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 September 30, 2009

o **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	45-0567010
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
4225 Executive Square, Suite 485 La Jolla, CA	92037
(Address of Principal Executive Offices)	(Zip Code)

(858) 457-5300
(Registrant's Telephone Number, Including Area Code)

(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 o

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 o NO o

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 o	Accelerated filer o	Non-accelerated filer o (Do not check if a smaller reporting company)	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 o NO ☑

As of November 9, 2009, 15,652,061 shares of issuer's common stock, with $0.001 par value per share were outstanding.

TRANSDEL PHARMACEUTICALS, INC.
(A Development Stage Company)

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PART I
FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	September 30, 2009 (Unaudited)	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,999,154	$ 5,111,031
Prepaid consulting fees	—	29,048
Prepaid expenses and other current assets	124,497	193,306
Total current assets	2,123,651	5,333,385
Equipment, net	1,658	2,450
Total assets	$ 2,125,309	$ 5,335,835
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 426,822	$ 556,390
Accrued Phase 3 expenses	411,543	141,952
Accrued expenses and payroll liabilities	62,884	65,651
Total liabilities	901,249	763,993
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized, none outstanding	—	—
Common stock, $0.001 par value; 50,000,000 shares authorized, 15,652,061 and 15,556,283 shares issued and outstanding as of September 30, 2009 (unaudited) and December 31, 2008, respectively	15,652	15,556
Additional paid-in capital	15,367,953	14,938,219
Deficit accumulated during the development stage	(14,159,545)	(10,381,933)
Total stockholders' equity	1,224,060	4,571,842
Total liabilities and stockholders' equity	$ 2,125,309	$ 5,335,835

See accompanying notes to these unaudited condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,		For the Period From July 24, 1998 (Inception) Through September 30,
	2009	2008	2009	2008	2009
Operating expenses:					
Selling, general and administrative	$ 364,087	$ 305,221	$ 1,193,411	$ 1,315,400	$ 6,032,723
Research and development	565,148	529,455	2,594,142	1,466,638	7,142,551
Operating loss	929,235	834,676	3,787,553	2,782,038	13,175,274
Other income (expense):					
Interest expense	—	—	—	—	(1,575,755)
Interest income	887	19,721	9,941	56,049	126,570
Gain on forgiveness of liabilities	—	—	—	—	89,914
Gain on settlement	—	—	—	375,000	375,000
Total other income (expense), net	887	19,721	9,941	431,049	(984,271)
Net loss	$ (928,348)	$ (814,955)	$ (3,777,612)	$ (2,350,989)	$ (14,159,545)
Basic and diluted loss per common share	$ (0.06)	$ (0.05)	$ (0.24)	$ (0.16)	
Weighted average common shares outstanding	15,632,006	15,462,616	15,599,828	14,586,704	

See accompanying notes to these unaudited condensed consolidated financial statements.

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

	Nine Months Ended September 30,		For The Period From July 24, 1998 (Inception) Through September 30,
	2009	2008	2009
Cash flows from operating activities:			
Net loss	$ (3,777,612)	$ (2,350,989)	$ (14,159,545)
Adjustments to reconcile net loss to net cash used in operating activities:			
Estimated fair value of contributed services	—	—	2,475,000
Gain on forgiveness of liabilities	—	—	(89,914)
Amortization of prepaid consulting fees	29,048	284,158	572,008
Depreciation	792	440	1,496
Non-cash interest on notes payable	—	—	1,575,755
Stock-based compensation	380,329	504,566	1,127,293
Changes in operating assets and liabilities:			
Prepaid consulting costs	—	—	(140,000)
Prepaid expenses and other current assets	68,809	(164,396)	(124,497)
Accounts payable	(129,568)	(250,751)	516,736
Accrued Phase 3 expenses	269,591	77,927	411,543
Accrued expenses and payroll liabilities	(2,766)	30,052	62,884
Net cash used in operating activities	(3,161,377)	(1,868,993)	(7,771,241)
Cash flows from investing activities:			
Purchase of fixed assets	—	(3,154)	(3,154)
Net cash used in investing activities	—	(3,154)	(3,154)
Cash flows from financing activities:			
Proceeds from notes payable to stockholders	—	—	226,300
Proceeds from notes payable	—	—	1,500,000
Capital contributions	—	—	168,707
Net proceeds from purchase of common stock and exercise of warrants and stock options	49,500	—	99,450
Net proceeds from Private Placements	—	3,941,301	7,779,092
Net cash provided by financing activities	49,500	3,941,301	9,773,549
Net change in cash and cash equivalents	(3,111,877)	2,069,154	1,999,154
Cash and cash equivalents, beginning of period	5,111,031	3,706,369	—
Cash and cash equivalents, end of period	$ 1,999,154	$ 5,775,523	$ 1,999,154
Supplemental disclosure of cash flow information:			
Issuance of and adjustment to common stock and warrants to consulting firms for prepaid consulting fees	$ —	$ (203,826)	$ 432,007
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 unaudited 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 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 September 30, 2009, the results of operations for three and nine months ended September 30, 2009 and 2008, and cash flows for the nine months ended September 30, 2009 and 2008, fairly stated. We have evaluated subsequent events through the filing date of this Form 10-Q, November 16, 2009, 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 unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2008 contained in Form 10-K filed on March 26, 2009 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, which includes 195,313 shares of restricted stock which were subject to forfeiture (see Note 6), were issued to the holders of Transdel Holdings' common stock. As a result of the transaction, the former owners of Transdel Holdings became the controlling stockholders of Transdel. Accordingly, the merger of Transdel Holdings and Transdel is a reverse merger that has been accounted for as a recapitalization of Transdel Holdings.

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

Note 4. Summary of Significant Accounting Policies

New Accounting Standard. In the third quarter of 2009, the Financial Accounting Standards Board ("FASB") issued the FASB Accounting Standards Codification (the "Codification"). The Codification is the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in preparation of financial statements in conformity with generally accepted accounting principles in the United States. All accounting guidance that is not included in the Codification will be considered to be non-authoritative. The FASB will issue Accounting Standard Updates ("ASUs"), which will serve only to update the Codification, provide background information about the guidance and provide the basis for conclusions on changes in the Codification.

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

Note 4. Summary of Significant Accounting Policies (continued)

ASUs are not authoritative in their own right. The Codification does not change GAAP and did not have an affect on the Company's financial position or results of operations.

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 $14.2 million at September 30, 2009. These factors, among others, raise substantial doubt about the Company's ability to continue as a going concern.

The Company's continuation as a going concern is dependent on its ability to obtain additional financing to fund operations, implement its business model, and ultimately, to attain profitable operations. 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 a development stage company as defined under FASB guidance. The Company is devoting substantially all of its present efforts to establish a new business, and its planned principal operations have not yet commenced. All losses accumulated since inception have been considered as part of the Company's development stage activities.

The accompanying unaudited 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 2009.

In order to execute the second Phase 3 clinical trial for Ketotransdel®, which is currently required by the U.S. Food and Drug Administration ("FDA") to obtain final regulatory approval for Ketotransdel®, the Company will need to secure additional funds through various means, including equity and debt financing, funding from a corporate partnership or licensing arrangement or any similar financing. There can be no assurance that the Company will be able to obtain additional debt or equity financing, if and when needed, on terms acceptable to the Company. Any additional equity or debt financing may involve substantial dilution to the Company's stockholders, restrictive covenants or high interest costs. The failure to raise needed funds on sufficiently favorable terms could have a material adverse effect on the execution of the Company's business plan, operating results 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 $458,000 as of September 30, 2009) in a combination of government issued and government backed securities. The remaining amount of cash is held in an operating account and in the form of multiple short term certificates of deposit, all of which (except for $100,000 of the operating account) are insured by the Federal Deposit Insurance Corporation ("FDIC") as they are individually under the insured maximum of $250,000.

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

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

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

Note 4. Summary of Significant Accounting Policies (continued)

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

As of September 30, 2009, the Company had not generated any revenues and the Company does not anticipate that it will generate any revenues until one or more of its drug candidates are approved by the FDA or until the Company is able to commercialize one or more of its cosmetic products. Also, effective sales and marketing support must be in place for either the drug candidates or the cosmetic products in order to generate any revenues. The FDA approval process is highly uncertain and the Company cannot estimate when it will generate revenues at this time from sales of its products.

Stock-Based Compensation. Under FASB guidance all share-based payments to employees, including grants of stock options to employees, directors and consultants and restricted stock grants, are to be recognized in the financial statements based upon their fair values. The Company recorded total stock-based compensation for employees, directors and consultants of $380,329, $504,566 and $1,127,293 for the nine months ended September 30, 2009 and 2008 and for the period from Inception to September 30, 2009, respectively, for options and restricted stock granted and vested which is included in general and administrative expenses and research and development expenses in the amount of $329,610 and $50,719, $204,323 and $300,243 and $677,939 and $449,354, respectively.

The Company's accounting policy for equity instruments issued to consultants and vendors in exchange for goods and services follows FASB guidance. As such, the value of the applicable stock-based compensation is periodically remeasured and income or expense is recognized during their vesting terms. The measurement date for the fair value of the equity instruments issued is determined at the earlier of (i) the date at which a commitment for performance by the consultant or vendor is reached or (ii) the date at which the consultant or vendor's performance is complete. In the case of equity instruments issued to consultants, the fair value of the equity instrument is primarily recognized over the term of the consulting agreement. In accordance with FASB guidance, an asset acquired in exchange for the issuance of fully vested, nonforfeitable equity instruments should not be presented or classified as an offset to equity on the grantor's balance sheet once the equity instrument is granted for accounting purposes. Accordingly, the Company recorded the fair value of nonforfeitable equity instruments issued for future consulting services as prepaid consulting fees in its consolidated balance sheets (see Note 5).

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

Basic and diluted net loss applicable to common stock per share is computed using the weighted average number of common shares outstanding during the period. Common stock equivalents (prior to application of the treasury stock, if converted method) from stock options and warrants were 2,192,730 and 1,812,730 for the nine months ended September 30, 2009 and 2008, respectively, are excluded from the calculation of diluted net loss per share for all periods presented because the effect is anti-dilutive.

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

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

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

Note 5. Stockholders' Equity

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

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

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

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

In accordance with FASB guidance, 100,000 of the 275,000 shares of common stock were subject to remeasurement on a periodic basis as the performance condition for these shares was not satisfied until the end of the contract term. The remeasurement for the 100,000 shares was completed in two stages. First, in February 2008, the consulting agreement associated with these shares was terminated and as a condition of the termination, the firm retained 50,000 shares and transferred the remaining 50,000 shares to another firm. Therefore, since the performance obligation related to the 50,000 shares, retained by the terminated consulting firm, was complete they were revalued as of the February termination date to $60,000. This was the fair market value of the shares on the February 2008 termination date of which approximately $30,000 was recorded as an expense in each of the fiscal years 2008 and 2007. Due to the final valuation of these shares an adjustment of $40,000 was recorded to decrease prepaid consulting costs and additional paid-in capital as the original value of these shares was $100,000. Second, the remaining 50,000 shares that were transferred to the other firm were intended to be utilized for the payment of investor relation services. During fiscal year 2008, through quarterly revaluations of these shares, the Company recorded a net decrease of $7,500 to prepaid consulting costs and additional paid-in capital. The Company originally estimated that these shares would be utilized and earned for investor relations services by the end of the one-year term, however, these 50,000 shares along with 32,568 (for an aggregate of 82,568) shares from the issuance of common stock to one of the other consulting firms were not earned as of the termination of the respective agreements. As a result, the aggregate expense recognized to date for the 82,568 shares of approximately $158,000 was reversed during fiscal year 2008 and since shares were considered not to be issued or outstanding, the same value was deducted (in the aggregate) from common stock and additional paid-in capital.

On October 27, 2008, the Company entered into an agreement with an investor relations firm ("IR Firm"), pursuant to which the IR Firm would provide certain investor relations and public relations services to the Company for a period of one year, beginning on November 1, 2008. In exchange for such services, the Company issued the 82,568 registered shares of its common stock, of which 68,667 shares were nonforfeitable (valued at $85,834 and recorded as prepaid consulting fees in the accompanying consolidated balance sheet as of December 31, 2008) and 13,901 shares were forfeitable, to the IR Firm as a prepayment of services to be received. The Company terminated the agreement with the IR Firm effective March 31, 2009. Therefore, 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.

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

Note 5. Stockholders' Equity (continued)

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 nine months ended September 30, 2009, $436 was amortized and included in selling, general and administrative expenses in the accompanying statement of operations

For the nine months ended September 30, 2009 and 2008 and for the period from Inception through September 30, 2009, the Company amortized $29,048, $284,598 and $572,008, respectively, of prepaid consulting fees which is included as part of selling, general and administrative expenses.

Note 6. Stock Option Plan

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

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

A summary of the Plan for the nine months ended September 30, 2009 is as follows:

	Number of Shares	Weighted Ave. Exercise Price	Weighted Ave. Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding — January 1, 2009	1,085,000	$ 1.63		
Granted	405,000	1.60		
Exercised	(50,000)	0.99		
Forfeited	—	—		
Cancelled	(50,000)	2.00		
Outstanding — September 30, 2009	1,390,000	$ 1.63	8.8	$ 413,500
Exercisable — September 30, 2009	507,250	$ 1.83	8.4	$ 75,254
Vested and expected to vest — September 30, 2009	1,331,500	$ 1.65	8.8	$ 375,025

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 September 30, 2009, based on the closing price of the Company's common stock of $1.85 on that date.

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

Note 6. Stock Option Plan (continued)

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. For the nine months ended September 30, 2009, the Company recorded stock-based compensation related to stock options for employees and directors of $243,682.

On December 19, 2008, the Board of Directors approved and the Company entered into a consulting agreement with a firm to provide the Company with business development services. As part of the compensation for the services, the Company issued the firm a non-qualified stock option, under the Plan, to purchase up to 50,000 shares of common stock. The stock option vested in full on March 19, 2009 and was fully exercised during the third quarter of 2009. The option was granted with an exercise price of $0.99. The option was revalued on an interim basis until the termination of the agreement and the final estimated fair value of the stock option, based on the Black-Scholes pricing model, was $20,205. This option was amortized over the term of the agreement which was approximately four months as the consulting agreement was terminated effective April 16, 2009. For the nine months ended September 30, 2009, the Company recorded stock-based compensation related to this stock option of $14,434.

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. A portion of the stock option (25,000 shares) became fully vested on October 6, 2009 and the remainder of the stock option (60,000 shares) will vest, on a quarterly basis, over a one-year term, if the consulting agreement is still effective and has 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. The unvested portion of the option will be revalued on an interim basis until the termination of the agreement. As of September 30, 2009, the revalued aggregate estimated fair value of the stock option, based on the Black-Scholes pricing model, was $114,376. For the nine months ended September 30, 2009, the Company recorded stock-based compensation related to this stock option of $58,735. Effective October 12, 2009, the consultant became an employee of the Company, therefore, in the fourth quarter of 2009, the final valuation of the option will be determined for the unvested portion and amortized over the remaining one-year term. In addition, on October 14, 2009, the employee was granted a non-qualified stock option, under the Plan, to purchase up to 215,000 shares of common stock. The option granted will vest on a quarterly basis over a three year period and has an exercise price of $1.70.

As of September 30, 2009, there was approximately $749,000 of total unrecognized compensation expense related to unvested stock options under the Plan. That expense is expected to be recognized over the weighted-average period of 2.0 years.

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

Also, on November 21, 2008, the Company issued a restricted stock grant to a director of the Company for 25,000 shares of the Company's common stock. The restricted stock grant is scheduled to vest over a one-year period, with one-quarter of the total number of shares subject to such grant vesting on the first quarterly anniversary of the grant date, and one-quarter of the total number of shares vesting on a quarterly basis thereafter. The fair value of the grant was determined to be $17,500 and will be amortized to selling, general and administrative expenses on a straight line basis over the one-year vesting period. For the nine months ended September 30, 2009, the Company recorded stock-based compensation related to this restricted stock of $13,122. As of September 30, 2009, there was $2,191 of total unrecognized compensation expense related to the unvested restricted stock grant. Also, if the director terminates his service prior to the end of the one-year period, any unvested portion of the restricted stock grant will be subject to forfeiture.

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

Note 7. Stock Warrants

In addition to the warrants issued in conjunction with the Private Placement and the Follow-On Private Placement, the Company issued a warrant to purchase shares of its common stock to a firm in connection with a consulting agreement at an exercise price of $2.00. The expiration of the outstanding warrants occurs through May 2013 at various periods (see Note 5).

A summary of the status of the warrants for the nine months ended September 30, 2009 is as follows:

	Number of Shares Subject to Warrants Outstanding	Weighted-Average Exercise Price
Warrants outstanding — January 1, 2009	802,730	$ 4.10
Granted	—	—
Exercised	—	—
Expired	—	—
Warrants outstanding and exercisable — September 30, 2009	802,730	$ 4.10
Weighted average remaining contractual life of the outstanding warrants — September 30, 2009	3.06 years	

Note 8. 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 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 is serving as the Company's strategic partner and contract research organization in conducting the Company's Phase 3 clinical program for Ketotransdel®, the Company's novel topical cream based non-steroidal anti-inflammatory drug for pain. Pursuant to the Agreement, the Company will make payments to Cato upon its completion of certain specified milestones. If all milestones under the Agreement are completed and the estimated pass-through costs are incurred, the Company's total costs under the Agreement are estimated at $3.3 million. In addition, any changes to budget parameters identified in the Agreement may result in additional costs to the Company.

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

Note 8. 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 Agreement

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

Note 9. Related Party Transaction

Mediation Settlement

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

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.

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 program for our novel analgesic and anti-inflammatory topical cream, Ketotransdel®, which contains ketoprofen. On October 6, 2009, as reported in our Form 8-K filing, we announced top-line clinical results for Ketotransdel® in a Phase 3 trial. This Phase 3 study consisted of a randomized, double-blind, placebo controlled trial to evaluate the efficacy and safety of Ketotransdel in acute soft tissue injuries of the upper and lower extremities over a one week treatment period with a one week post-treatment follow-up for safety. The multi-center trial was conducted at 26 sites in the United States and enrolled 364 patients, randomized 1:1 ratio Ketotransdel (active) versus placebo vehicle (identical to active without the drug ketoprofen). The primary efficacy endpoint was the difference in the change of baseline of pain during normal activity for the past 24 hours from measurement at the Day 3 clinical visit between active and placebo measured by using the Visual Analogue Scale (VAS), a well known and validated instrument for pain measurement. Secondary endpoints included safety assessments and other efficacy parameters measured by VAS.

We intend to continue working with the FDA to obtain regulatory approval to market Ketotransdel®, and plan to discuss with the FDA their current requirement to complete a second Phase 3 clinical trial for Ketotransdel®. If and when the FDA approves Ketotransdel® for the topical treatment of acute pain, inflammation and swelling associated with soft tissue injuries, we intend to pursue FDA approval of Ketotransdel® for other indications, such as osteoarthritis. Furthermore, we are either in or pursuing discussions with U.S. and foreign based potential partners with operations that have sales and marketing infrastructures to support Ketotransdel® in the event that the product is approved and commercialized.

Cosmeceutical/Cosmetic Product Development Program

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

On May 20, 2009, we entered into a license agreement with JH Direct, LLC ("JH Direct") providing JH Direct with the exclusive worldwide rights to our anti-cellulite cosmeceutical product. Under the terms of the agreement, JH Direct will pay us initial royalty advances 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. Under the JH Direct agreement, we are targeting to introduce the anti-cellulite product into the market in 2010.

Other Product Development Programs

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

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 September 30,		$	Nine months ended September 30,		$
	2009	2008	Variance	2009	2008	Variance
Selling, general and administrative	$ 364,087	$ 305,221	$ 58,866	$1,193,411	$1,315,400	$(121,989)

For the three months ended September 30, 2009, the increase of $58,866 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, personnel and consulting expenses, partially offset by a decrease in expenses for legal fees. Further explanations for these variances are as follows:

- The primary reason for the increase in investor relations expenses was the result of approximately $20,000 of expenses in the current period compared to approximately $2,000 in the prior year. The prior year amount was the net expense from a year-to-date reversal of costs in 2008 related to stock previously granted to investor relations firms that was not earned as of September 30, 2008. The increase in personnel expenses of approximately $26,000 is due to an increase in stock-based compensation granted to employees and board members in the fourth quarter of 2008 and during the second quarter of 2009. Consulting expenses increased by approximately $20,000 due to monthly fees for business development consulting services.

- The decrease in legal fees of approximately $10,000 is due to a lower amount of legal activity and related expense during the current period in comparison to the same period last year.

For the nine months ended September 30, 2009, the decrease of $121,989 in selling, general and administrative expense, as compared to the same period in the prior year, was primarily related to the decrease in investor relations and legal expenses, partially offset by increased expenses for personnel, consulting and insurance costs. Further explanations for these variances are as follows:

- The primary reason for the decrease in investor relations expense was due to the lower amount of amortization, approximately $200,000, related to the value of stock-based compensation for stock and warrants previously issued to investor relations firms. The decrease in legal fees of approximately $100,000 is due to a lower amount of legal activity and related expense during the current period in comparison to the same period last year. Also, travel and entertainment expenses decreased by approximately $30,000.

- The increase in personnel expenses of approximately $85,000 is due to an increase in wages (as of July 1, 2008) and additional stock-based compensation granted to employees and board members in the second and fourth quarters of 2008 and during the second quarter of 2009. Consulting expenses increased by approximately $80,000 primarily related to stock-based compensation and monthly fees for business development consulting services. Insurance costs increased by approximately $30,000 from two product liability policies that we obtained in the latter part of the second quarter 2008 and in the fourth quarter of 2008 for our Phase 3 clinical trial and our cosmeceutical products as well as other incremental insurance costs.

Research and Development Expenses

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

The table below provides information regarding research and development expenses:

	Three months ended September 30,		$	Nine months ended September 30,		$
	2009	2008	Variance	2009	2008	Variance
Research and development	$ 565,148	$ 529,455	$ 35,693	$2,594,142	$1,466,638	$1,127,504

For the three months ended September 30, 2009, the increase of $35,693 in research and development expense, as compared to the same period in the prior year, was primarily related to the increase of expenses for the current Phase 3 study, partially offset by decreased expenses related to contract manufacturing. Further explanations for these variances are as follows:

- Expenses related to the Phase 3 study were in excess of those reported in the prior year by approximately $100,000, primarily due to the fees incurred by our contract research organization for their services provided in conducting the study.
- In comparison to the same period in the prior year, we recognized a decrease of approximately $65,000 related to contract manufacturing activities for the Phase 3 clinical program.

For the nine months ended September 30, 2009, the increase of $1.1 million in research and development expense, as compared to the same period in the prior year, was primarily related to the increase of expenses for the current Phase 3 study, partially offset by decreased expenses related to personnel, contract manufacturing and non-clinical studies. Further explanations for these variances are as follows:

- During the current period, we recognized an increase of approximately $1.9 million of expenses related to the current Phase 3 study, primarily related to the investigator payments owed to the clinical sites for the patients they enrolled in the study and the fees incurred by our contract research organization for their services provided in conducting the study.
- The decrease in personnel expenses of approximately $370,000 was primarily related to stock-based compensation and wages of former employees recognized in the prior year. Also, during the same period in the prior year, we recognized approximately $380,000 of expenses related to contract manufacturing activities and non-clinical studies for the Phase 3 clinical program which were not incurred in the current period.

Interest Income

Interest income was $887 and $19,721, for the three months ended, and $9,941 and $56,049, for the nine months ended, September 30, 2009 and 2008, respectively. The decreases were due to a lower average cash balance and lower interest rates during the three and nine month periods ended September 30, 2009, as compared to the same periods in the prior year.

Gain on Settlement

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

Liquidity and Capital Resources

Since inception through September 30, 2009, we have incurred losses of approximately $14.2 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 September 30, 2009, we had $2.0 million in cash and cash equivalents. On each of September 17, 2007, and October 10, 2007, we completed private placements to selected institutional and accredited investors. In connection with these private placements, we raised approximately $3.8 million (net of placement agent fees and other costs aggregating $342,105) from the issuance of 2,071,834 shares of common stock and detachable redeemable warrants to purchase 517,958 shares of our common stock at a cash exercise price of $4.00 per share and a cashless exercise price of $5.00 per share. In May 2008, we completed another private placement to accredited investors, where we raised gross proceeds of approximately $4.0 million (net of legal fees aggregating $22,470) from the issuance of 1,818,180 shares of common stock and detachable warrants to purchase 227,272 shares of our common stock at a cash exercise price of $4.40 per share and a cashless exercise price of $5.50 per share.

We have limited funds to support our operations. 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 as a going concern subsequent to June 30, 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 September 30, 2009, with our current cash and cash equivalents position, we have forecasted and anticipate having adequate resources in order to execute a portion of our operating plan through the second quarter of 2010, which would include the final payments for the Phase 3 clinical recently completed. 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 on a timely basis, we may be required to cease operations.

Critical Accounting Policies

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

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

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

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

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

Off-Balance Sheet Arrangements

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

Recent Accounting Pronouncements

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

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

Item 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 Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

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

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 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, 2008, as filed with the Securities and Exchange Commission on March 26, 2009.

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 September 30, 2009, we have a deficit accumulated during the development stage of approximately $14.2 million, and for the nine months ended September 30, 2009, we experienced a net loss of approximately $3.8 million. In addition, we expect to incur increasing operating losses for the foreseeable future as we continue to incur costs for research and development and clinical trials, and in other development activities. Our ability to generate revenue and achieve profitability depends upon our ability, alone or with others, to complete the development of our proposed products, obtain the required regulatory approvals and manufacture, market and sell our proposed products. Development is costly and requires significant investment. In addition, we may choose to in-license rights to particular drugs or active ingredients for use in cosmetic/cosmeceutical products. The license fees for such drugs or active ingredients may increase our costs.

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

We will need additional financing to execute our business plan, 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 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 September 30, 2009, with our current cash and cash equivalents position, we have forecasted and anticipate having adequate resources in order to execute a portion of our operating plan through the second quarter of 2010, which would include completing the Phase 3 clinical trial currently in progress for Ketotransdel®. However, in order to execute the second Phase 3 clinical trial of Ketotransdel®, which is currently required by the FDA to obtain final regulatory approval for Ketotransdel®, we would need to secure additional funds. If adequate financing is not available, we will not be able to conduct the second Phase 3 clinical trial. In addition, if one or more of the risks discussed in these risk factors occur or our expenses exceed our expectations, we may be required to raise funds sooner than anticipated.

We may be required to pursue sources of additional capital to fund our operations through various means, including equity or debt financing, funding from a corporate partnership or licensing arrangement or any similar financing. Future financings through equity investments are likely to be dilutive to existing stockholders. Also, the terms of securities we may issue in future capital transactions may be more favorable for our new investors. Newly issued securities may include preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have additional dilutive effects. In addition, if we raise additional funds through collaboration and licensing arrangements, we may be required to relinquish potentially valuable rights to our product candidates or proprietary technologies, or grant licenses on terms that are not favorable to us. Further, we may incur substantial costs in pursuing future capital and/or financing, including investment banking fees, legal fees, accounting fees, printing and distribution expenses and other costs. We may also be required to recognize non-cash expenses in connection with certain securities we may issue, such as convertible notes and warrants, which will adversely impact our financial 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 execute the second Phase 3 clinical trial of Ketotransdel® currently required by the FDA and any other clinical trials we would want to commence for other products, could further impact the availability or cost of future financings. As a result, there can be no assurance that additional funds will be available when needed from any source or, if available, will be available on terms that are acceptable to us. If we are unable to raise funds to satisfy our capital needs on a timely basis, we may be required to cease operations.

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

We are subject to extensive government regulations. The process of obtaining FDA approval is costly, time consuming, uncertain and subject to unanticipated delays. Before obtaining regulatory approvals for the sale of any of our products, we must demonstrate through preclinical studies and clinical trials that the product is safe and effective for each intended use. Preclinical and clinical studies may fail to demonstrate the safety and effectiveness of a product. Even promising results from preclinical and early clinical studies do not always accurately predict results in later, large scale trials. A failure to demonstrate safety and efficacy would result in our failure to obtain regulatory approvals. Moreover, if the FDA grants regulatory approval of a product, the approval may be limited to specific indications or limited with respect to its distribution, which could limit revenues. On October 6, 2009, as reported in our Form 8-K filing, we announced top-line clinical results for Ketotransdel® in a Phase 3 trial.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We may be subject to product liability claims.

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

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

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

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

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

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

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

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

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

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

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

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

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

We recently expanded our product development program to include cosmetic/cosmeceutical products, which utilize our patented transdermal delivery system technology, Transdel™. Because our primary focus will remain on seeking FDA approval for Ketotransdel, we plan to use limited resources on our cosmetic/cosmeceutical development program and, as a result, we will need to partner with third parties to perform formulation, clinical research, manufacturing, sales and marketing activities. We have initial clinical information to support the efficacy of anti-cellulite and anti-aging products, and we are pursuing discussions with potential sales and marketing partners for these products. We cannot assure you that the results of any further studies that may be required before these products can be commercialized will be successful, that we will enter into commercial agreements (in addition to the license agreement entered into in the second quarter 2009 with JH Direct, LLC) with third parties for these products on acceptable terms, or at all, or that these products will be successfully commercialized. Even if we are not required to obtain FDA pre-market approval for these products, we will still be subject to a number of federal and state regulations, including regulation by the FDA and the Federal Trade Commission on any marketing claims we make about our products. There is no assurance that we will be successful in developing any other cosmetic/cosmeceutical products, including products for varicose veins and hyperpigmentation. Any products we develop may cause undesirable side effects that could limit their use, require their removal from the market and subject us to adverse regulatory action and product liability claims. Further, the market for cosmetic/cosmeceutical products is highly competitive, and there is no assurance that our products will be able to compete against the many products and treatments currently being offered or under development by other established, well-known and well-financed cosmetic, health care and pharmaceutical companies.

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

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

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

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

Risks Relating to Our Industry

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

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

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

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

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

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

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

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

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

Risks Relating to the Common Stock

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

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

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

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

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

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

Our stock price may be volatile.

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

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

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

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

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

Our common stock may be deemed a "penny stock", which would make it more difficult for our investors to sell their shares.

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

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

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

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

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

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

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

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

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

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

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

None

Item 6. Exhibits

Exhibit Number	Description
31.1*	Section 302 Certification of Principal Executive Officer
31.2*	Section 302 Certification of 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: November 16, 2009

By: /s/ Juliet Singh
Juliet Singh, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT INDEX

Exhibit Number	Description
31.1*	Section 302 Certification of Principal Executive Officer
31.2*	Section 302 Certification of Principal Financial Officer
32.1*	Section 906 Certification of Principal Executive Officer and Principal Financial Officer

* Filed herewith.

EXHIBIT 31.1

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

I, Juliet Singh, Ph.D., 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) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with 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) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and 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: November 16, 2009

/s/ Juliet Singh
Juliet Singh, Ph.D., Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

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

I, John T. Lomoro, 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) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with 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) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the 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: November 16, 2009

/s/ John T. Lomoro
John T. Lomoro, Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32.1

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 September 30, 2009 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, Juliet Singh, Ph.D., the Chief Executive Officer of Transdel Pharmaceuticals, Inc., and John T. Lomoro, the Chief Financial Officer of Transdel Pharmaceuticals, Inc., each certifies 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: November 16, 2009

/s/ Juliet Singh
Juliet Singh, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

/s/ John T. Lomoro
John T. Lomoro
Chief Financial Officer
(Principal Financial Officer)