

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended **June 30, 2008**

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

For the transition period from _____ to _____

Commission file number: 000-52998

Transdel Pharmaceuticals, Inc.

(Exact Name of Registrant in Its Charter)

Delaware

(State or Other Jurisdiction of Incorporation
or Organization)

45-0567010

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

4225 Executive Square, Suite 485
La Jolla, CA

(Address of Principal Executive Offices)

92037

(Zip Code)

(858) 457-5300

(Registrant's Telephone Number, Including Area Code)

4225 Executive Square, Suite 460
La Jolla, CA 92037

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

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

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

As of August 7, 2008, 15,545,184 shares of issuer's common stock, with \$0.001 par value per share were outstanding.

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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

	<u>June 30,</u> <u>2008</u>	<u>December 31,</u> <u>2007</u>
	<u>(Unaudited)</u>	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 6,710,629	\$ 3,706,369
Prepaid consulting fees	138,751	488,748
Prepaid expenses and other current assets	<u>330,067</u>	<u>45,604</u>
Total current assets	7,179,447	4,240,721
Equipment, net	<u>2,978</u>	<u>—</u>
Total assets	<u>\$ 7,182,425</u>	<u>\$ 4,240,721</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 879,416	\$ 696,340
Accrued expenses and payroll liabilities	<u>41,363</u>	<u>53,901</u>
Total liabilities	<u>920,779</u>	<u>750,241</u>
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, 15,545,184 and 13,727,004 shares outstanding as of June 30, 2008 and December 31, 2007, respectively	15,545	13,727
Additional paid-in capital	14,859,680	10,554,298
Deficit accumulated during the development stage	<u>(8,613,579)</u>	<u>(7,077,545)</u>
Total stockholders' equity	<u>6,261,646</u>	<u>3,490,480</u>
Total liabilities and stockholders' equity	<u>\$ 7,182,425</u>	<u>\$ 4,240,721</u>

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

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>		For the Period From July 24, 1998 (Inception) Through June 30, 2008
	<u>2008</u>	<u>2007</u>	<u>2008</u>	<u>2007</u>	<u>2008</u>
Operating expenses:					
Selling, general and administrative	\$ 562,324	\$ 151,115	\$ 1,010,179	\$ 251,336	\$ 4,093,760
Research and development	718,083	47,547	937,183	85,047	3,494,927
Operating loss	<u>1,280,407</u>	<u>198,662</u>	<u>1,947,362</u>	<u>336,383</u>	<u>7,588,687</u>
Other income (expense):					
Interest expense	—	(8,394)	—	(10,601)	(1,575,755)
Interest income	17,094	1,369	36,328	1,369	85,949
Gain on forgiveness of liabilities	—	89,914	—	89,914	89,914
Gain on settlement	—	—	375,000	—	375,000
Total other income (expense), net	<u>17,094</u>	<u>82,889</u>	<u>411,328</u>	<u>80,682</u>	<u>(1,024,892)</u>
Net loss	<u>\$ (1,263,313)</u>	<u>\$ (115,773)</u>	<u>\$ (1,536,034)</u>	<u>\$ (255,701)</u>	<u>\$ 8,613,579</u>
Basic and diluted loss per common share	<u>\$ (0.09)</u>	<u>\$ (0.01)</u>	<u>\$ (0.11)</u>	<u>\$ (0.04)</u>	
Weighted average common shares outstanding	<u>14,726,004</u>	<u>7,793,441</u>	<u>14,226,504</u>	<u>6,421,544</u>	

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

	Six Months Ended June 30,		For The Period From July 24, 1998 (Inception) Through June 30, 2008
	2008	2007	2008
Cash from operating activities:			
Net loss	\$ (1,536,034)	\$ (255,701)	\$ (8,613,579)
Adjustments to reconcile net loss to net cash used in operating activities:			
Estimated fair value of contributed services	—	175,000	2,475,000
Gain on forgiveness of liabilities	—	—	(89,914)
Amortization of prepaid consulting fees and depreciation	303,983	—	505,235
Non-cash interest on notes payable	—	10,601	1,575,755
Stock-based compensation	412,089	—	596,611
Changes in operating assets and liabilities:			
Prepaid consulting costs	—	—	(140,000)
Prepaid expenses and other current assets	(284,463)	(96,802)	(330,067)
Accounts payable	183,076	(96,260)	969,330
Accrued expenses and payroll liabilities	(12,538)	32,177	41,363
Net cash used in operating activities	(933,887)	(230,985)	(3,010,266)
Cash flows from investing activities:			
Purchase of equipment	(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	1,500,000
Capital contributions	—	105,907	168,707
Proceeds from purchase of common stock and exercise of warrants and stock options	—	25,700	49,950
Net proceeds from Private Placements	3,941,301	—	7,779,092
Net cash provided by financing activities	3,941,301	1,631,607	9,724,049
Net change in cash	3,004,260	1,400,622	6,710,629
Cash, beginning of period	3,706,369	542	—
Cash, end of period	\$ 6,710,629	\$ 1,401,164	\$ 6,710,629
Supplemental disclosure of cash flow information:			
(Revaluation) issuance of common stock and warrants to consulting firms for prepaid consulting fees, net	\$ (46,190)	\$ —	\$ 503,810
Conversion of notes payable and accrued interest into common stock	\$ —	\$ —	\$ 1,530,177
Forgiveness of notes payable and accrued interest to shareholders	\$ —	\$ 241,701	\$ 241,701
Conversion of notes payable to shareholders	\$ —	\$ —	\$ 196,300

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

Note 1. Business Description

Transdel Pharmaceuticals, Inc. (“Transdel” or the “Company”) is a specialty pharmaceutical company focused on the development and commercialization of non-invasive topically delivered medications. The Company’s lead topical drug, Ketotransdel™, utilizes the Company’s proprietary Transdel™ cream formulation to facilitate the passage of ketoprofen, a non-steroidal anti-inflammatory drug (“NSAID”), through the skin barrier to reach targeted underlying tissue where the drug exerts its prolonged localized anti-inflammatory and analgesic effect. The Company is also investigating other drug candidates and treatments for transdermal delivery using the Transdel™ platform technology for products in pain management and other therapeutic areas.

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 June 30, 2008, the results of operations for three and six months ended June 30, 2008 and 2007, and cash flows for the six months ended June 30, 2008 and 2007, fairly stated. The condensed consolidated financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2007 contained in Form 10-KSB filed on March 26, 2008 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 shares of Transdel common stock 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 included 195,313 shares of restricted stock which were subject to forfeiture (see Note 7), were issued to the holders of Transdel Holdings’ common stock. As a result of the transaction, the former owners of Transdel Holdings became the controlling stockholders of Transdel. Accordingly, the merger of Transdel Holdings and Transdel is a reverse merger that has been accounted for as a recapitalization of Transdel Holdings.

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

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

Note 4. Summary of Significant Accounting Policies

Going Concern. The accompanying unaudited 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 an accumulated deficit during the development stage of \$8,613,579 at June 30, 2008. These factors raise substantial doubt about the Company’s ability to continue as a going concern.

The Company’s continuation as a going concern is dependent on its ability to obtain additional financing to fund operations, implement its business model, and ultimately, to attain profitable operations. The Company intends to obtain additional financing to fund its operations through equity or debt financing or a corporate partnership for its lead topical drug, Ketotransdel™. However, there is no assurance that sufficient financing will be available or, if available, on terms that would be acceptable to the Company.

The unaudited 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 in Statement of Financial Accounting Standards (“SFAS”) No. 7, *Accounting and Reporting by Development Stage Enterprises*. The Company is devoting substantially all of its present efforts to establish a new business, and its planned principal operations have not yet commenced. All losses accumulated since Inception have been considered as part of the Company’s development stage activities.

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

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

Concentrations of Credit Risk. Financial instruments that potentially subject the Company to a concentration of credit risk consist primarily of cash and cash equivalents. In order to minimize the Company’s risk related to the cash equivalents, they are maintained in a money market demand account. Due to the short-term nature of this investment, the Company believes that there is no material exposure to interest rate risk. The Company maintains its cash and cash equivalents at a high-quality institution that is insured by the Federal Deposit Insurance Corporation (“FDIC”). At June 30, 2008, the Company had approximately \$6,610,629 on deposit in excess of the federally insured limit of \$100,000. The Company performs an ongoing evaluation of this institution to limit its concentration of risk exposure.

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

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

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 the SEC Staff Accounting Bulletin (“SAB”) No. 101, *Revenue Recognition*, as amended by SAB No. 104. SAB No. 104 requires that four basic criteria must be met before revenue can be recognized: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred; (3) the selling price is fixed and determinable; and (4) collectibility is reasonably assured. Determination of criteria (3) and (4) will be based on management’s judgments regarding the fixed nature of the selling prices of the products delivered and the collectibility of those amounts. Provisions for discounts and rebates to customers, estimated returns and allowances, and other adjustments will be provided for in the same period the related sales are recorded. The Company will defer any revenue for which the product has not been delivered or for which services have not been rendered or are subject to refund until such time that the Company and the customer jointly determine that the product has been delivered or services have been rendered or no refund will be required.

As of June 30, 2008, the Company had not generated any revenues and the Company does not anticipate that it will generate any revenues until one or more of its drug candidates are approved by the U.S. Food and Drug Administration (“FDA”) and effective sales and marketing support are in place. The FDA approval process is highly uncertain and the Company cannot estimate when it will generate revenues at this time.

Stock-Based Compensation. Effective January 1, 2006, the Company adopted SFAS No. 123 (revised 2004), *Share-Based Payment*, (“SFAS No. 123R”), which is a revision of SFAS No. 123, *Accounting for Stock-Based Compensation*. SFAS No. 123R supersedes Accounting Principles Board Opinion (“APB”) No. 25, *Accounting for Stock Issued to Employees*, and amends SFAS No. 95, *Statement of Cash Flows*. SFAS 123R requires all share-based payments to employees, including grants of employee stock options and restricted stock grants, to be recognized in the financial statements based upon their fair values. The Company recorded total stock-based compensation of \$412,089, \$0 and \$596,611 for the six months ended June 30, 2008 and 2007 and for the period from Inception to June 30, 2008, respectively, for options and restricted stock granted and vested which is included in general and administrative expenses and research and development expenses in the amount of \$129,366 and \$282,723, respectively, for the six months ended June 30, 2008 and \$192,945 and \$403,666, respectively, for the period from Inception to June 30, 2008. The fair value of the unvested stock option grants amounted to approximately \$885,000 as of June 30, 2008.

The Company’s accounting policy for equity instruments issued to consultants and vendors in exchange for goods and services follows the provisions of SFAS No. 123, EITF No. 96-18, *Accounting for Equity Instruments That are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, and EITF No. 00-18, *Accounting Recognition for Certain Transactions Involving Equity Instruments Granted to Other Than Employees*. As such, the value of the applicable stock-based compensation is periodically remeasured and income or expense is recognized during their vesting terms. The measurement date for the fair value of the equity instruments issued is determined at the earlier of (i) the date at which a commitment for performance by the consultant or vendor is reached or (ii) the date at which the consultant or vendor’s performance is complete. In the case of equity instruments issued to consultants, the fair value of the equity instrument is recognized over the term of the consulting agreement. In accordance with EITF No. 00-18, an asset acquired in exchange for the issuance of fully vested, nonforfeitable equity instruments should not be presented or classified as an offset to equity on the grantor’s balance sheet once the equity instrument is granted for accounting purposes. Accordingly, the Company recorded the fair value of the common stock issued for future consulting services as prepaid consulting fees in its condensed consolidated balance sheets (see Note 6).

Basic and Diluted Loss per Common Share. In accordance with SFAS No. 128, *Earnings Per Share*, and SAB No. 98, basic net loss per common share is computed by dividing net loss for the period by the weighted average number of common shares outstanding during the period. Under SFAS No. 128, diluted net loss per share is computed by dividing the net loss for the period by the weighted average number of common and common equivalent shares, such as stock options and warrants outstanding during the period.

Basic and diluted net loss applicable to common stock per share is computed using the weighted average number of common shares outstanding during the period. Common stock equivalents (prior to application of the treasury stock, if converted method) from stock options, warrants and convertible notes were 1,812,730 and 1,523,076 for the six months ended June 30, 2008 and 2007, respectively, are excluded from the calculation of diluted net loss per share for all periods presented because the effect is anti-dilutive.

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

Note 4. Summary of Significant Accounting Policies, continued

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 and realizability of contributed services, stock options, deferred taxes and stock-based compensation issued to non-employees. Actual results could differ from those estimates.

Note 5. Notes Payable

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

In May 2007, the holders of the Stockholders' Notes and related warrants forgave the amounts due and forfeited the related warrants. In connection with the forgiveness, the Company recorded additional paid-in capital of \$241,701 equal to the value of the Stockholders' Notes and related accrued interest. Interest expense on the Stockholders' Notes was \$3,150 and \$15,401 for six months ended June 30, 2007 and the period from Inception to June 30, 2008, respectively.

In May and June 2007, the Company issued convertible notes payable to various lenders for an aggregate amount of \$1,500,000 (collectively, the "2007 Notes"). Each of the 2007 Notes included interest at 7% per annum and were to mature on December 16, 2007 ("Maturity Date"). However, as a result of the Merger and Private Placement (see Note 6), the entire outstanding principal amount and accrued interest was converted into the Company's common stock at a conversion price equal to \$1.00 per share, which resulted in the issuance of 1,530,177 shares. Also, the Company recorded a debt discount of \$1,530,177, which was amortized immediately to interest expense upon the conversion of the 2007 Notes. Excluding the debt discount, interest expense on the 2007 Notes was \$7,451 and \$30,177 for the six months ended June 30, 2007 and the period from Inception to June 30, 2008.

Note 6. Stockholders' Equity

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.

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 incurred in 2008, and issued warrants to purchase up to 33,750 shares of common stock for a period of three years at a cash and cashless exercise price of \$4.00 and \$5.00 per share, respectively.

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

Note 6. Stockholders' Equity (continued)

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 are being amortized over the one-year terms.

In accordance with EITF No. 00-18, 100,000 of the 275,000 shares of common stock are subject to remeasurement on a periodic basis as the performance condition for these shares is 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, is complete, they were revalued as of the February termination date to \$60,000, which was the fair market value of the shares on the termination date. Second, the remaining 50,000 shares that were transferred to the other firm will be utilized for the payment of investor communications services to be provided through September 2008. In accordance with the related agreement, the Company initially recorded the value of these shares at \$100,000, which was revalued at June 30, 2008 to \$92,500 (the estimated fair market value based on the closing market price). In the aggregate, the remeasurement of the 50,000 shares earned and the transfer of the remaining 50,000 shares resulted in a reduction of additional paid in capital of \$47,500 (\$200,000 original value less \$152,500 remeasured value). For the six months ended June 30, 2008 and 2007 and for the period from Inception through June 30, 2008, the Company amortized \$303,807, \$0 and \$505,058, respectively, of prepaid consulting fees which is included as part of selling, general and administrative expenses.

On April 24, 2008, the Company entered into a one-year consulting agreement with a firm to provide the Company with financial advisory services. As compensation for the services, the Company issued a three-year warrant to purchase 5,000 shares of the Company's common stock at a cash and cashless price of \$2.00 per share. The fair value of the warrant, determined based on the Black-Scholes pricing model, was valued at \$1,310, which is being amortized over the one-year term.

Note 7. Stock Option Plans

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 1,500,000 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, for one year following the initial closing of the Private Placement, the Company may not issue options to purchase shares of common stock at an exercise price below \$2.00 per share. In addition, for a period of 18 months following the initial closing of the Private Placement, the Company may not file a registration statement, including, without limitation, a registration statement on Form S-8, covering the resale of any shares of common stock issued pursuant to an employee benefit plan.

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

Note 7. Stock Option Plans, continued

A summary of the status of the Plan for the six months ended June 30, 2008 is as follows:

	Number of Shares	Weighted Average Exercise Price
Options outstanding – Beginning of Period	610,000	\$ 2.01
Granted	600,000	2.00
Exercised	—	—
Cancelled	(200,000)	(2.00)
Options outstanding – End of Period	<u>1,010,000</u>	<u>\$ 2.01</u>
Options exercisable – End of Period	<u>125,091</u>	
Weighted average remaining contractual life of the outstanding options – End of period	<u>9.4 years</u>	
Aggregate intrinsic value – End of Period	<u>—</u>	

All options granted to date expire on the ten year anniversary of the issuance date and vest on a quarterly basis over one to three years. The Company uses the Black-Scholes option pricing model to estimate the grant-date fair value of share-based awards under SFAS No. 123R. The Black-Scholes model requires subjective assumptions regarding future stock price volatility and expected time to exercise, along with assumptions about the risk-free interest rate and expected dividends, which affect the estimated fair values of the Company's stock-based awards. The expected term of options granted was determined in accordance with the simplified approach as defined by SAB No. 107, *Share-Based Payment*, as the Company has very limited historical data on employee exercises and post-vesting employment termination behavior. The expected volatility is based on the historical volatilities of the common stock of comparable publicly traded companies based on the Company's belief that it currently has limited historical data regarding the volatility of its stock price on which to base a meaningful estimate of expected volatility. The risk-free rate selected to value any particular grant is based on the U.S. Treasury rate that corresponds to the expected term of the grant effective as of the date of the grant. The Company used 0% as an expected dividend yield assumption. These factors could change in the future, affecting the determination of stock-based compensation expense in future periods. Utilizing these assumptions, the fair value is determined at the date of grant. In accordance with SFAS No. 123R, the financial statement effect of forfeitures is estimated at the time of grant and revised, if necessary, if the actual effect differs from those estimates. As of June 30, 2008, management's future estimates are that the effect of forfeitures on the financial statements will be insignificant. As of June 30, 2008, there was approximately \$885,000 of total unrecognized compensation expense related to unvested stock-based compensation under the Plan. That expense is expected to be recognized over the weighted-average period of 2.9 years.

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

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

Note 8. Stock Warrants

In addition to the warrants issued in conjunction with the Private Placement and the Follow-On Private Placement, the Company issued a warrant to purchase shares of its common stock to a firm in connection with a consulting agreement at an exercise price of \$4.00 (or cashless exercise price of \$5.00). The expiration of the outstanding warrants occurs through May 2013 at various periods (see Note 6).

A summary of the status of the warrants for the period ended June 30, 2008, is as follows:

	Number of Shares Subject to Warrants Outstanding	Weighted- Average Exercise Price
Warrants outstanding – Beginning of Period	570,458	\$ 4.00
Granted	232,272	4.35
Exercised	—	—
Expired	—	—
Warrants outstanding – End of Period	<u>802,730</u>	<u>\$ 4.10</u>
Weighted average remaining contractual life of the outstanding warrants – End of Period	<u>4.32 years</u>	

Note 9. Recent Accounting Pronouncements

The following pronouncements have been issued by the Financial Accounting Standards Board (“FASB”):

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

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

Note 10. Commitments and Contingencies

Indemnities and Guarantees

The Company has made certain indemnities and guarantees, under which it may be required to make payments to a guaranteed or indemnified party, in relation to certain actions or transactions. The Company indemnifies its directors, officers, employees and agents, as permitted under the laws of the State of Delaware. The duration of the guarantees and indemnities varies, and is generally tied to the life of the agreement. 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 unaudited condensed consolidated balance sheet as of June 30, 2008.

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

Note 10. Commitments and Contingencies (continued)

Mediation Settlement

On February 5, 2008, as a result of mediation, the Company and a previously retained law firm reached an agreement related to certain alleged claims the Company had against 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 Company, the law firm and any other parties involved in the mediation, released and waived any future claims against each other, whether known or unknown at the time of the settlement. The net amount received by the Company was \$375,000 after fees paid to the Company's counsel and an executive and director of the Company. The fees paid to the executive and director, which were previously approved by the Board of Directors, are due to 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 prior to the Merger.

Cato Research Ltd. Agreement

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

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

Overview

We are a specialty pharmaceutical company focused on the development and commercialization of non-invasive topically delivered medications. Our lead topical drug, Ketotransdel™, utilizes our proprietary Transdel™ cream formulation to facilitate the passage of ketoprofen, a non-steroidal anti-inflammatory drug ("NSAID"), through the skin barrier to reach targeted underlying tissues where the drug exerts its localized anti-inflammatory and analgesic effect. A Phase 1/2 clinical trial supported the safety and efficacy of Ketotransdel™ for acute pain and muscle soreness.

Plan of Operations

For the next twelve months, our current operating plan is focused on the development of our lead drug, Ketotransdel™ for the indication of acute musculoskeletal pain. On June 16, 2008, we announced that we initiated our Phase 3 clinical program for our novel analgesic and anti-inflammatory topical cream, Ketotransdel™, which contains ketoprofen. The first Phase 3 study will consist of a randomized, double-blind, placebo controlled trial to evaluate the efficacy and safety of Ketotransdel™ in acute soft tissue injuries of the upper and lower extremities over a one week treatment period with a one week post-treatment follow-up for safety. The multi-center trial will be conducted at approximately 25 to 35 sites, mainly in the United States and potentially in Canada, and will enroll approximately 350 patients, randomized 1:1 ratio Ketotransdel™ (active) versus placebo vehicle (identical to active without the drug ketoprofen). The primary efficacy endpoint is the difference in the change of baseline of pain during normal activity for the past 24 hours from measurement at the Day 3 clinical visit between active and placebo measured by using the Visual Analogue Scale (VAS), a well known and validated instrument for pain measurement. Secondary endpoints include safety assessments and other efficacy parameters measured by VAS. As of July 31, 2008, we have initiated two study sites for this Phase 3 study. We would anticipate reporting top-line results in the second half of 2009. In addition, as required by the FDA, we will be initiating a second Phase 3 clinical study in acute musculoskeletal pain, potentially for the treatment of acute flare in osteoarthritis patients. We are currently assessing the design and timing of this additional study that will support the registration of Ketotransdel™ in the United States.

If and when the FDA approves Ketotransdel™ for treatment of acute pain, we intend to pursue FDA approval of Ketotransdel™ for other indications. We believe that the clinical success of Ketotransdel™ will facilitate the use of the Transdel™ delivery technology in other products. We are also investigating other drug candidates and treatments for transdermal delivery using the Transdel™ platform technology for products in pain management and other therapeutic areas. Furthermore, we are exploring potential partnerships with U.S. and foreign based companies that have sales and marketing infrastructures to support Ketotransdel™ in the event that the product is approved and commercialized. We are also looking to out-license our Transdel™ drug delivery technology for the development and commercialization of additional innovative drug products. In addition, we are exploring opportunities in the cosmeceutical industry which may use our patented delivery technology. There can be no assurance that any of these activities will lead to definitive agreements.

We believe that our current staff is sufficient to carry out our business plan in the coming twelve months, however, if our operations in the future require it, we will consider the employment of additional staff.

Liquidity and Capital Resources

Since July 24, 1998 ("Inception") through June 30, 2008, we have incurred losses of approximately \$8.6 million. These losses are primarily due to general and administrative and research and development expenses. Historically, our operations have been financed through capital contributions and debt and equity financings.

As of June 30, 2008, we had \$6.7 million in cash. On each of September 17, 2007, and October 10, 2007, we completed private placements to selected institutional and individual investors of our common stock and warrants. In connection with the 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 \$4.0 million 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 are assessing our financing needs for the foreseeable future. In order to execute our operating plan over the next twelve months, which includes the conduct of the Phase 3 clinical program, we will be required to raise additional funds to support our operations. This funding requirement raises substantial doubt about our ability to continue as a going concern. The accompanying unaudited 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.

Our continuation as a going concern is dependent on our ability to obtain additional financing to fund operations, implement our business model, and ultimately, to attain profitable operations. We intend to obtain additional financing to fund our operations through, and without limitation to, equity or debt financing, funding from a corporate partnership or licensing arrangement or any similar financing. There can be no assurance that such financing will be available on terms favorable to us or at all. If adequate financing is not available, we will have to delay, postpone or terminate the clinical program and curtail general and administrative operations, which would have a material adverse effect on us.

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

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

Stock-Based Compensation. Effective January 1, 2006, we adopted Statement of Financial Accounting Standards (“SFAS”) No. 123 (revised 2004), *Share-Based Payment*, (“SFAS No. 123R”), which is a revision of SFAS No. 123, *Accounting for Stock-Based Compensation*. SFAS No. 123R supersedes Accounting Principles Board No. 25, *Accounting for Stock Issued to Employees*, and amends SFAS No. 95, *Statement of Cash Flows*. SFAS No. 123R requires all share-based payments to employees, including grants of employee stock options and restricted stock grants, to be recognized in the financial statements based upon their fair values. We use the Black-Scholes option pricing model to estimate the grant-date fair value of share-based awards under SFAS No. 123R. Fair value is determined at the date of grant. In accordance with SFAS No. 123R, the financial statement effect of forfeitures is estimated at the time of grant and revised, if necessary, if the actual effect differs from those estimates. As of June 30, 2008, management estimates that the effect of forfeitures on the unaudited condensed financial statements will be insignificant.

Our accounting policy for equity instruments issued to consultants and vendors in exchange for goods and services follows the provisions of SFAS No. 123, Emerging Issues Task Force (“EITF”) No. 96-18, *Accounting for Equity Instruments That are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services* and EITF No. 00-18, *Accounting Recognition for Certain Transactions Involving Equity Instruments Granted to Other Than Employees*. As such, the value of the applicable stock-based compensation is periodically remeasured and income or expense is recognized during the vesting terms. The measurement date for the fair value of the equity instruments issued is determined at the earlier of (i) the date at which a commitment for performance by the consultant or vendor is reached or (ii) the date at which the consultant or vendor’s performance is complete. In the case of equity instruments issued to consultants, the fair value of the equity instrument is recognized over the term of the consulting agreement. In accordance with EITF No. 00-18, an asset acquired in exchange for the issuance of fully vested, nonforfeitable equity instruments should not be presented or classified as an offset to equity on the grantor’s balance sheet once the equity instrument is granted for accounting purposes. Accordingly, we recorded the fair value of the common stock issued for future consulting services as prepaid consulting fees in our unaudited condensed consolidated balance sheet.

Beneficial Conversion Feature. The convertible features of the convertible notes provided for a rate of conversion that was below market value (see Note 5). Such feature is normally characterized as a “beneficial conversion feature” (“BCF”). Pursuant to EITF No. 98-5 *Accounting For Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratio* and EITF No. 00-27, *Application of EITF Issue No. 98-5 To Certain Convertible Instruments*, the relative fair values of the BCFs have been recorded as a discount from the face amount of the respective debt instrument. We recorded the corresponding debt discount related to the BCF as interest expense, in fiscal year 2007, when the related instrument was converted into its common stock.

Off-Balance Sheet Arrangements

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

Recent Accounting Pronouncements

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

Item 4T. 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.

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 2. Unregistered Sales of Equity Securities and Use of Proceeds

Except as previously included in our Current Reports on Form 8-K filed with the Securities and Exchange Commission on May 15, 2008, we have not sold any equity securities during the period covered by this quarterly report on Form 10-Q that were not registered under the Securities Act of 1933, as amended.

Item 6. Exhibits

Exhibit Number	Description
10.1*	Clinical Trial Services Agreement by and between Transdel Pharmaceuticals, Inc. and Cato Research Ltd.
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: August 11, 2008

By: /s/ Juliet Singh

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

EXHIBIT INDEX

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* Filed herewith.



Proposal for Clinical Trial Services to Support Transdel Pharmaceuticals Inc.'s Ketotransdel for the Treatment of Mild to Moderate Acute Soft Tissue Injury

Prepared for:



4225 Executive Square Suite 460
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Revised: 10 June 2008

Prepared by:
Cato Research Ltd.

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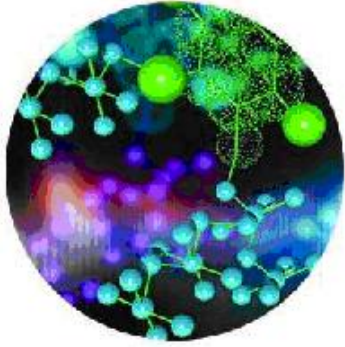
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Overview of the Proposal



When it comes to developing human therapeutics, Cato Research relies on sound principles of science and medicine.

This proposal is organized into the following parts:

Part A

- Introduction to Cato Research and Summary of Activities

Part B

- Experience in Neurology Clinical Trials

Part C

- Terms of Work

Appendix 1

- Project Timelines and Project Assumptions
- Summarized and Details of Costs, Estimated Pass Through Expenses, Estimated Milestone Completion Dates, and Fees Associated with Milestones

This proposal has been prepared based on information provided by Transdel Pharmaceuticals, Inc. and Cato Research's experience with similar projects. It is available to Transdel Pharmaceuticals for 45 days from the date of issuance. The proposal constitutes Cato Research confidential information and should not be disclosed to any third party without Cato Research's prior written consent.

Part A

**Introduction to Cato Research
and Summary of Activities**

Overview of Cato Research

Organization

Cato Research specializes in complex development programs requiring innovative regulatory and clinical strategies for pharmaceutical, biotechnology, and medical device companies.

Cato Research is a full-service CRO offering integrated drug development services, including clinical trial support and regulatory and product development strategy for drugs, biologics, diagnostics, and medical devices. Our staff has medical and scientific expertise necessary for the successful conduct of development programs across many different therapeutic areas and in multiple locations worldwide. We have offices in strategic locations around the world, as indicated on the cover page. Our staff members have relevant and diverse backgrounds, including previous experience in the pharmaceutical industry, biotechnology companies, academia, as well as basic and clinical research programs.

Founded in 1988, Cato Research has earned a reputation for speed and efficiency without sacrificing quality.

Regulatory Services

- Strategic consulting
- Integrated development plan preparation
- Pre-Investigational New Drug application (IND) and pre-investigational device exemption meeting package preparation and meeting conduct
- IND preparation and submission (common technical document and electronic common technical document format)
- Marketing application writing and submission
- Regulatory agency interactions
- Chemistry, manufacturing, and controls program management
- Nonclinical program design and management

Through strategic growth, Cato Research is positioned as a midsize CRO in key North American and international markets. Focusing on our core expertise in regulatory strategy, project management, and clinical trial management, we offer integrated development services and solutions from discovery to postmarketing.

Clinical Trial Services

- Protocol and case report form (CRF) design
- Regulatory application preparation and submission
- Clinical monitoring and management
- Medical monitoring and pharmacovigilance
- Data management, including electronic data capture (EDC)
- Statistical analysis and clinical study report writing
- Project management

Our experienced, multidisciplinary project teams take pride in their work and use established project management processes to provide flexible, responsive, and personalized services in collaboration with our sponsors.

Primary Therapeutic Areas

- Neurology
- Oncology
- Cardiology

Cato Research's Clinical Strategies and Solutions

Cato Research appreciates the opportunity to provide a proposal for services to support Transdel's protocol entitled, "A Randomized, Multicenter, Double-Blind, Placebo-Controlled, Parallel-Group, Phase 3 Study to Assess the Efficacy and Safety of Ketotransdel™ (Ketoprofen Topical Cream 10%) in the Treatment of Mild to Moderate Acute Soft Tissue Injury"

Cato Research understands that Transdel is interested in the following services:

Clinical Trial Preparation: including preparation of trial documents and monitoring plan, project-related meetings, and project-specific training

Clinical Trial Conduct: including all site visits, medical monitoring, and medical coding

Pharmacovigilance: including setup of an Argus Safety database and processing of all serious adverse events (SAEs) during the study

Data Management (etrials®): including project initiation, development of an electronic CRF (eCRF), edit checks, and server implementation, investigator training, data project management, data archiving, and study closeout

Statistics: including production of final data displays, listings, summary tables, and figures

Clinical Study Reports: including preparation of the clinical study report and appendices in electronic format

Regulatory: including ongoing tracking and management of study-related regulatory documentation

Project Management: including preparation of project work plans, timelines, budgets and study reports; internal team meetings to monitor project progression; creation of tracking reports; and document management of files

Sponsor Interactions: including routine monthly conference calls to discuss project status and development issues

A comprehensive, itemized list of all proposed activities and their costs is provided in Part C of this proposal.

Cato Research is an experienced provider of high-quality clinical trial services: from protocol development and site selection to clinical monitoring, pharmacovigilance services and biostatistical analysis. Cato Research can support the timely and cost-effective development of Ketotransdel. As a midsize CRO, we are able to offer our sponsors personal attention as well as access to the expertise of our senior management.

We have highlighted a few areas here that embody our unique perspective on management of clinical studies.

Project Management

We are a matrix organization that draws members from various operational groups to staff a project team with specific emphasis on matching project needs with expertise. We believe it is important for our project managers to have a comprehensive understanding of the clinical trial environment. As such, many of our project managers are Ph.D.-level scientists, have obtained certified clinical research professionals (C.C.R.P.) certifications, are regulatory affairs certified (R.A.C.), or are certified project management professionals (P.M.P.). In addition to having project management responsibilities, our project managers can also author and review protocols, development plans, and regulatory documentation. It is our experience that this advanced training and comprehensive knowledge of the dynamic development environment give Cato Research project teams the ability to maximize creative strategies and solutions while at the same time, remaining time- and cost-efficient.

Our project teams are led by experienced project managers, overseen by a program director, a senior staff member who provides expertise and guidance as necessary, and supported by a project coordinator, who handles the day-to-day tracking and logistical activities.

Cato Research believes that effective project management begins at project initiation. We recommend development of a detailed project plan, including a communications plan, in conjunction with our sponsors to set expectations, establish communication flow, and outline project tracking methods. We also recommend holding a face-to-face kick-off meeting to define the project scope, priorities, and timelines.

Clinical Management

Cato Research offers experienced monitoring teams with strong health care backgrounds. Many of our clinical research associates (CRAs) and clinical study managers (CSMs) are nurses, have earned C.C.R.A. accreditation, or have earned EDC certification. We have strong internal continuing education programs for our clinical staff, including a yearly clinical conference, monthly trainings on selected key topics, and ongoing study groups.

For our teams to function in the most efficient and cost-effective manner, we have divided some tasks traditionally seen as a CRA role into an in-house CSM role with the following responsibilities:

- Conceptualizing and evaluating study strategies with input from appropriate Cato Research project team members
- Reviewing the progress of the Cato Research project team and resolving technical and interpersonal issues
- Providing technical and administrative leadership
- Coordinating and planning project deliverables

- Communicating with program director and Cato Research senior management on study-related issues that require additional input
- Initiating and maintaining effective and efficient communication with the Cato Research project team and with Transdel in order to ensure activities meet predefined timelines
- Verifying that effective and efficient communication and follow-up is occurring between CRAs, investigative sites, Transdel, and any other contracted organizations (e.g., core lab)

Having the CRA function as the primary site contact and the CSM function as the in-house contact allows more consistency with study activities, providing the sites with another contact and overall consistency for the study.

Clinical Monitoring

At each pre-study site selection visit, the Cato Research CRA will spend 4 hours on-site to confirm that facilities are appropriate and that the site staff is qualified to conduct this clinical study.

Each site initiation visit will include 8 hours on-site. We recommend conducting the site initiation visit after investigational product is received at the site to confirm that the site is ready to begin subject enrollment. Cato Research welcomes participation by a Transdel representative at this visit.

During the 8-hour periodic site visits, the Cato Research CRA will conduct 100% source document verification of CRFs, perform drug-accountability activities, and review the regulatory site files to verify compliance (e.g., confirming that each subject has an informed consent form on file). Cato Research recommends that the first monitoring visit occur immediately after the first subject is treated at each site. This schedule enables identification of any data issues early in the study. The Cato Research CRA will collect completed CRFs from the site for data verification, the CRA or the site will enter the CRFs into the EDC database, and will work with data management and the site to resolve any data queries. For site visits performed remotely, the Cato Research monitors will review data by using the EDC system. Following patient visits, sites will forward the source documents to Cato Research for verification.

At the conclusion of the study, Cato Research will conduct an 8-hour closeout visit at each study site. We recommend conducting this visit when almost all queries are resolved so that all site activities can be closed out at this time. The CRA will perform final study activities such as drug reconciliation/accountability and final regulatory document review at this visit.

Each visit will be performed according to Cato Research SOPs. After each visit, the CRA will prepare a monitoring trip report that uses Cato Research's standard format. The report will be reviewed by the CSM before being delivered to Transdel.

Medical Management and Pharmacovigilance

Our medical team is supported by a dedicated pharmacovigilance group established to handle the processing of SAE reports to regulatory authorities and investigators. In addition to premarketed safety reporting, this group provides postmarketing spontaneous adverse event reporting. Our personnel have the training, education, and experience to provide a comprehensive range of safety reporting services to meet the demands of SAE reporting requirements of global drug/biologic/device investigational clinical programs and postmarketing surveillance programs.

Cato Research has the flexibility to design unique processes for safety management; alternatively, sponsors may choose to follow Cato Research's SOPs that include use of Argus Safety and the medical coding dictionaries MedDRA and WHO Drug. Once the sponsor and Cato Research have agreed upon processes and templates, the pharmacovigilance group will create and document sponsor-specific work practices and forms.

Typically, pharmacovigilance will process an SAE report and produce an initial MedWatch/CIOMS form within 24 hours of notification of the SAE; narratives are routinely generated for each SAE report. The MedWatch form is then reviewed by the medical monitor, the clinical project team, and a medical coder before submission to the appropriate regulatory agencies.

Electronic Data Capture

For this study, Cato Research is assuming the use of a full-scale, electronic data capture (EDC) system and has provided a budget by using etrials[®] EDC software. Using EDC will allow Transdel to have live, up-to-date information on enrollment and study progress, including data entry and data queries. We have found that using EDC in studies reduces queries (through real time edit checks), speeds up data collection, helps identify data issues or trends early, and importantly, shortens time to database closure. However, if a site runs into accessibility issues, we can quickly convert to a hybrid system, where we can provide paper copies of the entry screens to the site, thereby allowing the site to fax the information back to Cato Research. Our qualified data-entry personnel will then enter these data directly into the electronic system. This approach still takes advantage of the online validations and real time data benefit.

etrials has successfully conducted data management for over 900 studies encompassing all therapeutic areas across the globe. Cato Research and etrials have collaborated on many studies. For example, Cato Research recently initiated and managed a concentrated monitoring effort during the concluding months of a Phase 3 neurology study involving 600 patients and 50 sites; we were able to close the database within a 1 day of the last patients' final visit. In the 2 weeks before database closure, 20 patients completed the study, and 500 queries were resolved.

In addition, etrials' EDC system contains an ad hoc reporting tool that uses easy drag-and-drop features allowing users to design custom reports. Reports can contain any field in the database, can be saved for future use, and can be sent to or accessed by other users. Users can quickly obtain study information related to date of entry, query status, data modifications, and new entries in an easily accessible study reporting tool. Monitors can review subject data entered in the eCRF before they physically visit sites and can generate notes offsite that can be resolved by site staff before their site visits. Full tracking of all queries, including returned comments and final resolution, is contained within the EDC system.

Patient Diary

A paper subject diary has been proposed to support the daily completion of visual analog pain scales by study subjects. Due to the cost-prohibitive nature of using electronic hand-held devices for subject diaries, we recommend using a paper diary for either paper-based data management or EDC. Cato Research understands that subjects will complete the patient diary three times each day for the seven days. Patients are to perform study drug self administration and record pain intensity in the subject diary. Once complete, these diaries will be returned to the study site and data will be entered by the site or Cato Research into the data management system.

Statistics and Medical Writing

Cato Research has highly qualified and experienced statisticians and programmers who can create statistical analysis plans, conduct analyses, and assist in the preparation of reports for Phase 1 through Phase 4 studies. The statistical summary and data displays include data analyses, summaries, listings, and CRF tabulations that conform to the FDA or other regulatory agency guidelines for submissions.

Our statisticians, scientists, and physicians collaborate to provide high quality integrated clinical and statistical reports to provide a comprehensive overview of the trial and an integrated analysis of the clinical trial data. Our ICH E3-compliant report format was developed to facilitate review by regulatory agency personnel and includes in-text tables, figures, and convenient summaries that may be used by the FDA in the preparation of FDA reviewer documents. Numerous sponsors and FDA representatives have complimented Cato Research on the high quality and clarity of presentation of the Integrated Clinical and Statistical Reports produced by our project teams.

Part B

Experience in Neurology Clinical Trials

Experience in Neurology Clinical Trials

Cato Research has significant experience in all areas of analgesics development; our specific experience is outlined below:

Experience in conducting pain management trials (acute and chronic)

Cato Research has conducted multiple successful clinical studies for neurology indications, including pain management, in North America, Europe, and South Africa. Recent examples of Cato Research's clinical experience in pain management studies include the following:

- Clinical monitoring and management of three Phase 3 studies of chronic pain conducted at over 275 sites in North America and Europe
- Clinical monitoring and management of a Phase 2b acute pain study in postoperative subjects with approximate enrollment of 200 subjects across 40 sites in the United States
- Clinical monitoring and management of a 30-site Phase 2b study in Canada for the treatment of migraine pain
- Full service activities including clinical and data management of a Phase 2 neuropathic pain study involving 100 subjects and 10 sites

Not only does Cato Research have highly relevant clinical experience and therapeutic expertise, but we are also focused on having a flexible, proactive, and creative approach to managing clinical trials. At the start of any project, we work with the sponsor to determine project roles and responsibilities and how our staff can complement a sponsor's existing resources. This approach can be especially valuable to smaller companies, particularly those that function primarily as virtual entities.

Related clinical trial experience in the past 3 years

Phase 2 and Phase 3 clinical trials

Cato Research has conducted multiple successful Phase 2 and Phase 3 clinical trials in a variety of indications, including: acute and chronic pain (described above), depression, stroke, oncology, and infectious disease. Related experience includes:

- Clinical conduct of an 800-subject study in the United States of a selective serotonin inhibitor targeted to treat major depressive disorder
- Clinical monitoring and management, data management, and statistical services for a Phase 2b study of ischemic stroke conducted at over 100 sites in the United States, Canada, South Africa, and Europe
- Clinical monitoring and management of a 35-subject Phase 2 safety and tolerability study in Canada involving subjects with chronic hepatitis C
- Clinical monitoring, management, data management, and statistical services for a multicenter 60-subject Phase 2 study of HIV infection conducted in the United States
- Clinical monitoring, management, data management, and statistical services for a Phase 3 study of hepatitis C infection
- Clinical monitoring and management of a pivotal trial in 99 subjects with familial cold syndrome across 21 study centers in the United States
- Clinical monitoring and management of Phase 2, 3, and 3b trials involving a therapeutic for Alzheimer's disease across 76 study centers and involving a total of 554 subjects
- Clinical monitoring and management of a Phase 2 trial for an antidepressant compound involving 240 subjects and 22 study sites

In addition to experience conducting Phase 2 and Phase 3 clinical trials, Cato Research has extensive experience with the preparation of documents associated with clinical trials, such as clinical protocols, clinical study reports, investigator's brochures, study procedures manuals, monitoring plan, associated regulatory submissions, and CRFs (paper and electronic). We can also assist with organizing data and safety monitoring committees, as well as with investigator selection, investigator evaluation, and investigators' meeting planning.

Long-term safety studies

Cato Research has conducted several long-term safety clinical trials for a number of indications, including chronic pain. Our experience with long-term safety studies includes the following:

- Management of a 12-month, 1,200-subject, long-term safety study for chronic pain
- Pharmacovigilance, data management, and clinical trial management for a global Phase 3 study with a very active safety focus for a novel therapeutic immunogen (More than 1,100 safety reports are currently stored in the Cato Research database for this compound.)
- Management of a Phase 3b schizophrenia study including monitoring, all regulatory correspondence, clinical and nonclinical reports, and pharmacovigilance

Part C
Terms of Work

TERMS OF WORK

In accordance with the Master Services Agreement between Transdel Pharmaceuticals Inc. ("Client") and Cato Research Ltd. ("Cato Research") dated as of 10 April 2007 (the "Agreement"), Cato Research shall provide CRO Services to Client as outlined in the foregoing proposal.

The service fees and expenses set forth in this proposal are based on anticipated cooperation from Client's personnel and third parties and on the assumption that unexpected circumstances will not be encountered while providing CRO Services. If the details of the required CRO Services change significantly from those outlined in Appendix 1, we will notify you and obtain approval before incurring additional service fees.

The billing schedule will follow the format outlined in this proposal and all bills shall be issued and paid in accordance with the Agreement, except for payment terms of 90 days for the milestone payments of this proposal (unless otherwise noted) as outlined in Appendix 1 (all milestones will be invoiced upon completion). If the number of units performed exceeds the number of units in the budget, such additional units will be invoiced at the unit cost specified in the budget. In addition to the service fee, out of pocket expenses, pass-through costs and applicable taxes, if any, will be invoiced according to the Agreement and a 1.5% handling fee will be charged for all expenses and pass-through costs. If CRO Services are provided hereunder pursuant to a fixed service fee arrangement then, one year after the latest signature date below, and every year thereafter, the fee for all CRO Services for which Client is invoiced during the subsequent one year period shall increase by the greater of five percent (5%) or the rate of inflation as set forth in the Consumer Price Index - All Urban Consumers, All Items (1982-84=100) as of the last day of the previous month.

The terms and conditions outlined in this proposal are governed by the Agreement and, once signed by both parties, may not be changed except in accordance with the Agreement.

By signing below, each party agrees that it has reviewed the specifications and CRO Service fee set forth in the proposal and agrees that Cato Research shall provide, and Client shall pay Cato Research for, the CRO Services described in the proposal.

Cato Research Ltd.By: /s/ Jo Cato Name: Jo Cato Title: Managing Director Date: June 10, 2008 **Transdel Pharmaceuticals Inc.**By: /s/ Juliet Singh Name: Juliet Singh Title: Chief Executive Officer Date: June 10, 2008

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)) 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) 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
 - c) 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; and
- (5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies or material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 11, 2008

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

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)) 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) 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
 - c) 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; and
- (5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies or material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 11, 2008

/s/ John T. Lomoro

John T. Lomoro, Chief Financial Officer

(Principal Financial Officer)

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

In connection with the Quarterly Report of Transdel Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2008 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) of 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 11, 2008

/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)
