

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

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

For the fiscal year ended December 31, 2010

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES ACT OF 1934

Commission File Number: 000-52998

**TRANSDel PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of  
Incorporation or organization)

45-0567010

(IRS Employer Identification No.)

437 S. Hwy 101, Suite 209  
Solana Beach, CA 92075

(Address, including zip code, of principal executive offices)

4275 Executive Square, Suite 485, La Jolla, CA

(Former name or former address if changed since last report.)

(858) 433-2800

(Registrant's telephone number, including area code)

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

<u>Title of Each Class</u>	<u>Name of Each Exchange on Which Registered</u>
Common Stock, \$0.001 par value per share	

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, 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 Section 15(d) of the Exchange Act. Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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	<input type="radio"/>	Accelerated filer	<input type="radio"/>
Non-accelerated filer	<input type="radio"/>	Smaller reporting company	<input checked="" type="checkbox"/>

(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

As of June 30, 2010 approximately 15,852,061 shares of common stock were outstanding. The aggregate market value of the common stock held by non-affiliates of the registrant, as of June 30, 2010, the last business day of the second fiscal quarter, was approximately \$7,109,497 based on the average high and low price of \$1.15 for the registrant's common stock as quoted on the OTC Markets Pink Sheets on that date. Shares of common stock held by each director, each officer and each person who owns 10% or more of the outstanding common stock have been excluded from this calculation in that such persons may be deemed to be affiliates. The determination of affiliate status is not necessarily conclusive.

As of February 22, 2012, there were 15,900,811 shares of our common stock outstanding.

Documents incorporated by reference: None.



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## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain of the statements included in this Form 10-K, are “forward-looking statements.” Forward-looking statements include, without limitation, any statement that may predict, forecast, indicate, or imply future results, performance or achievements, and may contain the words “estimate,” “project,” “intend,” “forecast,” “anticipate,” “plan,” “planning,” “expect,” “believe,” “will,” “shall,” “will likely,” “should,” “could,” “would,” “may” or words or expressions of similar meaning, including when used in the negative. Forward-looking statements, include, but are not limited to: statements regarding our research and development programs; proposed marketing and sales; patents and regulatory approvals; the effect of competition and proprietary rights of third parties; our interpretation of the results of the Phase 3 clinical trial for Ketotransdel<sup>®</sup>; whether the results from the clinical trial, along with the other clinical trials that may be required by the FDA, will be sufficient to support a 505(b)(2) New Drug Approval (NDA) submission; the potential indications for use for Ketotransdel<sup>®</sup>; the market opportunity for our products; and our ability to complete additional development activities for products utilizing our proprietary transdermal delivery platform, the need for and availability of additional financing and our access to capital; the trading of our common stock, licensing, distribution, collaboration and marketing arrangements with pharmaceutical companies; and the period of time for which our existing cash will enable us to fund our operations. Information regarding factors that could cause actual results to differ materially from such expectations is disclosed in this Report, including, without limitation, information under the caption “Risk Factors.” You should not place undue reliance on such forward-looking statements, which are based on the information currently available to us and speak only as of the date on which this Annual Report was filed with the Securities and Exchange Commission (“SEC”). We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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## PART I

### ITEM 1. DESCRIPTION OF BUSINESS

#### Company Overview

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

Our common stock has been quoted on the OTC Market System since October 1, 2007 and currently trades on the OTC Market Pink Sheets under the symbol TDLP.PK. Prior to October 1, 2007, there was no active market for our common stock. On February 14, 2012, the closing price of our common stock was \$0.09 per share. Our executive offices are located at 437 S. Hwy 101, Suite 209, Solana Beach, CA 92075 and our telephone number at such office is (858) 433-2800. Our website address is [www.imprimispharma.com](http://www.imprimispharma.com).

#### 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 June 20, 2011, Transdel Holdings was merged with Transdel Pharmaceuticals, Inc., at which time Transdel Holdings ceased as a corporation, and Transdel Pharmaceuticals, Inc. remains as the sole surviving corporation.

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.

#### Recent Developments

##### *Bankruptcy Petition and Dismissal*

On June 26, 2011 we filed a voluntary petition for reorganization relief under Chapter 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the Southern District of California (the “Bankruptcy Court”), Case No. 11-10497-11 (the “Chapter 11 Case”). In connection with the Chapter 11 Case, we, as seller, and Cardium Healthcare, Inc., a wholly-owned subsidiary of Cardium Therapeutics, Inc., as purchaser (the “Cardium”), entered into an Asset Purchase Agreement dated June 26, 2011 (the “Asset Purchase Agreement”) pursuant to which we agreed to sell substantially all of our assets pursuant to Sections 105, 363 and 365 of the Bankruptcy Code, subject to court approval and the satisfaction of certain conditions set forth in the Asset Purchase Agreement.

Consummation of the sale to Cardium was subject to a number of conditions, including, among others, the approval by the Bankruptcy Court of the transactions contemplated by the Asset Purchase Agreement and compliance with certain specified deadlines for actions in connection with the Bankruptcy Case. The Asset Purchase Agreement was terminable by the parties under a number of circumstances, including failure to obtain certain Bankruptcy Court orders by agreed dates.

On July 26, 2011, the Bankruptcy Court denied our motion to sell our assets pursuant to the Asset Purchase Agreement. On October 7, 2011, we terminated the Asset Purchase Agreement pursuant to its terms. On November 21, 2011, in connection with the transactions described below, we requested that the Bankruptcy Court dismiss the Chapter 11 Case and retain jurisdiction to decide matters related to claims brought in the Bankruptcy Case by the Purchaser. On December 9, 2011, the Bankruptcy Court entered an order dismissing the Chapter 11 Case. In connection with the dismissal of the Chapter 11 Case, the Bankruptcy Court, among other things, declined to retain jurisdiction over claim objection proceedings and found moot our objection to certain claims to receive a break-up fee pursuant to the Asset Purchase Agreement of Cardium Therapeutics, Inc. and Cardium Healthcare, Inc., a wholly owned subsidiary of Cardium. The dismissal of the Chapter 11 Case was based upon the provisions of both 11 U.S.C. Sections 305(a) and 1112(b).

#### *Secured Line of Credit – Related Party*

On November 21, 2011, we entered into a Secured Line of Credit Letter Agreement (the “Line of Credit Agreement”) with DermaStar International, LLC (“DermaStar”), pursuant to which DermaStar agreed to lend us funds under a line of credit upon certain conditions, including the dismissal of the Chapter 11 Case by the Bankruptcy Court. The Line of Credit Agreement became effective on December 9, 2011, in connection with the dismissal of the Chapter 11 Case by the Bankruptcy Court. On December 9, 2011, as required by the Line of Credit Agreement, we entered into a Security Agreement and an Intellectual Property Security Agreement, pursuant to which we granted to DermaStar a blanket security interest in all of our assets, including our intellectual property. The Line of Credit Agreement provides for advances of up to an aggregate of \$750,000 (each an “Advance” and collectively the “Loan”), subject to the satisfaction by us of certain conditions in connection with the initial Advance and each subsequent Advance. Each Advance will be made pursuant to a Promissory Note in favor of DermaStar. On December 12, 2011, we requested and received advances totaling \$300,000.

#### *Change in Control – Preferred Stock*

In partial consideration for and in connection with the Line of Credit Agreement, on November 21, 2011 we executed a Securities Purchase Agreement (the “Purchase Agreement”) with DermaStar, pursuant to which we agreed to issue ten (10) shares of newly-designated Series A Convertible Preferred Stock (the “Series A Preferred Stock”) to DermaStar for an aggregate purchase price of \$100,000. The Purchase Agreement, as amended, became effective on December 9, 2011, in connection with the dismissal of the Chapter 11 Case by the Bankruptcy Court. On December 12, 2011, we and DermaStar consummated the transactions contemplated by the Purchase Agreement. The shares of Series A Preferred Stock issued to DermaStar in the offering are convertible into 59,988,002 shares of our Common Stock; however, until the effective date of the stockholder action by written consent to approve to increase the number of authorized shares of Common Stock through an amendment to the our Amended and Restated Certificate of Incorporation (as described below), DermaStar has the ability to convert five of its ten shares of Series A Preferred Stock into 29,994,001 shares of Common Stock, representing approximately 65% of the capital stock of the Company on an as-converted basis. Upon issuance of the Series A Preferred Stock, DermaStar, and its members individually, became control persons of the Company, and as such, this and any further transactions between the Company and DermaStar, and/or its members individually, will be disclosed as related party transactions. We appointed DermaStar Managing Members Mark L. Baum and Robert J. Kammer to our Board of Directors in December 2011.

#### *Settlement with the Holders of the Company’s 7.5% Convertible Promissory Note*

Effective as of January 25, 2012, we entered into separate waiver and settlement agreements with the two parties holding a \$1,000,000 7.5% convertible promissory note (the “Convertible Note”) issued by us on April 5, 2010. DermaStar had previously acquired eighty percent (80%) of the Convertible Note in a private transaction with Alexej Ladonnikov, the original purchaser of the Convertible Note. Mr. Ladonnikov is now the holder of twenty percent (20%) of the Convertible Note.

In connection with each of the waiver and settlement agreements, the holders of the Convertible Note each agreed to forever waive their rights to (i) accelerate the entire unpaid principal sum of the Convertible Note and all accrued interest pursuant to Section 1 of the Convertible Note related to the Company's Bankruptcy petition filed June 26, 2011, (ii) Section 7 of the Senior Convertible Note Purchase Agreement dated April 5, 2010, regarding the designation and creation of the Series A Convertible Preferred Stock and (iii) certain conversion rights pursuant to Section 3 of the Convertible Note related to the change of control that resulted from the sale of the Series A Convertible Preferred Stock. In addition, pursuant to the terms of the waiver and settlement agreement with DermaStar (the "DermaStar Waiver Agreement"), we and DermaStar agreed to the mandatory conversion of the eighty percent (80%) of the principal and accrued and unpaid interest of the Convertible Note held by DermaStar, at such time as we have a sufficient number of authorized common shares to effect such a conversion, into our common stock at a conversion price of \$0.01667 ("DermaStar Conversion Price"). Additionally, DermaStar agreed to a mandatory conversion of an additional \$56,087 in good and valid current accounts payable of the Company ("AP Conversion") currently held by DermaStar, at such time as we have a sufficient number of authorized common shares and DermaStar is able to convert the Convertible Note. The AP Conversion will be made at the DermaStar Conversion Price. Directors Mr. Baum and Dr. Kammer are both affiliates of DermaStar. The DermaStar Waiver Agreement was negotiated and approved by the sole disinterested director unaffiliated with DermaStar. Directors Mr. Baum and Dr. Kammer abstained from voting on this matter.

Pursuant to the terms of the waiver and settlement agreement with Mr. Ladonnikov (the "Ladonnikov Waiver Agreement"), we and Mr. Ladonnikov agreed to the mandatory conversion of the twenty percent (20%) of the principal and accrued and unpaid interest of the Convertible Note held by Mr. Ladonnikov, at such time as we have a sufficient number of authorized common shares to effect such a conversion, into our common stock a conversion price of \$0.015. Additionally, Mr. Ladonnikov agreed to make a one-time payment of \$50,000 to us at such time as the Convertible Note is converted into common stock.

At any time prior to the automatic conversions of the Convertible Note we retain the right to prepay the Convertible Note in full. As of February 15, 2012, the balance of the Convertible Note, including principal and accrued and unpaid interest, equals approximately \$1,139,932. At maturity, to the extent the number of authorized shares of common stock is increased, the conversion of the Convertible Note and AP Conversion would result in the issuance of approximately 73,269,391 additional shares of our common stock. A conversion of the Convertible Note would eliminate all amounts due to DermaStar and Alexej Ladonnikov in connection with the Convertible Note. Upon the effective date of the Certificate Amendment described below we will have sufficient authorized shares of common stock to enable the automatic conversion of the Convertible Note.

#### *Amendment to Certificate of Incorporation*

On January 25, 2012, the Board approved an amendment to our Amended and Restated Certificate of Incorporation (the "Certificate Amendment") and submitted the Certificate Amendment to our stockholders for approval. The Certificate Amendment: (i) increases the number of authorized shares of our capital stock to Four Hundred Million (400,000,000) and the number of authorized shares of common stock to Three Hundred Ninety-Five Million (395,000,000) (the "Share Increase"); and (ii) changes our name from Transdel Pharmaceuticals, Inc. to Imprimis Pharmaceuticals, Inc. Our stockholders approved the Certificate Amendment in an action by written consent on January 25, 2012. We expect the Certificate Amendment to become effective on February 28, 2012, following our compliance with certain information requirements of the SEC.

In addition, also on January 25, 2012, the Board approved and submitted to our stockholders a proposal to effect a reverse stock split of all of the outstanding shares of common stock (the "Reverse Stock Split") at an exchange ratio of either one-for-six, one-for-eight, one-for-ten or one-for-20, such exchange ratio to be determined by the Board of Directors in its sole discretion at any time following stockholder approval of the Reverse Stock Split through the date twelve months following the date of such stockholder approval. The Reverse Stock Split would preserve the existing aggregate par value of our common stock. In the event we effect the Reverse Stock Split, no stockholder holding greater than 100 common shares prior to the Reverse Stock Split will hold, after such Reverse Stock Split, less than 100 common shares. Our stockholders approved an Amendment to our Amended and Restated Certificate of Incorporation to effect the Reverse Stock Split (the "Reverse Split Certificate Amendment") in an action by written consent on January 25, 2012. The stockholder approval will become effective following the Company's compliance with certain information statement requirements of the SEC, which the Company expects to occur on or about February 28, 2012. At that time, the Board will effect a one-for-eight reverse stock split..

## *Amendments to 2007 Incentive Stock and Awards Plan*

The 2007 Incentive Stock and Awards Plan (the “Plan”) was originally approved by the Board and the stockholders of the Company on September 17, 2007 and prior to the approval of the amendments to the Plan discussed below, provided for the granting of stock options and awards to purchase up to a maximum of 3,000,000 shares of common stock (subject to adjustment in the event of certain capital changes). On January 25, 2012, our Board unanimously approved the below amendments to the Plan (collectively, the “Plan Amendments”) and recommended their approval to our stockholders. The Plan currently authorizes the grant of awards to Participants with respect to a maximum of 3,000,000 shares of Common Stock, which will increase to 30,000,000 as of the effective date of the Plan Amendment.

## *Changes in Management and Board of Directors*

As a result of the Chapter 11 Case, our management team has undergone significant changes during the fiscal year ending December 31, 2011. The Board accepted the resignation of John N. Bonfiglio, Ph.D. as Chief Executive Officer and President of the Company and as a director on the Board, effective May 13, 2011. On the same date, the Board appointed John T. Lomoro, to serve as the Company’s Principal Executive Officer. The Board accepted the resignation of John T. Lomoro as Principal Executive Officer, Chief Financial Officer and Treasurer of the Company, effective September 16, 2011. On the same date, the Board appointed Terry Nida, the Company’s Chief Business Officer, to serve as the Company’s Principal Executive Officer and Principal Financial Officer. Effective December 16, 2011, Terry Nida resigned as Principal Executive Officer and Principal Financial Officer of the Company.

Since January 1, 2012, we have assembled a new management team. Effective January 1, 2012, the Board appointed Balbir Brar, D.V.M., Ph.D. as President of the Company. Effective February 1, 2012, the Board appointed Andrew R. Boll as Vice-President of Accounting and Public Reporting and Principal Accounting and Financial Officer of the Company. Effective February 15, 2012, the Board appointed Joachim Schupp, M.D. as Chief Medical Officer of the Company. Mr. Baum, Chairman of our Board of Directors, currently serves as our Principal Executive Officer.

Our Board of Directors has also undergone significant change. Effective December 16, 2011, Mark L. Baum and Dr. Robert J. Kammer joined the Board of Directors. Mr. Baum and Dr. Kammer are the Managing Members of DermaStar and both Dr. Kammer and Mr. Baum hold ownership interests in DermaStar. There are no arrangements or understandings between either Mr. Baum or Dr. Kammer and any other persons pursuant to which either Mr. Baum or Dr. Kammer was elected as a director. Also effective December 16, 2011, Anthony S. Thornley resigned as a director from the Company’s Board of Directors. Effective February 15, 2012, Paul Finnegan, M.D. and Dr. Brar, our President, were appointed as directors of the Company. We currently have five directors: Jeffrey Abrams, M.D., Mr. Baum, Dr. Kammer, Dr. Finnegan and Dr. Brar. Mr. Baum serves as the Chairman of the Board of Directors.

## **Ketotransdel®**

Ketotransdel®, our lead drug candidate, 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 minimizes systemic exposure, especially for acute indications, and therefore, have the potential for fewer concerns pertaining to gastrointestinal, hepatic, cardiovascular and other adverse systemic effects, which are associated with orally administered NSAIDs.

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

## **Clinical Program for Ketotransdel®**

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



As we reported in October 2009, the top-line results showed that the study demonstrated failed to meet its primary endpoint, although a post-hoc analysis revealed that a modified intent-to-treat analysis showed statistical significance favoring. There were no Ketotransdel® treatment related gastrointestinal, cardiovascular, hepatic or other clinically relevant adverse events (AEs) reported. In particular, there was a low incidence of skin associated AEs, 1.1% with Ketotransdel® and 2.2% with placebo. Furthermore, Ketotransdel® was well absorbed through the skin and in support of the safety and tolerability only minimal blood concentrations of ketoprofen were detected in a subset of patients who underwent blood sampling for pharmacokinetic (PK) analyses following repeated topical applications. These PK results are consistent with our previous clinical study findings and support the strong safety profile.

In January 2010, we reported on further post-hoc analyses of the ITT data from the Ketotransdel® Phase 3 study. For the modified ITT analysis we identified 35 patients who did not meet study entry criteria at the time of randomization. Excluding these patients who did not meet the study entry criteria but was nevertheless randomized into the trial, the modified ITT population demonstrated statistical significance ( $p < 0.038$ ) on the primary efficacy endpoint for Ketotransdel® compared to placebo vehicle). This post-hoc analysis was confirmed by a third-party statistical expert.

The weight of evidence of a treatment effect in this study is further strengthened by a key secondary endpoint (pain intensity recorded 3 times daily on patient diary cards) that supports the primary endpoint. The pain curves over time show consistent separation between treatment groups reaching statistical significance in favor of Ketotransdel®; using both the original and modified ITT population. Furthermore, the proportion of subjects who were satisfied with the treatment and achieved moderate or higher pain relief - as recorded on a 7 point Likert Scale - was statistically significantly greater with Ketotransdel® on Day 3 ( $p = 0.023$ ).

Based on discussions with the FDA at least two adequate and well-controlled Phase 3 studies are required in order to obtain regulatory approval to market Ketotransdel®.

As part of a routine requirement to provide safety information in the NDA submission we have to perform studies such as to assess the allergenicity potential and absorption of ketoprofen during concurrent exercise and heat exposure with Ketotransdel®. These additional supportive trials will be conducted in healthy subjects. The timing of the second and third Phase 3 trial and the other supportive studies will be dependent on obtaining adequate financing to support the execution of these activities and for other working capital expenditures. Upon receipt of such financing, we anticipate initiating the second Phase 3 trial and supportive studies in 2012 (or 2013). Based on successful outcome of the two additional Phase 3 trials, we anticipate filing the 505(b)(2) application in a timely manner. We expect that Ketotransdel®, if and when approved by the FDA, could become the first topical NSAID cream product available by prescription in the United States for acute, localized pain management.

### **Cosmetic Product Development Program**

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

On August 25, 2008, the Company entered into an agreement with RIL-NA, LLC in order to enter into business relationships with third parties for certain of the Company's cosmetic product formulations. RIL-NA, LLC was to be paid a commission equal to approximately twenty percent (20%) of the adjusted gross revenues realized from transactions related to this agreement. This agreement is terminable with 60 days written notice by either RIL-NA or the Company. On June 12, 2011, the Company entered into another agreement with RIL-NA, LLC whereby RIL-NA paid approximately \$5,000 in related legal filing fees to acquire exclusive marketing rights for the Company's anti-cellulite product formulation from June 13, 2011 through August 11, 2011. This agreement automatically terminated on August 12, 2011, no revenues or amounts were paid to or on behalf of the Company.

On May 20, 2009, we entered into a license agreement with JH Direct, LLC ("JH Direct") providing JH Direct with the exclusive worldwide rights to our anti-cellulite cosmetic product. Under the terms of the agreement, JH Direct will pay us initial royalty advances if the product is marketed and a continuing licensing royalty on the worldwide sales of the anti-cellulite product. We retained the exclusive rights to seek pharmaceutical/dermatological partners for the anti-cellulite product for an initial period of one year following the launch of the product, thereafter JH Direct will be allowed to expand in this channel. In September 2010, it was announced that JH Direct had completed their initial product testing of our anti-cellulite formulation in 24 subjects, which consisted of observing the before and after results of applying the product over a 16 week period. The excellent results observed during this test have led JH Direct to initiate plans for a final test in approximately 25 subjects to be conducted by a third-party skin research center that will conduct a similar test to the initial test as well as obtain additional measurements over a 12 week period. JH Direct planned a commercial launch of the product for the first quarter of 2011 subject to successful completion of this final test. As of December 31, 2010, we received \$80,000 in advance non-refundable royalty payments and \$20,000 during April 2011. The Company has exercised its rights under the license agreement and terminated this contract effective January 30, 2012.

In June 2010, we entered into a license agreement with Jan Marini Skin Research, Inc. ("JMSR") providing JMSR with the exclusive U.S. rights to our transdermal delivery technology for use in an anti-cellulite cosmetic product for the dermatological market. Under the terms of the agreement, JMSR will pay us a licensing royalty on the U.S. and worldwide sales of an anti-cellulite product using our delivery technology. JMSR obtained an exclusive right to promote and sell a product in the U.S. dermatological market for approximately one year after which time they have a non-exclusive right. Also, JMSR obtained a non-exclusive right to promote and sell the product in the ex-U.S. dermatological market. The Company does not expect to receive future royalties from this agreement as JMSR has abandoned its efforts to commercialize the product at this time and the Company has exercised its rights under the license agreement and terminated this contract effective January 30, 2012. No revenues or amounts were paid to or on behalf of the Company related to this agreement.

### **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 utilizing the Transdel™ platform technology and we are exploring potential partnerships for these identified 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.

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. For the next twelve months, our current business plan is focused on raising capital in order to complete the development of our lead drug, Ketotransdel® for the indication of acute pain, inflammation and swelling associated with soft tissue injuries and potentially other acute musculoskeletal conditions. In addition, we intend to explore potential co-development opportunities in other therapeutic areas and also with cosmetic products utilizing our Transdel™ platform technology.

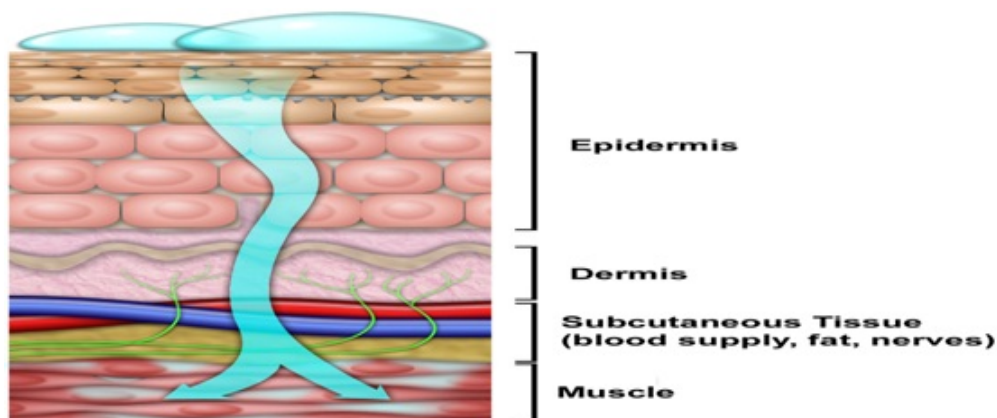
### **Market and Opportunity**

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

We believe that there is a significant unmet medical need for topical localized 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 combination of penetrating enhancers that enables topical delivery of drugs to the underlying target musculoskeletal tissue while avoiding first pass metabolism by the liver and minimizing systemic exposure. The Transdel™ drug delivery system facilitates the effective dissolution and delivery of a drug across the skin barrier to reach targeted underlying tissues as illustrated in the following diagram:



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

- Maximizes solubilization of drugs and components (lipophilic, hydrophilic and amphiphilic);
- Uses synergistic mechanisms to enhance penetration so that more effective concentrations of the beneficial drug or substances reach the dermal and subcutaneous tissue layers of the skin;
- Compatible with a broad range of drugs and molecular sizes;
- Biocompatible – Components generally regarded as safe (GRAS);
- Thermodynamically stable, insensitive to moisture and resistant to microbial contamination;
- Clinical data collected to date points to safety and potential efficacy;
- Expected to result in decreased safety concerns which are typically associated with oral or systemic drugs, (e.g. stomach irritation with oral NSAIDs);
- Not associated with limitations of transdermal patches; (e.g., non-sticking and peeling of mobile areas; tendency towards local skin irritation);
- Potentially produces patentable new products when combined with established drugs or new drugs.

## **Competition**

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

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

## **Third Party Service Agreements**

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

## **Governmental Regulation**

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

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

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

## FDA Approval Process

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

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

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

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

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

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

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

## Section 505(b)(2) New Drug Applications

Since the active pharmaceutical ingredient, in Ketotransdel® is ketoprofen (brandname: Orudis, Oruvail), the oral formulation of which has already been approved by the FDA, we are able to file a NDA under section 505(b)(2) of the Hatch-Waxman Act of 1984 for this product as well as other products that we may develop including approved active pharmaceutical ingredients. This is an alternate path to FDA approval for new formulations of previously approved products. Section 505(b)(2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The Hatch-Waxman Act permits the applicant to rely upon certain published nonclinical or clinical studies conducted for an approved product or the FDA's conclusions from prior review of such studies. The FDA may also require companies to perform additional studies or measurements to support any changes from the approved product. The FDA may then approve the new product for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant. While references to nonclinical and clinical data not generated by the applicant or for which the applicant does not have a right of reference are allowed, all development, process, stability, qualification and validation data related to the manufacturing and quality of the new product must be included in an NDA submitted under Section 505(b)(2).

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

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

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

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

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

## **Quality Assurance Requirements**

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

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

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

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

## **Other FDA Matters**

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

## **Intellectual Property**

We obtained a patent from the United States Patent and Trademark Office on our Transdel™ technology in 1998, which affords protection of Transdel™ through 2016 in the United States. This patent specifically lists over 500 different drugs in over 60 therapeutic areas, including both approved and established drugs. The Transdel™ technology may also have an application to deliver drugs not listed in its patent, including novel drugs. Also, it covers composition of matter, methods of use and methods of manufacture. In regard to this U.S. patent, we will be pursuing patent strategies that will potentially allow us to extend the life of the patent beyond 2016. The Company has been granted a patent related to its Transdel™ technology pending in Canada. The Company has filed additional patent applications in various jurisdictions in order to protect the Company's non-pharmaceutical and cosmetic intellectual property rights. The Company is committed to developing a robust intellectual property strategy in order to pursue its business objectives.

**Employees**

As of February 15, 2012, we employ one part-time individual and two full-time individuals, who are responsible for financial accounting and investor relations, business and corporate development, research and development management, and general administration. We are not party to any collective bargaining agreements with any of our employees. We have never experienced a work stoppage, and we believe our employee relations are good. We hire independent contractor labor and consultants on an as needed basis and have entered into consulting arrangements with certain directors in exchange for stock options and/or cash payments.

**SEC Filings; Internet Address**

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

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



## ITEM 1A. RISK FACTORS

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

### Risks Relating to Our Business

#### ***We will need to raise additional funds to operate our business.***

We expect that our operating expenses will increase substantially over the current fiscal annual period as we focus on resuming our operations. We have access to a Line of Credit with DermaStar, pursuant to which we may receive up to a maximum of \$750,000. In December 2011 we requested advances totaling \$300,000 under the Line of Credit. However, we expect that we will need to raise an additional \$6 million in funds in order to operate and execute our business plan during the 2012 fiscal year. Our estimate of total expenditures could increase if we encounter unanticipated difficulties. In addition, our estimates of the amount of cash necessary to fund our business may prove to be wrong, and we could spend our available financial resources much faster than we currently expect. We expect to continue to seek funding in order to pursue our business plan. Other than in connection with the Line of Credit, we do not have any arrangements in place for any future financing. If we cannot raise the money that we need in order to continue to develop our business, we will be forced to delay, scale back or eliminate some or all of our proposed operations, and our business may fail.

***The report of our independent registered public accounting firm on our 2010 consolidated financial statements contains a going concern modification, and we will need additional financing to execute our business plan, fund our operations and to continue as a going concern, which additional financing may not be available on a timely basis, or at all.***

We have limited remaining funds to support our operations. We have prepared our consolidated financial statements in this Form 10-K on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. We will not be able to execute our current business plan, fund our business operations or continue as a going concern long enough to achieve profitability unless we are able to secure additional funds. With our current cash and cash equivalents position as of December 31, 2010, we have forecasted and anticipate having adequate resources in order to execute a portion of our operating plan through the third quarter of 2012. This does not include any additional cash resources that would be required to begin additional Phase 3 clinical studies on Ketotransdel<sup>®</sup>. The Report of Independent Registered Public Accounting Firm on our December 31, 2010 consolidated financial statements includes an explanatory paragraph stating that the recurring losses incurred from operations and a working capital deficiency raise substantial doubt about our ability to continue as a going concern. However, in order to execute the additional Phase 3 and supportive studies to obtain regulatory approval to market Ketotransdel<sup>®</sup>, we will need to secure additional funds. If adequate financing is not available, we will not be able to meet the FDA's requirements to obtain regulatory approval to market Ketotransdel<sup>®</sup>. In addition, if one or more of the risks discussed in these risk factors occur or our expenses exceed our expectations, we may be required to raise further additional funds sooner than anticipated.

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

The significant downturn in the overall economy and the ongoing disruption in the capital markets has reduced investor confidence and negatively affected investments generally and specifically in the pharmaceutical industry. In addition, the fact that we are not profitable, have previously filed for Chapter 11 bankruptcy and will need significant additional funds to execute the second Phase 3 clinical trial and supportive studies in order to obtain regulatory approval to market Ketotransdel<sup>®</sup>, and our planned Phase 3b trial 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 prior to the end of 2012 we will be required to cease operations.

***We have incurred losses in the research and development of Ketotransdel® and our Transdel™ technology since inception. We may never generate revenue or become profitable.***

Since inception we have recorded operating losses from Inception through December 31, 2010, we have a deficit accumulated during the development stage of approximately \$17.5 million, and for the fiscal year ended December 31, 2010, we experienced a net loss of approximately \$2.5 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 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 products, there can be no assurance that we will ever be able to achieve or sustain market acceptance, profitability or positive cash flow. Our ultimate success will depend on many factors, including whether Ketotransdel® receives FDA approval. We cannot be certain that we will receive FDA approval for Ketotransdel®, or that we will reach the level of sales and revenues necessary to achieve and sustain profitability. Unless we raise additional capital, we will not be able to execute our business plan or fund business operations. Furthermore, we will be forced to reduce our expenses and cash expenditures to a material extent, which would impair or delay our ability to execute our business plan.

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

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

- the time and resources required to develop, conduct clinical trials and obtain regulatory approvals for our drug candidates;
- the costs to rebuild our management team following our filing for Chapter 11 bankruptcy, including attracting and retaining personnel with the skills required for effective operations; and
- the costs of preparing, filing, prosecuting, defending and enforcing patent claims and other patent related costs, including litigation costs and the results of such litigation.

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

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

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

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

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

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw our regulatory approval;
- suspend or terminate any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us;
- impose restrictions on our operations;
- close the facilities of our contract manufacturers; or
- seize or detain products or require a product recall.

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

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

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

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

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

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

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

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

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

Even if we obtain regulatory approvals, uncertainty exists as to whether the market will accept our products or if the market for our products is as large as we anticipate. A number of factors may limit the market acceptance of our products, including the timing of regulatory approvals and market entry relative to competitive products, the availability of alternative products, the price of our products relative to alternative products, the availability of third party reimbursement and the extent of marketing efforts by third party distributors or agents that we retain. We cannot assure you that our products will receive market acceptance in a commercially viable period of time, if at all. We cannot be certain that any investment made in developing products will be recovered, even if we are 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 products expose us to the risk of significant losses resulting from product liability claims. Although we have obtained and intend to maintain product liability insurance to offset some of this risk, we may be unable to maintain such insurance or it may not cover certain potential claims against us.

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

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

Our success will depend in part on our ability to:

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

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

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

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

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

***We may not be successful in receiving additional patents based on our intellectual property strategy.***

The Company has undertaken an effort to examine its intellectual property assets and has or shall file certain patents in certain jurisdictions, with the goal of attaining additional protections for the Company's technologies and future products related thereto. The applications filed or which shall be filed may never yield patents that protect the Company's inventions and intellectual property assets. Failure to receive additional patents may limit the Company's protection against generic drug manufacturers and other parties who may seek to copy or otherwise produce products substantially similar to those of the Company using technologies that may be substantially similar to those the Company owns.

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

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

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

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

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

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

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

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

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

**Our cosmetic product development program may not be successful.**

Our product development program have included cosmetic products, which utilizes the basis of our patented transdermal delivery system technology, Transdel™. Since our primary focus will remain on seeking FDA approval for Ketotransdel®, we plan to use limited resources on our cosmetic 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 entered into license agreements with two companies for a potential anti-cellulite product. We cannot assure you that the results of any further studies that may be required before this product can be commercialized will be successful, that we will enter into additional commercial agreements with third parties for this product on acceptable terms, or at all, or that this product will be successfully commercialized. Even if we are not required to obtain FDA pre-market approval for this product, 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 the anti-cellulite product. There is no assurance that we will be successful in developing any other cosmetic products, including products for hyperpigmentation and anti-aging. Any products we develop may cause undesirable side effects that could limit their use, require their removal from the market and subject us to adverse regulatory action and product liability claims. Further, the market for cosmetic 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.***

As we described elsewhere in this Annual Report, we experienced severe financial difficulties during 2011. As a result, we terminated all but a few of our employees. Since the dismissal of the Chapter 11 Case in December 2011, we have focused on rebuilding our management team and engaging consultants in order to begin operating our business. However, because of this history, we may have significant difficulty attracting and retaining necessary employees. In addition, because of the specialized scientific nature of our business, our ability to develop products and to compete will remain highly dependent, in large part, upon our ability to attract and retain qualified scientific, technical and commercial personnel. The loss of key scientific, technical and commercial personnel or the failure to recruit key scientific, technical and commercial personnel could have a material adverse effect on our business. While we have consulting agreements with certain key individuals and institutions, we cannot assure you that we will succeed in retaining personnel or their services under existing agreements. There is intense competition for qualified personnel in the pharmaceutical industry, and we cannot assure you that we will be able to continue to attract and retain the qualified personnel necessary for the development of our business.

## Risks Relating to Our Industry

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

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

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

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

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

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

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

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

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



## Risks Relating to the Common Stock

***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.

### ***Our stock price may be volatile.***

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

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

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

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

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

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

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

Furthermore, for companies whose securities are traded in the OTC Bulletin Board or OTC Markets, 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.

***Certain members of management and the Board of Directors collectively own or have the right to acquire 79% of our common stock. In addition to other risks relating to control by such persons of the Company, and conflicts of interest, the sale of such shares by management and the Board of Directors from time to time, will likely have an adverse affect on our stock price.***

There is no established trading market for our common stock, which trades at fluctuating rates, prices and volumes. Certain members of management, namely, Messrs. Kammer and Baum, directly and indirectly own, or have the right to acquire within 60 days, approximately 118,058,306 shares of our common stock constituting approximately 79% of the shares of common stock outstanding following such issuance to them. The issuance of these shares has been, and will be, highly dilutive to our other stockholders. In addition, the sale of even a portion of these shares by management will likely have a material adverse affect on our stock price.

In addition to the above risks, the ownership and control by management of such a large block of shares creates inherent conflicts of interest and, results in control of the Company by such persons, as discussed elsewhere in these risk factors. No person should consider an investment in the Company unless they fully understand the adverse effect that sales by management could have on our stock price and, further, should only invest if they understand the risks associated with control by management.

***Management and certain members of the Board of Directors own a controlling interest of our stock, including, without limitation, our Series A Convertible Preferred Stock; the existence of these derivative securities, may adversely affect your stock price and our ability to raise capital or into business ventures and transactions.***

Currently, 10 shares of Series A Convertible Preferred Stock are issued and outstanding and held by DermaStar, of which Messrs. Baum and Kammer are managing members. These shares are convertible into our common stock, have voting rights on an as-converted basis and contain other restrictive covenants. As a result, over 79% of our voting control is owned by DermaStar. Moreover, as shares of Series A preferred stock are converted and sold, such sales are likely to have a highly dilutive effect and perhaps create negative pressure on our stock price. Additionally, the existence of our outstanding preferred stock may hinder our ability to raise capital at favorable prices if and as needed, or to make acquisitions.

***Our principal stockholders have the ability to exert significant control in matters requiring stockholder vote and could delay, deter or prevent a change in control of our company.***

DermaStar holds voting power over 79% of our capital stock. Since our stock ownership is concentrated among a limited number of holders and our Bylaws permit our stockholders to act by written consent, DermaStar has the ability to approve stockholder actions without holding a meeting of stockholders and control the outcome of all actions requiring stockholder approval, including the election of our board of directors and change of control transactions. Directors Mark L. Baum, Esq. and Robert J. Kammer are Managing Members of DermaStar. Through their concentration of voting power, they could delay, deter or prevent a change in control of our company or other business combinations that might otherwise be beneficial to our other stockholders. In deciding how to vote on such matters, they may be influenced by interests that conflict with other stockholders. Accordingly, investors should not invest in the Company's securities without being willing to entrust the Company's business decisions to such persons.

Among other things, DermaStar has the ability to:

- control the composition of our board of directors; control our management and policies;
- determine the outcome of significant corporate transactions, including changes in control that may be beneficial to stockholders; and
- act in each of their own interests, which may conflict with, or be different from, the interests of each other or the interests of the other stockholders.

#### **ITEM 1B. UNRESOLVED STAFF COMMENTS**

Not Applicable.

#### **ITEM 2. PROPERTIES**

We lease approximately 1,486 square feet of office space in Solana Beach, California. The current lease term expires on February 28, 2014. 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**

#### **Bankruptcy Petition and Dismissal**

On June 26, 2011, we filed a voluntary petition for reorganization relief under Chapter 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the Southern District of California (the “Bankruptcy Court”), Case No. 11-10497-11 (the “Chapter 11 Case”).

In connection with the Chapter 11 Case, the Company, as seller, and Cardium Healthcare, Inc., a wholly-owned subsidiary of Cardium Therapeutics, Inc., as purchaser (the “Purchaser”), entered into an Asset Purchase Agreement dated June 26, 2011 (the “Asset Purchase Agreement”) pursuant to which the Company had agreed to sell substantially all of the assets of the Company pursuant to Sections 105, 363 and 365 of the Bankruptcy Code, subject to court approval and the satisfaction of certain conditions set forth in the Asset Purchase Agreement.

Pursuant to the terms of the Asset Purchase Agreement, the Purchaser agreed to purchase the Company’s assets for up to 6 million shares of Cardium Therapeutics, Inc. common stock (“Cardium Stock”) based upon the then current price of the Cardium Stock on the NYSE Amex. The actual number of shares of Cardium Stock provided to the Company at closing was subject to adjustment based on the closing price of the Cardium Stock as of the date of such closing.

Consummation of the sale to the Purchaser was subject to a number of customary conditions, including, among others, the approval of the Asset Purchase Agreement through a private sale in the Bankruptcy Court; the accuracy of the representations and warranties of the parties; material compliance by the parties with their obligations under the Asset Purchase Agreement; and compliance with certain specified deadlines for actions in connection with the Bankruptcy Case.

Consummation of the sale to the Purchaser was also subject to obtaining an order of approval from the Bankruptcy Court (the “Sale Order”). The Asset Purchase Agreement was terminable by the Purchaser under a number of circumstances, including the Company’s breach of certain representations and covenants and failure to obtain certain Bankruptcy Court orders by agreed dates.

The Company’s Motion to Sell Substantially all Assets of the Estate Free and Clear of Liens Claims and Interests and Assume and Assign Certain Executory Contracts Without Overbid (“Motion to Sell”) was set for a hearing on July 18, 2011.

The Company’s Motion to Sell, after proper notice to creditors and parties in interest came on for sequential hearings on July 18, 2011 and July 26, 2011 before the Honorable Peter W. Bowie, United States Bankruptcy Judge, presiding, was heard. The Court having read all documents filed in support and in opposition to the Motion, having heard oral argument of counsel, and good cause appearing, ordered that the Company’s Motion to Sell was denied.

On November 21, 2011, the Company requested that the Bankruptcy Court dismiss the Chapter 11 Case and retain jurisdiction to decide matters related to claims brought in the Bankruptcy Case by the Purchaser. On December 9, 2011, the Bankruptcy Court entered an order dismissing the Chapter 11 Case. In connection with the dismissal of the Chapter 11 Case, the Bankruptcy Court, among other things, declined to retain jurisdiction over claim objection proceedings and found moot the Company’s objection to the claims to receive a break-up fee pursuant to the Asset Purchase Agreement of Cardium Therapeutics, Inc. and Cardium Healthcare, Inc., a wholly owned subsidiary of Cardium. The dismissal of the Chapter 11 Case was based upon the provisions of both 11 U.S.C. Sections 305(a) and 1112(b).

Currently, there are no active or threatened legal proceedings.

### **ITEM 4. RESERVED**

## PART II

### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY

#### Market Information

October 1, 2007, our common shares began to trade on the Over-the-Counter Bulletin Board, or OTCBB, under the symbol TDLP.OB. Beginning in April 2011, our common stock ceased trading on the OTCBB and began trading on the OTC Market Group Pink Sheets. Following our entry into bankruptcy proceedings (described in more detail elsewhere in this Annual Report), our common stock traded under the symbol TDLPQ.PK. These markets are 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 the Pink Sheets on February 14, 2012 was \$0.09 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 2010</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 1.50	\$ 0.70
Second Quarter	\$ 1.20	\$ 0.61
Third Quarter	\$ 1.25	\$ 0.53
Fourth Quarter	\$ 0.90	\$ 0.30

<b>Fiscal Year 2009</b>	<b>High</b>	<b>Low</b>
First Quarter	\$ 1.10	\$ 0.60
Second Quarter	\$ 1.70	\$ 0.65
Third Quarter	\$ 1.99	\$ 0.80
Fourth Quarter	\$ 4.00	\$ 1.06

Our stock is quoted by the OTC Market Group Pink Sheets. Our stock is no longer trading on the OTC Bulletin Board as a result of our failure to timely file our periodic reports with the SEC and because the market maker that had filed originally to quote our stock on the OTC Bulletin Board is no longer providing quotes on the OTC Bulletin Board. A large number of initiating market makers have ceased to provide quotes on the OTC Bulletin Board causing many companies to cease having quotations on the OTC Bulletin Board during 2010 and 2011.

#### Holdings

As of February 14, 2012 we had approximately 54 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.

### ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

## 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 in this Annual Report Part I, Item 1A — Risk Factors. Although we may elect to update forward-looking statements in the future, we specifically disclaim any obligation to do so, even if our estimates change. Readers should not rely on those forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report.

### Overview

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

On September 17, 2007, we entered into an Agreement of Merger and Plan of Reorganization (the "Merger Agreement") with Transdel Pharmaceuticals Holdings, Inc., a privately held Nevada corporation ("Transdel Holdings"), and Trans-Pharma Acquisition Corp., our newly formed, wholly-owned Delaware subsidiary ("Acquisition Sub"). Upon closing of the merger transaction contemplated under the Merger Agreement (the "Merger"), Acquisition Sub merged with and into Transdel Holdings, and Transdel Holdings, as the surviving corporation, became our wholly-owned subsidiary. On June 20, 2011, Transdel Holdings was merged with Transdel Pharmaceuticals, Inc., at which time Transdel Holdings ceased as a corporation, and Transdel Pharmaceuticals, Inc. remains as the sole surviving corporation.

As is discussed further in the Liquidity and Capital Resources section below, we have limited funds to support our operations. Our continuation as a going concern subsequent to the fiscal year ended of 2012 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.

### Recent Developments

#### *Bankruptcy Petition and Dismissal*

On June 26, 2011 we filed a voluntary petition for reorganization relief under Chapter 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the Southern District of California (the "Bankruptcy Court"), Case No. 11-10497-11 (the "Chapter 11 Case"). In connection with the Chapter 11 Case, we, as seller, and Cardium Healthcare, Inc., a wholly-owned subsidiary of Cardium Therapeutics, Inc., as purchaser (the "Cardium"), entered into an Asset Purchase Agreement dated June 26, 2011 (the "Asset Purchase Agreement") pursuant to which we agreed to sell substantially all of our assets pursuant to Sections 105, 363 and 365 of the Bankruptcy Code, subject to court approval and the satisfaction of certain conditions set forth in the Asset Purchase Agreement. Consummation of the sale to Cardium was subject to a number of conditions, including, among others, the approval by the Bankruptcy Court of the transactions contemplated by the Asset Purchase Agreement and compliance with certain specified deadlines for actions in connection with the Bankruptcy Case. The Asset Purchase Agreement was terminable by the parties under a number of circumstances, including failure to obtain certain Bankruptcy Court orders by agreed dates.

On July 26, 2011, the Bankruptcy Court denied our motion to sell our assets pursuant to the Asset Purchase Agreement. On October 7, 2011, we terminated the Asset Purchase Agreement pursuant to its terms. On November 21, 2011, in connection with the transactions described below, we requested that the Bankruptcy Court dismiss the Chapter 11 Case and retain jurisdiction to decide matters related to claims brought in the Bankruptcy Case by the Purchaser. On December 9, 2011, the Bankruptcy Court entered an order dismissing the Chapter 11 Case. In connection with the dismissal of the Chapter 11 Case, the Bankruptcy Court, among other things, declined to retain jurisdiction over claim objection proceedings and found moot our objection to certain claims to receive a break-up fee pursuant to the Asset Purchase Agreement of Cardium Therapeutics, Inc. and Cardium Healthcare, Inc., a wholly owned subsidiary of Cardium. The dismissal of the Chapter 11 Case was based upon the provisions of both 11 U.S.C. Sections 305(a) and 1112(b).

#### *Secured Line of Credit – Related Party*

On November 21, 2011, we entered into a Secured Line of Credit Letter Agreement (the “Line of Credit Agreement”) with DermaStar International, LLC (“DermaStar”), pursuant to which DermaStar agreed to lend us funds under a line of credit upon certain conditions, including the dismissal of the Chapter 11 Case by the Bankruptcy Court. The Line of Credit Agreement became effective on December 9, 2011, in connection with the dismissal of the Chapter 11 Case by the Bankruptcy Court. On December 9, 2011, as required by the Line of Credit Agreement, we entered into a Security Agreement and an Intellectual Property Security Agreement, pursuant to which we granted to DermaStar a blanket security interest in all of our assets, including our intellectual property. The Line of Credit Agreement provides for advances of up to an aggregate of \$750,000 (each an “Advance” and collectively the “Loan”), subject to the satisfaction by us of certain conditions in connection with the initial Advance and each subsequent Advance. Each Advance will be made pursuant to a Promissory Note in favor of DermaStar. On December 12, 2011, we requested and received advances totaling \$300,000.

#### *Change in Control – Preferred Stock*

In partial consideration for and in connection with the Line of Credit Agreement, on November 21, 2011 we executed a Securities Purchase Agreement (the “Purchase Agreement”) with DermaStar, pursuant to which we agreed to issue ten (10) shares of newly-designated Series A Convertible Preferred Stock (the “Series A Preferred Stock”) to DermaStar for an aggregate purchase price of \$100,000. The Purchase Agreement, as amended, became effective on December 9, 2011, in connection with the dismissal of the Chapter 11 Case by the Bankruptcy Court. On December 12, 2011, we and DermaStar consummated the transactions contemplated by the Purchase Agreement. The shares of Series A Preferred Stock issued to DermaStar in the offering are convertible into 59,988,002 shares of our Common Stock; however, until the effective date of the stockholder action by written consent to approve to increase the number of authorized shares of Common Stock through an amendment to the our Amended and Restated Certificate of Incorporation (as described below), DermaStar has the ability to convert five of its ten shares of Series A Preferred Stock into 29,994,001 shares of Common Stock, representing approximately 65% of the capital stock of the Company on an as-converted basis. Upon issuance of the Series A Preferred Stock, DermaStar, and its members individually, became control persons of the Company, and as such, this and any further transactions between the Company and DermaStar, and/or its members individually, will be disclosed as related party transactions. We appointed DermaStar Managing Members Mark L. Baum and Robert J. Kammer to our Board of Directors in December 2011.

#### *Settlement with the Holders of the Company’s 7.5% Convertible Promissory Note*

Effective as of January 25, 2012, we entered into separate waiver and settlement agreements with the two parties holding a \$1,000,000 7.5% convertible promissory note (the “Convertible Note”) issued by us on April 5, 2010. DermaStar had previously acquired eighty percent (80%) of the Convertible Note in a private transaction with Alexej Ladonnikov, the original purchaser of the Convertible Note. Mr. Ladonnikov is now the holder of twenty percent (20%) of the Convertible Note.

In connection with each of the waiver and settlement agreements, the holders of the Convertible Note each agreed to forever waive their rights to (i) accelerate the entire unpaid principal sum of the Convertible Note and all accrued interest pursuant to Section 1 of the Convertible Note related to the Company’s Bankruptcy petition filed June 26, 2011, (ii) Section 7 of the Senior Convertible Note Purchase Agreement dated April 5, 2010, regarding the designation and creation of the Series A Convertible Preferred Stock and (iii) certain conversion rights pursuant to Section 3 of the Convertible Note related to the change of control that resulted from the sale of the Series A Convertible Preferred Stock. In addition, pursuant to the terms of the waiver and settlement agreement with DermaStar (the “DermaStar Waiver Agreement”), we and DermaStar agreed to the mandatory conversion of the eighty percent (80%) of the principal and accrued and unpaid interest of the Convertible Note held by DermaStar, at such time as we have a sufficient number of authorized common shares to effect such a conversion, into our common stock at a conversion price of \$0.01667 (“DermaStar Conversion Price”). Additionally, DermaStar agreed to a mandatory conversion of an additional \$56,087 in good and valid current accounts payable of the Company (“AP Conversion”) currently held by DermaStar, at such time as we have a sufficient number of authorized common shares and DermaStar is able to convert the Convertible Note. The AP Conversion will be made at the DermaStar Conversion Price. Directors Mr. Baum and Dr. Kammer are both affiliates of DermaStar. The DermaStar Waiver Agreement was negotiated and approved by the sole disinterested director unaffiliated with DermaStar. Directors Mr. Baum and Dr. Kammer abstained from voting on this matter.

Pursuant to the terms of the waiver and settlement agreement with Mr. Ladonnikov (the "Ladonnikov Waiver Agreement"), we and Mr. Ladonnikov agreed to the mandatory conversion of the twenty percent (20%) of the principal and accrued and unpaid interest of the Convertible Note held by Mr. Ladonnikov, at such time as we have a sufficient number of authorized common shares to effect such a conversion, into our common stock a conversion price of \$0.015. Additionally, Mr. Ladonnikov agreed to make a one-time payment of fifty thousand dollars (\$50,000) to us at such time as the Convertible Note is converted into common stock.

At any time prior to the automatic conversions of the Convertible Note we retain the right to prepay the Convertible Note in full. As of February 15, 2012, the balance of the Convertible Note, including principal and accrued and unpaid interest, equals approximately \$1,139,932. At maturity, to the extent the number of authorized shares of common stock is increased, the conversion of the Convertible Note and AP Conversion would result in the issuance of approximately 73,269,391 additional shares of our common stock. A conversion of the Convertible Note would eliminate all amounts due to DermaStar and Alexej Ladonnikov in connection with the Convertible Note. Upon the effective date of the Certificate Amendment described below we will have sufficient authorized shares of common stock to enable the automatic conversion of the Convertible Note.

## **Plan of Operations**

For the next twelve months, our current operating plan is focused on the development of our lead drug, Ketotransdel® for the indication of acute pain, inflammation and swelling associated with soft tissue injuries and potentially other acute musculoskeletal conditions. In addition, we intend to explore potential co-development opportunities in other therapeutic areas and also with cosmetic products utilizing our Transdel™ platform technology.

As is discussed further in the Liquidity and Capital Resources section below, we have limited funds to support our operations. Our continuation as a going concern subsequent to the fiscal year ended of 2012 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. Based on our current business plan, which includes conducting additional Phase 3 human clinical trials, we currently estimate we will need an additional \$6 million of new capital to execute our business plan through the fiscal year ended 2012.

## **Clinical Program for Ketotransdel®**

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

As we reported in October 2009, the top-line results showed that the study demonstrated failed to meet its primary endpoint, although a post-hoc analysis revealed that a modified intent-to-treat analysis showed statistical significance favoring Ketotransdel®. There was no Ketotransdel® treatment related gastrointestinal, cardiovascular, hepatic or other clinically relevant adverse events (AEs) reported. In particular, there was a low incidence of skin associated AEs, 1.1% with Ketotransdel® and 2.2% with placebo. Furthermore, Ketotransdel® was well absorbed through the skin and in support of the safety and tolerability only minimal blood concentrations of ketoprofen were detected in a subset of patients who underwent blood sampling for pharmacokinetic (PK) analyses following repeated topical applications. These PK results are consistent with our previous clinical study findings and support the strong safety profile.

In January 2010, we reported on further post-hoc analyses of the ITT data from the Ketotransdel® Phase 3 study. For the modified ITT analysis we identified 35 patients who did not meet study entry criteria at the time of randomization. Excluding these patients who did not meet the study entry criteria but was nevertheless randomized into the trial, the modified ITT population demonstrated statistical significance ( $p < 0.038$ ) on the primary efficacy endpoint for Ketotransdel® compared to placebo vehicle). This post-hoc analysis was confirmed by a third-party statistical expert.



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

Based on discussions with the FDA at least two adequate and well-controlled Phase 3 studies are required in order to obtain regulatory approval to market Ketotransdel®. As part of a routine requirement to provide safety information in the NDA submission we have to perform studies such as to assess the allergenicity potential and absorption of ketoprofen during concurrent exercise and heat exposure with Ketotransdel®. These additional supportive trials will be conducted in healthy subjects. The timing of the second and third Phase 3 trial and the other supportive studies will be dependent on obtaining adequate financing to support the execution of these activities and for other working capital expenditures. Upon receipt of such financing, we anticipate initiating the second Phase 3 trial and supportive studies in 2012 or 2013. Based on successful outcome of the two additional Phase 3 trials, we anticipate filing the 505(b)(2) application in a timely manner. We expect that Ketotransdel®, if and when approved by the FDA, could become the first topical ketoprofen and the first NSAID cream product available by prescription in the United States for acute, localized pain management.

### **Cosmetic Product Development Program**

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

On August 25, 2008, the Company entered into an agreement with RIL-NA, LLC in order to enter into business relationships with third parties for certain of the Company's cosmetic product formulations. RIL-NA, LLC was to be paid a commission equal to approximately twenty percent (20%) of the adjusted gross revenues realized from transactions related to this agreement. This agreement is terminable with 60 days written notice by either RIL-NA or the Company. On June 12, 2011, the Company entered into another agreement with RIL-NA, LLC whereby RIL-NA paid approximately \$5,000 in legal fees related to the agreement to acquire exclusive marketing rights for the Company's anti-cellulite product formulation from June 13, 2011 through August 11, 2011. This agreement automatically terminated on August 12, 2011, no revenues or amounts were paid to or on behalf of the Company.

On May 20, 2009, we entered into a license agreement with JH Direct, LLC ("JH Direct") providing JH Direct with the exclusive worldwide rights to our anti-cellulite cosmetic product. Under the terms of the agreement, JH Direct paid us initial royalty advances when the product was marketed and a continuing licensing royalty on the worldwide sales of the anti-cellulite product. We retained the exclusive rights to seek pharmaceutical/dermatological partners for the anti-cellulite product for an initial period of one year following the launch of the product, thereafter JH Direct will be allowed to expand in this channel. JH Direct planned a commercial launch of the product for the first quarter of 2011 subject to successful completion of this final test. As of December 31, 2010, we received \$80,000 in advance non-refundable royalty payments and \$20,000 during April 2011. The Company has exercised its rights under the license agreement and terminated this contract effective January 30, 2012.

In June 2010, we entered into a license agreement with Jan Marini Skin Research, Inc. ("JMSR") providing JMSR with the exclusive U.S. rights to our transdermal delivery technology for use in an anti-cellulite cosmetic product for the dermatological market. Under the terms of the agreement, JMSR will pay us a licensing royalty on the U.S. and worldwide sales of an anti-cellulite product using our delivery technology. JMSR obtained an exclusive right to promote and sell a product in the U.S. dermatological market for approximately one year after which time they have a non-exclusive right. Also, JMSR obtained a non-exclusive right to promote and sell the product in the ex-U.S. dermatological market. The Company does not expect to receive future royalties from this agreement as JMSR has abandoned its efforts to commercialize the product at this time and the Company has exercised its rights under the license agreement and terminated this contract effective January 30, 2012. No revenues or amounts were paid to or on behalf of the Company related to this agreement.

## 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 utilizing the Transdel™ platform technology and we are exploring potential partnerships for these identified 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.

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, 2010 and 2009

#### Selling, General and Administrative Expenses

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

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

	Year ended December 31,		\$
	2010	2009	Variance
<b>Selling, general and administrative</b>	<u>\$ 2,307,972</u>	<u>\$ 1,598,369</u>	\$ 709,603

For the fiscal year ended December 31, 2010, the increase of \$709,603 in selling, general and administrative expense, as compared to the prior year, was primarily related to a net increase in personnel expenses related to the separation agreement for our former chief executive officer, increases in investor relations, legal, travel and consulting expenses. Further explanations for these variances are as follows:

- As a result of the separation agreement entered into by us and our former chief executive officer, we recognized aggregate one-time expenses of approximately \$416,000. This amount was comprised of approximately \$242,000 related to the accrual of continued salary and medical benefits to be provided for a period of one year after the separation date of February 17, 2010 and approximately \$174,000 of stock-based compensation expense related to the modification of terms for the former chief executive officer's stock options.
- The one-time expense noted above, was partially offset by a decrease in personnel expenses of \$130,000 due to a lower salary base and stock-based compensation for employees. The salaries were \$28,000 lower as a result of net decrease in the salary base resulting from the resignation of the former chief executive officer, partially offset by the addition of the salary for the chief business officer hired in February 2010. Stock-based compensation was \$102,000 lower as the net number of options being amortized was less due to full vesting of the former chief executive officer's stock options in the first quarter of 2010, partially offset by the granting of stock options to the chief business officer in February 2010.
- The primary reason for the \$164,000 increase of investor relations expenses was due to stock-based compensation net increase of \$140,000 for investor relations services provided to us as well as an increase of \$24,000 for other expenses such as press releases and fees for investor conferences attended by the Company.

## Research and Development Expenses

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

The table below provides information regarding research and development expenses:

	Year ended December 31,		\$
	2010	2009	Variance
Research and development	\$ 194,588	\$ 2,965,707	\$ (2,771,119)

For the fiscal year ended December 31, 2010, the decrease of approximately \$2.8 million in research and development expense, as compared to the prior year, was primarily related to a significant decrease of activities for the Phase 3 study and consulting expenses, partially offset by increased expenses related to personnel costs. Further explanations for these variances are as follows:

- During the same period in the prior year, the Phase 3 study for Ketotransdel<sup>®</sup> was on-going and therefore, we incurred approximately \$2.6 million of expenses related to the study during that period. The expenses were primarily for the investigator payments owed to the clinical sites for the patients they enrolled in the study and the fees incurred by our contract research organization for their services provided in conducting the study. In the fiscal year ended December 31, 2010, we only recognized a minimal amount of expense, which was incurred by our contract research organization for final administrative activities related to the study.

In November 2010, the Company received a Federal grant amount of \$244,479 under the Qualifying Therapeutic Discovery Project that is part of the Patient Protection and Affordable Care Act and was accounted for as a reduction to research and development expenses during the year ended December 31, 2010. The funds were awarded in support of Ketotransdel, the Company's late-stage topical NSAID for the treatment of acute soft tissue injuries.

## Interest Income

Interest income was \$512 and \$10,440, for the years ended December 31, 2010 and 2009, respectively. The decrease was due to a lower average cash balance and lower interest rates during fiscal year 2010 as compared to fiscal year 2009

## Interest Expense

In April 2010, we issued a two year Senior Convertible Promissory Note (the "Note") to an existing investor through a private placement. The Note includes an annual interest rate of 7.5 percent; therefore, interest expense on the Note was \$55,479 for the year ended December 31, 2010.

## Forgiveness of Liabilities

In 2008, we entered into a payment agreement with a vendor, settling a balance of \$52,598. In accordance with the payment agreement, we paid \$26,299 and recognized a gain on forgiveness of liabilities of \$26,299.

## Liquidity and Capital Resources

Our cash on hand at December 31, 2010 and 2009 was \$291,462 and \$1,589,773, respectively. The decrease in cash is primarily attributable the lack of financing commitments made during the years ended December 31, 2010 and 2009 as compared to years prior, compounded by a lower beginning cash balance for the year ended December 31, 2010. Since inception through December 31, 2010, we have incurred losses of approximately \$17.5 million. These losses are primarily due to selling, general and administrative and research and development expenses incurred in connection with developing and seeking regulatory approval for our lead drug, Ketotransdel®. Historically, our operations have been financed through capital contributions and debt and equity financings.

As further described under the “Recent Developments” heading of this Item, on June 26, 2011 we filed a voluntary petition for reorganization relief under Chapter 11 of the U.S. Bankruptcy Code (the “Chapter 11 Case”). We suspended our operations and terminated almost all of our employees. After receiving certain commitments from DermaStar to provide funding to us under a secured line of credit (as described in more detail below), on November 21, 2011 we requested that the Bankruptcy Court dismiss the Chapter 11 Case. The Bankruptcy Court entered an order dismissing the Chapter 11 Case on December 9, 2011. Since December 9, 2011, we have focused on resuming the operation of our business, including assembling a management team and hiring employees.

The following table provides detailed information about our net cash flow for all financial statement periods presented in this Report.

Cash Flow (All amounts in U.S. dollars)	For The Years Ended December 31,	
	2010	2009
Net cash used in operating activities	\$ (2,298,311)	\$ (3,570,758)
Net cash used in investing activities	-	-
Net cash provided by financing activities	1,000,000	49,500
Net Decrease in Cash and Cash Equivalents	(1,298,311)	(3,521,258)
Cash and Cash Equivalents at Beginning of the Year	1,589,773	5,111,031
Cash and Cash Equivalents at End of the Year	\$ 291,462	\$ 1,589,773

### Operating Activities

Net cash used in operating activities was \$2,298,311 for the year ended December 31, 2010, as compared to \$3,570,758 used in operating activities during 2009. The decrease in net cash used in operating activities was mainly due to a decrease in clinical studies during the 2010 fiscal year.

## Investing Activities

Net cash used in investing activities for the years ended December 31, 2010 and 2009 was \$0, as the Company devoted almost all of its cash resources to operations.

## Financing Activities

Net cash provided by financing activities for the year ended December 31, 2010 was \$1,000,000, as compared to \$49,500 net cash provided by financing activities for the year ended December 31, 2009. The increase of net cash provided by financing activities was attributable to the issuance of a Senior Convertible Note with a principal balance of \$1,000,000 issued in exchange for cash of the same amount during April of 2010.

We have limited funds to support our operations. We have prepared our consolidated financial statements in this Form 10-K on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Our continuation as a going concern 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. We expect that we will need to raise an additional \$6 million in funds to operate and execute our business plan during the 2012 fiscal year. In order to conduct the second Phase 3 trial and the other routine supportive safety studies that are required in order to obtain regulatory approval to market Ketotransdel<sup>®</sup>, we will need to secure additional funds. We intend to seek additional financing to fund the clinical requirements for Ketotransdel<sup>®</sup> as well as to continue our cosmetic program and to explore co-development opportunities. If adequate financing is not available, we will not be able to meet the FDA's requirements to obtain regulatory approval to market Ketotransdel<sup>®</sup>.

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

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

As reported in the Report of Independent Registered Public Accounting Firm on our December 31, 2010 consolidated financial statements, we do not have adequate cash resources, as of the date of the Report, to support our operating plan for the next twelve to fifteen months and we have incurred recurring losses from operations and have an accumulated deficit that raises substantial doubt about our ability to continue as a going concern.

## 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 consolidated financial statements. An accounting policy is deemed to be critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made, and any changes in the different estimates that could have been used in the accounting estimates that are reasonably likely to occur periodically could materially impact our consolidated financial statements.

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

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

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

*Tax Liabilities.* As part of the process of preparing our financial statements, we must estimate our actual current tax liabilities together with assessing temporary differences resulting from differing treatment of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities, which are included within the balance sheet. We must assess the likelihood that the deferred tax assets will be recovered from future taxable income and, to the extent we believe that recovery is not likely, a valuation allowance must be established. To the extent we establish a valuation allowance or increase or decrease this allowance in a period, the impact will be included in the tax provision in the statement of operations.

## 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

We are not aware of any additional pronouncements that materially affect our financial position or results of operations.

## **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Not applicable.

## **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. CONTROLS AND PROCEDURES**

### **Disclosure Controls and Procedures**

We maintain disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) that are designed to ensure that information that would be required to be disclosed in Exchange Act reports is recorded, processed, summarized and reported within the time period specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including to our Principal Executive Officer and Principal Accounting and Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

As required by Rule 13a-15 under the Exchange Act, our management, including our Principal Executive Officer and Principal Accounting and Financial Officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2010. Based on that evaluation, our Principal Executive Officer and Principal Financial Officer concluded that as of December 31, 2010, and as of the date that the evaluation of the effectiveness of our disclosure controls and procedures was completed, our disclosure controls and procedures are not effective to satisfy the objectives for which they are intended.

### **Management's Annual Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. The Exchange Act defines internal control over financial reporting as a process designed by, or under the supervision of, our Principal Executive Officer and Principal Accounting and 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 accounting principles generally accepted in the United States of America and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States of America, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2010. In making this assessment, management used the framework set forth in the report entitled Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO. The COSO framework summarizes each of the components of a company's internal control system, including (i) the control environment, (ii) risk assessment, (iii) control activities, (iv) information and communication, and (v) monitoring. Based on our assessment we determined that, as of December 31, 2010, our internal controls over financial reporting are not effective at the reasonable assurance level based on those criteria, due to the following weakness described below.

*Insufficient segregation of duties in our finance and accounting functions due to limited personnel.* During the year ended December 31, 2010, the company internally performed all aspects of our financial reporting process, including, but not limited to, access to the underlying accounting records and systems, the ability to post and record journal entries and responsibility for the preparation of the financial statements. Due to the fact these duties were performed oftentimes by the same people, a lack of review was created over the financial reporting process that might result in a failure to detect errors in spreadsheets, calculations, or assumptions used to compile the financial statements and related disclosures as filed with the SEC. These control deficiencies could result in a material misstatement to our interim or annual financial statements that would not be prevented or detected.

*Insufficient corporate governance policies.* Although we have a code of ethics which provides broad guidelines for corporate governance, our corporate governance activities and processes are not always formally documented. Specifically, decisions made by the board to be carried out by management should be documented and communicated on a timely basis to reduce the likelihood of any misunderstandings regarding key decisions affecting our operations and management.

We intend to take appropriate and reasonable steps to make the necessary improvements to remediate these deficiencies and we intend to consider the results of our remediation efforts and related testing as part of our next year-end assessment of the effectiveness of our internal control over financial reporting.

This Report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to rules of the SEC that permit the Company to provide only management's report in this Report.

### **Changes in Internal Control over Financial Reporting**

There were no changes to internal controls over financial reporting during the fiscal year ended December 31, 2010. More recently, during the fiscal year ended December 31, 2011, our former Principal Accounting and Financial Officer resigned and as a result our internal control procedures have been materially affected. The Company also had resignations of several other members of its executive management team and its Board of Directors that affected its internal control process throughout the fiscal year ended December 31, 2011.

During the first quarter of fiscal 2012, we began taking the necessary actions to remediate material weaknesses described above. We expect to implement the following corrective actions, including testing, during the year ending December 31, 2012:



- Our Board of Directors has begun the process of re-forming an Audit Committee comprised of independent directors, appointing a financial expert to the Board, and reviewing our existing Audit Committee charter and/or adopting a new charter. We expect the Audit Committee will operate independently of the Board as contemplated by its proposed charter and will be tasked with oversight of selection of our independent registered public accounting firm for the audit of our financial statements.
- We are in the process of adopting procedures designed to ensure better coordination, oversight and communication among the finance, human resources, and legal functions to ensure that no one person or department would have complete control in the accounting and financial reporting process. We intend to increase our staffing in the aforementioned departments in order to further this process.

#### **Inherent Limitations on Effectiveness of Controls**

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

#### **ITEM 9B. OTHER INFORMATION**

None.

## PART III

### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

#### Executive Officers and Directors

The following table sets forth information regarding our executive officers and directors as of February 15, 2012:

Name	Age	Position
Joachim Schupp, M.D.	57	Chief Medical Officer
Balbir Brar D.V.M., Ph.D.	75	President and Director
Andrew R. Boll	29	Vice President of Accounting and Public Reporting
Mark L. Baum, Esq.	39	Executive Chairman of the Board and Director
Paul Finnegan, M.D.	51	Director
Jeffrey J. Abrams, M.D.	64	Director
Robert Kammer, D.D.S.	62	Director

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

**Joachim Schupp, M.D.** has been the Chief Medical Officer of the Company since February 2012. Dr. Schupp has more than 25 years of leadership experience in the pharmaceutical industry. He has achieved the professional distinction of leading international project teams that have brought several drugs through the development and the regulatory process and on to the market globally. Most recently, Dr. Schupp has worked as an Executive Consultant for pharmaceutical and biotechnology companies. He held positions as Vice-President of Clinical Development at Apricus Biosciences, Inc. from April 2011 to February 2012, Senior Consultant to and Chief Medical Officer at Transdel Pharmaceuticals, Inc. from May 2009 to April 2011, Vice President of Medical Affairs at Adventrx Pharmaceuticals from 2006 to 2008 and Vice President of Clinical Data Services at ProSanos Corporation from 2004 to 2006. In addition, Dr. Schupp spent 19 years with Novartis Pharmaceuticals in Switzerland where he held various positions in clinical development and global project management. Dr. Schupp began his pharmaceutical career at Ciba-Geigy, now Novartis, in 1985 where he was appointed to lead international clinical project teams to discover new non steroidal inflammatory drugs (NSAIDs) with improved gastrointestinal tolerability. Dr. Schupp received several prestigious awards at Ciba-Geigy and Novartis for his team leadership contributions. Dr. Schupp received his M.D. from the Free University of Berlin in Germany and he served on the faculty at the University of Pretoria, South Africa, in Internal Medicine and Rheumatology.

**Balbir Brar, D.V.M., Ph.D.**, has been President of the Company since January 2012. Dr. Brar has over 25 years of experience in drug and device development and worldwide registration of eight major drugs, including Botox. He has significant experience in research and development, conducting clinical trials, implementation of product development plans and working with U.S. and international regulators. For the past five years and presently, Dr. Brar serves as a consultant to four biotechnology companies: AtheroNova Inc., Aciont, Inc., Altheos, Inc., Aciex Therapeutics, Inc. Dr. Brar has worked with major pharmaceutical companies, including Lederle Laboratories (acquired by Wyeth, then by Pfizer, Inc. (NYSE: PFE), and served as Senior Director of Drug Safety at SmithKline Beckman, now GlaxoSmithKline plc (NYSE: GSK). In addition, he served as Vice President Drug Safety, Research & Development at Allergan, Inc. (NYSE: AGN), where he was responsible for regulatory submission of 50 IND's/510K's and worldwide approval of six New Drug Applications. Dr. Brar is listed as the inventor of numerous patents. He has a Ph.D. in Toxicology/Pathology from Rutgers University and D.V.M. from India with finance training from Harvard Business School. Dr. Brar is a recipient of numerous achievements awards for excellence belongs to a number of scientific organizations and is the author/coauthor of over 55 scientific publications.

**Andrew R. Boll** has been our Vice President of Accounting and Financial Reporting since February 2012. Mr. Boll has over seven years of experience in financial reporting and accounting including four years experience working with small capitalization companies, with a particular focus on restructured and reorganized businesses. From 2007 to 2011, Mr. Boll was an accountant for BCGU, LLC, a privately held fund manager that specializes in capital venture investment opportunities. There he provided consulting services to public company clients, compiled SEC financial reports, and accounted for numerous public company restructurings, financings and private to public mergers. From 2004 to 2007, Mr. Boll was an accountant for Welsh Companies, LLC, a privately held commercial real estate company, its fund and its other subsidiaries. Mr. Boll received his B.S. degree in Corporate and Public Finance, *summa cum laude*, from Huron University.

**Mark L. Baum, Esq.** has with more than 15 years experience in financing, operating and advising small capitalization publicly traded enterprises, with a particular focus on restructured or reorganized businesses. As a manager of capital, he has completed more than 125 rounds of financing for more than 40 publicly traded companies. As a securities attorney, Mr. Baum has focused his practice on US securities laws, reporting requirements and public company finance-related issues that affect small capitalization public companies. Mr. Baum has actively participated in numerous public company spin-offs, restructurings and recapitalizations, venture fundings, private-to-public mergers, asset acquisitions and divestitures. In addition to his fund management and legal experience, Mr. Baum has operational experience in the following industries: life science and diagnostics, closed door pharmacies, cleaner and renewable energy and retail home furnishings. Mr. Baum has served on numerous boards of directors, including Chembio Diagnostic Systems, Inc., Applied Natural Gas Fuels, Inc., Shrink Nanotechnologies, Inc. and You on Demand, Inc., as well as Boards of Advisors for domestic and international private and public companies. Mr. Baum founded and capitalized the Mark L. Baum Scholarship which has funded tuition grants to college students in Texas. He is a trustee of the Collier de Bleu Trust, based out of San Miguel de Allende, Mexico, which is dedicated to funding educational opportunities for non-English speaking children in and around the greater San Miguel de Allende area. Mr. Baum is a published inventor and a licensed attorney in California and Texas.

**Paul Finnegan, M.D.** brings to the Company experience as a board member and a global senior executive in the pharmaceutical and biotechnology industries. His expertise involves development, commercialization, and product launches of multiple novel drugs, both blockbusters and ultra-orphan therapeutics, which encompassed various clinical indications. He has served in leadership roles in commercial, clinical, medical affairs and business development functions of public and private companies. Most recently, from November 2008 to January 2012, Dr. Finnegan has been an entrepreneur in residence with Avalon Ventures, serving as President, Chief Executive Officer and Board Director of Avelas BioSciences and InCode Pharmaceuticals, as well as a member of the biotechnology investment team, leading the clinical, commercial and regulatory due diligence efforts for over three years. Dr. Finnegan served as Chief Operating Officer and Chief Medical Officer of the Company in 2008. Prior to Transdel, Dr. Finnegan served as the President and Chief Executive Officer of Cecoura Therapeutics, a private drug development company from 2007 to 2008. From 2001 to 2007, Dr. Finnegan served as Vice President of Global Strategic Marketing and Development and other senior management positions at Alexion Pharmaceuticals. Prior to joining Alexion in 2001, Dr. Finnegan served as Senior Director, Global Medical Marketing for Pharmacia Corporation and G.D. Searle & Co., providing medical affairs leadership for all therapeutic areas for the Asia-Pacific, Japan, Latin America and Canadian business regions. Dr. Finnegan served as a board observer at Anaptys, from 2008 to 2011, and as a member of the boards of directors of Avelas Biosciences from Nov 2008 to January 2011, and InCode Pharmaceuticals from April 2009 to present. Dr. Finnegan earned his MBA with Honors, in Finance and Strategy, from the University of Chicago, Graduate School of Business, and the degrees of MD, CM from McGill University, Faculty of Medicine, in Montreal. He is a Fellow of the Royal College of Physicians, Canada (FRCPC), Member of the American Society of Hematology and practiced as an interventional radiologist specializing in oncology and vascular diseases prior to transitioning to industry.

**Jeffrey J. Abrams, M.D., MPH**, has been a board member since the merger with Transdel Pharmaceuticals Holdings, Inc. on September 17, 2007 and served as Chairman of the Board from February 2010 until December 2011. Dr. Abrams has been a director of Transdel Pharmaceuticals Holdings, Inc. since 1998. Prior to joining Transdel Pharmaceuticals Holdings, Inc., Dr. Abrams was a practicing primary care clinician for over twenty years. Dr. Abrams received a B.A. from the State University of New York at Buffalo, an M.D. from the Albert Einstein College of Medicine and an M.P.H. from San Diego State University. Dr. Abrams was one of the co-founders of our company, and we believe that his qualifications to sit on our Board include his scientific and technical knowledge of our Transdel™ technology and our lead product candidate, Ketotransdel® and his years of experience as a practicing primary care clinician.

**Robert Kammer, D.D.S.**, received his Bachelor of Science Degree in 1971 from Xavier University, Cincinnati, Ohio. He received his Doctor of Dental Surgery Degree from the University of Iowa in 1974. Dr. Kammer is a Diplomat of The American Board of Orofacial Pain and a Founding Charter Member of The Academy for Sports Dentistry and Colorado Osseointegration Study Club. From 1979 to 1996, Dr. Kammer was an Associate Professor and Course Director of Orofacial Pain Section in the Department of Restorative Dentistry at The University of Colorado Health Science Center. From 1982 through 1993, he served on the Sports Medicine Advisory Committee at The University of Colorado Intercollegiate Athletics and was the Team Dentist for Football and Basketball. From 1983 to 1990, Dr. Kammer was a consultant to the Boulder-Denver Pain Control Center and from 1988 through 1991, he served as a Referee and Editorial Staff Consultant of the Journal of Orofacial Pain. Dr. Kammer recently contributed a chapter to the groundbreaking text Osteoperiosteal Flap, is consulting for Clear Choice Dental Implant Centers, co-authoring scientific papers and is a co-investigator for a landmark study of Titanium Implant Prostheses at the Mayo Institute.

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

## Section 16(a) Beneficial Ownership Reporting Compliance

Under U.S. securities laws, directors, certain executive officers and persons holding more than 10% of our common stock must report their initial ownership of the common stock, and any changes in that ownership, to the SEC. The SEC has designated specific due dates for these reports. Based solely on our review of copies of such reports filed with the SEC by and discussions with our directors and executive officers, we have no reason to believe that our directors and executive officers did not file the required reports on time in the 2010 fiscal year.

## 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).

## Board Committees

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

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

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

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

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

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

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

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

#### ITEM 11. EXECUTIVE COMPENSATION

The following table sets forth for the periods presented certain information concerning all compensation earned by or awarded or paid to our named executive officers serving during the fiscal year ended December 31, 2010. With the exception of Dr. Schupp who resigned in April 2011, and was re-hired effective February 15, 2012 and as noted below, none of our currently named executive officers received compensation during the 2009 and 2010 fiscal periods.

**Summary Compensation Table**

<u>Name</u>	<u>Year</u>	<u>Salary (\$)</u>	<u>Stock Awards (\$)</u>	<u>Option Awards (\$)(1)</u>	<u>Total (\$)</u>
John Bonfiglio (2)	2010	30,000	40,000	194,721	264,721
Former President and Chief Executive Officer	2009	-	-	-	-
Juliet Singh (3)	2010	246,789	-	174,000	420,789
Former Chief Executive Officer	2009	225,000	-	210,361	435,361
John T. Lomoro (6)	2010	170,000	-	-	170,000
Former Chief Financial Officer, Principal Executive Officer and Principal Financial Officer	2009	170,000	-	105,181	275,181
Joachim P.H. Schupp, M.D. (4)	2010	180,000	-	-	180,000
Chief Medical Officer	2009	40,269	-	220,404	260,673
Terry Nida (5)	2010	151,364	-	162,840	314,204
Former Chief Financial Officer, Principal Executive Officer and Principal Financial Officer	2009	-	-	-	-

- (1) Reflects the dollar amount of the grant date fair value of awards granted during the respective fiscal years, measured in accordance with guidance from the Financial Accounting Standards Board ("FASB"). As a result of changes to the rules relating to these disclosures, The assumptions used in the calculations for these amounts are described in the footnotes to our consolidated financial statements included herein.
- (2) Effective October 20, 2010, the Company appointed John N. Bonfiglio, Ph.D. as Chief Executive Officer and President of the Company. Dr. Bonfiglio was also appointed as a director on the Company's Board. The Board granted Dr. Bonfiglio a stock option for 400,000 shares of common stock and issued 50,000 shares of restricted common stock in accordance with the Company's 2007 Incentive Stock and Awards Plan. The stock option and the restricted common stock will vest as follows: 25% of the option shares and the restricted stock shall vest immediately upon grant, with the balance of the option shares and the restricted stock vesting in equal monthly installments over the next 36 months beginning 30 days after the grant date. The exercise price of the stock option is \$0.80 per share, the reported closing price of the Company's common stock on October 20, 2010. Mr. Bonfiglio resigned as Chief Executive Officer and President of the Company on May 13, 2011.
- (3) Effective February 17, 2010, the Board of Directors accepted the resignation of Dr. Juliet Singh as Chief Executive Officer and as a director on the Board. In connection with Dr. Singh's resignation, we entered into a separation agreement that provides her with one year of continued salary in accordance with the terms of her existing employment agreement as well as the accelerated vesting of 300,000 stock options previously granted. In addition, Dr. Singh will have three years from the date of her resignation to exercise her vested options.
- (4) On October 12, 2009, Joachim P.H. Schupp, M.D. was appointed as our Chief Medical Officer. In association with his appointment, Dr. Schupp was awarded an option for 215,000 shares of common stock at an exercise price of \$1.70, which vests quarterly over a three year period. Prior to his appointment, Dr. Schupp was retained by the company as a consultant in April 2009. Not included above is the compensation earned by Dr. Schupp as a consultant for the company which included a monthly cash retainer and an option for 85,000 shares of common stock at an exercise price of \$1.60 that was awarded to him in June 2009. This option vests over a one-year period and had a grant date fair value of approximately \$97,000 (as adjusted for modifications made to this award upon appointment as our Chief Medical Officer). Dr. Schupp resigned as Chief Medical Officer effective April 30, 2011, and was re-appointed effective February 15, 2012.
- (5) On February 26, 2010, the Company's Board of Directors granted 300,000 stock options to Terry Nida. All of the options were granted with an exercise price of \$0.90 and have a ten year life. Also, the options vest one-twelfth per quarter commencing on the first full quarter after the initial grant date of February 26, 2010. Mr. Nida resigned from his positions with the Company on December 16, 2011.
- (6) Effective September 16, 2011, Mr. Lomoro resigned from his positions with the Company.

## 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, 2010.

Option Awards				
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date
John Bonfiglio (1)	116,667	283,333	0.80	8/11/2011
Juliet Singh, Ph.D.	410,000	-	2.00	2/17/2013
	200,000	-	1.60	2/17/2013
John Lomoro (2)	50,000	50,000	1.60	12/15/2011
	83,333	16,667	2.00	12/15/2011
	150,000	-	2.00	12/15/2011
Joachim Schupp (3)	116,667	98,333	1.70	7/29/2011
	85,000	-	1.60	7/29/2011
Terry Nida (4)	75,000	225,000	0.90	3/15/2012

(1) The Board accepted the resignation of John N. Bonfiglio, Ph.D. as Chief Executive Officer of the Company and as a director on the Board, effective May 13, 2011. Any unvested options were forfeited at the resignation date and all vested options expired 90 days subsequent to the resignation date.

(2) The Board accepted the resignation of John T. Lomoro as Principal Executive Officer, Chief Financial Officer and Treasurer of the Company, effective September 16, 2011. Any unvested options were forfeited at the resignation date and all vested options expired 90 days subsequent to the resignation date.

(3) Effective April 30, 2011, Joachim P.H. Schupp resigned as Chief Medical Officer of the Company. Any unvested options were forfeited at the resignation date and all vested options expired 90 days subsequent to the resignation date.

(4) Effective December 16, 2011, Terry Nida resigned as Principal executive officer and Principal financial officer of the Company. Any unvested options were forfeited at the resignation date and all vested options expire 90 days subsequent to the resignation date.

## **Singh Separation Agreement**

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

## **Employment Agreements**

### **Dr. Balbir Brar**

Effective January 1, 2012, under the terms of his Employment Agreement with the Company, Dr. Brar will receive an initial base salary of \$84,000 per year. On January 23, 2012, the Board granted Dr. Brar an option to purchase 9,000,000 shares of common stock under the Plan, as amended. Pursuant to the terms of the Transdel Pharmaceuticals, Inc. 2007 Stock Incentive and Awards Plan (the "Plan"), the exercise price of the options is \$0.092, which is consistent with the definition of fair market value ("FMV") as defined in the Plan.

The stock option will vest as follows: 1/36<sup>th</sup> of the unvested shares will vest on each of the 36 monthly periods following the date of the grant provided Dr. Brar continues to be employed by the Company as of the applicable vesting date. The vesting of all options will fully accelerate upon a change of control (as such term is defined in the Stock Option Agreement). Dr. Brar has agreed to not sell more than five percent (5%) of the shares of the Company's common stock acquired through the exercise of his stock options in any monthly period. Dr. Brar also entered into the Company's standard forms of Incentive Stock Option Agreement and Employee Proprietary Information and Invention Assignment Agreement. Dr. Brar is also eligible to participate in the medical, insurance and 401(k) plans the Company offers to its other employees. Dr. Brar has executed Transdel's standard form Indemnification Agreement.

### **Dr. Joachim Schupp**

Effective February 15, 2012, under the terms of his Employment Agreement with the Company, Dr. Schupp will receive an initial base salary of \$204,000 per year. Upon his first day of employment with the Company, Dr. Schupp will be issued an option to purchase 3,000,000 shares of common stock under the Plan, as amended. The option will have a grant date of February 15, 2012. Pursuant to the terms of the Plan, the exercise price of the option will be the mean between the closing bid and asked prices of the Company's common stock on the Pink Sheets on February 10, the trading day immediately prior to the date of grant. The stock option will vest as follows: 750,000 shares on each anniversary of the grant date for the four anniversaries subsequent to the date of the grant; provided Dr. Schupp continues to be employed by the Company as of the applicable vesting date. The vesting of all options will fully accelerate upon a change of control (as such term is defined in the Stock Option Agreement). Dr. Schupp has agreed to not sell more than five percent (5%) of the shares of the Company's common stock acquired through the exercise of his stock options in any monthly period. Dr. Schupp will also be eligible to participate in the medical, insurance and 401(k) plans the Company offers to its other employees. Dr. Schupp also entered into the Company's standard forms of Incentive Stock Option Agreement and Employee Proprietary Information and Invention Assignment Agreement. Dr. Schupp has executed Transdel's standard form Indemnification Agreement.

### **Andrew R. Boll**

On January 25, 2012, the Company entered into an Employment Agreement with Mr. Boll, effective as of February 1, 2012. Under the terms of the Employment Agreement, Mr. Boll will receive an initial base salary of \$60,000 per year. On January 23, 2012, the Board granted Mr. Boll a stock option for 600,000 shares of common stock under the Plan. Pursuant to the terms of the Plan, the exercise price of the options is \$0.092, which is consistent with the definition of FMV as defined in the Plan. The stock option will vest as follows: 1/36<sup>th</sup> of the unvested shares will vest on each of the 36 monthly periods following the effective date of Mr. Boll's Employment Agreement provided Mr. Boll continues to be employed by the Company as of the applicable vesting date. The vesting of all options will fully accelerate upon a change of control (as such term is defined in the Stock Option Agreement). Mr. Boll will also be eligible to participate in the medical, insurance and 401(k) plans the Company offers to its other employees.



## 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. On January 25, 2012, the Board determined that it was in the best interests of the Company and its stockholders to amend the Transdel Pharmaceuticals, Inc. the Plan to, among other things, increase the maximum number of shares issuable under the Plan by 27,000,000 shares to 30,000,000 shares, and to reserve such Shares for issuance under the Plan (the "Plan Amendment"), subject to stockholder approval of the Plan Amendment. The Company's stockholders approved the Plan Amendment in an action by written consent on January 25, 2012. The Plan Amendment will become effective following the Company's compliance with certain information requirements of the U.S. Securities and Exchange Commission (the "SEC").

Following the effective date of the Plan Amendment, there will be outstanding options to purchase 23,801,217 shares of our common stock, 220,313 shares of restricted stock outstanding under the 2007 Plan, and 4,848,220 shares of our common stock available for issuance under the 2007 Plan.

## Director Compensation

We have not compensated any of our directors for their service on our Board during the fiscal years ended December 31, 2010 and December 31, 2009. 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 (other than those also serving as named executive officers) serving during the fiscal year ended December 31, 2010.

Name	Year	Fees Earned or Paid in Cash	Stock Awards(1)(8)	Option Awards(2)(8)	Total
John Bonfiglio (3)	2010	\$ -	\$ -	\$ -	\$ -
	2009	\$ -	\$ -	\$ -	\$ -
Juliet Singh (4)	2010	\$ -	\$ -	\$ -	\$ -
	2009	\$ -	\$ -	\$ -	\$ -
Jeffrey J. Abrams, M.D. (5)	2010	\$ -	\$ -	\$ -	\$ -
	2009	\$ -	\$ -	\$ -	\$ -
Anthony S. Thornley (6)	2010	\$ -	\$ -	\$ -	\$ -
	2009	\$ -	\$ -	\$ -	\$ -
Lynn C. Swann (1)(7)	2010	\$ -	\$ -	\$ -	\$ -
	2009	\$ -	\$ -	\$ -	\$ -

- (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.'s Singh and Bonfiglio, were awarded an option for 80,000 shares of common stock at an exercise price of \$0.70, which vests quarterly over a five year period. Also, in November 2008, upon his appointment, the Board of Directors granted Mr. Swann an option to purchase 25,000 shares of common stock at an exercise price of \$0.70, which vested quarterly over a 1 year period.
- (3) On October 21, 2010, the Company announced that the Board of Directors of the Company (the "Board") had appointed John N. Bonfiglio, Ph.D. as Chief Executive Officer and President of the Company, effective October 20, 2010. Dr. Bonfiglio was also appointed as a director on the Company's Board. Effective May 13, 2011 the Board accepted the resignation of John N. Bonfiglio, Ph.D. as Chief Executive Officer of the Company and as a director on the Board, effective May 13, 2011.
- (4) As noted previously, as of February 17, 2010, the Board accepted the resignation of Dr. Singh as Chief Executive Officer and as a director on the Board.
- (5) As of December 31, 2010, Dr. Abrams held 90,000 stock options, of which 42,000 were vested.
- (6) As of December 31, 2010, Mr. Thornley held 90,000 stock options, of which 42,000 were vested. Effective December 16, 2011, Anthony S. Thornley resigned as a director from the Company's Board of Directors
- (7) As of December 31, 2010, Mr. Swann held 105,000 stock options and 25,000 shares of restricted common stock, of which 57,000 and 25,000 were vested, respectively. Effective April 14, 2011, Lynn C. Swann resigned as a director from the Company's Board of Directors.
- (8) Reflects the dollar amount of the grant date fair value of awards granted during the respective fiscal years, measured in accordance with FASB guidance. The assumptions used in the calculations for these amounts are described in the footnotes of 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 regarding the beneficial ownership of common stock of the Company as of February 15, 2012 by: (i) each person who, to the Company’s knowledge, owns more than 5% of its common stock; (ii) each of the Company’s named executive officers and directors; and (iii) all of the Company’s named executive officers and directors as a group. Beneficial ownership is determined in accordance with the rules and regulations of the Commission. If a stockholder holds options or other securities that are exercisable or otherwise convertible into our common stock within 60 days of February 15, 2012, we treat the common stock underlying those securities as owned by that stockholder, and as outstanding shares when we calculate that stockholder’s percentage ownership of our common stock. However, we do not consider that common stock to be outstanding when we calculate the percentage ownership of any other stockholder. 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 is c/o Transdel Pharmaceuticals, Inc. 437 S. Hwy 101, Suite 209, Solana Beach, CA 92075.

Beneficial Owner	Number of Shares of Common Stock Beneficially Owned prior to the Effective Date (1)	Percentage Beneficially Owned prior to the Effective Date(1)	Number of Shares of Common Stock Beneficially Owned following the Effective Date (1)	Percentage Beneficially Owned following the Effective Date(1)
DermaStar International, LLC (8)	29,994,001(4)	65.35%	118,058,306(3)	79.15%
Juliet Singh, Ph.D.	2,564,125(5)	15.53%	2,564,125(5)	2.85%
Alexej Ladonnikov	-(6)	*	15,199,087(6)	17.05%
Joseph Grasela	1,171,875(7)	7.37%	1,171,875(7)	1.31%
John Grasela	1,171,875(7)	7.37%	1,171,875(7)	1.31%
<i>Directors &amp; Officers</i>				
Jeffery J. Abrams, M.D.	1,625,000(2)	10.22%	1,625,000(2)	1.82%
Mark L. Baum, Esq.	29,994,001(3)(4)	65.35%	118,058,306(3)(4)	79.15%
Robert J. Kammer, D.D.S.	29,994,001(3)	65.35%	118,058,306(3)	79.15%
Balbir Brar, D.V.M., Ph.D.	-(9)	*	-(9)	*
Paul Finnegan, M.D.	-(10)	*	-(10)	*
Andrew Boll	-(11)	*	-(11)	*
All current executive officers and directors as a group (5 persons)	31,619,001	68.78%	119,683,306	79.37%

\* Less than 1%

- (1) Based on 15,900,811 shares of our common stock issued and outstanding as of February 15, 2012. Corporate actions related to amending the Company’s Amended and Restated Certificate of Incorporation to increase the Company’s authorized common stock from 50,000,000 shares to 395,000,000 shares and amendment to the 2007 Plan are expected to become effective on or about February 28, 2012 (the “Effective Date”).
- (2) Jeffrey J. Abrams, M.D., a director, is a trustee of the Abrams Family Trust, which owns 1,562,500 shares of our common stock. Dr. Abrams has sole voting and investment control with respect to the shares of common stock owned by the Abrams Family Trust. Includes 74,500 shares of common stock issuable upon the exercise of stock options.

- (3) Pursuant to the Series A Convertible Preferred Stock Certificate of Designation, the ten outstanding shares of Series A Preferred Stock held by DermaStar International, LLC (“DermaStar”) are convertible into, and have voting power equivalent to, 59,988,002 shares of our common stock. Prior to the Effective Date of the Authorized Share Increase, our Amended and Restated Certificate of Incorporation authorizes us to issue up to 50,000,000 shares of capital stock. Until the Effective Date of the Authorized Share Increase, DermaStar has the ability to convert five of its ten shares of Series A Preferred Stock into 29,994,001 shares of common stock. Following the Effective Date of the Authorized Share Increase, DermaStar will be able to convert all ten shares of Series A Preferred Stock into 59,988,002 shares of common stock, representing approximately 79% of the capital stock of the Company on an as-converted basis. In addition, DermaStar is the holder of a convertible note and \$56,087 in unsecured accounts payable debt and that, upon the Effective Date of the Authorized Share Increase, will immediately convert into 58,198,498 shares of the Company’s common stock. The Company’s directors Mark L. Baum and Dr. Robert J. Kammer are the Managing Members of DermaStar and both Dr. Kammer and Mr. Baum hold ownership interests in DermaStar, and may be deemed to have voting and dispositive power over the shares. Mr. Baum and Dr. Kammer disclaim beneficial ownership over such shares.
- (4) Does not include stock option grant to Mr. Baum of 5,000,000 shares pursuant to the 2007 Plan, which will be effective as of the effective date of the Plan Amendment. When issued, the option will vest in twelve equal monthly periods, commencing on January 25, 2012 and ending on January 25, 2013.
- (5) Includes 610,000 shares of common stock issuable upon the exercise of stock options.
- (6) Prior to the Effective Date, includes shares of common stock issuable upon the conversion of \$1,000,000 principal balance 7.5% convertible note and its accrued interest through January 23, 2012 pursuant to the initial terms of the convertible note. Following the Effective Date of the Authorized Share Increase, Mr. Ladonnikov’s ownership of the convertible note will immediately convert into 15,234,703 shares of the Company’s common stock.
- (7) Joseph Grasela and John C. Grasela are adult siblings living in separate households.
- (8) The address for DermaStar International, LLC is 1302 Waugh Dr., Suite 618, Houston, TX 77019.
- (9) Following the Effective Date of the Plan Amendments, Dr. Brar will be eligible to purchase up to 9,000,000 shares of common stock under the 2007 Plan. None of these options have vested and none are currently exercisable.
- (10) Following the Effective Date of the Plan Amendments, Dr. Finnegan will be eligible to purchase up to 5,000,000 shares of common stock under the 2007 Plan. None of these options have vested and none are currently exercisable.
- (11) Following the Effective Date of the Plan Amendments, Mr. Boll will be eligible to purchase up to 600,000 shares of common stock under the 2007 Plan. None of these options have vested and none are currently exercisable.

## Securities Authorized for Issuance Under Equity Compensation Plans

The following table summarizes our compensation plans under which our equity securities are authorized for issuance as of December 31, 2010:

### EQUITY COMPENSATION PLAN INFORMATION (1)(2)

	<u>Number of Shares to be Issued Upon Exercise of Outstanding Stock Options</u>	<u>Weighted- Average Exercise Price of Outstanding Stock Options</u>	<u>Number of Shares Remaining Available for Future Issuance Under Equity Compensation Plans</u>
Equity compensation plans approved by security holders	3,000,000	\$ 1.34	123,470
Equity compensation plans not approved by security holders	5,000	2.00	-
Total	3,005,000	\$ 1.34	123,470

- (1) Includes the 2007 Incentive Stock and Awards Plan. See the footnotes found in the consolidated financial statements included herein for information related to the equity compensation plans.
- (2) On January 25, 2012, the Board determined that it was in the best interests of the Company and its stockholders to amend the 2007 Plan to, among other things, increase the maximum number of shares issuable under the 2007 Plan by 27,000,000 shares to 30,000,000 shares, and to reserve such shares for issuance under the 2007 Plan (the "Plan Amendment"), subject to stockholder approval of the Plan Amendment. Our stockholders approved the Plan Amendment in an action by written consent on January 25, 2012. The Plan Amendment will become effective on, or about, February 28, 2012, following our compliance with certain information requirements of the SEC

## ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

### Separation Agreement and General Release

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

### Certain Relationships and Related Party Transactions

Other than as described below, during the fiscal years ended December 31, 2010 and December 31, 2009, there were no transactions to which the Company was or is a party in which the amount involved exceeds \$120,000 and in which any director, officer or beneficial holder of more than 5% of any class of our voting securities or member of such person's immediate family had or will have a direct or indirect material interest.

The Chairman of our Board of Directors and our principal executive officer, Mr. Mark L. Baum, and director Robert J. Kammer, both serve as Managing Members of DermaStar International, LLC (“DermaStar”), the holder of over 65% of the voting interests in our capital stock. Mr. Baum and Mr. Kammer were appointed to our Board on December 12, 2011, following the closing of the Secured Line of Credit and purchase of the Series A Preferred Stock describe below:

#### *Secured Line of Credit – Related Party*

On November 21, 2011, we entered into a Secured Line of Credit Letter Agreement (the “Line of Credit Agreement”) with DermaStar, pursuant to which DermaStar agreed to lend us funds under a line of credit upon certain conditions, including the dismissal of the Chapter 11 Case by the Bankruptcy Court. The Line of Credit Agreement became effective on December 9, 2011, in connection with the dismissal of the Chapter 11 Case by the Bankruptcy Court. On December 9, 2011, as required by the Line of Credit Agreement, we entered into a Security Agreement and an Intellectual Property Security Agreement, pursuant to which we granted to DermaStar a blanket security interest in all of our assets, including our intellectual property. The Line of Credit Agreement provides for advances of up to an aggregate of \$750,000 (each an “Advance” and collectively the “Loan”), subject to the satisfaction by us of certain conditions in connection with the initial Advance and each subsequent Advance. Each Advance will be made pursuant to a Promissory Note in favor of DermaStar. On December 12, 2011, we requested and received advances totaling \$300,000. The Advances under the Line of Credit accrue interest at the rate of 10%.

#### *Series A Preferred Stock Purchase*

In partial consideration for and in connection with the Line of Credit Agreement, on November 21, 2011 we executed a Securities Purchase Agreement (the “Purchase Agreement”) with DermaStar, pursuant to which we agreed to issue ten (10) shares of newly-designated Series A Convertible Preferred Stock (the “Series A Preferred Stock”) to DermaStar for an aggregate purchase price of \$100,000. The Purchase Agreement, as amended, became effective on December 9, 2011, in connection with the dismissal of the Chapter 11 Case by the Bankruptcy Court. On December 12, 2011, we and DermaStar consummated the transactions contemplated by the Purchase Agreement. The shares of Series A Preferred Stock issued to DermaStar in the offering are convertible into 59,988,002 shares of our Common Stock; however, until the effective date of the stockholder action by written consent to approve to increase the number of authorized shares of Common Stock through an amendment to the our Amended and Restated Certificate of Incorporation (as described below), DermaStar has the ability to convert five of its ten shares of Series A Preferred Stock into 29,994,001 shares of Common Stock, representing approximately 65% of the capital stock of the Company on an as-converted basis.

#### *7.5% Convertible Promissory Note*

Effective as of January 25, 2012, we entered into separate waiver and settlement agreements with the two parties holding a \$1,000,000 7.5% convertible promissory note (the “Convertible Note”) issued by us on April 5, 2010. DermaStar had previously acquired eighty percent (80%) of the Convertible Note in a private transaction with the original purchaser of the Convertible Note. Under the waiver and settlement agreement, DermaStar agreed to waive (i) its right to accelerate the entire unpaid principal sum of the Convertible Note and all accrued interest pursuant to Section 1 of the Convertible Note related to the Company’s Bankruptcy petition filed June 26, 2011, (ii) its rights under Section 7 of the Senior Convertible Note Purchase Agreement dated April 5, 2010, regarding the designation and creation of the Series A Convertible Preferred Stock and (iii) its rights under certain conversion rights pursuant to Section 3 of the Convertible Note related to the change of control that resulted from the sale of the Series A Convertible Preferred Stock. In addition, we and DermaStar agreed to the mandatory conversion of the eighty percent (80%) of the principal and accrued and unpaid interest of the Convertible Note held by DermaStar, at such time as we have a sufficient number of authorized common shares to effect such a conversion, into our common stock at a conversion price of \$0.01667 (“DermaStar Conversion Price”). Additionally, DermaStar agreed to a mandatory conversion of an additional \$56,087 in good and valid current accounts payable of the Company (“AP Conversion”) currently held by DermaStar, at such time as we have a sufficient number of authorized common shares and DermaStar is able to convert the Convertible Note. The AP Conversion will be made at the DermaStar Conversion Price. The DermaStar Waiver Agreement was negotiated and approved by the sole disinterested director unaffiliated with DermaStar. Directors Mr. Baum and Dr. Kammer abstained from voting on this matter.

In addition, director Paul Finnegan currently serves as a consultant to the Company. On January 17, 2012, Dr. Finnegan entered into a Senior Advisory Agreement with the Company, pursuant to which he will provide certain consulting services to the Company in addition to his services as a director. Under the terms of the Senior Advisory Agreement, Dr. Finnegan will provide consulting services in the area of drug and technology development, among other things, and will receive \$18,000 per quarter through the term of the agreement. The Senior Advisory Agreement has a term of three years and is terminable by either party with 60 days written notice. In addition, on January 23, 2012, the Company granted Dr. Finnegan a non-qualified stock option to purchase 5,000,000 shares of common stock under the Plan pursuant to a Non-Qualified Stock Option Agreement. Pursuant to the terms of the Plan, the exercise price of the option is \$0.08 per share. The stock option will vest as follows: 2,000,000 shares on the first anniversary of the date of the Senior Advisory Agreement, 2,000,000 shares on the second anniversary of the date of the Senior Advisory Agreement and 1,000,000 on the third anniversary of the date of the Senior Advisory Agreement; provided however, that Dr. Finnegan must continue to serve as a consultant to the Company as of the applicable vesting date. Dr. Finnegan has agreed to not sell more than five percent (5%) of the shares of the Company's common stock acquired through the exercise of his stock options in any monthly period.

## **Director Independence**

### *Current Directors*

We are not currently listed on any national securities exchange that has a requirement that the Board of Directors be independent. However, Our Board of Directors has determined that each of current director Dr. Abrams, Mr. Kammer and Mr. Finnegan is an "independent director" as defined in Rule 5605(a)(2) of the Rules of The NASDAQ Stock Market LLC (the "NASDAQ Rules"). Current director Mr. Baum would not be considered independent because he currently serves as our principal executive officer. Director Dr. Brar would not be considered independent because he currently serves as our President.

We do not currently have an Audit Committee. However, the Board has determined that current director Dr. Abrams is independent within the meaning of Section 10A(m)(3) of the Exchange Act and Rule 10A-3(b)(1) thereunder, and satisfies the requirements for membership in the Audit Committee as set forth in Rule 5605(c)(2)(A) of the NASDAQ Rules. Mr. Kammer and Mr. Baum would not be considered independent for purposes of Audit Committee membership because they are each Managing Members of DermaStar, our majority stockholder and lender under our Line of Credit. Mr. Finnegan would not be considered independent because he has a consulting relationship with the Company. Dr. Brar would not be considered independent because he is our President.

### *Former Directors*

Lynn Swann was a director of the Company since November 2008 and resigned as a director effective April 14, 2011.

Anthony Thornley served as a director of the Company since November 2007 and resigned as a director effective December 16, 2011.

John Bonfiglio served as a director of the Company since October 2010, and resigned as a director effective May 13, 2011.

## 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, 2010 and 2009, were:

	<u>2010</u>	<u>2009</u>
Audit Fees	\$ 40,800	\$ 74,250

The *Audit Fees* for the years ended December 31, 2010 and 2009 were for professional services rendered for audits and quarterly reviews of our consolidated financial statements, and assistance with reviews of registration statements and documents filed with the SEC. There were no Audit-Related Fees, Tax Fees or All Other Fees billed by or paid to our principal accountant during the years ended December 31, 2010 and 2009.

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 2010 and 2009 were pre-approved by our Board of Directors.



**PART IV**

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

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

<b>Exhibit No.</b>	<b>Description</b>
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)
3.3	Certificate of Designation of Series A Convertible Preferred Stock of Transdel Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 3.1 in the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on December 20, 2011)
10.1	Form of September 2007 and October 2007 Private Offering Subscription Agreement (incorporated herein by reference to Exhibit 10.1 the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on September 21, 2007)
10.2	Form of Warrant to purchase Common Stock (incorporated herein by reference to Exhibit 10.2 the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on September 21, 2007)
10.3	Registration Rights Agreement dated October 10, 2007, by and between Transdel Pharmaceuticals, Inc. and each of the investors signatory thereto (incorporated herein by reference to Exhibit 10.3 the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on September 21, 2007)
10.4	Placement Agent Agreement, dated September 17, 2007, between Transdel Pharmaceuticals Holdings, Inc. and Granite Financial Group, LLC (incorporated herein by reference to Exhibit 10.5 the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on September 21, 2007)
10.5	Placement Agent Agreement, dated September 17, 2007, between Transdel Pharmaceuticals Holdings, Inc. and WFG Investments, Inc. (incorporated herein by reference to Exhibit 10.6 the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on September 21, 2007)

- 10.6 Placement Agent Agreement, dated September 17, 2007, by and between Transdel Pharmaceuticals Holdings, Inc. and Palladium Capital Advisors, LLC (incorporated herein by reference to Exhibit 10.7 the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on September 21, 2007)
- 10.7 Form of Directors and Officers Indemnification Agreement (incorporated herein by reference to Exhibit 10.8 the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on September 21, 2007)
- 10.8 Assignment of Employment Agreement, dated September 17, by and among Transdel Pharmaceuticals Holdings, Inc., Transdel Pharmaceuticals, Inc. and Juliet Singh, Ph.D. (incorporated herein by reference to Exhibit 10.9 the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on September 21, 2007)
- 10.9 Employment Agreement, dated June 27, 2007, by and between Transdel Pharmaceuticals Holdings, Inc. and Juliet Singh, Ph.D. (incorporated herein by reference to Exhibit 10.10 the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on September 21, 2007)
- 10.10 Transdel Pharmaceuticals, Inc. 2007 Incentive Stock and Awards Plan (incorporated herein by reference to Exhibit 10.11 the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on September 21, 2007)
- 10.11 Form of 2007 Incentive Stock Option Agreement (incorporated herein by reference to Exhibit 10.12 the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on September 21, 2007)
- 10.12 Form of 2007 Non-Qualified Stock Option Agreement (incorporated herein by reference to Exhibit 10.13 the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on September 21, 2007)
- 10.13 Stock Purchase Agreement, dated as of September 17, 2007, by and between Transdel Pharmaceuticals, Inc. and Rolf Harms. (incorporated herein by reference to Exhibit 10.14 to the Registration Statement on Form SB-2 of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on December 7, 2007)
- 10.14 Agreement of Conveyance, Transfer and Assignment of Assets and Assumption of Obligations, dated as of September 17, 2007, by and between Transdel Pharmaceuticals, Inc. and Bywater Resources Holdings Inc. (incorporated herein by reference to Exhibit 10.15 to the Registration Statement on Form SB-2 of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on December 7, 2007)
- 10.15 Form of Lock-Up Agreement (incorporated herein by reference to Exhibit 10.4 to the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on September 21, 2007)

- 10.16 Research and Development Services Agreement, dated October 11, 2007, by and between DPT Laboratories, Ltd. And Transdel Pharmaceuticals Holdings, Inc. (incorporated herein by reference to Exhibit 10.17 to the Registration Statement on Form SB-2 of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on December 7, 2007) (portions of this exhibit have been omitted pursuant to a request for confidential treatment)
- 10.17 Project Scope Document, effective May 30, 2007, by and between DPT Laboratories, Ltd. and Transdel Pharmaceuticals Holdings, Inc. (incorporated herein by reference to Exhibit 10.18 to the Registration Statement on Form SB-2 of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on December 27, 2007) (portions of this exhibit have been omitted pursuant to a request for confidential treatment)
- 10.18 Form of May 2008 Private Offering Subscription Agreement (incorporated herein by reference to Exhibit 10.1 the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on May 15, 2008)
- 10.19 Form of Warrant to purchase Common Stock (incorporated herein by reference to Exhibit 10.2 the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on May 15, 2008)
- 10.20 Clinical Trial Services Agreement by and between Transdel Pharmaceuticals, Inc. and Cato Research Ltd. (incorporated herein by reference to Exhibit 10.1 in the Quarterly Report on Form 10-Q of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on August 11, 2008)
- 10.21 Employment Agreement, dated October 18, 2010, between Transdel Pharmaceuticals, Inc. and John Bonfiglio, Ph.D. (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 November 14, 2010)
- 10.22 Nonqualified Stock Option Agreement, dated as of the 20<sup>th</sup> day of October, 2010, between Transdel Pharmaceuticals, Inc., and Dr. John Bonfiglio (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 November 14, 2010)
- 10.23 Restricted Stock Agreement, dated as of the 20<sup>th</sup> day of October, 2010, between Transdel Pharmaceuticals, Inc., and Dr. John Bonfiglio (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 November 14, 2010)
- 10.24 Separation Agreement and General Release between Juliet Singh and Transdel Pharmaceuticals, Inc. dated February 17, 2010 (incorporated herein by reference to Exhibit 10.21 in the Annual Report on Form 10-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on March 31, 2011)
- 10.25 Form of Senior Convertible Note Purchase Agreement (incorporated herein by reference to Exhibit 10.1 in the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on April 8, 2011)

10.26	Form of Senior Convertible Note Promissory Note (incorporated herein by reference to Exhibit 10.2 in the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on April 8, 2011)
10.27	Asset Purchase Agreement, dated June 26, 2011, by and among Transdel Pharmaceuticals, Inc. and Cardium Healthcare, Inc. (incorporated herein by reference to Exhibit 2.1 in the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on June 26, 2011)
10.28	Secured Line of Credit Letter Agreement, dated as of November 21, 2011, by and between Transdel Pharmaceuticals, Inc. and DermaStar International, LLC. (incorporated herein by reference to Exhibit 10.1 in the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on December 20, 2011)
10.29	Security Agreement, dated as of December 9, 2011, by and between Transdel Pharmaceuticals, Inc. and DermaStar International, LLC. (incorporated herein by reference to Exhibit 10.2 in the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on December 20, 2011)
10.30	Intellectual Property Security Agreement, dated as of December 9, 2011, by and between Transdel Pharmaceuticals, Inc. and DermaStar International, LLC. (incorporated herein by reference to Exhibit 10.3 in the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on December 20, 2011)
10.31	Securities Purchase Agreement, dated as of November 21, 2011, by and between Transdel Pharmaceuticals, Inc. and DermaStar International, LLC. (incorporated herein by reference to Exhibit 10.3 in the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on December 20, 2011)
10.32	Mutual General Release Agreement, dated December 13, 2011, by and between Transdel Pharmaceuticals, Inc. and the other signatories thereto. (incorporated herein by reference to Exhibit 10.4 in the Current Report on Form 8-K of Transdel Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on December 20, 2011)
<a href="#">23.1</a>	Consent of KMJ Corbin & Company LLP
<a href="#">31.1</a>	Certification of Mark L. Baum, Esq., Principal Executive Officer, pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities and Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes- Oxley Act of 2002.
<a href="#">31.2</a>	Certification of Andrew R. Boll, Principal Financial and Accounting Officer, pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities and Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes- Oxley Act of 2002
<a href="#">32.1</a>	Certification pursuant to 18 U.S.C Section 1350 as adopted pursuant to section 906 The Sarbanes-Oxley Act of 2002, executed by of Mark L. Baum, Esq., Principal Executive Officer.
<a href="#">32.2</a>	Certification pursuant to 18 U.S.C Section 1350 as adopted pursuant to section 906 The Sarbanes-Oxley Act of 2002, executed by Andrew R. Boll, Principal Financial and Accounting 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/ Mark Baum

Name: Mark L. Baum, Esq.

Title: Secretary and Chairman of the Board of  
Directors (Principal Executive Officer)

Date: February 23, 2012

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/ Andrew R. Boll</u> Andrew R. Boll	Vice President of Accounting and Public Reporting (Principal Accounting and Financial Officer)	February 23, 2012
<u>/s/ Mark L. Baum, Esq.</u> Mark L. Baum, Esq.	Chairman of the Board (Principal Executive Officer)	February 23, 2012
<u>/s/ Jeffrey J. Abrams</u> Jeffrey J. Abrams, M.D.	Director	February 23, 2012
<u>/s/ Balbir Brar</u> Balbir Brar, D.V.M., Ph.D.	President and Director	February 23, 2012
<u>/s/ Paul Finnegan</u> Paul Finnegan, M.D.	Director	February 23, 2012
<u>/s/ Robert J. Kammer</u> Robert J. Kammer, D.D.S.	Director	February 23, 2012

## FINANCIAL STATEMENTS

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

#### Index to Consolidated Financial Statements

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of  
Transdel Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Transdel Pharmaceuticals, Inc. and subsidiary (a development stage company) (the "Company") as of December 31, 2010 and 2009, and the related consolidated statements of operations, stockholders' deficit and cash flows for each of the two years in the period ended December 31, 2010 and for the period from July 24, 1998 (date of inception) through December 31, 2010. 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 also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Transdel Pharmaceuticals, Inc. and subsidiary as of December 31, 2010 and 2009, and the consolidated results of their operations and their cash flows for each of the two years in the period ended December 31, 2010 and for the period from July 24, 1998 (date of inception) through December 31, 2010 in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As more fully described in Note 2 to the consolidated financial statements, the Company has incurred significant operating losses, had negative cash flows from operations, has not recognized any revenues since inception and has a deficit accumulated during the development stage. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amount and classification of liabilities that may result from the outcome of this uncertainty.

/s/ KMJ Corbin & Company LLP

Costa Mesa, California

February 23, 2012

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

	<u>December 31,</u> <u>2010</u>	<u>December 31,</u> <u>2009</u>
<b><u>ASSETS</u></b>		
Current assets		
Cash and cash equivalents	\$ 291,462	\$ 1,589,773
Prepaid expenses and other current assets	60,492	80,917
Total current assets	<u>351,954</u>	<u>1,670,690</u>
Computer equipment, net	338	1,394
<b>TOTAL ASSETS</b>	<b><u>\$ 352,292</u></b>	<b><u>\$ 1,672,084</u></b>
<b><u>LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY</u></b>		
Current liabilities		
Accounts payable	\$ 73,632	\$ 681,014
Accrued Phase 3 expenses	111,871	343,633
Accrued expenses and payroll liabilities	69,532	70,226
Deferred revenue	80,000	-
Total current liabilities	<u>335,035</u>	<u>1,094,873</u>
Convertible note payable and accrued interest	1,055,479	-
<b>TOTAL LIABILITIES</b>	<b><u>1,390,514</u></b>	<b><u>1,094,873</u></b>
Commitments and contingencies		
<b>STOCKHOLDERS' (DEFICIT) EQUITY</b>		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized, none issued and outstanding	-	-
Common stock, \$0.001 par value, 50,000,000 shares authorized, 15,932,061 and 15,652,061 issued and outstanding at December 31, 2010 and December 31, 2009, respectively.	15,932	15,652
Additional paid-in capital	16,412,643	15,497,128
Deficit accumulated during the development stage	<u>(17,466,797)</u>	<u>(14,935,569)</u>
<b>TOTAL STOCKHOLDERS' (DEFICIT) EQUITY</b>	<b><u>(1,038,222)</u></b>	<b><u>577,211</u></b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY</b>	<b><u>\$ 352,292</u></b>	<b><u>\$ 1,672,084</u></b>

The accompanying notes are an integral part of these consolidated financial statements



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

	For The Year Ended December 31, 2010	For The Year Ended December 31, 2009	For the Period From July 24, 1998 (Inception) through December 31, 2010
Operating Expenses:			
Selling, general and administrative	2,307,972	1,598,369	8,745,653
Research and development	194,588	2,965,707	7,708,704
Loss from operations	<u>(2,502,560)</u>	<u>(4,564,076)</u>	<u>(16,454,357)</u>
Other income (expense)			
Interest expense	(55,479)	-	(1,631,234)
Interest income	512	10,440	127,581
Gain on settlement	-	-	375,000
Gain on forgiveness of liabilities	26,299	-	116,213
Total other income (expense)	<u>(28,668)</u>	<u>10,440</u>	<u>(1,012,440)</u>
Net loss	<u>\$ (2,531,228)</u>	<u>\$ (4,553,636)</u>	<u>\$ (17,466,797)</u>
Net loss per common share, basic and diluted	<u>\$ (0.16)</u>	<u>\$ (0.29)</u>	
Weighted average common shares outstanding, basic and diluted	<u>15,785,239</u>	<u>15,612,993</u>	

The accompanying notes are an integral part of these consolidated financial statements

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

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)**

For the years ended December 31, 2010 and 2009 and for the period from July 24, 1998 (Inception) through December 31, 2010

	Common Stock		Additional Paid-in Capital	Deficit accumulated during the development stage	Total Stockholders' Equity (Deficit)
	Shares	Par Value			
Balance at June 24, 1998 (Inception)	-	\$ -	\$ -	\$ -	\$ -
Estimated fair value of services contributed by stockholders	-	-	100,000	-	100,000
Net loss	-	-	-	(100,000)	(100,000)
Balance at 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 at December 31, 1999	-	-	300,000	(304,000)	(4,000)
Issuance of common stock at \$0.0064 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 at 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 at 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 at 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 at 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 at 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 \$0.0064 per share in August 2005	2,453,125	2,453	13,247	-	15,700
Exercise of stock options at \$0.0064 per share in August 2005	15,625	16	84	-	100
Estimated fair value of services contributed by stockholders	-	-	400,000	-	400,000
Net loss	-	-	-	(539,622)	(539,622)
Balance at 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 \$0.0064 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 at December 31, 2006	3,781,250	3,781	2,383,219	(2,793,005)	(406,005)
Issuance of common stock at \$0.0064 per share during January and March 2007	3,984,374	3,985	21,515	-	25,500
Exercise of stock options and warrants at \$0.0064 per share in April and August 2007	39,063	39	211	-	250
Estimated fair value of services contributed by stockholders	-	-	175,000	-	175,000
Capital contributions	-	-	105,907	-	105,907
Forgiveness of notes payable and interest	-	-	241,701	-	241,701

Issuance of restricted common stock at \$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 transaction 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 at December 31, 2007	<u>13,727,004</u>	<u>13,727</u>	<u>10,554,298</u>	<u>(7,077,545)</u>	<u>3,490,480</u>
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 agreement	(13,901)	(14)	(117,979)	-	(117,993)
Issuance of restricted stock at \$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 at 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>
Issuance of common stock and stock options related to consulting agreements	45,778	46	121,409	-	121,455
Exercise of stock options at \$0.99 per share August 2009	50,000	50	49,450	-	49,500
Stock-based compensation	-	-	388,050	-	388,050
Net loss	-	-	-	(4,553,636)	(4,553,636)
Balance at December 31, 2009	<u>15,652,061</u>	<u>15,652</u>	<u>15,497,128</u>	<u>(14,935,569)</u>	<u>577,211</u>
Issuance of common stock and stock options related to consulting agreements	230,000	230	367,670	-	367,900
Issuance of restricted stock at \$0.80 per share in October 2010	50,000	50	12,033	-	12,083
Stock-based compensation	-	-	535,812	-	535,812
Net loss	-	-	-	(2,531,228)	(2,531,228)
Balance at December 31, 2010	<u>15,932,061</u>	<u>15,932</u>	<u>16,412,643</u>	<u>(17,466,797)</u>	<u>(1,038,222)</u>

The accompanying notes are an integral part of these consolidated financial statements

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

	For The Year Ended December 31, 2010	For The Year Ended December 31, 2009	For The Period From July 24, 1998 (Inception) through December 31, 2010
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>			
Net loss	\$ (2,531,228)	\$ (4,553,636)	\$ (17,466,797)
Adjustments to reconcile net earnings to net cash used in operating activities:			
Estimated fair value of contributed services	-	-	2,475,000
Gain on forgiveness of liabilities	(26,299)	-	(116,213)
Amortization of prepaid consulting fees	235,600	29,048	807,608
Depreciation	1,056	1,056	2,816
Non-cash interest on notes payable	55,479	-	1,631,234
Stock-based compensation	680,195	509,505	1,936,663
Changes in assets and liabilities			
Prepaid consulting costs	-	-	(140,000)
Prepaid expenses and other current assets	20,425	112,389	(60,492)
Accounts payable	(607,382)	124,624	163,546
Accrued Phase 3 expenses	(231,762)	201,681	111,871
Accrued expenses and payroll liabilities	25,605	4,575	95,831
Deferred revenue	80,000	-	80,000
<b>NET CASH USED IN OPERATING ACTIVITIES</b>	<b>(2,298,311)</b>	<b>(3,570,758)</b>	<b>(10,478,933)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>			
Purchases of fixed assets	-	-	(3,154)
<b>NET CASH USED IN INVESTING ACTIVITIES</b>	<b>-</b>	<b>-</b>	<b>(3,154)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>			
Proceeds from notes payable to stockholders	-	-	226,300
Proceeds from notes payable	1,000,000	-	2,500,000
Capital contributions	-	-	168,707
Net proceeds from purchase of common stock and exercise of warrants and stock options	-	49,500	99,450
Proceeds from Private Placements	-	-	7,779,092
<b>NET CASH PROVIDED BY FINANCING ACTIVITIES</b>	<b>1,000,000</b>	<b>49,500</b>	<b>10,773,549</b>
<b>NET CHANGE IN CASH AND CASH EQUIVALENTS</b>	<b>(1,298,311)</b>	<b>(3,521,258)</b>	<b>291,462</b>
CASH AND CASH EQUIVALENTS BALANCES, beginning of period	1,589,773	5,111,031	-
<b>CASH AND CASH EQUIVALENTS BALANCES, end of period</b>	<b>\$ 291,462</b>	<b>\$ 1,589,773</b>	<b>\$ 291,462</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	\$ -	\$ -	\$ 432,007
Conversion of notes payable and accrued interest into common stock	\$ -	\$ -	\$ 1,530,177
Forgiveness of notes payable and accrued interest to stockholders	\$ -	\$ -	\$ 241,701
Conversion of advances to notes payable to stockholders	\$ -	\$ -	\$ 196,300

The accompanying notes are an integral part of these consolidated financial statements

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

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

**For the years ended December 31, 2010 and 2009 and the period from July 24, 1998 (Inception) through December 31, 2010**

**NOTE 1. ORGANIZATION**

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

As described in Note 12, on June 26, 2011, the Company filed a voluntary petition for reorganization relief under Chapter 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the Southern District of California (the “Bankruptcy Court”), Case No. 11-10497-11 (the “Chapter 11 Case”). On November 21, 2011, in connection with the other events and transactions described Note 12 the Company requested that the Bankruptcy Court dismiss the Chapter 11 Case, and on December 9, 2011, the Bankruptcy Court entered an order dismissing the Chapter 11 Case.

**NOTE 2. GOING CONCERN**

The accompanying consolidated financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred recurring operating losses, had negative operating cash flows and has not recognized any revenues since July 24, 1998 (Inception). In addition, the Company had a deficit accumulated during the development stage of \$17.5 million at December 31, 2010. These factors raise substantial doubt about the Company’s ability to continue as a going concern.

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

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

### **NOTE 3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

#### **Basis of Presentation**

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

#### **Principles of Consolidation**

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, 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, include only those of Transdel Holdings. All references to share and per share amounts in the accompanying consolidated financial statements and footnotes have been restated to reflect the aforementioned share exchange. All significant intercompany accounts and transactions have been eliminated in consolidation.

On June 20, 2011, Transdel Holdings was merged with Transdel Pharmaceuticals, Inc., at which time Transdel Holdings ceased as a corporation, and Transdel Pharmaceuticals, Inc. remains as the sole surviving corporation.

#### **Development Stage Enterprise**

The Company is a development stage company as defined by the Financial Accounting Standards Board (the “FASB”). 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 2012.

#### **Research and Development**

The Company expenses all costs related to research and development as they are incurred.

## **Revenue Recognition and Deferred Revenue**

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

As of December 31, 2010, the Company had not generated any revenues and the Company does not anticipate that it will generate any significant 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.

## **Cash and Cash Equivalents**

Cash equivalents include short-term, highly liquid investments with maturities of three months or less at the time of acquisition.

## **Concentrations of Credit Risk**

A financial instrument which potentially subjects the Company to concentrations of credit risk is cash. The Company places its cash with financial institutions deemed by management to be of high credit quality. The Federal Deposit Insurance Corporation ("FDIC") provides basic deposit coverage with limits to \$250,000 per owner. In addition to the basic insurance deposit coverage, the FDIC is providing temporary unlimited coverage for noninterest-bearing transaction accounts from December 31, 2010 to December 31, 2012. At December 31, 2010, there were no uninsured deposits.

## **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.

During the year ended December 31, 2010 and 2009 the Company recorded \$1,056 and \$1,056, respectively, in depreciation expense.

## **Fair Value Measurements**

Fair value measurements are determined based on the assumptions that market participants would use in pricing an asset or liability. GAAP establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. The established fair value hierarchy prioritizes the use of inputs used in valuation methodologies into the following three levels:



- Level 1: Quoted prices (unadjusted) for identical assets or liabilities in active markets. A quoted price in an active market provides the most reliable evidence of fair value and must be used to measure fair value whenever available.
- Level 2: Significant other observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.
- Level 3: Significant unobservable inputs that reflect a reporting entity's own assumptions about the assumptions that market participants would use in pricing an asset or liability. For example, level 3 inputs would relate to forecasts of future earnings and cash flows used in a discounted future cash flows method.

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

### **Stock-Based Compensation**

All share-based payments to employees, including grants of stock options to employees, directors and consultants and restricted stock grants, are recognized in the consolidated financial statements based upon their fair values.

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

### **Income Taxes**

We account for income taxes under the provision of Accounting Standards Codification 740, "Income Taxes", or ASC 740. As of December 31, 2010 and 2009, there were no unrecognized tax benefits included in the consolidated balance sheets that would, if recognized, affect the effective tax rate. Our practice is to recognize interest and/or penalties related to income tax matters in income tax expense. We had no accrual for interest or penalties on our consolidated balance sheets at December 31, 2010 and 2009, respectively and have not recognized interest and/or penalties in the consolidated statement of operations for the years ended December 31, 2010 and 2009. We are subject to taxation in the United States and California.

### **Basic and Diluted Loss per Common Share**

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

Basic and diluted net loss applicable to common stock per share is computed using the weighted average number of common shares outstanding during the period. Common stock equivalents (prior to application of the treasury stock, if converted method) from convertible notes, stock options and warrants were 4,330,676 and 2,407,730 for the years ended December 31, 2010 and 2009, respectively, are excluded from the calculation of diluted net loss per share for all periods presented because the effect is anti-dilutive.

	<u>For the year ended December 31, 2010</u>	<u>For the year ended December 31, 2009</u>
Numerator – loss	\$ (2,531,228)	\$ (4,553,636)
Denominator – weighted average number of shares outstanding	15,785,239	15,612,993
<b>Loss per share, basic and diluted</b>	<u>\$ (0.16)</u>	<u>\$ (0.29)</u>

### Use of Estimates

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

### Reclassification

Certain amounts in the 2009 consolidated financial statements have been reclassified to conform to the classifications used to prepare the 2010 consolidated financial statements. These reclassifications had no material impact on the Company's financial position, results of operations, or cash flow as previously reported.

### Recent Accounting Pronouncements

In January 2010, the FASB issued ASU, 2010-06, *Fair Value Measurement and Disclosures* (Topic 820-10-65-7), which relates to the disclosure requirements for fair value measurements and provides clarification for existing disclosure requirements. This update will require an entity to disclose separately the amounts of significant transfers in and out of Levels 1 and 2 fair value measurements and to describe the reasons for the transfers. It also will require entities to disclose information about purchases, sales, issuances and settlements to be presented separately (i.e. present the activity on a gross basis rather than net) in the reconciliation for fair value measurements using significant unobservable inputs (Level 3 inputs). This guidance clarifies existing disclosure requirements for the level of disaggregation used for classes of assets and liabilities measured at fair value and require disclosures about the valuation techniques and inputs used to measure fair value for both recurring and nonrecurring fair value measurements using Level 2 and Level 3 inputs. The new disclosures and clarifications of existing disclosures are effective for fiscal years beginning after December 15, 2009, except for the disclosure requirements related to the purchases, sales, issuances and settlements in the roll forward activity of Level 3 fair value measurements. Those disclosure requirements are effective for fiscal years ending after December 31, 2010. The adoption of the disclosure requirements did not have a material impact on the Company's consolidated financial statements.

In April 2010, the FASB issued ASU 2010-17, *Revenue Recognition-Milestone Method* (Topic 605). The update is intended to assist with the definition of a milestone event and determining when the application of milestone revenue recognition in connection with revenue recognition for research and development transaction. Disclosures will include the description of the milestone payment arrangement, a description of each milestone and the related payment or contingent payment, a determination whether the milestones are substantive, the factors considered in making the determination of the substantive nature of the milestones and the amount of revenue recognized during the period related to the milestone or milestones. The standard is effective for fiscal years beginning on or after June 15, 2010. The Company has adopted the standard but does not currently have any such contracts. The adoption of the standard has not had a material impact on the Company's consolidated financial statements.

In April 2010, the FASB issued ASU 2010-12, *Income Taxes (Topic 740) Accounting for Certain Tax Effects of the 2010 Health Care Reform Acts*. This update makes it clear that the two laws passed a few days apart and commonly known as health care reform will be treated as one for accounting purposes despite the fact that they may have been passed in two different fiscal years for some. The Company's adoption of ASU 2010-12 did not have a material impact on its consolidated financial statements.

**NOTE 4. NOTES PAYABLE**

**Convertible Notes – August 2005**

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 of 35,359 shares of the Company's common stock. The warrants were determined to have an insignificant fair value at the time of the grant.

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

**Convertible Notes – May and June 2007**

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

**Convertible Note – April 2010**

On April 5, 2010, the Company issued a Senior Convertible Promissory Note (the "Note") to an existing investor through a private placement. The Note includes an annual interest rate of 7.5 percent and (unless converted or prepaid, as noted below) all principal and interest are due and payable on its maturity date April 5, 2012 ("Maturity Date"). At any time prior to the Maturity Date, the investor may convert all or a portion of the outstanding principal and accrued interest at a conversion ratio of one share of Transdel's common stock for each \$1 (the fair market value of the Company's common stock on April 5, 2010) owed. Also, at any time prior to the Maturity Date, the Company has the option to prepay the outstanding principal and accrued interest. The Company received gross proceeds from the issuance of the Note in the aggregate amount of \$1,000,000. There were no discounts or commissions paid in connection with this private placement. Accrued interest on the Note was \$55,479 at December 31, 2010, and interest expense on the Note was \$55,479 for the year ended December 31, 2010. Subsequent to the year ended December 31, 2010, and following the Company's bankruptcy petition filed on June 26, 2011 (see Note 12), and the change in ownership control following the issuance of preferred stock (see Note 12), the entire unpaid principal sum of this Note, together with its accrued and unpaid interest became immediately due and payable. The Company, the noteholder and its assignee entered into a waiver and settlement agreement described in Note 12.

Notes Payable consists of the following

	<b>December 31, 2010</b>
7.5% convertible note due April 2012	<u>\$ 1,000,000</u>
Less: Current portion	-
<b>Long-term portion</b>	<u><u>\$ 1,000,000</u></u>

## NOTE 5. STOCKHOLDERS' EQUITY

### Common Stock

The following is a summary of common stock and capital contribution transactions from inception through December 31, 2010:

- 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 \$0.0064 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.
- In fiscal year 2005, the Company issued 2,468,750 shares of common stock at a price of \$0.0064 per share for gross proceeds of \$15,800 for common stock purchases and stock option exercises. The Company received additional capital contributions in cash of \$14,200 from the Company's stockholders and 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 \$0.0064 per share for gross proceeds of \$2,400. The Company received additional capital contributions in cash of \$48,600 from the Company's stockholders and 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.

- Prior to the Merger during fiscal year 2007, the Company issued 4,023,437 shares of its common stock at a price of \$0.0064 per share for proceeds of \$25,750, which includes the issuance of 31,250 shares upon the exercise of a warrant and 7,813 shares upon exercise of stock options. 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 consolidated statements of operations.
- Prior to the Merger during fiscal year 2007, the Company recorded additional paid-in capital of \$241,701 related to the forgiveness of Stockholders' Notes (see Note 4).
- 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.
- In connection with the Merger in 2007, 1,849,993 of Transdel common shares remained outstanding (see Note 3).
- Concurrent with the Merger in 2007, the Company sold 2,071,834 shares of common stock for net proceeds of \$3,837,791 (\$4,143,667 gross) 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 netted with the 2008 private placement discussed below) 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.
- Concurrent with the Merger in 2007, the Company issued 1,530,177 shares of common stock related to the conversion of the 2007 Notes and accrued interest of \$1,530,177 (see Note 4). Also, the Company recorded a debt discount of \$1,530,177 related to the 2007 Notes (see Note 4).
- In September 2007, the Company entered into three, one-year consulting agreements with three separate firms to provide services related to investor communications. 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.
- On May 12, 2008, the Company sold 1,818,180 shares of common stock for net proceeds of \$3,941,301 (\$4,000,000 gross) 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, and the gross proceeds were also netted with \$36,229 related to the 2007 private placement that was paid in 2008.
- In 2008, in connection with the termination of certain consulting agreements entered into in 2007 and 2008, 82,568 shares of common stock were forfeited at a value that was reversed of \$135,136. The Company also decreased additional paid-in capital and consulting expense by \$70,000 because of the remeasurement of certain consulting agreements. Additionally, during 2008, the Company entered into an agreement with an investor relations firm ("IR Firm"). Pursuant to the agreement with the IR Firm, the Company issued 68,667 shares of common stock during 2008 at a value of \$85,833. In a separate agreement, the Company entered into a consulting agreement in which 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. The net amount of shares forfeited during 2008 from consulting agreements and the IR Firm was (13,901) and the net expense reversed and charged to additional paid-in capital was (\$117,993).

- On November 21, 2008, the Company issued a restricted stock grant to a director of the Company for 25,000 shares of the Company's common stock. The restricted stock grant vested over a one-year period.
- During 2009, in connection with the agreement with the IR Firm, the Company issued 45,778 shares of common stock valued at \$50,356. In a separate agreement, the Company entered into a consulting agreement in which the Company issued a stock option to purchase 50,000 shares of the Company's common stock at an exercise price of \$0.99 per share. The fair value of the option, determined based on the Black-Scholes pricing model, was recorded as \$14,434. In another agreement, the Company entered into a consulting agreement in which the Company issued stock options to purchase 47,500 shares of the Company's common stock at an exercise price of \$1.60 per share. The fair value of the options, determined based on the Black-Scholes pricing model, was recorded at \$56,665. The total value of common stock, warrants and options recorded during 2009 was \$121,455.
- In August 2009, the Company issued 50,000 shares of common stock at a price of \$0.99 per share for gross proceeds of \$49,500 for stock option exercises.
- In June 2010, the Company entered into two separate agreements with an investor relations firm and a financial advisory services firm (collectively "the firms") in order to provide certain investor relations and advisory services to the Company for a period of one year. In exchange for such services, the Company issued 200,000 shares, in the aggregate, of its unregistered common stock, of which all shares were nonforfeitable (valued at \$208,000 and recorded as prepaid consulting fees upon issuance) to the firms as a prepayment of services to be received over a three-month period. The Company agreed to suspend the services related to these agreements, therefore, at this time no additional shares of common stock will be issued to the firms. For the year ended December 31, 2010, the Company recorded stock-based compensation related to the stock of \$208,000. On August 13, 2010, the Company entered into a consulting agreement in which the Company issued stock options to purchase 201,217 shares of the Company's common stock at an exercise price of \$1.07 per share (see Note 6). The fair value of the options, determined based on the Black-Scholes pricing model, was recorded at \$132,300. In September 2010, the Company entered an agreement with an investor relations firm in order to provide certain investor relations services to the Company for a period of six months. In exchange for such services, the Company issued 30,000 shares, in the aggregate, of its unregistered common stock, of which all shares were nonforfeitable (valued at \$27,600 and recorded as prepaid consulting fees upon issuance) to the investor relations firm as a prepayment of services to be received for the initial three-month period of the agreement. The agreement was terminated by the Company during November 2010. For the year ended December 31, 2010, the Company recorded stock-based compensation related to the restricted stock of \$27,600. The total number of shares issued to consultants during 2010 was 230,000 and the total value of common stock and options issued to consultants during 2010 was \$367,900.
- On October 20, 2010, the Company appointed John N. Bonfiglio, Ph.D. as Chief Executive Officer and President of the Company. Dr. Bonfiglio was also appointed as a director on the Company's Board. The Board granted Dr. Bonfiglio a stock option for 400,000 shares of common stock and issued 50,000 shares of restricted common stock in accordance with the Company's 2007 Incentive Stock and Awards Plan. The stock option and the restricted common stock vested as follows: 25% of the option shares and the restricted stock vested immediately upon grant, with the balance of the option shares and the restricted stock vesting in equal monthly installments over the next 36 months beginning 30 days after the grant date. The restricted stock was valued at \$0.80 per share, the reported closing price of the Company's common stock on October 20, 2010. For the year ended December 31, 2010, the Company recorded stock-based compensation expense related to the issuance and partial vesting of the restricted stock award of \$12,083.

For the year ended December 31, 2010, the Company recorded \$535,812 of stock-based compensation expense for employee options, \$12,083 of stock-based compensation expense related to the vesting of restricted stock, \$132,300 of expense for stock options issued for consulting services (total expense of \$680,195 related to stock options and restricted stock for employees and consultants) and \$235,600 of expense for stock issued for consulting services. For the year ended December 31, 2009, the Company recorded \$388,050 of stock-based compensation expense for employee options and vesting of restricted stock, \$50,356 of stock-based compensation expense related to the vesting of restricted stock issued for consulting services and \$71,099 of expense for stock options issued for consulting services (total expense of \$509,505 related to stock options and restricted stock for employees and consultants). For the period from Inception through December 31, 2010, the Company recorded stock-based compensation expense for employees, directors and consultants of \$1,936,663, respectively, for options and restricted stock granted and vested. The expense for options and restricted stock issued to employees and consultants included in selling, general and administrative expenses and research and development expenses for the years ended December 31, 2010 and 2009 and the period from inception through December 31, 2010 is \$579,592 and \$100,603, \$431,826 and \$77,679, and \$1,359,746, and \$576,917, respectively. For the years ended December 31, 2010 and 2009 and for the period from Inception through December 31, 2010, the Company amortized \$235,600, \$29,048 and \$807,608, respectively, of prepaid consulting fees which is included as part of selling, general and administrative expenses.

## NOTE 6. 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.

A summary of the Plan for the year ended December 31, 2010 is as follows:

	<u>Number of shares</u>	<u>Weighted Avg. Exercise Price</u>	<u>Weighted Avg. Remaining Contractual Life</u>	<u>Aggregate Intrinsic Value</u>
Outstanding - January 1, 2010	1,605,000	\$ 1.64		
Granted	901,217	0.89		
Exercised	-	-		
Cancelled/Forfeited	-	-		
Outstanding - December 31, 2010	<u>2,506,217</u>	<u>\$ 1.37</u>	<u>7.12</u>	<u>\$ 23,850</u>
Exercisable - December 31, 2010	<u>1,640,550</u>	<u>\$ 1.55</u>	<u>6.12</u>	<u>\$ 10,890</u>
Vested and expected to vest - December 31, 2010	<u>2,421,650</u>	<u>\$ 1.39</u>	<u>7.06</u>	<u>\$ 22,554</u>

The aggregate intrinsic value in the table above represents the total pre-tax amount of the proceeds, net of exercise price, which would have been received by option holders if all option holders had exercised and immediately sold all options with an exercise price lower than the market price on December 31, 2010, based on the closing price of the Company's common stock of \$0.79 on that date.

The options were granted to the employees, directors and consultants at exercise prices that ranged from \$0.70 to \$2.62, the estimated fair market value of the common stock on the dates of issuance. All options granted to date expire on the ten year anniversary of the issuance date and were vested immediately or on a quarterly basis up to five years. The Company uses the Black-Scholes option pricing model to estimate the grant-date fair value of share-based awards. The Black-Scholes model requires subjective assumptions regarding future stock price volatility and expected time to exercise, along with assumptions about the risk-free interest rate and expected dividends, which affect the estimated fair values of the Company's stock-based awards. The expected term of options granted was determined in accordance with the "simplified approach" as the Company has very limited historical data on employee exercises and post-vesting employment termination behavior. The expected volatility is based on the historical volatilities of the common stock of comparable publicly traded companies based on the Company's belief that it currently has limited historical data regarding the volatility of its stock price on which to base a meaningful estimate of expected volatility. The risk-free rate selected to value any particular grant is based on the U.S. Treasury rate that corresponds to the expected term of the grant effective as of the date of the grant. The Company used 0% as an expected dividend yield assumption. These factors could change in the future, affecting the determination of stock-based compensation expense in future periods. Utilizing these assumptions, the fair value is determined at the date of grant. The weighted fair value of the stock options granted to employees, directors and consultants during 2010 is \$0.58. For the years ended December 31, 2010 and 2009 and for the period from inception through December 31, 2010, the Company recorded stock-based compensation related to stock options for employees and directors of \$547,895, \$372,737 and \$1,269,012, which is included in selling, general and administrative expenses and research and development expenses in the amount of \$447,292 and \$100,603, \$351,723 and \$21,014 and \$869,703 and \$399,309, respectively.

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. For option grants to employees and directors in 2010, the Company assigned a forfeiture factor of 10%. This percentage was determined based on consideration of actual forfeitures realized to date and estimated forfeitures to potentially occur in the future.

As of December 31, 2010, there was approximately \$516,412 of total unrecognized compensation expense related to unvested stock options under the Plan. That expense is expected to be recognized over the weighted-average period of 2.17 years.

Effective February 17, 2010, the Board of Directors of the Company accepted the resignation of Dr. Juliet Singh as Chief Executive Officer of the Company and as a director on the Board. In connection with Dr. Singh's resignation, the Company and Dr. Singh entered into a separation agreement that provided Dr. Singh with one year of continued salary in accordance with the terms of her existing employment agreement as well as the accelerated vesting of 300,000 stock options previously granted. In addition, the term in which Dr. Singh may exercise the vested options (which included 610,000 options in total, comprised of 310,000 stock options that were vested as of the separation date as well as the 300,000 stock options subject to the accelerated vesting) was modified and extended to three years from the date of her resignation. In accordance with accounting guidance, since these stock options were modified, the value of the modification for each stock option was determined. For the stock options vested as of the separation date, the modified value was equal to the number of options multiplied by the difference in value (per the Black-Scholes option pricing model) between the original and modified terms of the stock options utilizing current values for market stock price, interest rate and volatility. For the stock options in which the vesting was accelerated, the new value for these stock options was calculated as of the separation date using the Black-Scholes option pricing model. In total, the additional stock based compensation expense recognized for the modified stock options was approximately \$174,000 and was recorded in additional paid-in capital and general and administrative expenses in the accompanying consolidated balance sheets and consolidated statement of operations as of and for the year ended December 31, 2010, respectively.

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

Effective October 20, 2010, the Company appointed John N. Bonfiglio, Ph.D. as Chief Executive Officer and President of the Company. Dr. Bonfiglio was also appointed as a director on the Company's Board. The Board granted Dr. Bonfiglio a stock option for 400,000 shares of common stock and issued 50,000 shares of restricted common stock in accordance with the Company's 2007 Incentive Stock and Awards Plan. The stock option and the restricted common stock will vest as follows: 25% of the option shares and the restricted stock shall vest immediately upon grant, with the balance of the option shares and the restricted stock vesting in equal monthly installments over the next 36 months beginning 30 days after the grant date; provided, however, Dr. Bonfiglio shall gain a vested interest in an additional 10% of the option shares and the restricted stock upon the closing of a Qualified Transaction. The exercise price of the stock option will be \$0.80 per share, the reported closing price of the Company's common stock on October 20, 2010. The vesting of all options will fully accelerate upon an involuntary termination of Dr. Bonfiglio's employment within twelve months following a change of control (as such terms are defined in the Employment Agreement). Subsequent to the year ended December 31, 2010, Dr. Bonfiglio resigned as described in Note 12.

The table below illustrates the fair value per share and Black-Scholes option pricing model with the following assumptions used for the grants issued to the employees and directors during the years ended December 31, 2010 and 2009

	<u>2010</u>	<u>2009</u>
Weighted-average fair value of options granted	\$ 0.56	\$ 1.15
Expected terms (in years)	6.0	6.0
Expected volatility	75%	75-85%
Risk-free interest rate	2.02%	2.97%
Dividend yield	-	-



On December 19, 2008, the Board of Directors approved and the Company entered into a consulting agreement with a firm to provide the Company with business development services. As part of the compensation for the services, the Company issued the firm a non-qualified stock option, under the Plan, to purchase up to 50,000 shares of common stock. The stock option vested in full on March 19, 2009 and was fully exercised during the third quarter of 2009. The option was granted with an exercise price of \$0.99. The option was revalued on an interim basis until the termination of the agreement and the final estimated fair value of the stock option, based on the Black-Scholes pricing model, was \$20,205. This option was amortized over the term of the agreement which was approximately four months as the consulting agreement was terminated effective April 16, 2009. For the years ended December 31, 2010, 2009 and the period from inception through December 31, 2010, the Company recorded stock-based compensation related to this stock option of \$0, \$14,434 and \$20,205, respectively.

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

On August 13, 2010, the Company entered into a consulting agreement (previously approved by the Board of Directors) with a retained search firm to provide the Company with executive recruitment services. In accordance with the agreement, the Company has the option to pay for such services in cash or by issuing stock options of an equivalent value. Per the agreement, 50% of the fee (deemed non-refundable) was due upon execution of the agreement and the remaining 50% was due if and when the retained search firm placed a candidate with the Company. The total fee ultimately owed to the retained search firm would not be finalized until an executive was hired as it will be based on the total compensation for the executive in the first year of employment. It was agreed between the retained search firm and the Company that the value of the stock option as of the execution of the agreement would be the basis for determining the number of stock options to be issued for the initial fee as well as in the total fee due to the retained search firm. The option value was determined to be \$0.6575 based on the Black-Scholes pricing model using an exercise price of \$1.07. Using an estimated first year salary (including bonus) of \$350,000, the total fee was estimated to be \$105,000. As noted above, the Company was obligated to pay 50% of the estimated total fee, or \$52,500, upon execution of the agreement, which the Company opted to issue a non-qualified stock option in lieu of cash. Therefore, the Company issued a non-qualified stock option, under the Plan, to purchase up to 80,000 shares of common stock in payment of this initial fee. The stock option is non-refundable and therefore, fully vested upon issuance. As a result, the total value of the fee/option was recognized in August 2010. October 20, 2010, the Board of Directors appointed a new president and chief executive officer that was a candidate referred to the Company from the retained search firm. The total first year compensation for the executive is estimated to be \$441,000, therefore, the final fee due to the retained search firm is \$132,300. The Company opted to pay the remainder of the fee due with a non-qualified stock option. Considering the option issued in August 2010 for the purchase of up to 80,000 shares of common stock, the final stock option issued in October 2010 will be to purchase an additional 121,217 shares of common stock. The value of this stock option representing the remainder of the fee, \$79,800, was recognized in October 2010. For the year ended December 31, 2010, the Company recorded stock-based compensation related to these stock options of \$132,300.

The table below illustrates the fair value per share and Black-Scholes option pricing model with the following assumptions used for the grants issued to consultants during the years ended December 31, 2010 and 2009:

	<u>2010</u>	<u>2009</u>
Weighted-average fair value of options granted	\$ 0.66	\$ 1.40
Expected terms (in years)	5.0	5.5
Expected volatility	75%	75%
Risk-free interest rate	1.63%	2.71%
Dividend yield	-	-

#### NOTE 7. WARRANTS

A summary of the status of the warrants for the year ended December 31, 2010 is as follows:

	<u>Number of Shares Subject to Warrants Outstanding</u>	<u>Weighted Avg. Exercise Price</u>
Warrants outstanding - January 1, 2010	802,730	\$ 4.10
Granted	-	
Exercised	-	
Expired	(33,750)	4.00
Warrants outstanding and exercisable - December 31, 2010	<u>768,980</u>	<u>\$ 4.11</u>
Weighted average remaining contractual life of the outstanding warrants in years - December 31, 2010	<u>1.90</u>	

The expiration of the outstanding warrants at December 31, 2010, occurs through May 2013 at various dates.

## NOTE 8. INCOME TAXES

The Company is subject to taxation in the United States and California. The Company does not have any income tax provision for the years ended December 31, 2010 and 2009 due to current and historical losses.

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:

	December 31, 2010	December 31, 2009
Federal tax benefit at statutory rate	\$ (842,257)	\$ (1,548,236)
State tax benefit, net	(161,372)	(261,667)
Research and development credits	(39,517)	(211,019)
Employee stock-based compensation	-	-
Other differences	46	1,128
Change in valuation allowance	1,043,100	2,019,794
Provision for income taxes	<u>\$ -</u>	<u>\$ -</u>

At December 31, 2010 and 2009, the Company had deferred tax assets of \$5,778,988 and \$4,735,888 respectively. Due to uncertainties surrounding the Company's ability to generate future taxable income to realize these assets, a full valuation allowance 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.

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

	December 31, 2010	December 31, 2009
Deferred tax assets		
Federal and state net operating loss carryforwards	\$ 4,565,466	\$ 3,928,340
Stock-based compensation	671,940	307,911
Tax credits	522,155	482,638
Other	19,427	16,999
Total deferred tax assets	<u>5,778,988</u>	<u>4,735,888</u>
Less: Valuation allowance	<u>(5,778,988)</u>	<u>(4,735,888)</u>
Net deferred income tax asset	<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 \$1.0 and \$2.0 million in 2010 and 2009, respectively.

As of December 31, 2010, the Company had federal and California net operating loss carryforwards of approximately \$11.5 million and \$11.3 million, respectively. The federal and California tax loss carry forwards will begin to expire in 2020 and 2015, respectively, unless previously utilized. The Company estimates its federal and California research and development tax credit carryforwards of approximately \$309,000 and \$323,000, respectively, which begin to expire in 2027 unless previously utilized.

A portion of the net operating loss carry forwards as of December 31, 2010 and 2009 include amounts related to stock option deductions. Excess tax benefits, if any, from share-based compensation are only realized when income taxes payable is reduced, with the corresponding credit posted to Additional Paid-in Capital.

The impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has 50% or less likelihood of being sustained upon examination. 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.

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, 2010 and 2009, and has not recognized interest and/or penalties in the consolidated statements of operations for the years ended December 31, 2010 and 2009. 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.

## **NOTE 9. COMMITMENTS AND CONTINGENCIES**

### **Commitments**

The Company leased its office facilities under a noncancelable operating lease, which expired in December 31, 2010. The Company renewed the lease effective January 1, 2011 to June 30, 2011, with a monthly amount due of \$3,835. For fiscal year 2011, the Company's lease commitment is \$23,010. Rent expense for the years ended December 31, 2010, 2009 and the period from Inception through December 31, 2010 was \$54,821, \$70,120, and \$225,656, respectively. The Company entered into a new lease agreement for office facilities effective February 15, 2012 to February 28, 2014. Monthly rent begins on March 1, 2012 of \$2,972 for the first 12 months, and \$3,715 is due monthly for the next 12 months.

### **Indemnities and Guarantees**

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

### **Cato Research Ltd. Agreement**

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

### **Cosmetic Products Consulting Agreement**

On August 25, 2008, the Company entered into an agreement with RIL-NA, LLC (“RIL-NA”) in order to enter into business relationships with third parties for certain of the Company’s cosmetic product formulations. RIL-NA was to be paid a commission equal to approximately twenty percent (20%) of the adjusted gross revenues realized from transactions related to this agreement. This agreement was terminable with 60 days written notice by either RIL-NA or the Company.

### **Cosmetic License Agreements**

On May 20, 2009, the Company and JH Direct, LLC (“JH Direct”) entered into a licensing agreement providing JH Direct with the exclusive worldwide rights to the Company’s anti-cellulite cosmetic product which utilizes the Company’s patented transdermal delivery system technology, Transdel™. Under the terms of the agreement, JH Direct will pay the Company initial royalty advances and a continuing licensing royalty on the worldwide sales of the anti-cellulite product. The Company retained the exclusive rights to seek pharmaceutical/dermatological partners for the anti-cellulite product for an initial period of one year following the launch of the product, thereafter JH Direct will be allowed to expand in this channel. The expiration date for this agreement is May 31, 2013. In accordance with the cosmetic products consulting agreement, the consulting firm will receive a percentage of the operating profits paid to the Company.

As of December 31, 2010, the Company had received non-refundable royalty advances totaling \$80,000 from JH Direct, and has deferred all of these revenues. The Company will receive an additional \$20,000 in royalty advances from this contract subsequent to the year ended December 31, 2010. Management believes JH Direct has abandoned its efforts to commercialize the anti-cellulite cream and the Company has exercised its rights to terminate the agreement in 2012, at which time all revenues from this agreement will be recognized in full.

In June 2010, the Company and Jan Marini Skin Research, Inc. (“JMSR”) entered into a licensing agreement providing JMSR with the exclusive U.S. rights to Transdel’s transdermal delivery technology for use in an anti-cellulite cosmetic product for the dermatological market. Under the terms of the agreement, JMSR will pay Transdel a licensing royalty on the U.S. and worldwide sales of an anti-cellulite product using Transdel’s delivery technology. JMSR obtained an exclusive right to promote and sell a product in the U.S. dermatological market for approximately one year after which time they have a non-exclusive right. Also, JMSR obtained a non-exclusive right to promote and sell the product in the ex-U.S. dermatological market. In accordance with the cosmetic products consulting agreement, the cosmetic consultants will receive a percentage of the royalties paid to the Company. Management believes JMSR has abandoned its efforts to commercialize the anti-cellulite cream and the Company will look to terminate this agreement in 2012. No revenues or amounts were paid to or on behalf of the Company related to this agreement.

## **Separation Agreement**

Effective February 17, 2010, the Board of Directors of the Company accepted the resignation of Dr. Juliet Singh as Chief Executive Officer of the Company and as a director on the Board. In connection with Dr. Singh's resignation, the Company and Dr. Singh entered into a separation agreement that provides Dr. Singh with one year of continued salary in accordance with the terms of her existing employment agreement as well as the accelerated vesting of 300,000 stock options previously granted. The separation agreement also includes a mutual release of claims. In accordance with this agreement, the Company recorded a one-time accrual of \$242,000 for the one year of continued salary (including the related employer payroll taxes) and medical benefits. Also, the Company recorded a total expense of approximately \$174,000 for the value of the modifications to the stock options. As of December 31, 2010, the Company has accrued \$30,906 related to remaining amounts payable under the separation agreement.

## **NOTE 10. RESEARCH AND DEVELOPMENT CREDIT**

In November 2010, the Company received a Federal grant amount of \$244,479 under the Qualifying Therapeutic Discovery Project that is part of the Patient Protection and Affordable Care Act. The funds were awarded in support of Ketotransdel, the Company's late-stage topical NSAID for the treatment of acute soft tissue injuries. The proceeds from this grant were recorded as a reduction in research and development expenses in the accompanying consolidated statement of operations.

## **NOTE 11. GAIN ON FORGIVENESS OF LIABILITIES**

On October 2, 2008, the Company entered into a payment agreement with a vendor, settling a balance of \$52,598. It was agreed between the Company and the vendor that 50% of the amount owed, or \$26,299, would be forgiven and the remainder would be paid in two installments, which were, 50%, or \$13,150, upon execution of the payment agreement and \$13,149 upon an infusion of capital into the Company. Since the inception of the payment agreement, the amount to be forgiven, \$26,299, continued to be recorded as an accounts payable up until the infusion of \$1 million from the issuance of the Note in April 2010. When the Note was issued, the final installment payment of \$13,149 was paid and the \$26,299 was recognized as a gain on forgiveness of liabilities by the Company during the year ended December 31, 2010.

## **NOTE 12. SUBSEQUENT EVENTS**

The Company has performed an evaluation of events occurring subsequent to the period end through the issuance date of this report. Based on our evaluation, nothing other than the events described below need to be disclosed.

### **Changes in Management and Board**

Effective April 14, 2011, Lynn C. Swann resigned as a director from the Company's Board of Directors.

The Board accepted the resignation of John N. Bonfiglio, Ph.D. as Chief Executive Officer and President of the Company and as a director on the Board, effective May 13, 2011. On the same date, the Board appointed John T. Lomoro, to serve as the Company's Principal Executive Officer.

The Board accepted the resignation of John T. Lomoro as Principal Executive Officer, Chief Financial Officer and Treasurer of the Company, effective September 16, 2011. On the same date, the Board appointed Terry Nida, the Company's Chief Business Officer, to serve as the Company's Principal Executive Officer and Principal Financial Officer.

Effective December 16, 2011, upon the unanimous consent of the Board, Mark L. Baum and Dr. Robert J. Kammer joined the Board of Directors, each to serve until his resignation or removal or until his successor is duly elected and qualified. Mr. Baum and Dr. Kammer are the Managing Members of DermaStar International, LLC (“DermaStar”) and both Dr. Kammer and Mr. Baum hold ownership interests in DermaStar. There are no arrangements or understandings between either Mr. Baum or Dr. Kammer and any other persons pursuant to which either Mr. Baum or Dr. Kammer was elected as a director.

Effective December 16, 2011, Anthony S. Thornley resigned as a director from the Company’s Board of Directors.

Effective December 16, 2011, Terry Nida resigned as Principal Executive Officer and Principal Financial Officer of the Company.

### **Bankruptcy Petition and Dismissal**

On June 26, 2011 we filed a voluntary petition for reorganization relief under Chapter 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the Southern District of California (the “Bankruptcy Court”), Case No. 11-10497-11 (the “Chapter 11 Case”). In connection with the Chapter 11 Case, we, as seller, and Cardium Healthcare, Inc., a wholly-owned subsidiary of Cardium Therapeutics, Inc., as purchaser (the “Cardium”), entered into an Asset Purchase Agreement dated June 26, 2011 (the “Asset Purchase Agreement”) pursuant to which we agreed to sell substantially all of our assets pursuant to Sections 105, 363 and 365 of the Bankruptcy Code, subject to court approval and the satisfaction of certain conditions set forth in the Asset Purchase Agreement.

Consummation of the sale to Cardium was subject to a number of conditions, including, among others, the approval by the Bankruptcy Court of the transactions contemplated by the Asset Purchase Agreement and compliance with certain specified deadlines for actions in connection with the Bankruptcy Case. The Asset Purchase Agreement was terminable by the parties under a number of circumstances, including failure to obtain certain Bankruptcy Court orders by agreed dates.

On July 26, 2011, the Bankruptcy Court denied our motion to sell our assets pursuant to the Asset Purchase Agreement. On October 7, 2011, we terminated the Asset Purchase Agreement pursuant to its terms. On November 21, 2011, in connection with the transactions described below, we requested that the Bankruptcy Court dismiss the Chapter 11 Case and retain jurisdiction to decide matters related to claims brought in the Bankruptcy Case by the Purchaser. On December 9, 2011, the Bankruptcy Court entered an order dismissing the Chapter 11 Case. In connection with the dismissal of the Chapter 11 Case, the Bankruptcy Court, among other things, declined to retain jurisdiction over claim objection proceedings and found moot our objection to certain claims to receive a break-up fee pursuant to the Asset Purchase Agreement of Cardium Therapeutics, Inc. and Cardium Healthcare, Inc., a wholly owned subsidiary of Cardium. The dismissal of the Chapter 11 Case was based upon the provisions of both 11 U.S.C. Sections 305(a) and 1112(b).

### **Change in Control - Preferred Stock**

In partial consideration for and in connection with the Line of Credit Agreement, on November 21, 2011, the Company entered into a Securities Purchase Agreement (the “Purchase Agreement”) with DermaStar, pursuant to which the Company agreed to issue ten (10) shares of newly-designated Series A Convertible Preferred Stock (the “Series A Preferred Stock”) to DermaStar for an aggregate purchase price of \$100,000. The Purchase Agreement became effective on December 9, 2011, in connection with the dismissal of the Chapter 11 Case by the Bankruptcy Court. On December 12, 2011, the Company and DermaStar consummated the transactions contemplated by the Purchase Agreement. The shares of Series A Preferred Stock issued to DermaStar in the offering are convertible into 59,988,002 shares of the Company’s Common Stock, however, following shareholder action and approval to increase the number of authorized shares of Common Stock through an amendment to the Company’s Amended and Restated Certificate of Incorporation, DermaStar has the ability to convert five of its ten shares of Series A Preferred Stock into 29,994,001 shares of Common Stock, representing approximately 65% of the capital stock of the Company on an as-converted basis. Upon issuance of the Series A Preferred Stock, Dermastar, and its members individually, became control persons of the Company, and as such, this and any further transactions between the Company and Dermastar, and/or its members individually, will be disclosed as related party transactions. On December 31, 2011 and made effective November 21, 2011, the Company entered into a First Amendment to Securities Purchase Agreement (the “Amendment”). Pursuant to the terms of the Amendment, DermaStar agreed not to convert more than five (5) shares of Series A Preferred Stock into common stock until such time as the Company has a sufficient number of authorized shares of common stock to enable the conversion of all ten shares of Series A Preferred Stock held by DermaStar. The five shares of preferred stock can be converted into 29,994,001 shares of common stock, which represents approximately 65% of the capital stock of the Company on an as-converted basis.

## **Secured Line of Credit – Related Party**

On November 21, 2011, the Company entered into a Secured Line of Credit Letter Agreement (the “Line of Credit Agreement”) with DermaStar . The Line of Credit Agreement became effective on December 9, 2011, in connection with the dismissal of the Chapter 11 Case by the Bankruptcy Court. On December 9, 2011, as required by the Line of Credit Agreement, the Company entered into a Security Agreement and an Intellectual Property Security Agreement with DermaStar, pursuant to which the Company granted to DermaStar a blanket security interest in all of its assets, including its intellectual property. The Line of Credit Agreement provides for advances to the Company of up to an aggregate of \$750,000 (each an “Advance” and collectively the “Loan”), subject to the satisfaction by the Company of certain conditions in connection with the initial Advance and each subsequent Advance. Each Advance will be made pursuant to a Promissory Note in favor of DermaStar. The Company has received advances totaling \$300,000 at December 31, 2011. The Promissory Notes accrue interest at 10% annually and mature one year after the effective dates.

## **Settlement with the Holders of the Company’s 7.5% Convertible Promissory Note**

As of January 25, 2012, the Board of Directors of the Company approved, and the Company entered into, separate waiver and settlement agreements with the two parties holding a \$1,000,000 7.5% convertible promissory note (the “Convertible Note”) issued by the Company on April 5, 2010. DermaStar had previously acquired 80% of the Convertible Note in a private transaction with Alexej Ladonnikov, the original purchaser of the Convertible Note. Mr. Ladonnikov is now the holder of 20% of the Convertible Note.

In connection with each of the waiver and settlement agreements, the holders of the Convertible Note each agreed to forever waive their rights to (i) accelerate the entire unpaid principal sum of the Convertible Note and all accrued interest pursuant to Section 1 of the Convertible Note related to the Company’s Bankruptcy petition filed June 26, 2011, (ii) Section 7 of the Senior Convertible Note Purchase Agreement dated April 5, 2010, regarding the designation and creation of the Series A Convertible Preferred Stock and (iii) certain conversion rights pursuant to Section 3 of the Convertible Note related to the change of control that resulted from the sale of the Series A Convertible Preferred Stock. In addition, pursuant to the terms of the waiver and settlement agreement by and between the Company and DermaStar (the “DermaStar Waiver Agreement”), DermaStar and the Company agreed to the mandatory conversion of the 80% of the principal and accrued and unpaid interest of the Convertible Note held by DermaStar, at such time as (and not until) the Company has a sufficient number of authorized common shares to effect such a conversion, into the common stock of the Company at a conversion price of \$0.01667 (“DermaStar Conversion Price”). Additionally, DermaStar agreed to a mandatory conversion of an additional \$56,087 in good and valid current accounts payable of the Company (“AP Conversion”) currently held by DermaStar, at such time as (and not until) the Company has a sufficient number of authorized common shares and is able to convert the Convertible Note. The AP Conversion will be made at the DermaStar Conversion Price. Directors Mr. Baum and Dr. Kammer are both affiliates of DermaStar. The DermaStar Waiver Agreement was negotiated and approved by a disinterested director unaffiliated with DermaStar. Directors Mr. Baum and Dr. Kammer abstained from voting on this matter.

Pursuant to the terms of the waiver and settlement agreement by and between the Company and Mr. Ladonnikov (the “Ladonnikov Waiver Agreement”), Mr. Ladonnikov and the Company agreed to the mandatory conversion of the twenty percent (20%) of the principal and accrued and unpaid interest of the Convertible Note held by Mr. Ladonnikov, at such time as (and not until) the Company has a sufficient number of authorized common shares to effect such a conversion, into the common stock of the Company at a conversion price of \$0.015. Additionally, Mr. Ladonnikov agreed to make a one-time payment to the Company, at such time as the Convertible Note is converted into Company common stock, of \$50,000.



At any time prior to the automatic conversions of the Convertible Note, the Company retains the right to pay the Convertible Note off in full. As of February 15, 2012, the balance of the Convertible Note, including principal and accrued and unpaid interest, equals approximately \$1,139,932. At maturity, to the extent the number of authorized Company common shares was increased, the conversion of the Convertible Note and AP Conversion would result in the issuance of approximately 73,269,391 additional shares of the Company's common stock. A conversion of the Convertible Note would eliminate all amounts due to DermaStar and Alexej Ladonnikov in connection with the Convertible Note.

### **Amendment to Certificate of Incorporation**

On January 25, 2012, the Board approved an amendment to our Amended and Restated Certificate of Incorporation (the "Certificate Amendment" and submitted the Certificate Amendment to our stockholders for approval. The Certificate Amendment: (i) increases the number of authorized shares of our capital stock to Four Hundred Million (400,000,000) and the number of authorized shares of common stock to Three Hundred Ninety-Five Million (395,000,000) (the "Share Increase"); and (ii) changes our name from Transdel Pharmaceuticals, Inc. to Imprimis Pharmaceuticals, Inc. Our stockholders approved the Certificate Amendment in an action by written consent on January 25, 2012. We expect the Certificate Amendment to become effective on February 28, 2012, following our compliance with certain information requirements of the SEC.

In addition, also on January 25, 2012, the Board approved and submitted to our stockholders a proposal to effect a reverse stock split of all of the outstanding shares of common stock (the "Reverse Stock Split") at an exchange ratio of either one-for-six, one-for-eight, one-for-ten or one-for-20, such exchange ratio to be determined by the Board of Directors in its sole discretion at any time following stockholder approval of the Reverse Stock Split through the date twelve months following the date of such stockholder approval. The Reverse Stock Split would preserve the existing aggregate par value of our common stock. In the event we effect the Reverse Stock Split, no stockholder holding greater than 100 common shares prior to the Reverse Stock Split will hold, after such Reverse Stock Split, less than 100 common shares. Our stockholders approved an Amendment to our Amended and Restated Certificate of Incorporation to effect the Reverse Stock Split (the "Reverse Split Certificate Amendment") in an action by written consent on January 25, 2012. The stockholder approval will become effective following the Company's compliance with certain information statement requirements of the SEC, which the Company expects to occur on or about February 28, 2012. At that time, the Board will effect a one-for-eight reverse stock split.

### **Amendments to 2007 Incentive Stock and Awards Plan**

The 2007 Incentive Stock and Awards Plan (the "Plan") was originally approved by the Board and the stockholders of the Company on September 17, 2007 and prior to the approval of the amendments to the Plan discussed below, provided for the granting of stock options and awards to purchase up to a maximum of 3,000,000 shares of common stock (subject to adjustment in the event of certain capital changes). On January 25, 2012, the Board unanimously approved the below amendments to the Plan (collectively, the "Plan Amendments") and recommended their approval to the stockholders. The Plan currently authorizes the grant of awards to Participants with respect to a maximum of 3,000,000 shares of Common Stock, which will increase to 30,000,000 as of the effective date of the Plan Amendment.

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in Registration Statement No. 333-159159 on Form S-8 of our report dated February 23, 2012, relating to the consolidated financial statements of Transdel Pharmaceuticals, Inc. and subsidiary (the "Company") (which report expresses an unqualified opinion and includes an explanatory paragraph relating to the substantial doubt about the Company's ability to continue as a going concern), appearing in this Annual Report on Form 10-K of Transdel Pharmaceuticals, Inc. for the year ended December 31, 2010.

/s/ KMJ Corbin & Company LLP

Costa Mesa, California  
February 23, 2012

**CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER UNDER  
SECTION 302 OF THE SARBANES-OXLEY ACT**

I, Mark L. Baum, Principal Executive Officer of Transdel Pharmaceuticals, Inc., certify that:

- (1) I have reviewed this annual report on Form 10-K of 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 the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- (4) I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to 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 generally accepted accounting principles;
  - 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 the 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 the annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;
- (5) I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies or 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: February 23, 2012

/s/ Mark L. Baum

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Mark L. Baum, Esq.  
Secretary and Chairman of the Board of Directors  
(Principal Executive Officer)

**CERTIFICATION OF THE PRINCIPAL FINANCIAL OFFICER UNDER  
SECTION 302 OF THE SARBANES-OXLEY ACT**

I, Andrew R. Boll, Principal Financial Officer of Transdel Pharmaceuticals, Inc., certify that:

- (1) I have reviewed this annual report on Form 10-K of 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 the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- (4) I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to 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 generally accepted accounting principles;
  - 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 the 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 the annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;
- (5) I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies or 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: February 23, 2012

/s/ Andrew R. Boll

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Andrew R. Boll

Vice-President of Accounting and Public Reporting  
(Principal Financial Officer)

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

The undersigned, Mark L. Baum, Principal Executive Officer of Transdel Pharmaceuticals, Inc. (the "**Company**"), DOES HEREBY CERTIFY that:

1. The Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (the "**Report**"), fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934; and
2. Information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

IN WITNESS WHEREOF, the undersigned has executed this statement this 23<sup>rd</sup> day of February, 2012.

/s/ Mark L. Baum

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Mark L. Baum, Esq.  
Secretary and Chairman of the Board of Directors  
(Principal Executive Officer)

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

The forgoing certification is being furnished to the Securities and Exchange Commission pursuant to § 18 U.S.C. Section 1350. It is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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

The undersigned, Andrew R. Boll, Principal Accounting and Financial Officer of Transdel Pharmaceuticals, Inc. (the “**Company**”), DOES HEREBY CERTIFY that:

1. The Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2010 (the “**Report**”), fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934; and
2. Information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

IN WITNESS WHEREOF, the undersigned has executed this statement this 23<sup>rd</sup> day of February, 2012.

/s/ Andrew R. Boll

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Andrew R. Boll  
Vice-President of Accounting and Public Reporting  
(Principal Financial Officer)

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

The forgoing certification is being furnished to the Securities and Exchange Commission pursuant to § 18 U.S.C. Section 1350. It is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.