



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, 2008

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 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 the definitions of "large accelerated filer," "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, 2008 (the last business day of the registrant's most recently completed second fiscal quarter) of \$1.85 per share as reported by the OTC Bulletin Board, was approximately \$17,818,477. 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, 2008. This determination of affiliate status is not necessarily a conclusive determination for any other purposes.

As of March 3, 2009, there were 15,570,184 shares of our Common Stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

None.

---

---

## TABLE OF CONTENTS

### **PART I**

<a href="#">Item 1.</a>	<a href="#">Description of Business</a>	1
<a href="#">Item 1A.</a>	<a href="#">Risk Factors</a>	7
<a href="#">Item 2.</a>	<a href="#">Properties</a>	14
<a href="#">Item 3.</a>	<a href="#">Legal Proceedings</a>	14
<a href="#">Item 4.</a>	<a href="#">Submission of Matters to a Vote of Security Holders</a>	15

### **PART II**

<a href="#">Item 5.</a>	<a href="#">Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</a>	16
<a href="#">Item 7.</a>	<a href="#">Management’s Discussion and Analysis of Financial Condition and Results of Operations</a>	16
<a href="#">Item 8.</a>	<a href="#">Financial Statements and Supplementary Data</a>	21
<a href="#">Item 9.</a>	<a href="#">Changes in and Disagreements with Accountants on Accounting and Financial Disclosures</a>	21
<a href="#">Item 9A(T).</a>	<a href="#">Controls and Procedures</a>	21
<a href="#">Item 9B.</a>	<a href="#">Other Information</a>	22

### **PART III**

<a href="#">Item 10.</a>	<a href="#">Directors, Executive Officers and Corporate Governance</a>	22
<a href="#">Item 11.</a>	<a href="#">Executive Compensation</a>	24
<a href="#">Item 12.</a>	<a href="#">Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</a>	27
<a href="#">Item 13.</a>	<a href="#">Certain Relationships and Related Transactions and Director Independence</a>	28
<a href="#">Item 14.</a>	<a href="#">Principal Accountant Fees and Services</a>	28

### **PART IV**

<a href="#">Item 15.</a>	<a href="#">Exhibits, Financial Statement Schedules</a>	29
<a href="#">SIGNATURES</a>		32
<a href="#">EX-31.1</a>		
<a href="#">EX-31.2</a>		
<a href="#">EX-32</a>		

---

## **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; 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: obtain substantial additional funds, 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, meet obligations and required milestones under agreements, be capable of manufacturing and distributing products in commercial quantities at reasonable costs, 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”) is a specialty pharmaceutical company developing non-invasive, topically- delivered medications. Our innovative patented Transdel™ cream formulation technology is designed to facilitate the effective penetration of drugs through the tough skin barrier to reach the target underlying tissues. In the case of Ketotransdel® (our lead drug currently in a Phase 3 trial), the Transdel™ cream allows the active ingredient ketoprofen to reach the target soft tissue and exert its well-known anti-inflammatory and analgesic effects.

We are also investigating other drug candidates and treatments for transdermal delivery using our patented Transdel™ platform technology, for products in pain management, other therapeutic areas and for cosmetic/cosmeceutical products. 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 TDLP.OB. Prior to that date, there was no active market for our common stock. On March 3, 2009, the closing price of our common stock was \$0.99 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](http://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, renal, 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 clinical and medical track record for safety and efficacy with low incidences of kidney, liver and skin reactions when administered topically.

### **Clinical results with 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®.

The clinical study for acute pain and muscle soreness demonstrated a significant medical benefit from Ketotransdel® in terms of relief of pain and muscle soreness. The topical Ketotransdel® has approximately 1/100th of the blood levels of ketoprofen found in the circulatory system as compared to a comparable dose of commercially available oral ketoprofen. Thus, we believe that the topical Ketotransdel® can potentially provide a safer alternative to pain management as compared to the orally administered pain medications. No adverse reactions to Ketotransdel®, such as rash or irritation were reported.

### **Clinical Program for Ketotransdel®**

On June 16, 2008, we announced that we initiated our Phase 3 clinical program for our novel analgesic and anti-inflammatory topical cream, Ketotransdel® and on September 22, 2008 we announced the enrollment of our first patient. The first Phase 3 study consists of a randomized, double-blind, placebo controlled trial to evaluate the efficacy and safety of Ketotransdel® in acute soft tissue injuries of the upper and lower extremities over a one week treatment period with a one week post-treatment follow-up for safety. The multi-center trial will be conducted at approximately 30 sites in the United States and will enroll approximately 350 patients, randomized 1:1 ratio Ketotransdel® (active) versus placebo vehicle (identical to active without the drug ketoprofen). The primary efficacy endpoint is the difference in the change of baseline of pain during normal activity for the past 24 hours from measurement at the Day 3 clinical visit between active and placebo measured by using the Visual Analogue Scale (VAS), a well known and validated instrument for pain measurement. Secondary endpoints include safety assessments and other efficacy parameters measured by VAS. As of March 17, 2009, we have initiated 30 study sites for this Phase 3 study and approximately 50% of the patients have been enrolled. We anticipate reporting top-line results in the second half of 2009. In addition, as required by the U.S. Food and Drug Administration ("FDA"), we will be initiating a second Phase 3 clinical study in acute musculoskeletal pain, potentially for the treatment of acute flare in osteoarthritis patients. We are currently assessing the design and timing of this additional study that will support the registration of Ketotransdel® in the United States. If and when the FDA approves Ketotransdel® for treatment of acute pain, we intend to pursue FDA approval of Ketotransdel® for other indications, such as osteoarthritis. Furthermore, we are either in or pursuing discussions with U.S. and foreign based potential partners with sales and marketing infrastructures to support Ketotransdel® in the event that the product is approved and commercialized.

### **Cosmeceutical/Cosmetic Product Development Program**

In addition, we have expanded our product development programs to include cosmetic/cosmeceutical products, which utilize our patented transdermal delivery system technology, Transdel™. For our anti-cellulite and anti-aging products, we have initial clinical information supporting the efficacy of these key cosmetic/cosmeceutical products. Also, we are either in or pursuing discussions with potential sales and marketing partners for these cosmetic/cosmeceutical products and are targeting to introduce these initial products into the market in 2009. Our potential pipeline of other cosmetic/cosmeceutical products includes varicose vein and hyperpigmentation formulations.

### **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. 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**

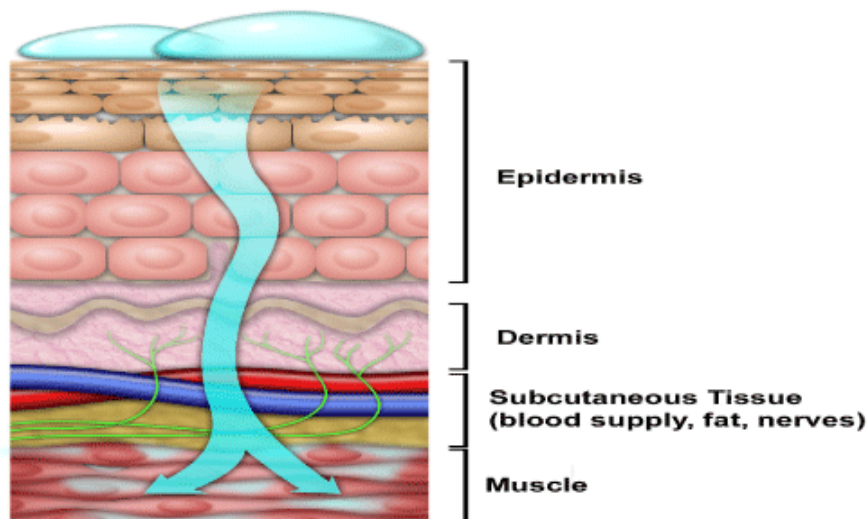
The market for NSAIDs and COX-2 inhibitors in the United States may exceed \$6 billion. Since the withdrawal of major COX-2 inhibitors in 2005, oral NSAIDs have captured a share of the multibillion retail market for COX-2 inhibitors. Oral NSAIDs remain one of the most prescribed classes of drugs in the pain management market. Over 30 million people worldwide use prescription and over-the-counter NSAIDs daily.

## [Table of Contents](#)

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 an ideal vehicle for topical drug administration:

- biocompatible — it hydrates the skin;
- enhanced skin penetration — it has a balance of hydrophilic and hydrophobic properties that allow efficient partitioning of drugs into the skin;
- low toxicity and biodegradable — its components are non-immunogenic and are generally regarded as safe;
- thermodynamically stable, insensitive to moisture and resistant to microbial contamination; and
- has desired skin adherence, spreadability, and cohesiveness for use as a topical agent.

Other key features of Transdel™ technology include:

- allows maximal solubilization of drug;
- clinical data supports safety and efficacy;
- potentially result in decreased safety concerns which are associated with oral drugs;
- rapid and efficient transdermal drug delivery;
- enables painless administration of medications and avoids stomach irritation;
- Not associated with limitations of transdermal patches;
- Can potentially be used for a number of different injuries or diseases;
- highly flexible — allows the delivery of a wide range of different medications;
- 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 products that would compete with our product if and when approved by the FDA. Also, we are aware of companies developing patch products and other pain formulations.



## Table of Contents

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 many of our national 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**

FDA approval is typically required before any new drug can be marketed. A NDA is a filing submitted to the FDA to obtain approval of new chemical entities and other innovations for which thorough applied research is required to demonstrate safety and effectiveness in use. The NDA must contain complete preclinical and clinical safety and efficacy data or a reference to such data. Since the active pharmaceutical ingredients in our topical drug candidates, such as ketoprofen, have already been approved by the FDA, we are able to file NDAs under section 505(b)(2) of the Hatch-Waxman Act of 1984. Under Section 505(b)(2) we may rely on data from pre-clinical and clinical studies that were not conducted by or for us and for which we have not obtained a right of reference or use from the person by or for whom the investigation was conducted. The FDA has determined that a 505(b)(2) NDA may be submitted for products that represent changes from approved drugs in conditions of use, active ingredient(s), route of administration, dosage form, strength, or bioavailability.

## Table of Contents

A 505(b)(2) applicant must provide the FDA with any additional clinical data necessary to demonstrate the safety and effectiveness of the product with the proposed change(s). Consequently, although duplication of preclinical and certain clinical studies is avoided through the use a 505(b)(2) application, specific studies may be required by the FDA. Such studies are typically conducted in three sequential phases, although 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.

Each trial 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) NDA is relying on the findings for an already-approved drug, the applicant is required to certify that there are no patents for that drug or that (i) the patent has expired, (ii) the patent has not expired, but will expire on a particular date and approval is sought after patent expiration or (iii) the patent is invalid or will not be infringed by the manufacture, use or sale of the new product.

A certification that the new product will not infringe the already approved product's 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) NDA will not be approved until all the listed patents as well as any additional period of exclusivity have expired.

A paragraph IV certification sent to the FDA must also be sent to the relevant patent holders once the 505(b)(2) NDA has been accepted for filing by the FDA. The patent holders may then initiate a legal challenge to the paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of receipt of a paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA until the earliest of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant. Thus, a Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its products only to be subject to significant delay and patent litigation before its products may be commercialized.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years, certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA changes its interpretation of Section 505(b)(2), this could delay or even prevent the FDA from approving any Section 505(b)(2) NDA that we submit.

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.

## Table of Contents

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 with 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 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 or 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.

### **Employees**

As of March 3, 2009, we employed three individuals, including one in management, one in financial accounting and one in administration. We currently believe that our employee relations are good. Also, we have engaged with a pharmaceutical consultant, to lead our business development activities, especially the out-licensing of our lead product Ketotransdel®

## 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. For the fiscal year ended December 31, 2008, we have a deficit accumulated during the development stage of approximately \$10.4 million, and for the year ended December 31, 2008, we experienced a net loss of approximately \$3.3 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 may not be able to execute our business plan or fund business operations. Furthermore, we may 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.

***We will need additional financing to execute our business plan and fund our operations, which additional financing may not be available on a timely basis, or at all.***

We have limited funds to support our operations and we may not be able to execute our current business plan and fund business operations long enough to achieve profitability unless we are able to secure additional funds. 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 over the next twelve months, which would include completing the Phase 3 clinical trial currently in progress for Ketotransdel®. However, in order to execute the second Phase 3 clinical trial of Ketotransdel®, which is currently required by the FDA to obtain final regulatory approval for Ketotransdel®, we would need to secure additional funds. If adequate financing is not available, we will not be able to conduct the second Phase 3 clinical trial. 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 funds sooner than anticipated.

We may 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 condition.

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 execute the second Phase 3 clinical trial of Ketotransdel® currently required by the FDA and any other clinical trials we would want to 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.

***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. 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;
- 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.

## Table of Contents

***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 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 expand patent protection for our specific products and technologies both in the United States and other countries. We cannot guarantee that any patents will be issued from any pending or future patent applications owned by or licensed to us. Alternatively, a third party may successfully circumvent our patents. Our rights under any issued patents may not provide us with sufficient protection against competitive products or otherwise cover commercially valuable products or processes. In addition, because patent applications in the United States are maintained in secrecy for eighteen months after the filing of the applications, and publication of discoveries in the scientific or patent literature often lag behind actual discoveries, we cannot be sure that the inventors of subject matter covered by our patents and patent applications were the first to invent or the first to file patent applications for these inventions. In the event that a third party has also filed a patent on a similar invention, we may have to participate in interference proceedings declared by the United States Patent and Trademark Office to determine priority of invention, which could result in a loss of our patent position. Furthermore, we may not have identified all United States and foreign patents that pose a risk of infringement.

***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 rely on third parties to conduct and manage clinical and non-clinical studies of our drug candidates and provide us with other services. Such third party contractors are subject to FDA requirements. Our business and financial viability are dependent on the regulatory compliance of these third parties, and on the strength, validity and terms of our various contracts with these third parties. In addition, if the current adverse economic conditions continue for a prolonged period or become more severe, one or more of our suppliers may be forced to close their business or to refuse or be unable to perform in accordance with our contracts. Any interruption or failure by these third party contractors to meet their obligations pursuant to various agreements with us may be outside of our control and could have a material adverse effect on our business, financial condition and results of operations.

***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 to support the efficacy of anti-cellulite and anti-aging products, and we are either in or pursuing discussions with potential sales and marketing partners for these products. We 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 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 varicose veins and hyperpigmentation. 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, especially our Chief Executive Officer, Juliet Singh, Ph.D. 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 and have an employment agreement with our Chief Executive Officer, 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 more well 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.



## [Table of Contents](#)

***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 required us to conduct an annual management assessment of the effectiveness of our internal controls over financial reporting for this 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 ended December 31, 2009. These reporting and other obligations will place significant demands on our management, administrative, operational, and accounting resources. We anticipate that we will need to upgrade our systems; implement additional financial and management controls, reporting systems and procedures; implement an internal audit function; and hire additional accounting, internal audit 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 certifications 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 may be deemed a “penny stock”, which would make it more difficult for our investors to sell their shares.***

Our common stock may be 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.

***Our directors and executive officers can exert significant control over our business and affairs and may have actual or potential interests that may depart from those of our other stockholders.***

Our directors and executive officers together beneficially own a significant percentage of our issued and outstanding common stock, which percentage may increase in the event that they exercise any options or warrants to purchase shares of our common stock that they may hold or in the future are granted to them. The interests of such persons may differ from the interests of other stockholders. Such persons will have significant influence over all corporate actions requiring stockholder approval, irrespective of how our other stockholders may vote, including the following actions:

- the election of our directors;
- amendment of our Certificate of Incorporation or By-laws; and
- mergers, sales of assets or other corporate transactions.

Concentration of stock ownership among a few stockholders may discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control of our company, which in turn could reduce our stock price or prevent our stockholders from realizing a premium over our stock price.

***Raising additional funds by issuing securities or through collaboration and licensing arrangements may cause dilution to existing stockholders, restrict operations or require us to relinquish proprietary rights.***

We may raise additional funds through public or private equity offerings or corporate collaboration and licensing arrangements. To the extent that we raise additional capital by issuing equity securities, our existing stockholders’ ownership will be diluted. In addition, if we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish potentially valuable rights to our potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. Further, we may not be able to obtain additional funding, particularly if the volatile conditions in the stock and financial markets, and more particularly the market for pharmaceutical company stocks, persist. If we are unable to obtain additional funding, we may be required to delay, further reduce the scope of or discontinue one or more of our research and development projects, sell the company or certain of its assets or technologies, or dissolve and liquidate the company’s assets.

## **ITEM 2. PROPERTIES**

### **Facilities**

We lease approximately 1,681 square feet of office space in La Jolla, California. The current lease term expires on August 31, 2009 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. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

The following proposals were submitted for shareholder vote in conjunction with the Company's Annual Meeting of Stockholders held on November 5, 2008:

- (a) The votes received for the nominees for the Board of Directors were elected by a vote of the stockholders as follows:

	<u>Votes For</u>	<u>Votes Withheld</u>
Juliet Singh	13,170,074	2,000
Jeffrey Abrams	13,170,074	2,000
Anthony Thornley	13,171,074	1,000

- (b) the amendment to increase the number of shares of common stock from 1,500,000 to 3,000,000 available for issuance under the 2007 Incentive Stock and Awards Plan was approved by a vote of the stockholders as follows:

<u>Votes For</u>	<u>Votes Against</u>	<u>Abstain</u>	<u>Broker Non-Votes</u>
11,448,870	497,989	137,018	—

- (c) the ratification of the selection of KMJ Corbin & Company LLP as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2008 was approved by a vote of the stockholders as follows:

<u>Votes For</u>	<u>Votes Against</u>	<u>Abstain</u>
13,036,056	—	136,018

**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 3, 2009 was \$0.99 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.

<b>Fiscal Year 2008</b>	<b>High</b>	<b>Low</b>
First Quarter	\$2.94	\$1.05
Second Quarter	\$1.98	\$1.10
Third Quarter	\$1.75	\$1.00
Fourth Quarter	\$1.39	\$0.55
<b>Fiscal Year 2007</b>	<b>High</b>	<b>Low</b>
Fourth Quarter (starting October 1, 2007)	\$3.10	\$2.00

**Holder**

As of March 3, 2009 we had approximately 95 stockholders of record (excluding an indeterminable 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**

On November 21, 2008, in connection with his appointment to the Board of Directors, Lynn C. Swann received a stock option to purchase 80,000 shares of our common stock at an exercise price of \$0.70 per share, which was the closing bid price of the our common stock on the date of grant. The options vest in equal quarterly installments over a five-year period measured from the grant date. Also, Mr. Swann received a stock option to purchase 25,000 shares of our common stock at an exercise price of \$0.70 per share. This option vests in equal quarterly installments over a one-year period measured from the grant date. We also issued Mr. Swann 25,000 shares of restricted stock at a price of \$0.70 per share. We have the right to repurchase the restricted stock from Mr. Swann, which right terminates in four equal installments over a one-year period measured from the grant date.

On November 21, 2008, two of our directors, Jeffrey Abrams, M.D. and Anthony Thornley, were each granted stock options to purchase 80,000 shares of our common stock at an exercise price of \$0.70 per share, which was the closing bid price of our common stock on the date of grant. The options vest in equal quarterly installments over a five-year period measured from the grant date.

On December 19, 2008, we entered into an agreement with consulting firm ("Firm"), pursuant to which the Firm will provide certain business development services to us. As part of the compensation for such services, we granted a stock option to the Firm to purchase 50,000 shares of our common stock at an exercise price of \$0.99, which was the closing bid price of our common stock on the date of the grant.

The offers, sales and issuances of these securities were deemed to be exempt from registration under the Securities Act in reliance on Section 4(2) of the Securities Act, and/or Regulation D and the other rules and regulations promulgated thereunder, or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions not involving a public offering or transactions under compensatory benefit plans and contracts relating to compensation as provided under such Rule 701. The recipients of securities in each such transaction represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the share certificates and options issued in such transactions.

**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 below 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 medications. Our innovative patented proprietary Transdel™ cream formulation technology is designed to facilitate the effective penetration of drugs through the tough skin barrier to reach the target underlying tissues. In the case of Ketotransdel®, the Transdel™ cream allows the active ingredient ketoprofen to reach the target soft tissue and exert its well-known anti-inflammatory and analgesic effects. We are also investigating other drug candidates and treatments for transdermal delivery using the patented Transdel™ platform technology for products in pain management, other therapeutic areas and for cosmetic/cosmeceutical products.

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.

## 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 musculoskeletal pain, development of cosmetic/cosmeceutical products and co-development opportunities in other therapeutic areas utilizing our Transdel platform technology.

## Clinical Program for Ketotransdel®

On June 16, 2008, we announced that we initiated our Phase 3 clinical program for our novel analgesic and anti-inflammatory topical cream, Ketotransdel®, which contains ketoprofen and on September 22, 2008, we announced the enrollment of our first patient. The first Phase 3 study consists of a randomized, double-blind, placebo controlled trial to evaluate the efficacy and safety of Ketotransdel® in acute soft tissue injuries of the upper and lower extremities over a one week treatment period with a one week post-treatment follow-up for safety. The multi-center trial will be conducted at approximately 30 sites in the United States and will enroll approximately 350 patients, randomized 1:1 ratio Ketotransdel™ (active) versus placebo vehicle (identical to active without the drug ketoprofen). The primary efficacy endpoint is the difference in the change of baseline of pain during normal activity for the past 24 hours from measurement at the Day 3 clinical visit between active and placebo measured by using the Visual Analogue Scale (VAS), a well known and validated instrument for pain measurement. Secondary endpoints include safety assessments and other efficacy parameters measured by VAS. As of March 17, 2009, we have initiated 30 study sites for this Phase 3 study and approximately 50% of the patients have been enrolled. We anticipate reporting top-line results in the second half of 2009. In addition, as required by the FDA, we will be initiating a second Phase 3 clinical study in acute musculoskeletal pain, potentially for the treatment of acute flare in osteoarthritis patients. We are currently assessing the design and timing of this additional study that will support the registration of Ketotransdel® in the United States. If and when the FDA approves Ketotransdel® for treatment of acute pain, we intend to pursue FDA approval of Ketotransdel® for other indications, such as osteoarthritis. Furthermore, we are either in or pursuing discussions with U.S. and foreign based potential partners with operations that have sales and marketing infrastructures to support Ketotransdel® in the event that the product is approved and commercialized.

## 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™. For our anti-aging and anti-cellulite products, we have initial clinical information supporting the efficacy of these key cosmetic/cosmeceutical products. Also, we are either in or pursuing discussions with potential sales and marketing partners for these cosmetic/cosmeceutical products and are targeting to introduce these initial products into the market in 2009. Our potential pipeline of other cosmetic/cosmeceutical products includes varicose vein and hyperpigmentation formulations.

## 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.

## [Table of Contents](#)

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.

### **Results of Operations**

#### **Comparisons of Years Ended December 31, 2008 and 2007**

##### **Selling, General and Administrative Expenses**

Selling, general and administrative expenses were approximately \$1.8 million in 2008 as compared to approximately \$1.0 million for the same period in 2007. The increase is primarily related to higher personnel, investor relations and other corporate expenses associated with a full twelve months of operations as a public company in 2008 compared to approximately four months in 2007, which was the period of time subsequent to the Merger we completed in September 2007. The primary reason that personnel expenses increased by approximately \$350,000 in 2008 compared to 2007 is due to a full year of amortization expense for stock options granted to personnel and directors in 2008 and 2007. Also, investor relations expense increased in 2008 compared to 2007 by approximately \$200,000 primarily related to the amortization of the value of stock provided to investor relations firms for their services and the investor relations activities incurred by our personnel. Other corporate expenses (such as rent, insurance and legal fees) increased due the full year of activity in 2008 compared to the partial year in 2007.

##### **Research and Development Expenses**

Research and development expenses were approximately \$2.0 million in 2008 as compared to approximately \$1.8 million for the same period in 2007. There were substantial research and development activities during all of 2008 and the latter part of 2007 that resulted in a consistent level of expenses between the two years. Personnel costs for the two years were consistent, but in 2008 approximately \$1.1 million of expenses were incurred for the on-going Phase 3 trial of Ketotransdel®. In 2007 approximately \$1.1 million of expense was incurred as well, but it was related to contract manufacturing activities, non-clinical studies and consulting services related to the preparation of the February 2008 Phase 3 clinical study filing with the FDA.

##### **Interest Expense**

In 2007, as a result of and in conjunction with the Merger, the entire outstanding principal amount of \$1.5 million of convertible notes and accrued interest was converted into our common stock at a conversion price equal to \$1.00 per share, which was at a rate below the \$2.00 common stock market value. Therefore, due to this "beneficial conversion feature" that resulted in the issuance of 1,530,177 shares, we recognized a debt discount of \$1,530,177. Prior to the conversion of the convertible notes, we recognized interest expense on these convertible notes and previously outstanding shareholder notes of approximately \$30,000.

##### **Interest Income**

Interest income was approximately \$67,000 in 2008 compared to approximately \$48,000 in 2007. The increase in 2008 resulted from a higher average balance of cash and cash equivalents in 2008 compared to 2007. Interest income was negatively impacted in 2008 as a result of the decrease in the average interest rate of 1.8% in 2008 compared to 2.9% in 2007.

##### **Gain on Settlement**

In 2008, we obtained \$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.

##### **Forgiveness of Liabilities**

In 2007, we entered into a mutual release agreement with a vendor, settling a balance of \$170,914. In accordance with the mutual release agreement, we paid \$81,000 and recognized a gain of \$89,914.

##### **Liquidity and Capital Resources**

Since inception through December 31, 2008, we have incurred losses of approximately \$10.4 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.



## Table of Contents

As of December 31, 2008, we had \$5.1 million in cash and cash equivalents. On each of September 17, 2007, and October 10, 2007, we completed private placements to selected institutional and accredited investors. In connection with these private placements, we raised approximately \$3.8 million (net of placement agent fees and other costs aggregating \$342,105) from the issuance of 2,071,834 shares of common stock and detachable redeemable 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 May 2008, we completed another 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. Our continuation as a going concern subsequent to fiscal year 2009 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. 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 over the next twelve months, which would include completing the Phase 3 clinical trial currently in progress. However, in order to execute the second Phase 3 clinical trial of Ketotransdel® which is currently required by the FDA to obtain final regulatory approval for Ketotransdel we would need to raise additional funds. We intend to seek additional financing to fund the second Phase 3 clinical trial 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 conduct the second Phase 3 trial.

We may 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 condition.

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.

### **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.

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 audited 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 audited consolidated financial statements.

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

*Stock-Based Compensation.* Effective January 1, 2006, we adopted Statement of Financial Accounting Standards (“SFAS”) No. 123 (revised 2004), *Share-Based Payment*, (“SFAS No. 123R”), which is a revision of SFAS No. 123, *Accounting for Stock-Based Compensation*. SFAS No. 123R supersedes Accounting Principles Board No. 25, *Accounting for Stock Issued to Employees*, and amends SFAS No. 95, *Statement of Cash Flows*. SFAS No. 123R requires 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 under SFAS No. 123R. Fair value is determined at the date of grant. In accordance with SFAS No. 123R, 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, management assigned a forfeiture factor of 10%, which will be assigned to future director and employee options. This percentage was determined based on consideration of actual forfeitures realized during fiscal year 2008 and estimated forfeitures to potentially occur in the future.



## [Table of Contents](#)

Our accounting policy for equity instruments issued to consultants and vendors in exchange for goods and services follows the provisions of SFAS No. 123, Emerging Issues Task Force (“EITF”) No. 96-18, *Accounting for Equity Instruments That are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services* and EITF No. 00-18, *Accounting Recognition for Certain Transactions Involving Equity Instruments Granted to Other Than Employees*. 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. In accordance with EITF No. 00-18, 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 recorded 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 December 2007, the FASB issued SFAS No. 141R, *Business Combinations*. SFAS No. 141R provides companies with principles and requirements on how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, liabilities assumed, and any noncontrolling interest in the acquiree as well as the recognition and measurement of goodwill acquired in a business combination. SFAS No. 141R also requires certain disclosures to enable users of the financial statements to evaluate the nature and financial effects of the business combination. Acquisition costs associated with the business combination will generally be expensed as incurred. SFAS No. 141R is effective for business combinations occurring in fiscal years beginning after December 15, 2008. Early adoption of SFAS No. 141R is not permitted. We do not anticipate that SFAS No. 141R will have any material effect on us.

We adopted SFAS, No. 157, *Fair Value Measurements*. In February 2008, the FASB issued FASB Staff Position (“FSP”) No. 157-2, *Effective Date of FASB Statement No. 157*, which provides a one year deferral of the effective date of SFAS No. 157 for non-financial assets and non-financial liabilities, except those that are recognized or disclosed in the financial statements at fair value in the financial statements on a recurring basis, at least annually. The delay is intended to allow FASB and constituents additional time to consider the effect of various implementation issues that have arisen, or that may arise, from the application of SFAS No. 157. Therefore, we have adopted the provisions of SFAS No. 157 with respect to our financial assets and liabilities only. SFAS No. 157 defines fair value, establishes a framework for measuring fair value under accounting principles generally accepted in the United States of America and enhances disclosures about fair value measurements. Fair value is defined under SFAS No. 157 as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. We also adopted FSP No. 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active*. FSP No. 157-3 clarifies the application of SFAS No. 157, in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. This FSP applies to financial assets within the scope of accounting pronouncements that require or permit fair value measurements in accordance with SFAS No. 157, as required, except as it applies to those nonfinancial assets and nonfinancial liabilities as noted in FSP No. 157-2. During the year ended December 31, 2008, the adoption of SFAS No. 157 did not have an impact on our consolidated financial statements.

In December 2007, the SEC issued Staff Accounting Bulletin No. 110 (“SAB 110”). SAB 110 amends and replaces Question 6 of Section D.2 of Topic 14, *Share-Based Payment*, of the Staff Accounting Bulletin series. Question 6 of Section D.2 of Topic 14 expresses the views of the staff regarding the use of the “simplified” method in developing an estimate of the expected term of “plain vanilla” share options and allows usage of the “simplified” method for share option grants prior to December 31, 2007. SAB 110 allows public companies which do not have historically sufficient experience to provide a reasonable estimate to continue to use the “simplified” method for estimating the expected term of “plain vanilla” share option grants after December 31, 2007. We adopted SAB 110 on January 1, 2008. We will continue to use the “simplified” method until we have enough historical experience to provide a reasonable estimate of expected term in accordance with SAB 110.

In December 2007, the FASB ratified EITF No. 07-1, *Accounting for Collaborative Agreements* (“EITF No. 07-1”). EITF No. 07-1 provides guidance regarding financial statement presentation and disclosure of collaborative arrangements, as defined, which includes arrangements we may enter into regarding development and commercialization of products. EITF No. 07-1 is effective for us as of January 1, 2009. We do not believe the adoption of this statement will have a material effect on our consolidated results of operations, financial position or liquidity.

## [Table of Contents](#)

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements* (“SFAS No. 160”), which will require noncontrolling interests (previously referred to as minority interests) to be treated as a separate component of equity, not as a liability or other item outside of permanent equity. SFAS No. 160 applies to the accounting for noncontrolling interests and transactions with non-controlling interest holders in consolidated financial statements. SFAS No. 160 will be applied prospectively to all noncontrolling interests, including any that arose before the effective date except that comparative period information must be recast to classify noncontrolling interests in equity, attribute net income and other comprehensive income to noncontrolling interests, and provide other disclosures required by SFAS No. 160. SFAS No. 160 is effective for periods beginning on or after December 15, 2008. Since we currently do not have any noncontrolling interests, the adoption of SFAS No. 160 is not expected to have a material impact on our consolidated results of operations, financial position or liquidity.

Other recent accounting pronouncements issued by the FASB (including the EITF) and the American Institute of Certified Public Accountants 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 Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure. In 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 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 quarter covered by this annual report on Form 10-K. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

#### **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 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, 2008.

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.

[Table of Contents](#)

**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.

**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.

<u>Name</u>	<u>Age</u>	<u>Position</u>
Juliet Singh, Ph.D.	49	Chief Executive Officer, Chairman of the Board
John T. Lomoro	39	Chief Financial Officer
Jeffrey J. Abrams, M.D.	61	Director
Anthony S. Thornley	62	Director
Lynn C. Swann	56	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.

**Biographies**

**Juliet Singh, Ph.D.** has been a director and our chief executive officer since the merger with Transdel Pharmaceuticals Holdings, Inc. on September 17, 2007. Dr. Singh was the Chief Executive Officer of Transdel Pharmaceuticals Holdings, Inc. since 2005. From 2000 to 2003, Dr. Singh was a corporate officer-vice president of regulatory affairs and quality assurance of Collateral Therapeutics, Inc., a developer of non-surgical gene therapy products for the treatment of cardiovascular disease, which was acquired by Schering AG in 2002. From 1996 to 2000, Dr. Singh was the director of worldwide regulatory affairs for Allergan Corporation, where she oversaw the registration of BOTOX™ in the United States, Canada, Europe Asia, and South America. Prior to joining Allergan, Dr. Singh was the assistant director of regulatory affairs for Baxter Healthcare Corp., where she provided leadership in obtaining worldwide regulatory approval for recombinant factor VIII. Dr. Singh holds a Ph.D. in endocrinology from the University of California, Davis.

## Table of Contents

**John T. Lomoro** has been 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.

**Jeffrey J. Abrams, M.D., MPH**, has been 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.

**Anthony S. Thornley** has been a director since November 6, 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.

**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 and Harrah's Entertainment, Inc. 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.

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, 2008, 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](http://www.transdelpharma.com).

**Director Independence**

We believe that Anthony S. Thornley and Lynn C. Swann 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 a national securities exchange, although we are not required to comply with such requirements until we seek listing on a securities exchange. Additionally, the Board will direct each committee to adopt a charter to govern its duties and actions.

**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 President and Chief Executive Officer, has abstained from any board discussions with respect to her compensation.

**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.

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

**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, 2008, and for two of our former executives.

**Summary Compensation Table**

Name	Year	Salary (\$)	Stock Awards \$(1)	Option Awards \$(2)	Total (\$)
Juliet Singh, Ph.D., President and Chief Executive Officer	2008	210,000	—	140,644	350,644
	2007	116,071	—	32,561	148,632
John T. Lomoro, Chief Financial Officer	2008	160,000	—	89,832	249,832
	2007	50,000	—	21,321	71,321
Paul Finnegan, M.D., M.B.A., F.R.C.P.C. (3) Former Chief Medical Officer and Chief Operating Officer	2008	102,955	—	8,014	110,969
Balbir Brar, DVM, Ph.D. Former Vice President of Research & Development	2008	34,308	298,110(4)	—	332,418
	2007	70,000	92,517(4)	28,425	190,942

## [Table of Contents](#)

- (1) Amount reflects the non-cash compensation cost for the year ended December 31, 2008 and 2007 of the named executive officer's stock, calculated in accordance with SFAS 123R. Assumptions used in the calculation of these amounts are included in Note 7 to our consolidated financial statements included herein.
- (2) Amount reflects the non-cash compensation expense for the years ended December 31, 2008 and 2007 of the named executive officer's options, calculated in accordance with SFAS 123R and using a Black-Scholes-Merton valuation model. Assumptions used in the calculation of these amounts are included in Note 7 to our consolidated financial statements included herein.
- (3) On April 23, 2008, Dr. Finnegan was granted an option to purchase 300,000 shares of common stock at an exercise price of \$2.00 per share. The option vested on a quarterly basis and was to fully vest on April 23, 2011. However, on November 15, 2008, Dr. Finnegan ended his employment and as of this date, Dr. Finnegan had vested in 50,000 shares of this grant. Dr. Finnegan had 90 days subsequent to November 15, 2008 in order to purchase his vested shares, however, this was not completed by Dr. Finnegan and his option shares expired unexercised.
- (4) In August 2007, we issued a restricted stock grant to Dr. Brar for 195,313 shares of our common stock upon closing of the Merger. These shares were subject to forfeiture in the event that Dr. Brar's employment was terminated for cause or he resigned without good reason prior to March 17, 2009. On April 4, 2008, our Board of Directors waived any restrictions or forfeiture conditions on the 195,313 shares of restricted common stock previously granted to Dr. Brar in conjunction with his resignation and a separation agreement entered into between Transdel and Dr. Brar. As a result of the waived restrictions, in April 2008, we recognized the unamortized value of this restricted stock.

### 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, 2008.

Name	Option Awards		Option Exercise Price (\$)	Option Expiration Date
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable		
Juliet Singh, Ph.D.	33,333	166,667	2.00	4/23/2018
	10,000	—	2.00	9/16/2017
	83,333	116,667	2.00	9/16/2017
John T. Lomoro	16,667	83,333	2.00	4/23/2018
	62,500	87,500	2.00	9/16/2017
Paul Finnegan, M.D., M.B.A., F.R.C.P.C.	50,000	—	2.00	2/15/2009

### Employment Agreements

We have entered into an employment agreement with Juliet Singh, Ph.D. to serve as our chief executive officer. Pursuant to this employment agreement, Dr. Singh is entitled to receive an annual base salary of \$195,000, subject to annual reviews by our board of directors. Dr. Singh is 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. If we terminate Dr. Singh's employment without cause, we will continue to pay Dr. Singh, as severance, her then current annual base salary for one year, payable in accordance with standard payroll procedures and the pro-rata amount of any accrued annual bonus.

### 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.

## [Table of Contents](#)

As of March 3, 2009, there were outstanding options to purchase 1,085,000 shares of our common stock, 220,313 shares of restricted stock outstanding under the 2007 Plan, and 1,694,687 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, 2008.

Name	Year	Fees Earned or Paid in Cash (\$)	Stock Awards (\$)(1)	Option Awards (\$)(2)(7)	Total (\$)
Juliet Singh, Ph.D. (3)	2008	\$—	\$ —	\$10,181	\$10,181
Jeffrey J. Abrams, M.D. (4)	2008	\$—	\$ —	\$11,010	\$11,010
Anthony S. Thornley (5)	2008	\$—	\$ —	\$18,121	\$18,121
Lynn C. Swann (6)	2008	\$—	\$2,188	\$ 2,050	\$ 4,238

- (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 for 25,000 shares of common stock at an exercise price of \$0.70, which vests quarterly over a 1 year period.
- (3) The compensation noted in the table is specifically related to the stock option grant of 10,000 shares that Dr. Singh, our President and Chief Executive Officer, was awarded on September 17, 2007 for her service on the Board of Directors for fiscal year 2007 and became fully vested on September 17, 2008. Dr. Singh has not received any additional compensation for her service on the Board of Directors.
- (4) As of December 31, 2008, Dr. Abrams held 90,000 stock options, of which 10,000 were vested.
- (5) As of December 31, 2008, Mr. Thornley held 90,000 stock options, of which 10,000 were vested.
- (6) As of December 31, 2008, Mr. Swann held 105,000 stock options and 25,000 shares of restricted common stock, of which none were vested.
- (7) Amount reflects the non-cash compensation expense for the years ended December 31, 2008 and 2007 of the named board member's options, calculated in accordance with SFAS 123R and using a Black-Scholes-Merton valuation model. Assumptions used in the calculation of these amounts are included in Note 7 to our consolidated financial statements included herein.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The following table sets forth certain information as of March 3, 2009, 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 3, 2009, 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.	2,130,792(6)	13.5%
Jeffrey J. Abrams, M.D.	1,576,500(2)	10.1%
The Abrams Family Trust	1,562,500(3)	10.0%
Anthony S. Thornley	87,400(4)	*
Lynn C. Swann	35,250(5)	*
John T. Lomoro	108,333(7)	*
Joseph Grasela(8)	1,171,875	7.5%
John C. Grasela(8)	1,171,875	7.5%
Paul Finnegan, M.D., M.B.A., F.R.C.P.C.	—	—
Balbir Brar, D.V.M., Ph.D.	398,438	2.6%
All executive officers and directors as a group (5 persons)	3,938,275	24.8%

\* less than 1%

- (1) Based on 15,570,184 shares of our common stock issued and outstanding as of March 3, 2009.
- (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 14,000 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 14,000 shares of common stock issuable upon the exercise of warrants and stock options, respectively.
- (5) Includes 10,250 shares of common stock issuable upon the exercise of stock options and 25,000 shares of restricted stock.
- (6) Includes 176,667 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.

The following table summarizes our compensation plans under which our equity securities are authorized for issuance as of December 31, 2008:

**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	1,085,000	\$ 1.63	1,694,687
Equity compensation plans not approved by security holders	5,000	2.00	—
<b>Total</b>	<b>1,090,000</b>	<b>\$ 1.64</b>	<b>1,694,687</b>

- (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 transactions 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 2007 and 2008 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 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.

**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, 2008 and 2007, were:

	<u>2008</u>	<u>2007</u>
Audit Fees	\$98,750	\$67,100

The *Audit Fees* for the years ended December 31, 2008 and 2007 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 our principal accountant during the years ended December 31, 2008 and 2007.

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 2008 and 2007 were pre-approved by our Board of Directors.

**PART IV**

**ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

(a) Financial Statements and Financial Statement Schedules:

The following documents are 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)
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)

## Table of Contents

<u>Exhibit No.</u>	<u>Description</u>
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)
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)
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)

## Table of Contents

<u>Exhibit No.</u>	<u>Description</u>
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)
31.1	Section 302 Certification of Principal Executive Officer
31.2	Section 302 Certification of 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/ Juliet Singh

Name: Juliet Singh, Ph.D.

Title: Chief Executive Officer

Date: March 26, 2009

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/ Juliet Singh</u> Juliet Singh, Ph.D.	President, Chief Executive Officer and Chairman of the Board (Principal Executive Officer)	March 26, 2009
<u>/s/ John T. Lomoro</u> John T. Lomoro	Chief Financial Officer (Principal Accounting and Financial Officer)	March 26, 2009
<u>/s/ Jeffrey J. Abrams</u> Jeffrey J. Abrams, M.D.	Director	March 26, 2009
<u>/s/ Anthony S. Thornley</u> Anthony S. Thornley	Director	March 26, 2009
<u>/s/ Lynn C. Swann</u> Lynn C. Swann	Director	March 26, 2009

[Table of Contents](#)

**FINANCIAL STATEMENTS**

**Transdel Pharmaceuticals, Inc.  
(A Development Stage Company)**

**Index to Consolidated Financial Statements**

<a href="#">Report of Independent Registered Public Accounting Firm</a>	F-2
<a href="#">Consolidated Balance Sheets at December 31, 2008 and 2007</a>	F-3
<a href="#">Consolidated Statements of Operations for the Years Ended December 31, 2008 and 2007 and for the Period from July 24, 1998 (Inception) Through December 31, 2008</a>	F-4
<a href="#">Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2008 and 2007 and for the Period from July 24, 1998 (Inception) Through December 31, 2008</a>	F-5
<a href="#">Consolidated Statements of Cash Flows for the Years Ended December 31, 2008 and 2007 and for the Period from July 24, 1998 (Inception) Through December 31, 2008</a>	F-7
<a href="#">Notes to the Consolidated Financial Statements</a>	F-8

[Table of Contents](#)

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, 2008 and 2007, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2008 and for the period from July 24, 1998 (date of inception) through December 31, 2008. 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 for 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, 2008 and 2007, and the consolidated results of their operations and their cash flows for each of the two years in the period ended December 31, 2008 and for the period from July 24, 1998 (date of inception) through December 31, 2008 in conformity with accounting principles generally accepted in the United States of America.

/s/ KMJ Corbin & Company LLP  
KMJ Corbin & Company LLP  
Costa Mesa, California  
March 18, 2009

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

	December 31,	
	2008	2007
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 5,111,031	\$ 3,706,369
Prepaid consulting fees	29,048	488,748
Prepaid expenses and other current assets	193,306	45,604
Total current assets	5,333,385	4,240,721
Computer equipment, net	2,450	—
Total assets	<u>\$ 5,335,835</u>	<u>\$ 4,240,721</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 698,342	\$ 696,340
Accrued expenses and payroll liabilities	65,651	53,901
Total current liabilities	<u>763,993</u>	<u>750,241</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, 15,556,283 and 13,727,004 shares outstanding as of December 31, 2008 and 2007, respectively	15,556	13,727
Additional paid-in capital	14,938,219	10,554,298
Deficit accumulated during the development stage	(10,381,933)	(7,077,545)
Total stockholders' equity	4,571,842	3,490,480
Total liabilities and stockholders' equity	<u>\$ 5,335,835</u>	<u>\$ 4,240,721</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>		<u>For the Period</u>
	<u>2008</u>	<u>2007</u>	<u>From July 24,</u>
			<u>1998 (Inception)</u>
			<u>Through</u>
			<u>December 31,</u>
			<u>2008</u>
Operating expenses:			
Selling, general and administrative	\$ 1,755,731	\$ 1,026,644	\$ 4,839,312
Research and development	1,990,665	1,832,744	4,548,409
Operating loss	<u>3,746,396</u>	<u>2,859,388</u>	<u>9,387,721</u>
Other income (expense):			
Interest expense	—	(1,563,504)	(1,575,755)
Interest income	67,008	48,438	116,629
Gain on settlement	375,000	—	375,000
Gain on forgiveness of liabilities	—	89,914	89,914
Total other income (expense), net	<u>442,008</u>	<u>(1,425,152)</u>	<u>(994,212)</u>
Net loss	<u>\$ (3,304,388)</u>	<u>\$ (4,284,540)</u>	<u>\$ (10,381,933)</u>
Basic and diluted loss per common share	<u>\$ (0.22)</u>	<u>\$ (0.48)</u>	
Weighted average common shares outstanding, basic and diluted	<u>14,822,062</u>	<u>8,846,801</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, 2008 AND 2007 AND FOR THE PERIOD FROM JULY 24, 1998**  
**(INCEPTION) THROUGH DECEMBER 31, 2008**

	<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, 2008 AND 2007 AND FOR THE PERIOD FROM JULY 24, 1998**  
**(INCEPTION) THROUGH**  
**DECEMBER 31, 2008**

	Common Stock		Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficit)
	Shares	Amount			
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	<u>15,556,283</u>	<u>\$ 15,556</u>	<u>\$ 14,938,219</u>	<u>\$ (10,381,933)</u>	<u>\$ 4,571,842</u>

*See accompanying notes to these consolidated financial statements.*

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

	<b>Year Ended December 31,</b>		<b>For The Period</b>
	<b>2008</b>	<b>2007</b>	<b>From July 24, 1998 (Inception) Through December 31, 2008</b>
<b>Cash flows from operating activities:</b>			
Net loss	\$(3,304,388)	\$(4,284,540)	\$(10,381,933)
Adjustments to reconcile net loss to net cash used in operating activities:			
Estimated fair value of contributed services	—	175,000	2,475,000
Gain on forgiveness of liabilities	—	(89,914)	(89,914)
Amortization of prepaid consulting fees	341,708	201,252	542,960
Depreciation	704	—	704
Non-cash interest on notes payable	—	1,563,504	1,575,755
Stock-based compensation	562,442	184,522	746,963
Changes in operating assets and liabilities:			
Prepaid consulting costs	—	(140,000)	(140,000)
Prepaid expenses and other current assets	(147,702)	(39,908)	(193,306)
Accounts payable	2,001	612,562	788,256
Accrued expenses and payroll liabilities	11,750	53,901	65,651
Net cash used in operating activities	<u>(2,533,485)</u>	<u>(1,763,621)</u>	<u>(4,609,864)</u>
<b>Cash flows from investing activities:</b>			
Purchase of fixed assets	(3,154)	—	(3,154)
Net cash used in investing activities	<u>(3,154)</u>	<u>—</u>	<u>(3,154)</u>
<b>Cash flows from financing activities:</b>			
Proceeds from notes payable to stockholders	—	—	226,300
Proceeds from notes payable	—	1,500,000	1,500,000
Capital contributions	—	105,907	168,707
Net proceeds from purchase of common stock and exercise of warrants and stock options	—	25,750	49,950
Proceeds from Private Placements	3,941,301	3,837,791	7,779,092
Net cash provided by financing activities	<u>3,941,301</u>	<u>5,469,448</u>	<u>9,724,049</u>
<b>Net change in cash and cash equivalents</b>	<b>1,404,662</b>	<b>3,705,827</b>	<b>5,111,031</b>
<b>Cash and cash equivalents, beginning of period</b>	<b>3,706,369</b>	<b>542</b>	<b>—</b>
<b>Cash and cash equivalents, end of period</b>	<b><u>\$ 5,111,031</u></b>	<b><u>\$ 3,706,369</u></b>	<b><u>\$ 5,111,031</u></b>
<b>Supplemental disclosure of cash flow information:</b>			
Issuance of and adjustment to common stock and warrants to consulting firms for prepaid consulting fees	<u>\$ (117,993)</u>	<u>\$ 550,000</u>	<u>\$ 432,007</u>
Conversion of notes payable and accrued interest into common stock	<u>\$ —</u>	<u>\$ 1,530,177</u>	<u>\$ 1,530,177</u>
Forgiveness of notes payable and accrued interest to shareholders	<u>\$ —</u>	<u>\$ 241,701</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”) is a specialty pharmaceutical company developing non-invasive, topically-delivered medications. Our innovative patented Transdel™ cream formulation technology is designed to facilitate the effective penetration of drugs through the tough skin barrier to reach the target underlying tissues. In the case of Ketotransdel®, the Transdel™ cream allows the active ingredient ketoprofen to reach the target soft tissue and exert its well-known anti-inflammatory and analgesic effects. We are also investigating other drug candidates and treatments for transdermal delivery using the patented Transdel™ platform technology for products in pain management, other therapeutic areas and for cosmetic/cosmeceutical products.

**Note 2. Basis of Presentation**

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States, 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.

**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**

*Development Stage Enterprise.* The Company is a development stage company as defined in Statement of Financial Accounting Standards (“SFAS”) No. 7, *Accounting and Reporting by Development Stage Enterprises*. 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 2009. As discussed in Note 6, the Company raised an additional \$4,000,000 (\$3,978,000 proceeds, net of fees) in May 2008 as a result of an issuance of equity securities in a private placement. Management believes its cash and cash equivalents balance as of December 31, 2008 is sufficient to meet the Company’s capital and operating requirements for the next 12 months to execute a portion of their operating plan, which would include completing the Phase 3 trial currently in progress. Therefore, this has alleviated the substantial doubt about the Company’s ability to continue as a going concern that existed as of December 31, 2007.

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

**Note 4. Summary of Significant Accounting Policies (continued)**

In order to execute the second Phase 3 clinical trial for Ketotransdel®, which is currently 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 or 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 or financial condition.

*Research and Development.* Research and development costs are charged to expense 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 \$1,480,000 as of December 31, 2008) in a combination of government issued and government backed securities. The remaining amount of cash is held in the form of multiple short term certificates of deposit, all of which 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.

*Beneficial Conversion Feature.* The convertible features of the convertible notes provided for a rate of conversion that was below market value (see Note 5). Such feature is normally characterized as a “beneficial conversion feature” (“BCF”). Pursuant to Emerging Issues Task Force (“EITF”) No. 98-5 *Accounting For Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratio* and EITF No. 00-27, *Application of EITF Issue No. 98-5 To Certain Convertible Instruments*, the relative fair values of the BCFs have been recorded as a discount from the face amount of the respective debt instrument. The Company recorded the corresponding debt discount related to the BCF as interest expense when the related instrument was converted into the Company’s common stock.

*Revenue Recognition.* The Company will recognize revenues in accordance with the SEC’s Staff Accounting Bulletin (“SAB”) No. 101, *Revenue Recognition*, as amended by SAB No. 104. SAB No. 104 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.

As of December 31, 2008, 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.

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

**Note 4. Summary of Significant Accounting Policies (continued)**

*Stock-Based Compensation.* Effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment*, ("SFAS 123R"), which is a revision of SFAS No. 123, *Accounting for Stock-Based Compensation*. SFAS 123R supersedes APB No. 25, *Accounting for Stock Issued to Employees*, and amends SFAS No. 95, *Statement of Cash Flows*. SFAS 123R requires all share-based payments to employees, including grants of stock options to employees, directors and consultants and restricted stock grants, 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 \$562,442, \$184,522 and \$746,963 for the years ended December 31, 2008 and 2007 and the period from Inception through December 31, 2008, 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 \$284,750 and \$277,692, \$120,943 and \$63,579, and \$348,328 and \$398,635, respectively. The fair value of the unvested stock options and restricted stock grants amounted to \$679,210 as of December 31, 2008.

The Company's accounting policy for equity instruments issued to consultants and vendors in exchange for goods and services follows the provisions of SFAS No. 123, EITF No. 96-18, *Accounting for Equity Instruments That are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, and EITF No. 00-18, *Accounting Recognition for Certain Transactions Involving Equity Instruments Granted to Other Than Employees*. 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 recognized over the term of the consulting agreement. In accordance with EITF No. 00-18, 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.* In accordance with SFAS No. 128, *Earnings Per Share*, and SAB No. 98, *Computation of Earnings Per 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. Under SFAS No. 128, 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 1,887,730 and 1,180,458 for the years ended December 31, 2008 and 2007, 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 generally accepted accounting principles in the United States 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.

**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 \$3,150 and \$15,401 for the year ended December 31, 2007 and the period from Inception through December 31, 2008, respectively. 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").



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

**Note 5. Notes Payable (continued)**

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 and \$30,177 for the year ended December 31, 2007 and 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 EITF No. 00-18, 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. 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.



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

**Note 6. Stockholders' Equity (continued)**

On October 27, 2008, the Company entered into an agreement with an investor relations firm ("IR Firm"), pursuant to which the IR Firm will 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 are nonforfeitable (valued at \$85,834 and recorded as prepaid consulting fees in the accompanying consolidated balance sheet) and 13,901 shares are forfeitable, to the IR Firm as a prepayment of services to be received. Beginning on or about March 1, 2009, the Company has agreed to issue an additional 22,889 shares of unregistered common stock to the IR Firm on a monthly basis thereafter for the term of the agreement. Since 13,901 shares are forfeitable and unearned as of December 31, 2008, the shares are being held for final disposition for investor relation services to be provided to the Company. As a result, in accordance with EITF Topic D-90, these shares are not considered issued and outstanding as of December 31, 2008. The Company intends to utilize these shares for payment of investor relation services during the first half of fiscal year 2009.

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 is being amortized over the one-year term.

For the year ended December 31, 2008 and 2007 and for the period from Inception through December 31, 2008, the Company amortized \$341,708, \$201,252 and \$542,960, 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.
- 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.

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

**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. In addition, the Company was restricted through March 17, 2009 from filing 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, 2008 is as follows:

	Number of Shares	Weighted Ave. Exercise Price	Weighted Ave. Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding — January 1, 2008	610,000	\$ 2.01		
Granted	925,000	1.56		
Exercised	—	—		
Cancelled/forfeited	(450,000)	2.00		
Outstanding — December 31, 2008	<u>1,085,000</u>	<u>\$ 1.63</u>	<u>9.3</u>	<u>\$ 80,000</u>
Exercisable — December 31, 2008	<u>288,333</u>	<u>\$ 2.02</u>	<u>8.9</u>	<u>\$ —</u>
Vested and expected to vest — December 31, 2008	<u>1,058,500</u>	<u>\$ 1.66</u>	<u>9.3</u>	<u>\$ 72,050</u>

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

**Note 7. Stock Option Plans (continued)**

The options were granted to the employees, directors and a consultant at exercise prices that ranged from \$0.70 to \$2.62, the estimated fair market value of the common stock on the date of the 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 under SFAS 123R. 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 defined by SAB No. 107, *Share-Based Payment* 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 \$556,671, \$184,522 and \$741,192 for the years ended December 31, 2008 and 2007 and the period from Inception through December 31, 2008, respectively, for options and restricted stock granted and vested which is included in general and administrative expenses and research and development expenses in the amount of \$278,979 and \$277,692, \$120,943 and \$63,579, and \$342,557 and \$398,635, respectively.

The aggregate intrinsic value in the table above represents the total pre-tax amount, net of exercise price, which would have been received by option holders if all option holders had exercised all options with an exercise price lower than the market price on December 31, 2008, based on the closing price of the Company's common stock of \$1.00 on that date.

In accordance with SFAS 123R, 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 will be assigned to future director and employee options. This percentage was determined based on consideration of actual forfeitures realized during fiscal year 2008 and estimated forfeitures to potentially occur in the future.

As of December 31, 2008, there was \$679,210 of total unrecognized compensation expense related to unvested stock-based compensation under the Plan. That expense is expected to be recognized over the weighted-average period of 2.6 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 as a result of the waiver of the restrictions and forfeiture conditions.

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 is scheduled to vest over a one-year period, with one-quarter of the total number of shares subject to such grant vesting on the first quarterly anniversary of the grant date, and one-quarter of the total number of shares vesting on a quarterly basis thereafter. The fair value of the grant was determined to be \$17,500 and will be amortized to selling, general and administrative expenses on a straight line basis over the one-year vesting period. As of December 31, 2008, there was \$15,313 of total unrecognized compensation expense related to the unvested restricted stock grant. Also, if the director terminates his service prior to the end of the one-year period, any unvested portion of the restricted stock grant will be subject to forfeiture.

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, 2008 and 2007:

	2008	2007
Weighted-average fair value of options granted	\$0.65	\$1.48
Expected term (in years)	6.1	6.0
Expected volatility	85%	85%
Risk-free interest rate	2.73%	4.14%
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 will vest in full on March 19, 2009 if the agreement is still effective and has not been terminated by either party prior to that date. The option was granted with an exercise price of \$0.99 and has a ten year life.

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

**Note 7. Stock Option Plan (continued)**

The estimated fair value of the stock option at December 31, 2008, based on the Black-Scholes pricing model was \$34,625, which is being amortized over the three month term. As of December 31, 2008, there was \$28,854 of total unrecognized compensation expense related to this unvested stock option grant.

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

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

**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, 2008 is as follows:

	Number of Shares Subject to Warrants Outstanding	Weighted- Average Exercise Price
Warrants outstanding — January 1, 2008	570,458	\$ 4.00
Granted	232,272	4.35
Exercised	—	—
Expired	—	—
Warrants outstanding — December 31, 2008	<u>802,730</u>	<u>\$ 4.10</u>
Weighted average remaining contractual life of the outstanding warrants — December 31, 2008	<u>3.81 years</u>	

**Note 9. Income Taxes**

On July 13, 2006, the Financial Accounting Standards Board (“FASB”) issued FASB Interpretation No. (“FIN”) 48. Under FIN 48, the impact of an uncertain income tax positions 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, FIN 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. For public companies, FIN 48 was effective for fiscal years beginning after December 15, 2006.

The Company has evaluated the impact of FIN 48 on its financial statements, which was effective beginning January 1, 2007. The evaluation of a tax position in accordance with FIN 48 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 FIN 48. The cumulative effect, if any, of applying FIN 48 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 FIN 48.

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

**Note 9. Income Taxes (continued)**

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, 2008 and 2007, and has not recognized interest and/or penalties in the consolidated statements of operations for the years ended December 31, 2008 and 2007.

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, 2008 and 2007, the Company had deferred tax assets of \$2,716,094 and \$1,186,226, 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 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, 2008, the Company had federal and California net operating loss carryforwards of approximately \$5.8 million and \$5.6 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 \$161,000 and \$168,000 respectively which begin to expire in 2027 unless previously utilized.

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

	<u>2008</u>	<u>2007</u>
<b>Deferred tax assets:</b>		
Federal and state net operating loss carryforwards	\$ 2,295,402	\$ 1,106,112
Stock-based compensation	134,688	60,404
Tax credits	271,618	—
Other	14,386	19,710
Total deferred tax assets	2,716,094	1,186,226
Less valuation allowance	(2,716,094)	(1,186,226)
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 \$1.5 million and \$991,000 in 2008 and 2007, respectively.

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

**Note 9. Income Taxes (continued)**

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>2008</u>	<u>2007</u>
Federal tax benefit at statutory rate	\$ 1,123,492	\$ 1,456,744
State tax benefit, net	181,563	239,314
Non-deductible services	—	(69,563)
Non-deductible beneficial conversion costs	—	(621,492)
Research and development credits	271,618	—
Employee stock-based compensation	(56,929)	(12,944)
Other differences	10,124	(595)
Increase in valuation allowance	(1,529,868)	(991,464)
Provision for income taxes	<u>\$ —</u>	<u>\$ —</u>

A portion of the net operating loss carry forwards as of December 31, 2008 and 2007 include amounts related to stock option deductions. Under SFAS 123R, 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**

The following pronouncements have been issued by the FASB:

In December 2007, the FASB issued SFAS No. 141R, *Business Combinations*. SFAS No. 141R provides companies with principles and requirements on how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, liabilities assumed, and any noncontrolling interest in the acquiree as well as the recognition and measurement of goodwill acquired in a business combination. SFAS No. 141R also requires certain disclosures to enable users of the financial statements to evaluate the nature and financial effects of the business combination. Acquisition costs associated with the business combination will generally be expensed as incurred. SFAS No. 141R is effective for business combinations occurring in fiscal years beginning after December 15, 2008. Early adoption of SFAS No. 141R is not permitted. The Company is currently evaluating the impact SFAS No. 141R will have on any future business combinations.

The Company adopted SFAS, No. 157, *Fair Value Measurements*. In February 2008, the FASB issued FASB Staff Position ("FSP") No. 157-2, *Effective Date of FASB Statement No. 157*, which provides a one year deferral of the effective date of SFAS No. 157 for non-financial assets and non-financial liabilities, except those that are recognized or disclosed in the financial statements at fair value in the financial statements on a recurring basis, at least annually. The delay is intended to allow FASB and constituents additional time to consider the effect of various implementation issues that have arisen, or that may arise, from the application of SFAS No. 157. Therefore, the Company has adopted the provisions of SFAS No. 157 with respect to its financial assets and liabilities only. SFAS No. 157 defines fair value, establishes a framework for measuring fair value under accounting principles generally accepted in the United States of America and enhances disclosures about fair value measurements. Fair value is defined under SFAS No. 157 as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The Company also adopted FSP No. 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active*. FSP No. 157-3 clarifies the application of SFAS No. 157, in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. This FSP applies to financial assets within the scope of accounting pronouncements that require or permit fair value measurements in accordance with SFAS No. 157, as required, except as it applies to those nonfinancial assets and nonfinancial liabilities as noted in FSP No. 157-2. During the year ended December 31, 2008, the adoption of SFAS No. 157 did not have an impact on the Company's consolidated financial statements.

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

**Note 10. Recent Accounting Pronouncements (continued)**

In December 2007, the SEC issued Staff Accounting Bulletin No. 110 (“SAB 110”). SAB 110 amends and replaces Question 6 of Section D.2 of Topic 14, *Share-Based Payment*, of the Staff Accounting Bulletin series. Question 6 of Section D.2 of Topic 14 expresses the views of the staff regarding the use of the “simplified” method in developing an estimate of the expected term of “plain vanilla” share options and allows usage of the “simplified” method for share option grants prior to December 31, 2007. SAB 110 allows public companies which do not have historically sufficient experience to provide a reasonable estimate to continue to use the “simplified” method for estimating the expected term of “plain vanilla” share option grants after December 31, 2007. The Company adopted SAB 110 on January 1, 2008. The Company is continuing to use the “simplified” method until it has enough historical experience to provide a reasonable estimate of expected term in accordance with SAB 110.

In December 2007, the FASB ratified EITF No. 07-1, *Accounting for Collaborative Agreements* (“EITF No. 07-1”). EITF No. 07-1 provides guidance regarding financial statement presentation and disclosure of collaborative arrangements, as defined, which includes arrangements the Company may enter into regarding development and commercialization of products. EITF No. 07-1 is effective for the Company as of January 1, 2009. The Company does not believe the adoption of this statement will have a material effect on its consolidated results of operations, financial position or liquidity.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements* (“SFAS No. 160”), which will require noncontrolling interests (previously referred to as minority interests) to be treated as a separate component of equity, not as a liability or other item outside of permanent equity. SFAS No. 160 applies to the accounting for noncontrolling interests and transactions with non-controlling interest holders in consolidated financial statements. SFAS No. 160 will be applied prospectively to all noncontrolling interests, including any that arose before the effective date except that comparative period information must be recast to classify noncontrolling interests in equity, attribute net income and other comprehensive income to noncontrolling interests, and provide other disclosures required by SFAS No. 160. SFAS No. 160 is effective for periods beginning on or after December 15, 2008. Since the Company currently does not have any noncontrolling interest, the adoption of SFAS No. 160 is not expected to have a material impact on the Company’s consolidated results of operations, financial position or liquidity.

Other recent accounting pronouncements issued by the FASB (including the EITF) and the American Institute of Certified Public Accountants did not or are not believed by management to have a material impact on the Company’s present or future consolidated financial statements.

**Note 11. Commitments and Contingencies**

Commitments

The Company leases its office facilities under a noncancelable operating lease, which expires in August 2009. For fiscal year 2009, the Company’s lease commitment is approximately \$71,000. Rent expense for the years ended December 31, 2008, 2007 and the period from Inception through December 31, 2008, was \$71,237, \$29,478 and \$100,715, 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.



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

**Note 11. Commitments and Contingencies (continued)**

Cato Research Ltd. Agreement

In accordance with the Master Services Agreement, dated April 10, 2007, between the Company and Cato Research Ltd., a contract research and development organization (“Cato”), the Company entered into a clinical trial services agreement with Cato on June 10, 2008 (“Agreement”). Under the Agreement, Cato will serve as the Company’s strategic partner and contract research organization in conducting the Company’s Phase 3 clinical program for Ketotransdel®, the Company’s novel topical cream based non-steroidal anti-inflammatory drug for pain. Pursuant to the Agreement, the Company will make payments to Cato upon its completion of certain specified milestones. If all milestones under the Agreement are completed and the estimated pass-through costs are incurred, the Company’s total costs under the Agreement are estimated at \$3.3 million. In addition, any changes to budget parameters identified in the Agreement may result in additional costs to the Company. There can be no assurance that Cato will complete its performance under the Agreement, and to the extent that such performance is completed that the clinical trial results for Ketotransdel® will be satisfactory.

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.

**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 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 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.



## CERTIFICATION

I, Juliet Singh, Chief Executive Officer of Transdel Pharmaceuticals, Inc., certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2008 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. The registrant's other certifying officer and I are 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 us 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 our 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. The registrant's other certifying officer and I have disclosed, based on our 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 26, 2009

By: /s/ Juliet Singh  
Juliet Singh  
Chief Executive Officer  
(Principal Executive Officer)

## CERTIFICATION

I, John T. Lomoro, 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, 2008 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. The registrant's other certifying officer and I are 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 us 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 our 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. The registrant's other certifying officer and I have disclosed, based on our 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 26, 2009

By : /s/ John T. Lomoro

\_\_\_\_\_  
John T. Lomoro

Chief Financial Officer

(Principal Financial and Accounting Officer)

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

Juliet Singh, Chief Executive Officer of Transdel Pharmaceuticals, Inc. (the "Company") and John T. Lomoro, Chief Financial Officer of the Company, each 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 their knowledge:

- (1) The Annual Report on Form 10-K of the Company for the fiscal year ended December 31, 2008 (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 26, 2009

/s/ Juliet Singh

Juliet Singh, CEO

/s/ John T. Lomoro

John T. Lomoro, CFO

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.