amended herein, Employee acknowledges that she must exercise her vested options in accordance with the terms and conditions of the Stock Option Agreements evidencing her Options.

1.5 Consulting Agreement. In exchange for the promises set forth herein, the Company agrees to enter into a Consulting Agreement with Employee, in the form attached hereto as Exhibit B.

1.6 Health Benefits. For purposes of clarity, Employee shall be entitled to the continued health benefits as provided in Section 9.3 of the Employment Agreement.

2. Cooperation. Employee agrees that for the next thirty (30) days Employee shall make herself reasonably available by telephone to answer questions and assist Company with the transition of Employee's duties as may be reasonably necessary in Company's discretion. As part of this cooperation, Employee shall provide Company with Employee's professional contact information including, but not limited to, the names, titles, company affiliation, telephone numbers, physical addresses, and email addresses for all of potential investors Employee has had contact with during the last twelve (12) months.

3. Covenant Not to Solicit Stockholders. Through December 31, 2010, Employee covenants not to solicit votes or encourage other stockholders of Company to take actions or to vote their shares of stock against or in a manner contrary to the actions or matters recommended to Company's stockholders for approval by a majority of the Board.

4. Restriction on Transfer of Common Stock. In addition to any other restrictions and limitations on the transfer of any common stock Employee holds as of the Separation Date (the "Securities") under the applicable federal and state securities laws and the other agreements to which Employee is bound, Employee agrees from the Separation Date through the later of (a) 90 days after the Separation Date or (b) the term of the Consulting Agreement (as defined in Section 2.3 of the Consulting Agreement), each sale of the Securities (which shall include any offer, pledge, contract to sell, any option, right or warrant to sell, lend, or otherwise transfer or dispose of, directly or indirectly, any of the economic consequences of ownership of the Securities) shall be made in compliance with the volume restrictions applicable to an "affiliate" of Company under Rule 144 of the Securities Exchange Act of 1933, as amended.

5. Mutual General Release.

5.1 General Release by Employee. Employee unconditionally, irrevocably and absolutely releases and discharges Company, and any parent and subsidiary corporations, divisions and affiliated corporations, partnerships or other affiliated entities of

Company, past and present, as well as Company's employees, officers, directors, agents, successors and assigns (collectively, "Released Parties"), from all claims related in any way to the transactions or occurrences between them to date, to the fullest extent permitted by law, including, but not limited to, Employee's employment with Company, the termination of Employee's employment, and all other losses, liabilities, claims, charges, demands and causes of action, known or unknown, suspected or unsuspected, arising directly or indirectly out of or in any way connected with Employee's employment with Company. This release is intended to have the broadest possible application and includes, but is not limited to, any tort, contract, common law, constitutional or other statutory claims, including, but not limited to, alleged violations of the California Labor Code, the California Fair Employment and Housing Act, Title VII of the Civil Rights Act of 1964, the Americans with Disabilities Act, and all claims for attorneys' fees, costs and expenses. Employee expressly waives Employee's right to recovery of any type, including damages or reinstatement, in any administrative or court action, whether state or federal, and whether brought by Employee or on Employee's behalf, related in any way to the matters released herein. However, this general release is not intended to bar any claims that, by statute, may not be waived, such as claims for workers' compensation benefits, unemployment insurance benefits, and statutory indemnity.

Employee acknowledges that Employee may discover facts or law different from, or in addition to, the facts or law that Employee knows or believes to be true with respect to the claims released in this Separation Agreement and agrees, nonetheless, that this Separation Agreement and the release contained in it shall be and remain effective in all respects notwithstanding such different or additional facts or the discovery of them.

Employee declares and represents that Employee intends this Separation Agreement to be complete and not subject to any claim of mistake, and that the release herein expresses a full and complete release and Employee intends the release herein to be final and complete. Employee executes this release with the full knowledge that this release covers all possible claims against the Released Parties, to the fullest extent permitted by law.

5.2 General Release by Company. The Company, on behalf of itself, its affiliates, successors, heirs, administrators, and assigns, as well as Company's officers and directors, fully and forever releases Employee, her heirs, administrators and assigns (collectively, "Employee Released Parties") from any and all claims, losses, liabilities, actions, causes of actions, demands, rights, damages, costs and expenses of any kind, to the fullest extent permitted by law, arising out of Employee's employment or services as an officer or director, except for any claims or causes of action based on fraud, known or unknown, suspected or unsuspected. This release is intended to have the broadest possible application and includes but is not limited to any tort other than fraud, contract, common law, constitutional or other statutory claims.

5.3 Company and Employee each acknowledge that they may discover facts or law different from, or in addition to, the facts or law that they know or believe to be true with respect to the claims released in this Separation Agreement and agree, nonetheless, that this Separation Agreement and the release contained in it shall be and remain effective in all respects notwithstanding such different or additional facts or the discovery of them.

5.4 Company and Employee each declare and represent that they intend this Separation Agreement to be complete and not subject to any claim of mistake, and that the release herein expresses a full and complete release and Company and Employee each intend the release herein to be final and complete. Company and Employee each

execute this release with the full knowledge that this release covers all possible claims against the Released Parties, to the fullest extent permitted by law.

6. California Civil Code Section 1542 Waiver. Company, on behalf of itself, its affiliates, successors, heirs, administrators, and assigns, and Employee, on her behalf, each expressly acknowledge and agree that all rights under Section 1542 of the California Civil Code are expressly waived. That section provides:

A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS WHICH THE CREDITOR DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE, WHICH IF KNOWN BY HIM OR HER MUST HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR.

7. Representation Concerning Filing of Legal Actions. Employee represents that, as of the date of this Separation Agreement, Employee has not filed any lawsuits, charges, complaints, petitions, claims or other accusatory pleadings against Company or any of the other Released Parties in any court or with any governmental agency. Employee further agrees that, to the fullest extent permitted by law, Employee will not prosecute, nor allow to be prosecuted on Employee's behalf, in any administrative agency, whether state or federal, or in any court, whether state or federal, any claim or demand of any type related to the matters released in this Separation Agreement; provided, however, that Employee may file a claim for unemployment benefits and the Company will not take any actions to dispute or challenge Employee's claim to unemployment benefits.

8. Mutual Nondisparagement. Employee agrees that Employee will not make any written or verbal statements, or encourage others to make any such statements, that defame, disparage or criticize the personal or business reputation, practices or conduct of Company or any of the other Released Parties. In exchange for Employee's promises set forth herein, neither the Company nor the members of its Board of Directors will make, and the Company agrees to instruct its officers to not make, any voluntary statements, written or oral, or cause or encourage others to make any such statements that defame, disparage or in any way criticize Employee or Employee's personal and/or business reputation.

9. Confidentiality and Return of Company Property. Employee understands and agrees that as a condition of receiving the Severance Package in paragraph 1, all Company property must be returned to Company; provided, however, the Employee shall be entitled to keep the blackberry and computer she used during her service at the Company (the "Employee Retained Property"). By signing this Separation Agreement, Employee represents and warrants that Employee has returned to Company all Company property, data and information belonging to Company (other than the Employee Retained Property) and agrees that Employee will not use or disclose to others any confidential or proprietary information of Company or the Released Parties (including any confidential or proprietary information of the Company or the Release parties contained on the Employee Retained Property). In addition, Employee agrees to keep the terms of this Separation Agreement confidential between Employee and Company, except that Employee may tell Employee's immediate family and attorney or accountant, if any, as needed, but in no event should Employee discuss this Separation Agreement or its terms with any current or prospective employee of Company. The Company agrees to allow a representative of Employee to pick up all of Employee's personal property at the Company's premises on Friday, February 19, 2010 at 4:00 p.m., or at such other time mutually agreed by the Company and Employee.

10. Continuing Obligations. Employee further agrees to comply with the continuing obligations regarding confidentiality set forth in the surviving provisions of Company's Information and Inventions Agreement previously signed by Employee.

11. Consideration Period. Employee has until 5:00 p.m. on February 17, 2010 to consider whether or not to enter into this Separation Agreement. This Separation Agreement shall not become effective or enforceable until the day Employee signs this Separation Agreement ("Effective Date"). If the signed Separation Agreement is not received by Company's legal counsel, Jeff Thacker, DLA Piper, 4365 Executive Drive, Suite 1100, San Diego, CA 92121-2133, Fax No. (858) 638-5128, by 5:00 p.m. Pacific Time on February 17, 2010, Company will assume that Employee is not interested in the Severance Package, the offer will be automatically withdrawn and Company will terminate Employee's employment without Cause on the Separation Date.

12. No Admissions. By entering into this Separation Agreement, the Released Parties make no admission that they have engaged, or are now engaging, in any unlawful conduct. The parties understand and acknowledge that this Separation Agreement is not an admission of liability and shall not be used or construed as such in any legal or administrative proceeding.

13. Severability. In the event any provision of this Separation Agreement shall be found unenforceable, the unenforceable provision shall be deemed deleted and the validity and enforceability of the remaining provisions shall not be affected thereby.

14. Legal Representation. Employee acknowledges and agrees that DLA Piper LLP (US) represents only the Company with respect to her separation of employment from Company and this Separation Agreement and that it does not represent Employee. In addition, Employee acknowledges and agrees that she has obtained her own legal counsel to review and negotiate the terms of this Separation Agreement.

15. Full Defense. This Separation Agreement may be pled as a full and complete defense to, and may be used as a basis for an injunction against, any action, suit or other proceeding that may be prosecuted, instituted or attempted by Employee or the Company, as applicable. Employee agrees that in the event an action or proceeding is instituted by the Released Parties in order to enforce the terms or provisions of this Separation Agreement, the Released Parties shall be entitled to an award of reasonable costs and attorneys' fees incurred in connection with enforcing this Separation Agreement, to the fullest extent permitted by law. Company agrees that in the event an action or proceeding is instituted by the Employee Released Parties in order to enforce the terms or provisions of this Separation Agreement, the Employee Released Parties shall be entitled to an award of reasonable costs and attorneys' fees incurred in connection with enforcing this Separation Agreement, to the fullest extent permitted by law.

16. Applicable Law. The validity, interpretation and performance of this Separation Agreement shall be construed and interpreted according to the laws of the United States of America and the State of California.

17. Entire Agreement; Modification. This Separation Agreement, including the surviving provisions of Company's Information and Inventions Agreement previously executed by Employee and Company's Plan and related stock option agreements, the sections of the Employment Agreement referenced herein and the Consulting Agreement are intended to be the entire agreement between the parties and supersedes and cancels any and all other and prior agreements, written or oral, between the parties regarding the subject matters in the Separation Agreement and the Consulting Agreement. This Separation Agreement may be amended only by a written instrument executed by all parties hereto.

THE PARTIES TO THIS SEPARATION AGREEMENT HAVE READ THE FOREGOING SEPARATION AGREEMENT AND FULLY UNDERSTAND EACH AND EVERY PROVISION CONTAINED HEREIN. WHEREFORE, THE PARTIES HAVE EXECUTED THIS SEPARATION AGREEMENT ON THE DATES SHOWN BELOW.

Dated: 2/17/10

By: /s/ Juliet Singh

Juliet Singh

Transdel Pharmaceuticals, Inc.

Dated: 2/17/10

By: /s/ John Lomoro

John Lomoro

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-159159 on Form S-8 of our report dated March 31, 2010, relating to the consolidated financial statements of Transdel Pharmaceuticals, Inc. and subsidiaries (the "Company") (which report expresses an unqualified opinion and includes an explanatory paragraph relating to the substantial doubt about the Company's ability to continue as a going concern), appearing in this Annual Report on Form 10-K of Transdel Pharmaceuticals, Inc. for the year ended December 31, 2009.

/s/ KMJ Corbin & Company LLP

Costa Mesa, California
March 31, 2010

CERTIFICATION

I, John Lomoro, Acting Chief Executive Officer and Chief Financial Officer of Transdel Pharmaceuticals, Inc., certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2009 for Transdel Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report.
4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2010

By: /s/ John Lomoro

John Lomoro
Acting Chief Executive Officer and
Chief Financial Officer
(Principal Executive Officer and
Principal Accounting Officer)

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, John Lomoro, Acting Chief Executive Officer and Chief Financial Officer of Transdel Pharmaceuticals, Inc. (the "Company") certify under the standards set forth and solely for the purposes of 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) The Annual Report on Form 10-K of the Company for the fiscal year ended December 31, 2009 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 31, 2010

/s/ John Lomoro

John Lomoro, Acting Chief Executive Officer and Chief
Financial Officer

This certification accompanies each Report pursuant to § 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of §18 of the Securities Exchange Act of 1934, as amended.

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.