



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

FORM 10-Q

(Mark One)

**QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE OF 1934**

For the quarterly period ended June 30, 2010

**TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE EXCHANGE ACT**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 000-52998

**Transdel Pharmaceuticals, Inc.**

(Exact Name of Registrant in Its Charter)

Delaware

(State or Other Jurisdiction of Incorporation or Organization)

45-0567010

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

4275 Executive Square, Suite 230  
La Jolla, CA

(Address of Principal Executive Offices)

92037

(Zip Code)

(858) 457-5300

(Registrant's Telephone Number, Including Area Code)

4225 Executive Square, Suite 485, La Jolla, CA 92037

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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 Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES  NO

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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

As of August 10, 2010, 15,852,061 shares of issuer's common stock, with \$0.001 par value per share were outstanding.

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

Table of Contents

	<u>Page</u>
<u>Part I FINANCIAL INFORMATION</u>	3
<u>Item 1. Financial Statements</u>	3
<u>Condensed Consolidated Balance Sheets — June 30, 2010 (Unaudited) and December 31, 2009</u>	3
<u>Unaudited Condensed Consolidated Statements of Operations for the three and six-month periods ended June 30, 2010 and 2009 and for the Period from July 24, 1998 (Inception) Through June 30, 2010</u>	4
<u>Unaudited Condensed Consolidated Statements of Cash Flows for the six-month periods ended June 30, 2010 and 2009 and for the Period from July 24, 1998 (Inception) Through June 30, 2010</u>	5
<u>Notes to the Unaudited Condensed Consolidated Financial Statements</u>	6
<u>Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	14
<u>Item 4T. Controls and Procedures</u>	19
<u>Part II OTHER INFORMATION</u>	20
<u>Item 1. Legal Proceedings</u>	20
<u>Item 1A. Risk Factors</u>	20
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	28
<u>Item 6. Exhibits</u>	28
<u>Signatures</u>	29
<u>Exhibit 31.1</u>	
<u>Exhibit 32.1</u>	

**PART I**  
**FINANCIAL INFORMATION**

**Item 1. Financial Statements.**

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

	<u>June 30,</u> <u>2010</u>	<u>December 31,</u> <u>2009</u>
	<u>(Unaudited)</u>	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 1,042,614	\$ 1,589,773
Prepaid consulting fees	154,134	—
Prepaid expenses and other current assets	44,423	80,917
Total current assets	1,241,171	1,670,690
Equipment, net	866	1,394
Total assets	<u>\$ 1,242,037</u>	<u>\$ 1,672,084</u>
<b>LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 122,206	\$ 681,014
Accrued Phase 3 expenses	138,038	343,633
Accrued separation expenses	149,456	—
Accrued expenses and payroll liabilities	41,880	70,226
Total current liabilities	451,580	1,094,873
Senior convertible note and accrued interest	1,017,671	—
Total liabilities	1,469,251	1,094,873
Stockholders' (deficit) equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized, none outstanding	—	—
Common stock, \$0.001 par value; 50,000,000 shares authorized, 15,852,061 and 15,652,061 shares issued and outstanding as of June 30, 2010 (unaudited) and December 31, 2009, respectively	15,852	15,652
Additional paid-in capital	16,051,116	15,497,128
Deficit accumulated during the development stage	(16,294,182)	(14,935,569)
Total stockholders' (deficit) equity	(227,214)	577,211
Total liabilities and stockholders' (deficit) equity	<u>\$ 1,242,037</u>	<u>\$ 1,672,084</u>

*See accompanying notes to these unaudited condensed consolidated financial statements.*

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

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>		<b>For the Period</b>
	<b>2010</b>	<b>2009</b>	<b>2010</b>	<b>2009</b>	<b>From July 24,</b>
					<b>1998 (Inception)</b>
					<b>Through June 30,</b>
					<b>2010</b>
<b>Operating expenses:</b>					
Selling, general and administrative	\$ 409,810	\$ 347,850	\$ 1,165,397	\$ 829,324	\$ 7,603,078
Research and development	86,954	882,443	202,112	2,028,994	7,716,228
Operating loss	<u>496,764</u>	<u>1,230,293</u>	<u>1,367,509</u>	<u>2,858,318</u>	<u>15,319,306</u>
<b>Other income (expense):</b>					
Interest expense	(17,671)	—	(17,671)	—	(1,593,426)
Interest income	135	2,265	268	9,054	127,337
Gain on forgiveness of liabilities	26,299	—	26,299	—	116,213
Gain on settlement	—	—	—	—	375,000
Total other income (expense), net	<u>8,763</u>	<u>2,265</u>	<u>8,896</u>	<u>9,054</u>	<u>(974,876)</u>
Net loss	<u>\$ (488,001)</u>	<u>\$ (1,228,028)</u>	<u>\$ (1,358,613)</u>	<u>\$ (2,849,264)</u>	<u>\$ (16,294,182)</u>
Basic and diluted loss per common share	<u>\$ (0.03)</u>	<u>\$ (0.08)</u>	<u>\$ (0.09)</u>	<u>\$ (0.18)</u>	
Weighted average common shares outstanding	<u>15,703,490</u>	<u>15,602,061</u>	<u>15,677,917</u>	<u>15,583,472</u>	

*See accompanying notes to these unaudited condensed consolidated financial statements.*

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

	<b>Six Months Ended June 30,</b>		<b>For The Period</b>
	<b>2010</b>	<b>2009</b>	<b>From July 24, 1998 (Inception) Through June 30, 2010</b>
<b>Cash flows from operating activities:</b>			
Net loss	\$ (1,358,613)	\$ (2,849,264)	\$ (16,294,182)
Adjustments to reconcile net loss to net cash used in operating activities:			
Estimated fair value of contributed services	—	—	2,475,000
Gain on forgiveness of liabilities	(26,299)	—	(116,213)
Amortization of prepaid consulting fees	53,866	29,048	625,874
Depreciation	528	528	2,288
Non-cash interest on notes payable	17,671	—	1,593,426
Stock-based compensation	346,188	224,190	1,602,656
Changes in operating assets and liabilities:			
Prepaid consulting costs	—	—	(140,000)
Prepaid expenses and other current assets	36,494	122,162	(44,423)
Accounts payable	(532,509)	46,672	238,419
Accrued Phase 3 expenses	(205,595)	233,865	138,038
Accrued separation expenses	149,456	—	149,456
Accrued expenses and payroll liabilities	(28,346)	(16,011)	41,880
Net cash used in operating activities	(1,547,159)	(2,208,810)	(9,727,781)
<b>Cash flows from investing activities:</b>			
Purchase of fixed assets	—	—	(3,154)
Net cash used in investing activities	—	—	(3,154)
<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	—	—	99,450
Net proceeds from Private Placements	—	—	7,779,092
Net cash provided by financing activities	1,000,000	—	10,773,549
<b>Net change in cash and cash equivalents</b>	(547,159)	(2,208,810)	1,042,614
<b>Cash and cash equivalents, beginning of period</b>	1,589,773	5,111,031	—
<b>Cash and cash equivalents, end of period</b>	\$ 1,042,614	\$ 2,902,221	\$ 1,042,614
<b>Supplemental disclosure of cash flow information:</b>			
Issuance of and adjustment to common stock and warrants to consulting firms for prepaid consulting fees	\$ 208,000	\$ —	\$ 640,008
Conversion of notes payable and accrued interest into common stock	\$ —	\$ —	\$ 1,530,177
Forgiveness of notes payable and accrued interest to shareholders	\$ —	\$ —	\$ 241,701
Conversion of advances to notes payable to shareholders	\$ —	\$ —	\$ 196,300

*See accompanying notes to these unaudited condensed consolidated financial statements.*

**TRANSDel PHARMACEUTICALS, INC.**

**(A Development Stage Company)**

**NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**Note 1. Business Description**

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

**Note 2. Basis of Presentation**

The Company has prepared the accompanying condensed consolidated financial statements in accordance with United States generally accepted accounting principles (“GAAP”) for interim financial information and with the rules and regulations of the Securities and Exchange Commission (the “SEC”) related to a Quarterly Report on Form 10-Q and Article 8 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by GAAP for annual financial statements. The condensed consolidated financial statements include the accounts of Transdel and its wholly owned subsidiary, Transdel Pharmaceuticals Holdings, Inc. (formerly known as Trans-Pharma Corporation). All significant intercompany balances and transactions have been eliminated in consolidation. In the opinion of the Company’s management, the accompanying condensed consolidated financial statements contain all the adjustments necessary (consisting only of normal recurring accruals) to make the financial position of the Company as of June 30, 2010, the results of operations for three and six months ended June 30, 2010 and 2009, and cash flows for the six months ended June 30, 2010 and 2009, fairly stated. We have evaluated subsequent events through the filing date of this Form 10-Q and determined that no subsequent events have occurred that would require recognition in the condensed consolidated financial statements or disclosure in the notes thereto other than as disclosed in the accompanying notes. The condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2009 contained in Form 10-K filed on March 31, 2010 with the SEC. Interim operating results are not necessarily indicative of operating results for the full year.

**Note 3. Merger with Public Company and Reorganization**

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

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

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

**Note 4. Summary of Significant Accounting Policies**

*Going Concern.* The accompanying condensed 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 \$16.3 million at June 30, 2010. These factors raise substantial doubt about the Company’s ability to continue as a going concern.

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

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

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

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

*Development Stage Enterprise.* The Company is devoting substantially all of its present efforts to establishing 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.

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

In order to execute the second Phase 3 clinical trial and other supportive safety studies for Ketotransdel<sup>®</sup>, which are required by the U.S. Food and Drug Administration ("FDA") to obtain final regulatory approval for Ketotransdel<sup>®</sup>, 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. On April 5, 2010, the Company received gross proceeds of \$1 million from the issuance of a 2-year senior convertible note (see Note 5); however, there can be no assurance that the Company will be able to obtain additional debt or equity financing, if and when needed, on terms acceptable to the Company. Any additional equity or debt financing may involve substantial dilution to the Company's stockholders, restrictive covenants or high interest costs. The failure to raise needed funds on sufficiently favorable terms could have a material adverse effect on the execution of the Company's business plan, operating results and financial condition. The Company's long term liquidity also depends upon its ability to generate revenues from the sale of its products and achieve profitability. The failure to achieve these goals could have a material adverse effect on the execution of the Company's business plan, operating results and financial condition.

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

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

*Concentrations of Credit Risk.* Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash and cash equivalents. The Company invests its excess cash balances (approximately \$300,000 as of June 30, 2010) in a combination of government issued and government backed securities. The remaining amount of cash is held in an operating account and in the form of multiple short term certificates of deposit, all of which (except for \$100,000 of the operating account) are insured by the Federal Deposit Insurance Corporation ("FDIC") as they are individually under the insured maximum of \$250,000.

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

*Fair Value of Financial Instruments.* The Company's financial instruments consist of cash and cash equivalents, accounts payable, accrued expenses and the convertible note payable. The carrying value for all such instruments approximates fair value at June 30, 2010. The difference between the fair value and recorded value of the convertible note payable is not significant.

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

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

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

As of June 30, 2010, the Company had not generated any revenues and the Company does not anticipate that it will generate any revenues until one or more of its drug candidates are approved by the FDA or until the Company is able to commercialize one or more of its cosmetic products. Also, effective sales and marketing support must be in place in order for either the drug candidates or the cosmetic products to generate any revenues. The FDA approval process is highly uncertain and at this time the Company cannot estimate when it will generate revenues from sales of its products.

*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 financial statements based upon their fair values. The Company recorded total stock-based compensation for employees, directors and consultants of \$346,188, \$224,190 and \$1,602,656 for the six months ended June 30, 2010 and 2009 and the period from Inception through June 30, 2010, respectively, for options and restricted stock granted and vested which is included in selling, general and administrative expenses and research and development expenses in the amount of \$282,317 and \$63,871, \$223,989 and \$201, and \$1,062,472 and \$540,184, respectively.

The value of equity instruments issued to consultants and vendors in exchange for goods and services 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. An asset acquired in exchange for the issuance of fully vested, nonforfeitable equity instruments should not be presented or classified as an offset to equity on the grantor's balance sheet once the equity instrument is granted for accounting purposes. Accordingly, the Company recorded the fair value of nonforfeitable equity instruments issued for future consulting services as prepaid consulting fees in its condensed consolidated balance sheets (see Note 6).

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

Basic and diluted net loss applicable to common stock per share is computed using the weighted average number of common shares outstanding during the period. Common stock equivalents (prior to application of the treasury stock, if converted method) from stock options and warrants were 3,707,730 and 2,242,730 for the six months ended June 30, 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. If the Company reported net income for these periods, after applying the treasury stock method, common stock equivalents of 1,169,348 and 149,286 would have been included in the number of shares used to calculate diluted earnings per share in each of the six months ended June 30, 2010 and 2009, respectively.

*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.

**Note 5. Senior Convertible Promissory Note**

On April 5, 2010, the Company issued a two (2)-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 and (unless converted or prepaid, as noted below) all principal and interest are due and payable on 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. Interest expense on the Note was \$17,671 for the six months ended June 30, 2010.

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

**Note 6. Stockholders' Equity**

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 primarily 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. Beginning in September 2010, the Company has agreed to issue an additional 65,000 shares, in the aggregate, of unregistered common stock to the firms on a monthly basis thereafter for the term of the agreement, unless terminated earlier by the Company or the firms.

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

On April 24, 2008, the Company entered into a one-year consulting agreement with a firm to provide the Company with financial advisory services. As compensation for the services, the Company issued a three-year warrant to purchase 5,000 shares of the Company's common stock at a cash and cashless price of \$2.00 per share. The fair value of the warrant, determined based on the Black-Scholes pricing model, was valued at \$1,310, which was amortized over the one-year term ending in April 2009. For the six months ended June 30, 2009, \$436 was amortized and included in selling, general and administrative expenses in the accompanying condensed consolidated statement of operations.

For the six months ended June 30, 2010 and June 30, 2009 and for the period from Inception through June 30, 2010, the Company amortized \$53,866, \$29,048 and \$625,874, respectively, of prepaid consulting fees which is included as part of selling, general and administrative expenses.

**Note 7. Stock Option Plan**

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

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

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

A summary of the Plan for the six months ended June 30, 2010 is as follows:

	<b>Number of Shares</b>	<b>Weighted Ave. Exercise Price</b>	<b>Weighted Ave. Remaining Contractual Life</b>	<b>Aggregate Intrinsic Value</b>
Outstanding – January 1, 2010	1,605,000	\$ 1.64		
Granted	300,000	0.90		
Exercised	—	—		
Forfeited	—	—		
Cancelled	—	—		
Outstanding – June 30, 2010	<u>1,905,000</u>	<u>\$ 1.53</u>	<u>6.8</u>	<u>\$ 194,750</u>
Exercisable – June 30, 2010	<u>1,149,500</u>	<u>\$ 1.75</u>	<u>5.3</u>	<u>\$ 50,150</u>
Vested and expected to vest – June 30, 2010	<u>1,834,783</u>	<u>\$ 1.54</u>	<u>6.7</u>	<u>\$ 180,315</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 June 30, 2010, based on the closing price of the Company's common stock of \$1.15 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 vest on a quarterly basis over three months to five years. The Company uses the Black-Scholes option pricing model to estimate the grant-date fair value of share-based awards. The Black-Scholes model requires subjective assumptions regarding future stock price volatility and expected time to exercise, along with assumptions about the risk-free interest rate and expected dividends, which affect the estimated fair values of the Company's stock-based awards. The expected term of options granted was determined in accordance with the "simplified approach" as the Company has very limited historical data on employee exercises and post-vesting employment termination behavior. The expected volatility is based on the historical volatilities of the common stock of comparable publicly traded companies based on the Company's belief that it currently has limited historical data regarding the volatility of its stock price on which to base a meaningful estimate of expected volatility. The risk-free rate selected to value any particular grant is based on the U.S. Treasury rate that corresponds to the expected term of the grant effective as of the date of the grant. The Company used 0% as an expected dividend yield assumption. These factors could change in the future, affecting the determination of stock-based compensation expense in future periods. Utilizing these assumptions, the fair value is determined at the date of grant. The fair value of the stock options granted during 2010 is 0.60. For the six months ended June 30, 2010, the Company recorded stock-based compensation related to stock options for employees and directors of \$346,188.

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 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. 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 six months ended June 30, 2009, the Company recorded stock-based compensation related to this stock option of \$14,434.

**TRANSDel PHARMACEUTICALS, INC.**

**(A Development Stage Company)**

**NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

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

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 \$36,658) of this portion of the option was determined and recorded in the fourth quarter of 2009. The remainder of the stock option (60,000 shares) was scheduled to vest, on a quarterly basis, over a one-year term, if the consulting agreement was still effective and had not been terminated by either the Company or the consultant prior to the one-year vesting term. The option was granted with an exercise price of \$1.60 and has a ten year life. However, effective October 12, 2009, the consultant became an employee of the Company. Therefore, the original stock option agreement was amended and effectively removed the requirement for the consulting agreement to be in place for the remainder of term, but rather that the individual retains the employee status through the remaining vesting term that will end on June 1, 2010. Since this option effectively was transformed into an employee stock option agreement with the change in status, the final valuation of the option was determined. For the portion of the 60,000 options that vested prior to the change in status, the amount associated with those vested shares was recorded as a consulting stock-based compensation expense in the fourth quarter of 2009. The expense related to the options that vest subsequent to the hire date, are recorded as employee stock-based compensation.

As of June 30, 2010, there was approximately \$511,000 of total unrecognized compensation expense related to unvested stock options under the Plan. That expense is expected to be recognized over the weighted-average remaining vesting term of 2.1 years for the outstanding stock options.

Also, on November 21, 2008, the Company issued a restricted stock grant to a director of the Company for 25,000 shares of the Company's common stock. The restricted stock grant vested over a one-year period. The fair value of the grant was determined to be \$17,500 and was amortized to selling, general and administrative expenses on a straight line basis over the one-year vesting period. For the six months ended June 30, 2009 and the period from Inception through June 30, 2010, the Company recorded stock-based compensation related to this restricted stock of \$8,748, and \$17,500, respectively.

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 condensed consolidated balance sheets and condensed consolidated statement of operations as of and for the six-month period ended June 30, 2010, respectively.

**Note 8. Stock Warrants**

The Company issued warrants to purchase shares of its common stock in conjunction with private placement offerings in 2007 and 2008 and a consulting agreement in 2008. The expiration of the outstanding warrants occurs through May 2013 at various periods.

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

**Note 8. Stock Warrants (continued)**

A summary of the status of the warrants for the six months ended June 30, 2010 is as follows:

	<b>Number of Shares Subject to Warrants Outstanding</b>	<b>Weighted- Average Exercise Price</b>
Warrants outstanding – January 1, 2010	802,730	\$ 4.10
Granted	—	—
Exercised	—	—
Expired	—	—
Warrants outstanding and exercisable – June 30, 2010	<u>802,730</u>	<u>\$ 4.10</u>
Weighted average remaining contractual life of the outstanding warrants – June 30, 2010	<u>2.31 years</u>	

**Note 9. 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 senior convertible promissory note (the “Note”) in April 2010 (see Note 5). When the Note was issued, the final installment payment of \$13,149 was paid and the \$26,299 was recognized as a gain by the Company.

**Note 10. Commitments and Contingencies**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 condensed 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 June 30, 2010, 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.

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

**Note 10. Commitments and Contingencies (continued)**

Cosmetic Products Consulting Agreement

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

Cosmeceutical License Agreements

*JH Direct, LLC License Agreement*

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

*Jan Marini Skin Research License Agreement*

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 cosmeceutical 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 consulting firm will receive a percentage of the royalties paid to the Company.

As noted above, the Company will receive a royalty from these agreements, which varies per agreement. The royalty percentages are in the low to mid single digits.

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, as noted in Note 7, the Company recorded a total expense of approximately \$174,000 for the value of the modifications to the stock options.

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

### Overview

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

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

As is discussed further in the Liquidity and Capital Resources section below, we have limited funds to support our operations and have incurred net losses since our inception. We expect to incur losses in the future as we pursue the clinical development of our product candidates. Our continuation of operations subsequent to the fourth quarter of 2010 is dependent on our ability to obtain additional financing to fund the continued operation of our business model for a long enough period to achieve profitable operations.

### Plan of Operations

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

### Clinical Program for Ketotransdel®

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

As we reported in October 2009, the top-line results showed that the study demonstrated statistical significance in its primary endpoint in the per protocol analysis and was favorable for Ketotransdel® in the Intent-To Treat (ITT) analysis. Ketotransdel® also demonstrated an excellent safety and tolerability profile. 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 excellent safety profile.

In January 2010, we reported on further in-depth analyses of the ITT data from the Ketotransdel® Phase 3 study. For the modified ITT analysis we identified 35 patients who did not meet study entry criteria at the time of randomization. Excluding the data from these patients who should not have been randomized into the study based on information that was not known at the time of enrollment, the study demonstrated statistical significance ( $p < 0.038$ ) on the primary efficacy endpoint. This analysis was confirmed by 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®. We believe that the first Phase 3 trial will qualify as one adequate and well-controlled trial because there is statistical significance on the primary endpoint in an objectively defined modified ITT population, and statistical significance on secondary endpoints. We are in the process of determining the design of the second Phase 3 trial. There is no assurance that the FDA will accept our conclusion of the modified ITT data from the first Phase 3 study as sufficient as part of the requirements for regulatory approval.

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

We expect that Ketotransdel®, if and when approved by the FDA, could become the first topical NSAID cream product available by prescription in the United States for acute pain management. We are seeking a commercial partner for Ketotransdel®, and are actively pursuing discussions with U.S. and foreign based potential partners with sales and marketing infrastructures. There can be no assurance that any of the discussions will lead to a definitive agreement.

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

We have expanded our product development programs to include cosmetic/cosmeceutical products, which utilize our patented transdermal delivery system technology, Transdel™. Our lead product is an anti-cellulite formulation, for which we have initial clinical information supporting the beneficial effects of this key cosmetic/cosmeceutical product on skin appearance. Our potential pipeline of cosmetic/cosmeceutical products includes hyperpigmentation and anti-aging formulations. We are pursuing discussions with potential sales and marketing partners for these cosmetic/cosmeceutical products. There can be no assurance that any of the discussions will lead to a definitive agreement.

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

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 cosmeceutical 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. We anticipate that JMSR will launch the product during the fourth quarter of 2010 or the first quarter of 2011.

As noted above, we will receive a royalty from these agreements, which varies per agreement. The royalty percentages are in the low to mid single digits.

### **Other Product Development Programs**

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

We believe that our current staff is sufficient to carry out our business plan in the coming twelve months, however, if our operations in the future require it, we will consider the employment of additional staff or the use of consultants. Upon the resignation of our Chief Executive Officer, effective February 17, 2010, our Board of Directors appointed our Chief Financial Officer, John Lomoro, as the acting Chief Executive Officer in addition to his continuing duties as Chief Financial Officer.

### **Results of Operations**

#### **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:

	Three months ended		\$ Variance	Six months ended		\$ Variance
	June 30,			June 30,		
	2010	2009		2010	2009	
<b>Selling, general and administrative</b>	<u>\$ 409,810</u>	<u>\$ 347,850</u>	\$ 61,960	<u>\$ 1,165,397</u>	<u>\$ 829,324</u>	\$ 336,073

For the three months ended June 30, 2010, the increase of \$61,960 in selling, general and administrative expense, as compared to the same period in the prior year, was primarily related to an increase in investor relations and consulting expenses, partially offset by a decrease in personnel expenses. Further explanations for these variances are as follows:

- The primary reason for the \$66,000 increase of investor relations expenses was due to stock-based compensation of \$54,000 for investor relations services provided to us as well as other expenses such as press releases and fees for investor conferences attended by the company.
- In the second quarter of 2009, we recorded a credit of \$13,000 for an adjustment of stock-based compensation charges related to consulting services primarily for business development services and in the second quarter of 2010, we incurred a net increase of \$7,000 for fees related to consulting services. Therefore, the combination of these two items resulted in a net increase of approximately \$21,000 related to consulting expenses.
- The primary reason for the decrease in personnel expenses of \$27,000 is due to a lower salary base and stock-based compensation for employees. The salaries were \$11,000 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 \$16,000 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.

For the six months ended June 30, 2010, the increase of \$336,073 in selling, general and administrative expense, as compared to the same period in the prior year, was primarily related to a net increase in personnel expenses related to the separation agreement for our former chief executive officer, partially offset by a decrease in expenses for consulting services. 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 \$55,000 due to a lower salary base and stock-based compensation for employees. The salaries were \$19,000 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 \$36,000 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 \$36,000 decrease in consulting services is due to \$63,000 of monthly fees and stock-based compensation charges incurred during the same period of 2009 primarily for business development consulting services, offset by the \$27,000 of consulting expenses incurred during the current period.

### 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 first 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:

	Three months ended			Six months ended		
	June 30,		\$	June 30,		\$
	2010	2009		2010	2009	
<b>Research and development</b>	<u>\$ 86,954</u>	<u>\$ 882,443</u>	<u>\$ (795,489)</u>	<u>\$ 202,112</u>	<u>\$ 2,028,994</u>	<u>\$ (1,826,882)</u>

For the three months ended June 30, 2010, the decrease of \$795,489 in research and development expense, as compared to the same period in 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 was on-going and therefore, we recognized approximately \$853,000 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.
- The decrease in consulting expenses of approximately \$34,000 is due to fees and stock-based compensation incurred by a consultant for management of the Phase 3 trial in the prior period.
- The increase in personnel expenses of approximately \$83,000 was primarily related to stock-based compensation and wages of our chief medical officer who was hired in October 2009. This position was not filled in the same period of the prior year.

For the six months ended June 30, 2010, the decrease of \$1.8 million in research and development expense, as compared to the same period in 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 was on-going and therefore, we recognized approximately \$2.0 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 current period, we only recognized a minimal amount of expense, which was incurred by our contract research organization for final administrative activities related to the study.
- The decrease in consulting expenses of approximately \$20,000 is due to \$32,000 of fees and stock-based compensation primarily incurred by a consultant for management of the Phase 3 trial in the prior period, offset by \$12,000 of consulting fees incurred in the current period.
- The increase in personnel expenses of approximately \$159,000 was primarily related to stock-based compensation and wages of our chief medical officer who was hired in October 2009. This position was not filled in the same period of the prior year.

#### **Interest Expense**

In April 2010, we issued a two (2)-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 \$17,671 for the six months ended June 30, 2010.

#### **Interest Income**

Interest income was \$135 and \$2,265 for the three months ended, and \$268 and \$9,054 for the six months ended, June 30, 2010 and 2009, respectively. The decreases were due to a lower average cash balance and lower interest rates during the three and six month periods ended June 30, 2010, as compared to the same periods in the prior year.

## **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 of \$26,299.

## **Liquidity and Capital Resources**

Since inception through June 30, 2010, we have incurred losses of approximately \$16.3 million. These losses are primarily due to selling, general and administrative and research and development expenses incurred in connection with developing and seeking regulatory approval for our lead drug, Ketotransdel®. Historically, our operations have been financed through capital contributions and debt and equity financings.

As of June 30, 2010, we had approximately \$1.0 million in cash and cash equivalents. We have limited funds to support our operations. We have prepared our condensed consolidated financial statements in this Form 10-Q on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Our continuation of operations subsequent to the fourth quarter of 2010 is dependent on our ability to obtain additional financing to fund the continued operation of our business model for a long enough period to achieve profitable operations. As of June 30, 2010, with our current cash and cash equivalents position, we have forecasted and anticipate having adequate resources in order to execute a portion of our operating plan into the fourth quarter of 2010, which would include the final payments for the Phase 3 clinical trial completed in 2009 and general and administrative expenses. However, in order to execute the second Phase 3 clinical trial of Ketotransdel® which is currently required by the FDA to obtain final regulatory approval for Ketotransdel® we would need to raise additional funds. We intend to seek additional financing to fund the second Phase 3 clinical trial as well as to continue our cosmetic/cosmeceutical program and to explore co-development opportunities. If adequate financing is not available, we will not be able to conduct the second Phase 3 trial.

We may be required to pursue sources of additional capital to fund our operations through various means, including equity or debt financing, funding from a corporate partnership or licensing arrangement or any similar financing. Future financings through equity investments are likely to be dilutive to existing stockholders. Also, the terms of securities we may issue in future capital transactions may be more favorable for our new investors. Newly issued securities may include preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have additional dilutive effects. In addition, if we raise additional funds through collaboration and licensing arrangements, we may be required to relinquish potentially valuable rights to our product candidates or proprietary technologies, or grant licenses on terms that are not favorable to us. Further, we may incur substantial costs in pursuing future capital and/or financing, including investment banking fees, legal fees, accounting fees, printing and distribution expenses and other costs. We may also be required to recognize non-cash expenses in connection with certain securities we may issue, such as convertible notes and warrants, which will adversely impact our financial 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 prior to the end of 2010 we will be required to cease operations.

## **Critical Accounting Policies**

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

We believe that the accounting policies described below are critical to understanding our business, results of operations and financial condition because they involve more significant judgments and estimates used in the preparation of our condensed 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 condensed consolidated financial statements.

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

*Going Concern.* Our condensed 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. We have incurred recurring operating losses, had negative operating cash flows and have not recognized any revenues since July 24, 1998 (Inception). In addition, we had a deficit accumulated during the development stage of \$16.3 million at June 30, 2010. These factors raise substantial doubt about our ability to continue as a going concern.

Our continuation as a going concern is dependent on our ability to obtain additional financing to fund operations, implement our business model, and ultimately, to attain profitable operations. We intend to raise additional financing 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, there is no assurance that sufficient financing will be available or, if available, on terms that would be acceptable to us.

The condensed 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 we be unable to continue as a going concern.

*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.

#### **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**

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

#### **Item 4T. Controls and Procedures.**

##### *Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures*

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Commission’s rules and forms and that such information is accumulated and communicated to our management, including our acting Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Commission Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our acting Chief Executive Officer and the Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the quarter covered by this quarterly report on Form 10-Q. Based on the foregoing, our acting Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

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

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

**PART II  
OTHER INFORMATION**

**Item 1. Legal Proceedings**

None.

**Item 1A. Risk Factors**

*You should consider carefully the following information about the risks described below, together with the other information contained in this quarterly report on Form 10-Q and in our other filings with the Securities and Exchange Commission, before you decide to buy or maintain an investment in our common stock. We believe the risks described below are the risks that are material to us as of the date of this quarterly report. If any of the following risks actually occur, our business financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of the money you paid to buy our common stock. The risk factors set forth below with an asterisk (\*) next to the title are new risk factors or risk factors containing changes, including any material changes from the risk factors set forth in our annual report on Form 10-K for the fiscal year ended December 31, 2009, as filed with the Securities and Exchange Commission on March 31, 2010.*

**Risks Relating to Our Business**

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

Since inception we have recorded operating losses. From Inception through June 30, 2010, we have a deficit accumulated during the development stage of approximately \$16.3 million, and for the six months ended June 30, 2010, we experienced a net loss of approximately \$1.4 million. In addition, we expect to incur increasing operating losses for the foreseeable future as we continue to incur costs for research and development and clinical trials, and in other development activities. Our ability to generate revenue and achieve profitability depends upon our ability, alone or with others, to complete the development of our proposed products, obtain the required regulatory approvals and manufacture, market and sell our proposed products. Development is costly and requires significant investment. In addition, we may choose to in-license rights to particular drugs or active ingredients for use in cosmetic/cosmeceutical products. The license fees for such drugs or active ingredients may increase our costs.

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

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

We have limited remaining funds to support our operations. We have prepared our condensed consolidated financial statements in this Form 10-Q on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. We will not be able to execute our current business plan, fund our business operations or continue as a going concern long enough to achieve profitability unless we are able to secure additional funds. As of June 30, 2010, with our current cash and cash equivalents position we have forecasted and anticipate having adequate resources in order to execute a portion of our operating plan into the fourth quarter of 2010, which would include the final payments for the Phase 3 clinical trial completed in 2009 and general and administrative expenses. The Report of Independent Registered Public Accounting Firm on our December 31, 2009 consolidated financial statements included an explanatory paragraph stating that the recurring losses incurred from operations and a working capital deficiency raise substantial doubt about our ability to continue as a going concern. However, in order to meet the FDA's requirement for two adequate and well controlled Phase 3 clinical trials in order to obtain regulatory approval to market Ketotransdel®, we will need to secure additional funds. If adequate financing is not available, we will not be able to meet the FDA's requirements to obtain regulatory approval to market Ketotransdel®. In addition, if one or more of the risks discussed in these risk factors occur or our expenses exceed our expectations, we may be required to raise further additional funds sooner than anticipated.

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

The significant downturn in the overall economy and the ongoing disruption in the capital markets has reduced investor confidence and negatively affected investments generally and specifically in the pharmaceutical industry. In addition, the fact that we are not profitable and will need significant additional funds to meet the FDA's requirement for two adequate and well controlled Phase 3 clinical trials in order to obtain regulatory approval to market Ketotransdel® and any other clinical trials we would want to 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 2010 we will be required to cease operations.

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

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

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

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

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

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

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

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

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw our regulatory approval;
- suspend or terminate any of our ongoing clinical trials;
- 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<sup>®</sup>, have commenced clinical trials.***

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

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

Even if we obtain regulatory approvals, uncertainty exists as to whether the market will accept our products or if the market for our products is as large as we anticipate. A number of factors may limit the market acceptance of our products, including the timing of regulatory approvals and market entry relative to competitive products, the availability of alternative products, the price of our products relative to alternative products, the availability of third party reimbursement and the extent of marketing efforts by third party distributors or agents that we retain. We cannot assure you that our products will receive market acceptance in a commercially viable period of time, if at all. We cannot be certain that any investment made in developing products will be recovered, even if we are successful in commercialization. To the extent that we expend significant resources on research and development efforts and are not able, ultimately, to introduce successful new products as a result of those efforts, our business, financial position and results of operations may be materially adversely affected, and the market value of our common stock could decline.

***We may be subject to product liability claims.***

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

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

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

Our success will depend in part on our ability to:

- obtain and 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<sup>™</sup> technology in 1998, which affords protection of Transdel<sup>™</sup> through 2016 in the United States. We may not be successful in our efforts to extend the date of our patent protection beyond 2016.

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

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

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

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

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

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

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

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

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

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

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

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

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

We recently expanded our product development program to include cosmetic/cosmeceutical products, which utilize our patented transdermal delivery system technology, Transdel™. Since our primary focus will remain on seeking FDA approval for Ketotransdel®, we plan to use limited resources on our cosmetic/cosmeceutical development program and, as a result, we will need to partner with third parties to perform formulation, clinical research, manufacturing, sales and marketing activities. We have initial clinical information supporting the beneficial effects of our anti-cellulite product on skin appearance and have entered into license agreements with two companies for this 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/cosmeceutical products, including products for hyperpigmentation and anti-aging. Any products we develop may cause undesirable side effects that could limit their use, require their removal from the market and subject us to adverse regulatory action and product liability claims. Further, the market for cosmetic/cosmeceutical products is highly competitive, and there is no assurance that our products will be able to compete against the many products and treatments currently being offered or under development by other established, well-known and well-financed cosmetic, health care and pharmaceutical companies.

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

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

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

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

## Risks Relating to Our Industry

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

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

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

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

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

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

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

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

The healthcare industry is changing rapidly as the public, governments, medical professionals and the pharmaceutical industry examine ways to broaden medical coverage while controlling the increase in healthcare costs. Potential changes could put pressure on the prices of prescription pharmaceutical products and reduce our business or prospects. In the United States, the Federal government recently passed comprehensive healthcare reform legislation. Many of the details regarding the implementation of this legislation are yet to be determined and we currently cannot predict whether or to what extent such implementation or adoption of reforms may affect our business.

## Risks Relating to the Common Stock

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

We are subject to reporting and other obligations under the Securities Exchange Act of 1934, as amended, (the "Exchange Act") including the requirements of Section 404 of the Sarbanes-Oxley Act. Section 404 requires us to conduct an annual management assessment of the effectiveness of our internal controls over financial reporting for the annual report on Form 10-K. However, due to recently passed legislation, we are exempt from the requirement to obtain a report by our independent registered public accounting firm addressing our management assessment of our internal controls until our market capitalization exceeds \$75 million. Once we are potentially subject to these reporting requirements and other obligations, it will place significant demands on our management, administrative, operational, and accounting resources. We anticipate that we may need to upgrade our systems; implement additional financial and management controls, reporting systems and procedures; implement or outsource an internal audit function; and hire additional accounting and finance staff. Once we are subject to these reporting requirements, if we are unable to accomplish these objectives in a timely and effective fashion, our ability to comply with our financial reporting requirements and other rules that apply to reporting companies could be impaired and we may not be able to obtain the independent registered public accounting firm opinion required by Section 404. Any failure to maintain effective internal controls could have a negative impact on our ability to manage our business and on our stock price.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## **Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

Since April 1, 2010, we have issued or agreed to issue the following shares of our common stock that have not been registered under the Securities Act of 1933, as amended:

On June 6, 2010 we issued 120,000 shares of unregistered common stock to an investor relations firm for certain investor relations services provided to us over a three-month period.

On June 10, 2010, we issued 80,000 shares of unregistered common stock to an advisory services firm for certain advisory services provided to us over a three-month period.

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

## **Item 6. Exhibits**

<b>Exhibit Number</b>	<b>Description</b>
31.1*	Section 302 Certification of Principal Executive Officer and Principal Financial Officer
32.1*	Section 906 Certification of Principal Executive Officer and Principal Financial Officer

\* Filed herewith.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Transdel Pharmaceuticals, Inc.

Dated: August 12, 2010

By: /s/ John Lomoro  
John Lomoro  
Acting Chief Executive Officer and Chief Financial Officer  
(Principal Executive Officer and Principal Financial Officer)

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>
31.1*	Section 302 Certification of Principal Executive Officer and Principal Financial Officer
32.1*	Section 906 Certification of Principal Executive Officer and Principal Financial Officer

\* Filed herewith.

## CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER UNDER SECTION 302 OF THE SARBANES-OXLEY ACT

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

- (1) I have reviewed this quarterly report on Form 10-Q 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: August 12, 2010

/s/ John Lomoro

John Lomoro

Acting Chief Executive Officer and Chief Financial Officer  
(Principal Executive Officer and Principal Financial Officer)

CERTIFICATION PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Transdel Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2010 as filed with the Securities and Exchange Commission on the date hereof (the "Report") pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, I, John Lomoro, Acting Chief Executive Officer and Chief Financial Officer of Transdel Pharmaceuticals, Inc., certify that:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 12, 2010

/s/ John T. Lomoro

John T. Lomoro

Acting Chief Executive Officer and Chief Financial Officer

(Principal Executive Officer and Principal Financial Officer)