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

### **FORM 10-Q**

(Mark One)		
<b>7</b>	QUARTERLY REPORT UNDER SECTI EXCHANGE OF 1934	ON 13 OR 15(d) OF THE SECURITIES
	For the quarterly period en	ded September 30, 2010
0	TRANSITION REPORT UNDER SECTION	ON 13 OR 15(d) OF THE EXCHANGE ACT
	For the transition period from	to
	Commission file nu	mber: 000-52998
	<b>Transdel Pharm</b>	aceuticals, Inc.
	(Exact Name of Regis	trant in Its Charter)
	Delaware	45-0567010
(State or Other Jurisdiction of Incorporation or Organization)		(I.R.S. Employer Identification No.)
	4275 Executive Square, Suite 230	
	La Jolla, CA	92037
	(Address of Principal Executive Offices)	(Zip Code)
	(858) 457	7-5300
	(Registrant's Telephone Num	ber, Including Area Code)
Exchange A		eports required to be filed by Section 13 or 15(d) of the Securities horter period that the registrant was required to file such reports) ays. Yes $\square$ No o
Interactive :		electronically and posted on its corporate Web site, if any, every Rule 405 of Regulation S-T (§232.405 of this chapter) during the serequired to submit and post such files). YES o NO o
reporting co		ated filer, an accelerated filer, a non-accelerated filer, or a smalle accelerated filer" and "smaller reporting company" in Rule 12b-2

Large accelerated filer o

Accelerated filer o

Non-accelerated filer o

Smaller reporting company  $\square$ 

(Do not check if a smaller reporting company)

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

As of November 5, 2010, 15,932,061 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, 2010 (Unaudited)		De	ecember 31, 2009
ASSETS	`	,		
Current assets:				
Cash and cash equivalents	\$	467,278	\$	1,589,773
Prepaid consulting fees		18,400		_
Prepaid expenses and other current assets		93,097		80,917
Total current assets		578,775		1,670,690
Equipment, net		602		1,394
Total assets	\$	579,377	\$	1,672,084
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY				
Current liabilities:				
Accounts payable	\$	75,859	\$	681,014
Accrued Phase 3 expenses		135,140		343,633
Accrued separation expenses		91,019		_
Accrued expenses and payroll liabilities		61,182		70,226
Total current liabilities		363,200		1,094,873
Senior convertible note and accrued interest		1,036,575		<u> </u>
Total liabilities		1,399,775		1,094,873
Stockholders' (deficit) equity:				
Preferred stock, \$0.001 par value; 5,000,000 shares authorized, none outstanding		_		_
Common stock, \$0.001 par value; 50,000,000 shares authorized, 15,882,061 and 15,652,061 shares issued and outstanding as of September 30, 2010 (unaudited) and December 31, 2009, respectively		15,882		15,652
Additional paid-in capital		16,204,362		15,497,128
Deficit accumulated during the development stage	(	(17,040,642)	_	(14,935,569)
Total stockholders' (deficit) equity		(820,398)		577,211
Total liabilities and stockholders' (deficit) equity	\$	579,377	\$	1,672,084

See accompanying notes to these unaudited condensed consolidated financial statements.

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

For the Period

									Fı	or the Period com July 24, 1998 (Inception)
		Three Mor				Nine Mon			0	Through
		Septem 2010	iber 3	2009	September 3 2010			2009		ptember 30, 2010
										_
Operating expenses:										
Selling, general and administrative	\$	584,983	\$	364,087	\$ 1	,750,380	\$ 1	,193,411	\$	8,188,061
Research and development		142,788		565,148		344,900	2	,594,142		7,859,016
Operating loss	_	727,771	_	929,235		2,095,280	3	,787,553	_	16,047,077
Other income (expense):										
Interest expense		(18,904)		_		(36,575)		_		(1,612,330)
Interest income		215		887		483		9,941		127,552
Gain on forgiveness of liabilities		_		_		26,299		_		116,213
Gain on settlement		_								375,000
Total other income (expense), net	_	(18,689)	_	887		(9,793)		9,941	_	(993,565)
Net loss	\$	(746,460)	\$	(928,348)	\$ (2	2,105,073)	\$ (3	,777,612)	\$	(17,040,642)
Basic and diluted loss per common share	\$	(0.05)	\$	(0.06)	\$	(0.13)	\$	(0.24)		
Weighted average common shares outstanding		15,859,887		15,632,006	15	5,739,240	15	,599,828		

See accompanying notes to these unaudited condensed consolidated financial statements.

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

For The Period From July 24,

					(	om July 24, 1998 Inception) Through	
	Nine Mo	onths Ende	ed Sei	ptember 30,		ptember 30,	
	_	2010			_	2010	
Cash flows from operating activities:							
Net loss	\$ (2,1	05,073)	\$	(3,777,612)	\$	(17,040,642)	
Adjustments to reconcile net loss to net cash used in operating activities:							
Estimated fair value of contributed services		_		_		2,475,000	
Gain on forgiveness of liabilities	(	26,299)		_		(116,213)	
Amortization of prepaid consulting fees	2	17,200		29,048		789,208	
Depreciation		792		792		2,552	
Non-cash interest on notes payable		36,575				1,612,330	
Stock-based compensation	4	71,864		380,329		1,728,332	
Changes in operating assets and liabilities:							
Prepaid consulting costs		_		_		(140,000)	
Prepaid expenses and other current assets	(	12,180)		68,809		(93,097)	
Accounts payable	(5	78,856)		(129,568)		192,072	
Accrued Phase 3 expenses	(2	08,493)		269,591		135,140	
Accrued separation expenses		91,019		_		91,019	
Accrued expenses and payroll liabilities		(9,044)		(2,766)		61,182	
Net cash used in operating activities	(2,1	22,495)		(3,161,377)		(10,303,117)	
Cash flows from investing activities: Purchase of fixed assets		_		_		(3,154)	
Net cash used in investing activities				_		(3,154)	
C							
Cash flows from financing activities:							
Proceeds from notes payable to stockholders		_		_		226,300	
Proceeds from notes payable	1,0	00,000		_		2,500,000	
Capital contributions		_		_		168,707	
Net proceeds from purchase of common stock and exercise of							
warrants and stock options		_		49,500		99,450	
Net proceeds from Private Placements						7,779,092	
Net cash provided by financing activities	1,0	00,000		49,500		10,773,549	
Net change in cash and cash equivalents		22,495)		(3,111,877)		467,278	
Cash and cash equivalents, beginning of period		89,773		5,111,031		_	
Cash and cash equivalents, end of period	\$ 4	67,278	\$	1,999,154	\$	467,278	
Summary and a displacement of such flow informations							
Supplemental disclosure of cash flow information:							
Issuance of and adjustment to common stock and warrants to	¢ n	25 600	¢		ď	640,000	
consulting firms for prepaid consulting fees		35,600	\$		\$	640,008	
Conversion of notes payable and accrued interest into common stock	\$		\$	_	\$	1,530,177	
Forgiveness of notes payable and accrued interest to shareholders	\$		\$		\$	241,701	
Conversion of advances to notes payable to shareholders	\$		\$	_	\$	196,300	

See accompanying notes to these unaudited condensed consolidated financial statements.

#### **Note 1. Business Description**

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

#### Note 2. Basis of Presentation

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

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

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

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

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

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

Going Concern. The accompanying condensed consolidated financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred recurring operating losses, had negative operating cash flows and has not recognized any revenues since July 24, 1998 (Inception). In addition, the Company had a deficit accumulated during the development stage of approximately \$17.0 million at September 30, 2010. With the Company's current cash and cash equivalents position as of September 30, 2010 of approximately \$467,000 and factoring in the \$244,479 of allocated funds awarded to the Company (and anticipated to be received by the end of 2010) by the Internal Revenue Service based on our application for the Qualifying Therapeutic Discovery Project under section 48D of the Internal Revenue Code, the Company has forecasted and anticipate having adequate resources in order to execute a portion their operating plan through the fourth quarter of 2010, which would include the final payments for the Phase 3 clinical trial completed in 2009 and general and administrative expenses. However, in order to execute the second Phase 3 clinical and supportive trials of Ketotransdel® which are currently required by the FDA to obtain final regulatory approval for Ketotransdel® and the planned Phase 3b trial, the Company will need to raise additional funds. These factors raise substantial doubt about the Company's ability to continue as a going concern.

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

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

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

*Development Stage Enterprise.* The Company is devoting substantially all of its present efforts to establishing a new business, and its planned principal operations have not yet commenced. All losses accumulated since inception have been considered as part of the Company's development stage activities.

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

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

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

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

Concentrations of Credit Risk. Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash and cash equivalents. The Company invests its excess cash balances (approximately \$27,000 as of September 30, 2010) in a combination of government issued and government backed securities. The remaining amount of cash is held in an operating account and in the form of multiple short term certificates of deposit, all of which (except for \$100,000 of the operating account) are insured by the Federal Deposit Insurance Corporation ("FDIC") as they are individually under the insured maximum of \$250,000.

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

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

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

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

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

Stock-Based Compensation. All share-based payments to employees, including grants of stock options to employees, directors and consultants and restricted stock grants, are recognized in the financial statements based upon their fair values. The Company recorded total stock-based compensation for employees, directors and consultants of \$471,864, \$380,329 and \$1,728,332 for the nine months ended September 30, 2010 and 2009 and the period from Inception through September 30, 2010, respectively, for options and restricted stock granted and vested which is included in selling, general and administrative expenses and research and development expenses in the amount of \$389,627 and \$82,237, \$329,610 and \$50,719, and \$1,169,782 and \$558,551, respectively.

The value of equity instruments issued to consultants and vendors in exchange for goods and services is periodically remeasured and income or expense is recognized during their vesting terms. The measurement date for the fair value of the equity instruments issued is determined at the earlier of (i) the date at which a commitment for performance by the consultant or vendor is reached or (ii) the date at which the consultant or vendor's performance is complete. In the case of equity instruments issued to consultants, the fair value of the equity instrument is primarily recognized over the term of the consulting agreement. An asset acquired in exchange for the issuance of fully vested, nonforfeitable equity instruments should not be presented or classified as an offset to equity on the grantor's balance sheet once the equity instrument is granted for accounting purposes. Accordingly, the Company recorded the fair value of fully vested nonforfeitable equity instruments issued for future consulting services as prepaid consulting fees in its condensed consolidated balance sheets (see Note 6).

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

Basic and diluted net loss applicable to common stock holders per share is computed using the weighted average number of common shares outstanding during the period. Common stock equivalents (prior to application of the treasury stock, if converted method) from stock options and warrants were 3,753,980 and 2,192,730 for the nine months ended September 30, 2010 and 2009, respectively, are excluded from the calculation of diluted net loss per share for all periods presented because the effect is anti-dilutive. If the Company reported net income for these periods, after applying the treasury stock method, common stock equivalents of 58,889 and 223,514 would have been included in the number of shares used to calculate diluted earnings per share in each of the nine months ended September 30, 2010 and 2009, respectively.

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

#### **Note 5. Senior Convertible Promissory Note**

On April 5, 2010, the Company issued a two (2)-year Senior Convertible Promissory Note (the "Note") to an existing investor through a private placement. The Note includes an annual interest rate of 7.5 percent and (unless converted or prepaid, as noted below) all principal and interest are due and payable on April 5, 2012 ("Maturity Date"). At any time prior to the Maturity Date, the investor may convert all or a portion of the outstanding principal and accrued interest at a conversion ratio of one share of Transdel's common stock for each \$1 (the fair market value of the Company's common stock on April 5, 2010) owed. Also, at any time prior to the Maturity Date, the Company has the option to prepay the outstanding principal and accrued interest. The Company received gross proceeds from the issuance of the Note in the aggregate amount of \$1,000,000. There were no discounts or commissions paid in connection with this private placement. Interest expense on the Note was \$36,575 for the nine months ended September 30, 2010.

#### Note 6. Stockholders' Equity

In September 2010, the Company entered an agreement with an investor relations firm in order to primarily provide certain investor relations services to the Company for a period of six months. In exchange for such services, the Company issued 30,000 shares, in the aggregate, of its unregistered common stock, of which all shares were nonforfeitable (valued at \$27,600 and recorded as prepaid consulting fees upon issuance) to the investor relations firm as a prepayment of services to be received for the initial three-month period of the agreement. Beginning in December 2010, the Company has agreed to issue an additional 30,000 shares of unregistered common stock to the investor relations firm for the final three month term of the agreement, unless terminated earlier by the Company or the investor relations firm. For the nine months ended September 30, 2010, the Company recorded stock-based compensation related to the restricted stock of \$9,200.

In June 2010, the Company entered into two separate agreements with an investor relations firm and a financial advisory services firm (collectively "the firms") in order to primarily provide certain investor relations and advisory services to the Company for a period of one year. In exchange for such services, the Company issued 200,000 shares, in the aggregate, of its unregistered common stock, of which all shares were nonforfeitable (valued at \$208,000 and recorded as prepaid consulting fees upon issuance) to the firms as a prepayment of services to be received over a three-month period. As of September 2010, it was agreed to suspend the services related to these agreements, therefore, at this time no additional shares of common stock will be issued to the firms. For the nine months ended September 30, 2010, the Company recorded stock-based compensation related to the restricted stock of \$208,000.

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

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

For the nine months ended September 30, 2010 and September 30, 2009 and for the period from Inception through September 30, 2010, the Company amortized \$217,200, \$29,048 and \$789,208, respectively, of prepaid consulting fees which is included as part of selling, general and administrative expenses.

#### Note 7. Stock Option Plan

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

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

A summary of the Plan for the nine months ended September 30, 2010 is as follows:

_	Number of Shares	Ex	eighted Ave. Gercise Price	Weighted Ave. Remaining Contractual Life	Ii	ggregate itrinsic Value
Outstanding — January 1, 2010	1,605,000	\$	1.64			
Granted	380,000		0.94			
Exercised	_		_			
Forfeited	_		_			
Cancelled	_		_			
		,				
Outstanding — September 30, 2010	1,985,000	\$	1.51	6.7	\$	53,000
Exercisable — September 30, 2010	1,328,583	\$	1.68	5.6	\$	21,800
Vested and expected to vest — September 30, 2010	1,922,275	\$	1.52	6.6	\$	49,880

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, 2010, based on the closing price of the Company's common stock of \$0.90 on that date.

The options were granted to the employees, directors and consultants at exercise prices that ranged from \$0.70 to \$2.62, the estimated fair market value of the common stock on the dates of issuance. All options granted to date expire on the ten year anniversary of the issuance date and were vested immediately or on a quarterly basis up to five years. The Company uses the Black-Scholes option pricing model to estimate the grant-date fair value of share-based awards. The Black-Scholes model requires subjective assumptions regarding future stock price volatility and expected time to exercise, along with assumptions about the risk-free interest rate and expected dividends, which affect the estimated fair values of the Company's stock-based awards. The expected term of options granted was determined in accordance with the "simplified approach" as the Company has very limited historical data on employee exercises and post-vesting employment termination behavior. The expected volatility is based on the historical volatilities of the common stock of comparable publicly traded companies based on the Company's belief that it currently has limited historical data regarding the volatility of its stock price on which to base a meaningful estimate of expected volatility. The risk-free rate selected to value any particular grant is based on the U.S. Treasury rate that corresponds to the expected term of the grant effective as of the date of the grant. The Company used 0% as an expected dividend yield assumption. These factors could change in the future, affecting the determination of stock-based compensation expense in future periods. Utilizing these assumptions, the fair value is determined at the date of grant. The weighted fair value of the stock options granted during 2010 is \$0.61. For the nine months ended September 30, 2010, the Company recorded stock-based compensation related to stock options for employees and directors of \$419,364.

On August 13, 2010, the Company entered into a consulting agreement (previously approved by the Board of Directors) with a retained search firm to provide the Company with executive recruitment services. It accordance with the agreement, the Company has the option to pay for such services in cash or by issuing stock options of an equivalent value. Per the agreement, 50% of the fee (deemed non-refundable) was due upon execution of the agreement and the remaining 50% was due if and when the retained search firm placed a candidate with the Company. The total fee ultimately owed to the retained search firm would not be finalized until an executive was hired as it will be based on the total compensation for the executive in the first year of employment. It was agreed between the retained search firm and the Company that the value of the stock option as of the execution of the agreement would be the basis for determining the number of stock options to be issued for the initial fee as well as in the total fee due to the retained search firm. The option value was determined to be \$0.6575 based on the Black-Scholes pricing model using an exercise price of \$1.07. Using an estimated first year salary (including bonus) of \$350,000, the total fee was estimated to be \$105,000. As noted above, the Company was obligated to pay 50% of the estimated total fee, or \$52,500, upon execution of the agreement, which the Company opted to issue a non-qualified stock option in lieu of cash. Therefore, the Company issued a non-qualified stock option, under the

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

Plan, to purchase up to 80,000 shares of common stock in payment of this initial fee. The stock option is non-refundable and therefore, fully vested upon issuance. As a result, the total value of the fee/option was recognized in August 2010. Effective October 20, 2010, the Board of Directors appointed a new president and chief executive officer that was a candidate referred to the Company from the retained search firm. The total first year compensation for the executive is estimated to be \$441,000, therefore, the final fee due to the retained search firm is \$132,300. The Company opted to pay the remainder of the fee due with a non-qualified stock option. Considering the option issued in August 2010 for the purchase of up to 80,000 shares of common stock, the final stock option issued in October 2010 will be to purchase an additional 121,217 shares of common stock. The value of this stock option representing the remainder of the fee, \$79,800, will be recognized in October 2010.

On December 19, 2008, the Board of Directors approved and the Company entered into a consulting agreement with a firm to provide the Company with business development services. As part of the compensation for the services, the Company issued the firm a non-qualified stock option, under the Plan, to purchase up to 50,000 shares of common stock. The stock option vested in full on March 19, 2009 and was exercised during the third quarter of 2009. The option was granted with an exercise price of \$0.99. The option was revalued on an interim basis until the termination of the agreement and the final estimated fair value of the stock option, based on the Black-Scholes pricing model. This option was amortized over the term of the agreement which was approximately four months as the consulting agreement was terminated effective April 16, 2009. For the 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. Per the option agreement, a portion of the stock option (25,000 shares) became fully vested once the Company announced the results from the Phase 3 trial of Ketotransdel®, which occurred on October 6, 2009. Therefore, the final valuation (of \$36,658) of this portion of the option was determined and recorded in the fourth quarter of 2009. The remainder of the stock option (60,000 shares) was scheduled to vest, on a quarterly basis, over a one-year term, if the consulting agreement was still effective and had not been terminated by either the Company or the consultant prior to the one-year vesting term. The option was granted with an exercise price of \$1.60 and has a ten year life. However, effective October 12, 2009, the consultant became an employee of the Company. Therefore, the original stock option agreement was amended and effectively removed the requirement for the consulting agreement to be in place for the remainder of term, but rather that the individual retains the employee status through the remaining vesting term that will end on June 1, 2010. Since this option effectively was transformed into an employee stock option agreement with the change in status, the final valuation of the option was determined. For the portion of the 60,000 options that vested prior to the change in status, the amount associated with those vested shares was recorded as a consulting stock-based compensation expense in the fourth quarter of 2009. The expense related to the options that vest subsequent to the hire date, are recorded as employee stock-based compensation.

As of September 30, 2010, there was approximately \$438,000 of total unrecognized compensation expense related to unvested stock options under the Plan. That expense is expected to be recognized over the weighted-average remaining vesting term of 2.2 years for the outstanding stock options.

Also, on November 21, 2008, the Company issued a restricted stock grant to a director of the Company for 25,000 shares of the Company's common stock. The restricted stock grant vested over a one-year period. The fair value of the grant was determined to be \$17,500 and was amortized to selling, general and administrative expenses on a straight line basis over the one-year vesting period. For the nine months ended September 30, 2009 and the period from Inception through September 30, 2010, the Company recorded stock-based compensation related to this restricted stock of \$13,122, and \$17,500, respectively.

Effective February 17, 2010, the Board of Directors of the Company accepted the resignation of Dr. Juliet Singh as Chief Executive Officer of the Company and as a director on the Board. In connection with Dr. Singh's resignation, the Company and Dr. Singh entered into a separation agreement that provided Dr. Singh with one year of continued salary in accordance with the terms of her existing employment agreement as well as the accelerated vesting of 300,000 stock options previously granted. In addition, the term in which Dr. Singh may exercise the vested options (which included 610,000 options in total, comprised of 310,000 stock options that were vested as of the separation date as well as the 300,000 stock options subject to the accelerated vesting) was modified and extended to three years from the date of her resignation. In accordance with accounting guidance, since these stock options were modified, the value of the modification for each stock option was determined. For the stock options vested as of the separation date, the modified value was equal to the number of options multiplied by the difference in value (per the Black-Scholes option pricing

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

model) between the original and modified terms of the stock options utilizing current values for market stock price, interest rate and volatility. For the stock options in which the vesting was accelerated, the new value for these stock options was calculated as of the separation date using the Black-Scholes option pricing model. In total, the additional stock based compensation expense recognized for the modified stock options was approximately \$174,000 and was recorded in additional paid-in capital and general and administrative expenses in the accompanying condensed consolidated balance sheets and condensed consolidated statement of operations as of and for the nine-month period ended September 30, 2010, respectively.

#### **Note 8. Stock Warrants**

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

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

	Number of Shares Subject to Warrants Outstanding	Av Ex	ghted- erage ercise rice
Warrants outstanding — January 1, 2010	802,730	\$	4.10
Granted	_		_
Exercised	_		_
Expired	(33,750)		4.00
Warrants outstanding and exercisable — September 30, 2010	768,980	\$	4.11
Weighted average remaining contractual life of the outstanding warrants — September 30, 2010	2.06 years		

#### Note 9. Gain on Forgiveness of Liabilities

On October 2, 2008, the Company entered into a payment agreement with a vendor, settling a balance of \$52,598. It was agreed between the Company and the vendor that 50% of the amount owed, or \$26,299 would be forgiven and the remainder would be paid in two installments, which were, 50%, or \$13,150, upon execution of the payment agreement and \$13,149 upon an infusion of capital into the Company. Since the inception of the payment agreement, the amount to be forgiven, \$26,299, continued to be recorded as an accounts payable up until the infusion of \$1 million from the issuance of the Note in April 2010 (see Note 5). When the Note was issued, the final installment payment of \$13,149 was paid and the \$26,299 was recognized as a gain by the Company.

#### Note 10. Commitments and Contingencies

### **Indemnities and Guarantees**

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

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

#### Cato Research Ltd. Agreement

In accordance with the Master Services Agreement, dated April 10, 2007, between the Company and Cato Research Ltd. ("Cato"), a contract research and development organization, the Company entered into a clinical trial services agreement ("Agreement") with Cato on June 10, 2008. Under the Agreement, Cato served as the Company's strategic partner and contract research organization in conducting the Company's Phase 3 clinical trial for Ketotransdel®. As of September 30, 2010, the Company incurred approximately \$3.2 million (original estimate of costs was \$3.3 million) related to Cato's fees as well as pass-through costs incurred by Cato or payable to the clinical sites for patients enrolled in the study. The Company does not anticipate incurring any additional costs related to this Agreement.

#### Cosmetic Products Consulting Agreement

On August 25, 2008, the Company entered into a consulting agreement with a cosmetic consulting firm ("cosmetic consultants") 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 cosmetic consultants will receive a percentage of the operating profits from the third party agreement as agreed upon in the consulting agreement.

#### Cosmeceutical License Agreements

#### JH Direct, LLC License Agreement

On May 20, 2009, the Company and JH Direct, LLC ("JH Direct") entered into a licensing agreement providing JH Direct with the exclusive worldwide rights to the Company's anti-cellulite cosmeceutical product which utilizes the Company's patented transdermal delivery system technology, Transdel<sup>TM</sup>. 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 cosmetic consultants will receive a percentage of the royalties paid to the Company.

#### Jan Marini Skin Research License Agreement

In June 2010, the Company and Jan Marini Skin Research, Inc. ("JMSR") entered into a licensing agreement providing JMSR with the exclusive U.S. rights to Transdel's transdermal delivery technology for use in an anti-cellulite cosmeceutical product for the dermatological market. Under the terms of the agreement, JMSR will pay Transdel a licensing royalty on the U.S. and worldwide sales of an anti-cellulite product using Trandel's delivery technology. JMSR obtained an exclusive right to promote and sell a product in the U.S. dermatological market for approximately one year after which time they have a non-exclusive right. Also, JMSR obtained a non-exclusive right to promote and sell the product in the ex-U.S. dermatological market. In accordance with the cosmetic products consulting agreement, the cosmetic consultants will receive a percentage of the royalties paid to the Company.

As noted above, the Company will receive a royalty from these agreements, which varies per agreement. The royalty percentages are in the low to mid single digits. As of September 30, 2010, the Company has not received any royalties related to these agreements.

#### Separation Agreement

Effective February 17, 2010, the Board of Directors of the Company accepted the resignation of Dr. Juliet Singh as Chief Executive Officer of the Company and as a director on the Board. In connection with Dr. Singh's resignation, the Company and Dr. Singh entered into a separation agreement that provides Dr. Singh with one year of continued salary in accordance with the terms of her existing employment agreement as well as the accelerated vesting of 300,000 stock options previously granted. The separation agreement also includes a mutual release of claims. In accordance with this agreement, the Company recorded a one-time accrual of \$242,000 for the one year of continued salary (including the related employer payroll taxes) and medical benefits. Also, as noted in Note 7, the Company recorded a total expense of approximately \$174,000 for the value of the modifications to the stock options. As of September 30, 2010, the Company has accrued \$91,019 related to remaining amounts payable under the separation agreement.

#### **Note 11. Subsequent Event**

#### **Employment Agreement**

Effective October 20, 2010, the Board of Directors (the "Board") appointed John N. Bonfiglio, Ph.D. as Chief Executive Officer and President of the Company. Dr. Bonfiglio was also appointed as a director on the Company's Board.

Under the terms of his Employment Agreement with the Company, Dr. Bonfiglio will receive an initial base salary of \$150,000 per year. Dr. Bonfiglio will also be eligible to receive a performance-based cash bonus award equal up to 40% of his base salary, commencing in fiscal 2011. Immediately upon the date that (i) the Company closes a debt or equity financing in which the gross proceeds to the Company equals or exceeds \$3 million; or (ii) completes a corporate partnership transaction that includes gross proceeds to the Company of at least \$3 million to support the Company's general and administrative expenses (each a "Qualified Transaction"), Dr. Bonfiglio's base salary shall be increased to \$315,000 per year. In addition, upon the closing of a Qualified Transaction, the Company will pay Dr. Bonfiglio a bonus equal to the product of (i) \$165,000 times (ii) the number of days between October 20, 2010 and the closing of a Qualified Transaction divided by 365 days.

Also on October 20, 2010, the Board granted Dr. Bonfiglio a stock option for 400,000 shares of common stock and issued 50,000 shares of restricted common stock in accordance with the Company's 2007 Incentive Stock and Awards Plan. The stock option and the restricted common stock will vest as follows: 25% of the option shares and the restricted stock shall vest immediately upon grant, with the balance of the option shares and the restricted stock vesting in equal monthly installments over the next 36 months beginning 30 days after the grant date; provided, however, Dr. Bonfiglio shall gain a vested interest in an additional 10% of the option shares and the restricted stock upon the closing of a Qualified Transaction. The exercise price of the stock option will be \$0.80 per share, the reported closing price of the Company's common stock on October 20, 2010. The vesting of all options will fully accelerate upon an involuntary termination of Dr. Bonfiglio's employment within twelve months following a change of control (as such terms are defined in the Employment Agreement). Dr. Bonfiglio will also be eligible to participate in the medical, insurance and 401(k) plans the Company offers to its other employees.

#### Qualifying Therapeutic Discovery Project

On November 1, 2010, the Company received notice from the U.S. Internal Revenue Service that it was approved to receive a Federal grant in the amount of approximately \$244,000 under the Qualifying Therapeutic Discovery Project that is part of the Patient Protection and Affordable Care Act. The funds were awarded in support of Ketotransdel, the Company's late-stage topical NSAID for the treatment of acute soft tissue injuries. The Company expects to receive the funds by the end of 2010.

#### 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<sup>TM</sup> cream formulation technology is designed to facilitate the effective penetration of a variety of products through the tough skin barrier. Ketotransdel<sup>®</sup>, our lead pain product, utilizes the Transdel<sup>TM</sup> 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<sup>TM</sup> platform technology to expand and create a portfolio of topical products for a variety of indications.

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

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

#### **Plan of Operations**

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

#### Clinical Program for Ketotransdel®

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

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

In January 2010, we reported on further in-depth analyses of the ITT data from the Ketotransdel® Phase 3 study. For the modified ITT analysis we identified 35 patients who did not meet study entry criteria at the time of randomization. Excluding the data from these patients who should not have been randomized into the study based on information that was not known at the time of enrollment, the study demonstrated statistical significance (p<0.038) on the primary efficacy endpoint. This post-hoc analysis was confirmed by a third-party statistical expert.

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

Based on discussions with the FDA at least two adequate and well-controlled Phase 3 studies are required in order to obtain regulatory approval to market Ketotransdel®. We believe that the first Phase 3 trial will qualify as one adequate and well-controlled trial because there is statistical significance on the primary endpoint in an objectively defined, though "post-hoc", modified ITT population. The study also showed statistical significance on secondary endpoints in the original ITT population.

A special protocol assessment ("SPA") request of our suggested design of a second Phase 3 trial was submitted to the FDA. As part of this request, we also submitted a summarized clinical study report on the first Phase 3 trial. In their response to our special protocol assessment request, the FDA provided feedback that the proposed design appears to be adequate and recommended statistical analysis modifications to the Phase 3 protocol that we will make and re-submit for final SPA agreement. The design of the second Phase 3 trial is similar to the first Phase 3 trial in that it will be conducted with approximately 360 patients and the indication will be for acute soft tissue injuries.

As part of a routine requirement to provide safety information in the NDA submission we have to perform studies such as to assess the allergenicity potential and absorption of ketoprofen during concurrent exercise and heat exposure with Ketotransdel®. These additional supportive trials will be conducted in healthy subjects. The timing of the second Phase 3 trial and the other supportive studies will be dependent on obtaining adequate financing to support the execution of these activities and for other working capital expenditures. Upon receipt of such financing, we anticipate initiating the second Phase 3 trial and supportive studies in 2011. Based on successful outcome of the second Phase 3 trial, we anticipate filing the 505(b)(2) application in 2012 with a possible approval approximately one year from acceptance of filing.

There is no assurance that the FDA will accept our conclusion of the modified ITT data from the first Phase 3 trial as sufficient as part of the requirements for regulatory approval. Therefore, it is possible that another trial, in addition to the second Phase 3 trial, will be required even if we have a successful outcome in the second Phase 3 trial. To mitigate risk to the Ketotransdel program, we are planning to conduct a Phase 3b trial in 2012 with data to be available during the FDA's review of the 505(b)(2) application. A Phase 3b trial is typically conducted after regulatory submission, but before approval. The data from the Phase 3b trial will be available to address any potential issues from the FDA's review. The design of the Phase 3b trial is currently under consideration, but we anticipate enrolling fewer patients than were enrolled in the first Phase 3 trial and are targeting for the second Phase 3 trial.

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

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

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

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

In June 2010, we entered into a license agreement with Jan Marini Skin Research, Inc. ("JMSR") providing JMSR with the exclusive U.S. rights to our transdermal delivery technology for use in an anti-cellulite cosmeceutical product for the dermatological market. Under the terms of the agreement, JMSR will pay us a licensing royalty on the U.S. and worldwide sales of an anti-cellulite product using our delivery technology. JMSR obtained an exclusive right to promote and sell a product in the U.S. dermatological market for approximately one year after which time they have a non-exclusive right. Also, JMSR obtained a non-exclusive right to promote and sell the product in the ex-U.S. dermatological market. We anticipate that JMSR will launch the product during the first half of 2011.

As noted above, we will receive a royalty from these agreements, which varies per agreement. The royalty percentages are in the low to mid single digits. As of September 30, 2010, we have not received any royalties related to these agreements.

#### **Other Product Development Programs**

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

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

#### **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 mor	ıths ended		Nine mon			
	Septem	September 30,		Septem	ber 30,	\$	
	2010	2009	Variance	2010	2009	Variance	
Selling, general and administrative	\$ 584,983	\$ 364,087	\$ 220,896	\$1,750,380	\$1,193,411	\$ 556,969	

For the three months ended September 30, 2010, the increase of \$220,896 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, consulting expenses, legal and travel, partially offset by a decrease in personnel expenses. Further explanations for these variances are as follows:

- The primary reason for the \$170,000 increase of investor relations expenses was due to stock-based compensation of \$163,000 for investor relations services provided to us as well as other expenses such as press releases and fees for investor conferences attended by the Company.
- Consulting expenses in the third quarter of 2010 were \$64,000 more than the prior year quarter mainly due to the stock-based compensation charge of \$53,000 for the value of a stock option provided to an executive recruiter for a retained executive search.
- Also, we incurred an additional \$16,000 for legal fees on general corporate matters and \$17,000 for travel costs related to the investor outreach conducted by us during this quarter and other business meetings.
- The primary reason for the decrease in personnel expenses of \$59,000 is due to a lower salary base and stock-based compensation for employees. The salaries were \$8,000 lower as a result of a net decrease in the salary base resulting from the resignation of the former chief executive officer, partially offset by the addition of the salary for the chief business officer hired in February 2010. Stock-based compensation was \$51,000 lower as the net number of options being amortized was less due primarily to full vesting of the former chief executive officer's stock options in the first quarter of 2010, partially offset by the granting of stock options to the chief business officer in February 2010.

For the nine months ended September 30, 2010, the increase of \$556,969 in selling, general and administrative expense, as compared to the same period in the prior year, was primarily related to a net increase in personnel expenses related to the separation agreement for our former chief executive officer, increases in investor relations, legal, travel and consulting expenses. Further explanations for these variances are as follows:

As a result of the separation agreement entered into by us and our former chief executive officer, we recognized aggregate
one-time expenses of approximately \$416,000. This amount was comprised of approximately \$242,000 related to the
accrual of continued salary and medical benefits to be provided for a period of one year after the separation date of
February 17, 2010 and approximately \$174,000 of stock-based compensation expense related to the modification of terms
for the former chief executive officer's stock options.

- The one-time expense noted above, was partially offset by a decrease in personnel expenses of \$130,000 due to a lower salary base and stock-based compensation for employees. The salaries were \$28,000 lower as a result of net decrease in the salary base resulting from the resignation of the former chief executive officer, partially offset by the addition of the salary for the chief business officer hired in February 2010. Stock-based compensation was \$102,000 lower as the net number of options being amortized was less due to full vesting of the former chief executive officer's stock options in the first quarter of 2010, partially offset by the granting of stock options to the chief business officer in February 2010.
- The primary reason for the \$164,000 increase of investor relations expenses was due to stock-based compensation net increase of \$140,000 for investor relations services provided to us as well as an increase of \$24,000 for other expenses such as press releases and fees for investor conferences attended by the Company.
- Also, we incurred an additional \$38,000 for legal fees on general corporate and intellectual property matters and \$37,000 for travel costs primarily related the investor outreach conducted by us during this year and other business meetings.
- Consulting expenses for this period of 2010 were \$28,000 more than the prior year mainly due to the net stock-based compensation charge increase of \$38,000 primarily from the stock option provided to an executive recruiter for a retained executive search, offset by a decrease of \$10,000 in consulting fees for other consulting services provided.

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

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

The table below provides information regarding research and development expenses:

	Three mor	nths ended		Nine months ended				
	Septem	September 30,		Septen	nber 30,	\$		
	2010	2009	Variance	2010	2009	Variance		
Research and development	\$ 142,788	\$ 565,148	\$ (422,360)	\$ 344,900	\$2,594,142	\$(2,249,242)		

For the three months ended September 30, 2010, the decrease of \$422,360 in research and development expense, as compared to the same period in the prior year, was primarily related to a significant decrease of activities for the Phase 3 study and consulting expenses, partially offset by increased expenses related to personnel costs and contract manufacturing fees. Further explanations for these variances are as follows:

- During the same period in the prior year, the Phase 3 study for Ketotransdel® was on-going and therefore, we recognized approximately \$478,000 of expenses related to the study during that period. The expenses were primarily for the investigator payments owed to the clinical sites for the patients they enrolled in the study and the fees incurred by our contract research organization for their services provided in conducting the study.
- The decrease in consulting expenses of approximately \$70,000 is due to fees and stock-based compensation incurred by a consultant for management of the Phase 3 trial in the prior period.
- The increase in personnel expenses of approximately \$63,000 was primarily related to stock-based compensation and wages of our chief medical officer who was hired in October 2009. This position was not filled in the same period of the prior year.
- Due to additional services and analysis performed by our contract manufacturer, these costs increased by \$52,000 in comparison to the same period last year.

For the nine months ended September 30, 2010, the decrease of \$2.2 million in research and development expense, as compared to the same period in the prior year, was primarily related to a significant decrease of activities for the Phase 3 study and consulting expenses, partially offset by increased expenses related to personnel costs. Further explanations for these variances are as follows:

During the same period in the prior year, the Phase 3 study for Ketotransdel® was on-going and therefore, we recognized approximately \$2.45 million of expenses related to the study during that period. The expenses were primarily for the investigator payments owed to the clinical sites for the patients they enrolled in the study and the fees incurred by our contract research organization for their services provided in conducting the study. In the current period, we only recognized a minimal amount of expense, which was incurred by our contract research organization for final administrative activities related to the study.

- The decrease in consulting expenses of approximately \$90,000 is due to \$59,000 less of fees and stock-based compensation
  primarily incurred by a consultant for management of the Phase 3 trial in the prior period and \$31,000 of other additional
  consulting fees incurred in the same period last year.
- The increase in personnel expenses of approximately \$222,000 is primarily related to stock-based compensation and wages of our chief medical officer who was hired in October 2009. This position was not filled in the same period of the prior year.
- Due to additional services and analysis performed by our contract manufacturer, these costs increased by \$55,000 in comparison to the same period last year.

#### **Interest Expense**

In April 2010, we issued a two (2)-year Senior Convertible Promissory Note (the "Note") to an existing investor through a private placement. The Note includes an annual interest rate of 7.5 percent, therefore, interest expense on the Note was \$36,575 for the nine months ended September 30, 2010.

#### **Interest Income**

Interest income was \$215 and \$887 for the three months ended, and \$483 and \$9,941 for the nine months ended, September 30, 2010 and 2009, 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, 2010, as compared to the same periods in the prior year.

#### Forgiveness of Liabilities

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

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

Since inception through September 30, 2010, we have incurred losses of approximately \$17.0 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, 2010, we had approximately \$467,000 in cash and cash equivalents. We have limited funds to support our operations. We have prepared our condensed consolidated financial statements in this Form 10-Q on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Our continuation of operations subsequent to the fourth quarter of 2010 is dependent on our ability to obtain additional financing to fund the continued operation of our business model for a long enough period to achieve profitable operations. With our current cash and cash equivalents position as of September 30, 2010 and factoring in the \$244,479 of allocated funds awarded to us (and anticipated to be received by the end of 2010) by the Internal Revenue Service based on our application for the Qualifying Therapeutic Discovery Project under section 48D of the Internal Revenue Code, we have forecasted and anticipate having adequate resources in order to execute a portion of our operating plan through the fourth quarter of 2010, which would include the final payments for the Phase 3 clinical trial completed in 2009 and general and administrative expenses. However, in order to execute the second Phase 3 clinical and supportive trials of Ketotransdel® which are currently required by the FDA to obtain final regulatory approval for Ketotransdel® and our planned Phase 3b trial, we will need to raise additional funds. We intend to seek additional financing to fund the second Phase 3 clinical trial, the Phase 3b trial and the supportive safety studies as well as to continue our cosmetic/cosmeceutical program and to explore codevelopment opportunities. If adequate financing is not available, we will not be able to conduct the clinical development program as described.

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

The significant downturn in the overall economy and the ongoing disruption in the capital markets has reduced investor confidence and negatively affected investments, generally and specifically, in the pharmaceutical industry. In addition, the fact that we are not profitable and need significant additional funds to complete our clinical trials, could further impact the availability or cost of future financings. As a result, there can be no assurance that additional funds will be available when needed from any source or, if available, will be available on terms that are acceptable to us. If we are unable to raise funds to satisfy our capital needs prior to the end of 2010 we will be required to cease operations.

#### **Critical Accounting Policies**

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

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

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

Going Concern. Our condensed consolidated financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. We have incurred recurring operating losses, had negative operating cash flows and have not recognized any revenues since July 24, 1998 (Inception). In addition, we had a deficit accumulated during the development stage of approximately \$17.0 million at September 30, 2010. With our current cash and cash equivalents position as of September 30, 2010 of approximately \$467,000 and factoring in the \$244,479 of allocated funds awarded to us (and anticipated to be received by the end of 2010) by the Internal Revenue Service based on our application for the Qualifying Therapeutic Discovery Project under section 48D of the Internal Revenue Code, we have forecasted and anticipate having adequate resources in order to execute a portion of our operating plan through the fourth quarter of 2010, which would include the final payments for the Phase 3 clinical trial completed in 2009 and general and administrative expenses. However, in order to execute the second Phase 3 clinical and supportive trials of Ketotransdel® which are currently required by the FDA to obtain final regulatory approval for Ketotransdel® and our planned Phase 3b trial, we will need to raise additional funds. These factors raise substantial doubt about our ability to continue as a going concern.

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

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

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

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

#### **Off-Balance Sheet Arrangements**

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

#### **Recent Accounting Pronouncements**

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

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

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Commission's rules and forms and that such information is accumulated and communicated to our management, including our 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 as of the end of the quarter covered by this quarterly report on Form 10-Q.

Changes in Internal Control Over Financial Reporting

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

#### PART II OTHER INFORMATION

#### Item 1. Legal Proceedings

None.

#### Item 1A. Risk Factors

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

#### **Risks Relating to Our Business**

\*We have incurred losses in the research and development of Ketotransdel® and our Transdel $^{\text{TM}}$  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, 2010, we have a deficit accumulated during the development stage of approximately \$17.0 million, and for the nine months ended September 30, 2010, we experienced a net loss of approximately \$2.1 million. In addition, we expect to incur increasing operating losses for the foreseeable future as we continue to incur costs for research and development and clinical trials, and in other development activities. Our ability to generate revenue and achieve profitability depends upon our ability, alone or with others, to complete the development of our proposed products, obtain the required regulatory approvals and manufacture, market and sell our proposed products. Development is costly and requires significant investment. In addition, we may choose to in-license rights to particular drugs or active ingredients for use in cosmetic/cosmeceutical products. The license fees for such drugs or active ingredients may increase our costs.

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

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

We have limited remaining funds to support our operations. We have prepared our condensed consolidated financial statements in this Form 10-Q on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. We will not be able to execute our current business plan, fund our business operations or continue as a going concern long enough to achieve profitability unless we are able to secure additional funds. With our current cash and cash equivalents position as of September 30, 2010 and factoring in the \$244,479 of allocated funds awarded to us (and anticipated to be received by the end of 2010) by the Internal Revenue Service based on our application for the Qualifying Therapeutic Discovery Project under section 48D of the Internal Revenue Code, we have forecasted and anticipate having adequate resources in order to execute a portion of our operating plan through the fourth quarter of 2010, which would include the final payments for the Phase 3 clinical trial completed in 2009 and general and administrative expenses. The Report of Independent Registered Public Accounting Firm on our December 31, 2009 consolidated financial statements included an explanatory paragraph stating that the recurring losses incurred from operations and a working capital deficiency raise substantial doubt about our ability to continue as a going concern. However, in order to execute the second Phase 3 clinical trial and supportive studies in order to obtain regulatory approval to market Ketotransdel®, and our planned Phase 3b trial, we will need to secure additional funds. If adequate financing is not available, we will not be able to meet the FDA's requirements to obtain regulatory approval to market Ketotransdel®. In addition, if one or more of the risks discussed in these risk factors occur or our expenses exceed our expectations, we may be required to raise further additional funds sooner than anticipated.

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

The significant downturn in the overall economy and the ongoing disruption in the capital markets has reduced investor confidence and negatively affected investments generally and specifically in the pharmaceutical industry. In addition, the fact that we are not profitable and will need significant additional funds to execute the second Phase 3 clinical trial and supportive studies in order to obtain regulatory approval to market Ketotransdel®, and our planned Phase 3b trial and any other clinical trials we would want to commence for other products, could further impact the availability or cost of future financings. As a result, there can be no assurance that additional funds will be available when needed from any source or, if available, will be available on terms that are acceptable to us. If we are unable to raise funds to satisfy our capital needs prior to the end of 2010 we will be required to cease operations.

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

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

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

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

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

We cannot assure you that the FDA or other regulatory agencies will approve any products developed by us, on a timely basis, if at all, or, if granted, that such approval will not subject the marketing of our products to certain limits on indicated use. In particular, the outcome of the final analyses of the data from the Phase 3 clinical trials for Ketotransdel® may vary from our initial conclusions or the FDA may not agree with our interpretation of such results or may challenge the adequacy of our clinical trial design or the execution of the clinical trial, including our modified ITT analysis for our first Phase 3 clinical trial of Ketotransdel®. The FDA is requiring two adequate and well controlled Phase 3 clinical trials and supportive studies 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 maintain patent protection with respect to our products;
- prevent third parties from infringing upon our proprietary rights;
- maintain trade secrets;
- operate without infringing upon the patents and proprietary rights of others; and
- obtain appropriate licenses to patents or proprietary rights held by third parties if infringement would otherwise occur, both in the U.S. and in foreign countries.

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

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

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

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

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

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

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

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

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

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

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

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

#### **Risks Relating to Our Industry**

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

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

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

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

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

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

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

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

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

#### **Risks Relating to the Common Stock**

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

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

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

Effective internal control is necessary for us to provide reliable financial reports and prevent fraud. If we cannot provide reliable financial reports or prevent fraud, we will not be able to manage our business as effectively, and our business and reputation with investors would be harmed. Any such 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 is classified as a "penny stock", which makes it more difficult for our investors to sell their shares.

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

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

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

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

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

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

On September 7, 2010 we issued 30,000 shares of unregistered common stock to an investor relations firm for certain investor relations services to be provided to us over a three-month period.

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

#### Item 6. Exhibits

Exhibit Number	Description
10.1	Employment Agreement, dated October 18, 2010, between Transdel Pharmaceuticals, Inc. and John Bonfiglio, Ph.D.
10.2	Nonqualified Stock Option Agreement, dated as of the 20 <sup>th</sup> day of October, 2010, between Transdel Pharmaceuticals, Inc., and Dr. John Bonfiglio
10.3	Restricted Stock Agreement, dated as of the 20 <sup>th</sup> day of October, 2010, between Transdel Pharmaceuticals, Inc., and Dr. John Bonfiglio
31.1*	Section 302 Certification of Principal Executive Officer
31.2*	Section 906 Certification of Principal Financial Officer
32.1*	Section 906 Certification of Principal Executive Officer and Principal Financial Officer

<sup>\*</sup> Filed herewith.

Dated: November 8, 2010

### **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.

By: /s/ John Bonfiglio

John Bonfiglio, Ph.D. Chief Executive Officer (Principal Executive Officer)

### **EXHIBIT INDEX**

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<sup>\*</sup> Filed herewith.

#### TRANSDEL PHARMACEUTICALS, INC.

#### EMPLOYMENT AGREEMENT

This EMPLOYMENT AGREEMENT (the "Agreement") is made effective as of October 18, 2010 (the "Effective Date"), by and between Transdel Pharmaceuticals, Inc., a Delaware corporation (the "Company"), and Dr. John Bonfiglio ("Executive"):

WHEREAS, The Company and the Executive desire to enter into this Agreement to provide for Executive's employment by the Company, upon the terms and conditions set forth herein.

The parties hereby agree as follows:

#### 1. Duties.

- **1.1 Position**. Executive shall serve as the Company's Chief Executive Officer and President, and serve as a director on the Company's Board of Directors (the "Board"), and shall have the duties and responsibilities incident to such position and such other duties as may be determined in consultation with the Board. Executive shall perform faithfully, cooperatively and diligently all of his job duties and responsibilities and agrees to and shall devote his full time, attention and effort to the business of the Company and other assignments as directed by the Board. The Executive will report directly to the Board.
- **1.2 Best Efforts.** Executive will expend his best efforts on behalf of the Company in connection with his employment and will abide by all policies and decisions made by Board, as well as all applicable federal, state and local laws, regulations or ordinances.
- **1.3 Start Date**. Executive agrees that he will report to work at the Company's headquarters on October 20, 2010 (the "Start Date"). For purposes of clarity, the Start Date will be used to calculate Executive's compensation and benefits pursuant to Sections 3 through 7 of this Agreement.
- **2. At-Will Employment**. Executive's employment with the Company is not for a specific term and can be terminated by Executive or the Company at any time and for any reason, with or without cause or advanced notice. The at-will nature of Executive's employment described in this Agreement shall constitute the entire agreement between Executive and the Company concerning the nature and duration of Executive's employment and the circumstance under which Executive or the Company may terminate the employment relationship. No oral statement by any person can change the at-will nature of Executive's employment with the Company. If Executive shall cease serving as the Company's Chief Executive Officer, Executive agrees to simultaneously submit his resignation from the Board. In addition, Executive agrees to continue to abide by the Company's Information and Inventions Agreement following his resignation or the termination of his employment with the Company.

#### 3. Compensation.

- **3.1 Annual Base Salary**. As compensation for Executive's performance of his duties hereunder, the Company shall pay to Executive an initial base annual salary of One Hundred Fifty Thousand Dollars (\$150,000), starting on the Start Date ("Annual Base Salary"), payable in accordance with the normal payroll practices of Company, less required deductions for state and federal withholding tax, social security and all other employment taxes and payroll deductions.
- **3.2 Annual Bonus**. The Executive shall be eligible to receive an annual cash bonus in an amount up to 40% of his Annual Base Salary (the "Annual Bonus") beginning in fiscal 2011. The actual amount of the Annual Bonus will be determined by the Board based on Executive's achieving Company and personal goals established and mutually agreed upon between the Executive and the Board of Directors. Both the goals for the Company and the Executive shall be agreed to by Executive and the Board of Directors as follows: (i) for the remainder of fiscal year 2010, on or before November 15, 2010; and (ii) for fiscal year 2011, on or before January 31, 2011; and (iii) for each fiscal year thereafter, on or before January 31 for that particular year. In addition, the Board of Directors and the Executive hereby agree that the objectives for the other officers or employees will be determined on the same dates as set forth above. If awarded, the Annual Bonus will be paid on or before March 15 of the year following the year in which the Annual Bonus was earned.
- **3.3 Salary Increase and Special Bonus**. Immediately upon the date that (i) the Company closes a debt or equity financing in which the gross proceeds to the Company equals or exceeds \$ 3 million; or (ii) completes a corporate partnership transaction that includes gross proceeds to the Company of at least \$3 million to support the Company's general and administrative expenses (each a "Qualified Transaction"), the Executive's Annual Base Salary shall be increased to Three Hundred and Fifteen Thousand Dollars (\$315,000). In addition, upon the closing of a Qualified Transaction, the Company will pay Executive a bonus equal to the product of (i) \$165,000 times (ii) the number of days between the Start Date and the closing of a Qualified Transaction dividend by 365 days (the "Special Bonus").
- **3.4 Equity Grants.** Subject to approval of the Board of Directors, the Executive shall be eligible to receive a stock option grant for 400,000 shares of common stock and 50,000 shares of restricted common stock in accordance with Transdel's 2007 Incentive Stock and Awards Plan. For these initial grants of stock options and restricted common stock, they will vest as follows: 25% of the option shares and the restricted stock shall vest immediately upon the Start Date, with the balance of the option shares and the restricted stock vesting in equal monthly installments over the next 36 months beginning 30 days after the Start Date; provided, however, the Executive shall gain a vested interest in an additional 10% of the option shares and the restricted stock upon the closing of a Qualified Transaction. The exercise price of the stock option will be the reported closing price of the Company's common stock on the date of grant. The vesting of all options will fully accelerate upon an Involuntary Termination of Executive's employment within twelve months following a Change of Control (as such terms are defined in Executive's Option Agreement).

- **3.5 Additional Equity Grant**. Contingent upon the closing of a Contingent Financing with (i) any entity that is not listed in Exhibit A, attached hereto and incorporated herein by reference, or (ii) any entity that is introduced to the Company by Executive after the Start Date, the Company will issue Executive an option to purchase 200,000 shares of common stock, with 25% of the option shares vested on the date of grant and the balance vesting in equal monthly installments over the next 36 months. The exercise price of this option will be the reported closing price of the Company's common stock on the date of grant, which will take place following the public announcement of such Qualified Transaction.
- **3.6 Future Equity Grants**. In addition, in connection with setting the Executive's annual compensation, the Board will agree to examine the Executive's overall annual compensation package and issue an appropriate stock option grant or other equity award based on the Company's comparator group.
- **4. Health and Welfare Benefit Plans**. The Company will provide to Executive and his family throughout the term of this Agreement health, dental and vision and other benefits on the same or substantially similar terms as those provided to Executive and the other executive officers of the Company during the first six months of Executive's employment with the Company.
- **5. Customary Benefits**. Executive shall be entitled to all customary and usual fringe benefits and shall be entitled to participate in all savings and retirement plans, practices, policies and programs generally applicable to employees of the Company that are in effect during the Employment Term, subject to the terms and conditions of Company's benefit plan documents, as applicable.
- **6. Business Expenses**. Executive shall be entitled to receive prompt reimbursement for all reasonable, out of- pocket business expenses incurred in the performance of his duties on behalf of Company (including, but not limited to, cell phone, computer and internet expenses). In addition, Executive shall be entitled to receive prompt reimbursement for all reasonable travel and lodging expenses related to providing services at the Company's headquarters, with all business expense plans (i.e., how many flights back and forth per month) and amounts to be pre-approved by the Board.
- **7. Vacation**. Executive shall be entitled to paid vacation, personal and sick days each calendar year, in accordance with the Company's plans, policies and programs then in effect. Initially Executive will be granted four (4) weeks of paid vacation, with the Executive's vacation for 2010 pro-rated based on the period of his service during 2010.
- **8. Relocation Expenses.** Contingent upon the closing of a Qualified Transaction, the Company agrees to reimburse Executive for up to \$30,000 in relocation expenses associated with Executive's relocation to San Diego County; provided, however, that Executive shall promptly repay the Company for any reimbursement payments made by the Company to Executive should Executive terminate his employment from the Company for other than Good Reason (as such term is defined in Executive's Option Agreement) within 12 months of the Start Date.

- **9. Indemnification**. In connection with the execution of the Agreement, the Company will also enter into a customary indemnification agreement with Executive.
- **10. Severance Benefits.** Executive and the Board recognize the fact that the Company at the time of this Agreement, does not have the financial capacity to offer a full typical Chief Executive Officer severance package. However, upon the closing of a Qualified Transaction, a severance package of at least one year's pay and continued company paid healthcare expenses will automatically be instituted.
- **11. Section 409A of the U.S. Internal Revenue Code.** The Company and Executive intend in good faith that this Agreement comply with the applicable requirements of Section 409A of the Internal Revenue Code of 1986 and that this Agreement be construed, interpreted and administered in accordance with such intent.
- 12. Dispute Resolution. In the event of any dispute or claim relating to or arising out of Executive's employment relationship with Company, this agreement, or the termination of Executive's employment with Company for any reason (including, but not limited to, any claims of breach of contract, defamation, wrongful termination or age, sex, sexual orientation, race, color, national origin, ancestry, marital status, religious creed, physical or mental disability or medical condition or other discrimination, retaliation or harassment), Executive and Company agree that all disputes shall be fully resolved by confidential, binding arbitration conducted by a single neutral arbitrator in San Diego, California through the American Arbitration Association ("AAA") pursuant to the AAA's Employment Arbitration Rules, which are available at the AAA's website at www.adr.org or by requesting a copy from the President of the Company. The arbitrator shall permit adequate discovery and is empowered to award all remedies otherwise available in a court of competent jurisdiction and any judgment rendered by the arbitrator may be entered by any court of competent jurisdiction. The arbitrator shall issue an award in writing and state the essential findings and conclusions on which the award is based. To the fullest extent permitted by applicable law, by signing this letter, Executive and Company both waive the rights to have any disputes or claims tried before a judge or jury.

#### 13. General Provisions.

- **13.1** Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their heirs, personal representatives and successors, including any successor of the company by reason of any dissolution, merger, consolidation, sale of assets or other reorganization of the Company.
- 13.2 Waiver. The rights and remedies of the parties to this Agreement are cumulative and not alternative. Neither the failure nor any delay by any party in exercising any right, power or privilege under this Agreement or the documents referred to in this Agreement will operate as a waiver of such right, power or privilege; and no single or partial exercise of any such right, power or privilege will preclude any other or further exercise of such right, power or privilege. To the maximum extent permitted by applicable law, (i) no claim or right arising out of this Agreement or the documents referred to in this Agreement can be discharged by one party, in whole or in part, by a waiver or renunciation of the claim or right unless in writing signed by the other party; (ii) no waiver that may be given by a party will be applicable except in the specific instance for which it is given; and (iii) no notice to or demand on one party will be deemed to be a waiver of any obligation of such party or of the right of the party giving such notice or demand to take further action without notice or demand as provided in this Agreement or the documents referred to in this Agreement.

- **13.3 Validity**. The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement, which shall remain in full force and effect.
- **13.4 Headings**. The headings set forth in this Agreement are for convenience only and shall not be used in interpreting this Agreement.
- **13.5 Governing Law**. This Agreement will be governed by and construed in accordance with the laws of the United States and the State of California, without reference to its conflicts of laws principles.
- **13.6 Counterparts**. This Agreement may be executed in one or more counterparts, all of which when fully executed and delivered by all parties hereto and taken together shall constitute a single agreement, binding against each of the parties.
  - 13.7 Survival. Sections 8, 9, 10, 11 and, 12 of this Agreement shall survive Executive's employment by Company.
- **13.8 Notices**. All notices, consents, waivers and other communications under this Agreement shall be in writing and will be deemed to have been duly given when (i) delivered by hand (with written confirmation of receipt); (ii) sent by facsimile (with written confirmation of receipt); or (iii) when received by the addressee, if sent by a nationally recognized overnight delivery service, return

If to Executive:

John Bonfiglio 125 Edgewood Drive Durham, NC 27713

If to the Company:

Dr. Jeffrey Abrams Transdel Pharmaceuticals, Inc. 4275 Executive Square, Suite 230 La Jolla, CA 92037

or to such other address as either party shall have furnished to the other in writing in accordance herewith.

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IN WITNESS WHEREOF, THE PARTIES TO THIS AGREEMENT HAVE READ THE FOREGOING AGREEMENT AND FULLY UNDERSTAND EACH AND EVERY PROVISION CONTAINED HEREIN.

# **EXECUTIVE**

/s/ John Bonfiglio
John Bonfiglio

# TRANSDEL PHARMACEUTICALS, INC.

By: <u>/s/ J</u>effrey Abrams

Name: Dr. Jeffrey Abrams
Title: Chairman of the Board

[Signature Page to Employment Agreement]

### TRANSDEL PHARMACEUTICALS, INC. 2007 INCENTIVE STOCK AND AWARD PLAN

#### NONQUALIFIED STOCK OPTION AGREEMENT

This NONQUALIFIED STOCK OPTION AGREEMENT (the "Option Agreement"), dated as of the 20<sup>th</sup> day of October, 2010 (the "Grant Date"), is between Transdel Pharmaceuticals, Inc., a Delaware corporation (the "Company"), and Dr. John Bonfiglio (the "Optionee"), the Chief Executive Officer and a director of the Company , pursuant to the Transdel Pharmaceuticals, Inc. 2007 Incentive Stock and Awards Plan (the "Plan"). Defined terms not explicitly defined in this Nonqualified Stock Option Agreement but defined in the Plan shall have the same definitions as in the Plan.

WHEREAS, the Company desires to give the Optionee the opportunity to purchase shares of common stock of the Company, par value \$0.001 ("Common Shares") in accordance with the provisions of the Plan, a copy of which is attached hereto;

NOW, THEREFORE, in consideration of the mutual covenants hereinafter set forth and for other good and valuable consideration, the parties hereto, intending to be legally bound hereby, agree as follows:

- 1. <u>Grant of Option</u>. The Company hereby grants to the Optionee the right and option (the "Option") to purchase all or any part of an aggregate of 400,000 Common Shares. The Option is in all respects limited and conditioned as hereinafter provided, and is subject in all respects to the terms and conditions of the Plan now in effect and as it may be amended from time to time (but only to the extent that such amendments apply to outstanding options). Such terms and conditions are incorporated herein by reference, made a part hereof, and shall control in the event of any conflict with any other terms of this Option Agreement. The Option granted hereunder is intended to be a nonqualified stock option ("NQSO") and <u>not</u> an incentive stock option ("ISO") as such term is defined in section 422 of the Internal Revenue Code of 1986, as amended (the "Code").
- 2. <u>Exercise Price</u>. The exercise price of the Common Shares covered by this Option shall be \$0.80 per share. It is the determination of the committee administering the Plan (the "Committee") that on the Grant Date the exercise price was not less than the greater of (i) 100% of the "Fair Market Value" (as defined in the Plan) of a Common Share, or (ii) the par value of a Common Share.
- 3. <u>Term</u>. Unless earlier terminated pursuant to any provision of the Plan or of this Option Agreement, this Option shall expire ten years from Grant Date (the "Expiration Date"). This Option shall not be exercisable on or after the Expiration Date.

- 4. <u>Exercise of Option</u>. The Optionee shall have the right to purchase from the Company, on and after the following dates, the following number of Common Shares, provided the Optionee has not terminated his or her service as of the applicable vesting date:
  - (a) 25% of the Common Shares shall vest immediately upon October 20, 2010; and
- (b) the balance of the Common Shares shall vest in equal monthly installments over the next 36 months beginning 30 days after October 20, 2010;
- (c) provided, however, that Optionee shall gain a vested interest in an additional 10% of the Common Shares upon the closing of a Qualified Transaction.

A "Qualified Transaction" shall mean (i) a debt or equity financing in which the gross proceeds to the Company equals or exceeds \$3 million; or (ii) a corporate partnership transaction that includes gross proceeds to the Company of at least \$3 million to support the Company's general and administrative expenses.

The Committee may accelerate any exercise date of the Option, in its discretion, if it deems such acceleration to be desirable. Once the Option becomes exercisable, it will remain exercisable until it is exercised or until it terminates.

5. <u>Method of Exercising Option</u>. Subject to the terms and conditions of this Option Agreement and the Plan, the Option may be exercised by written notice to the Company at its principal office. The form of such notice is attached hereto and shall state the election to exercise the Option and the number of whole shares with respect to which it is being exercised; shall be signed by the person or persons so exercising the Option; and shall be accompanied by payment of the full exercise price of such shares. Only full shares will be issued.

The exercise price shall be paid to the Company —

- (a) in cash, or by certified check, bank draft, or postal or express money order;
- (b) through the delivery of Common Shares;
- (c) by delivering a properly executed notice of exercise of the Option to the Company and a broker, with irrevocable instructions to the broker promptly to deliver to the Company the amount necessary to pay the exercise price of the Option;
  - (d) in Common Shares newly acquired by the Optionee upon the exercise of the Option; or

(e) in any combination of (a), (b), (c), or (d) above.

In the event the exercise price is paid, in whole or in part, with Common Shares, the portion of the exercise price so paid shall be equal to the Fair Market Value of the Common Shares surrendered on the date of exercise.

Upon receipt of notice of exercise and payment, the Company shall deliver a certificate or certificates representing the Common Shares with respect to which the Option is so exercised. The Optionee shall obtain the rights of a shareholder upon receipt of a certificate(s) representing such Common Shares.

Such certificate(s) shall be registered in the name of the person so exercising the Option (or, if the Option is exercised by the Optionee and if the Optionee so requests in the notice exercising the Option, shall be registered in the name of the Optionee and the Optionee's spouse, jointly, with right of survivorship) and shall be delivered as provided above to, or upon the written order of, the person exercising the Option. In the event the Option is exercised by any person or persons after the death or disability (as determined in accordance with section 22(e)(3) of the Code) of the Optionee, the notice shall be accompanied by appropriate proof of the right of such person or persons to exercise the Option. All Common Shares that are purchased upon exercise of the Option as provided herein shall be fully paid and non-assessable.

Upon exercise of the Option, Optionee shall be responsible for all employment and income taxes then or thereafter due (whether Federal, State or local), and if the Optionee does not remit to the Company sufficient cash (or, with the consent of the Committee, Common Shares to satisfy all applicable withholding requirements, the Company shall be entitled to satisfy any withholding requirements for any such tax by disposing of Common Shares at exercise, withholding cash from Optionee's salary or other compensation or such other means as the Committee considers appropriate to the fullest extent permitted by applicable law. Nothing in the preceding sentence shall impair or limit the Company's rights with respect to satisfying withholding obligations under Section 10 of the Plan.

- 6. <u>Transferability of Option</u>. This Option is not assignable or transferable, in whole or in part, by the Optionee other than by will or by the laws of descent and distribution. During the lifetime of the Optionee, the Option shall be exercisable only by the Optionee or, in the event of his or her disability, by his or her guardian or legal representative.
- 7. <u>Termination of Service by Optionee</u>. If the Optionee's service with the Company is terminated by the Optionee for any reason other than death or disability prior to the Expiration Date, this Option may be exercised, to the extent of the number of Common Shares with respect to which the Optionee could have exercised it on the date of such termination of service by the Optionee at any time prior to the earlier of (i) the Expiration Date or (ii) ninety (90) days after the date of such termination of service. The Plan provides for this period as a default. The Committee may provide for different exercise periods in any particular NQSO. Any part of the Option that was not exercisable immediately before the Optionee's termination of service shall terminate at that time.

- 8. <u>Disability</u>. If the Optionee becomes disabled (as determined in accordance with section 22(e)(3) of the Code) during his or her service and, prior to the Expiration Date, the Optionee's service is terminated as a consequence of such disability, this Option may be exercised, to the extent of the number of Common Shares with respect to which the Optionee could have exercised it on the date of such termination of service by the Optionee or by the optionee's legal representative, at any time prior to the earlier of (i) the Expiration Date or (ii) one year after such termination of service. Any part of the Option that was not exercisable immediately before the Optionee's termination of service shall terminate at that time.
- 9. <u>Termination of Service by Company without Cause or by Optionee with Good Reason</u>. If the Optionee's service with the Company is terminated by the Company for any reason other than Cause (or is terminated by the Optionee for Good Reason) prior to the Expiration Date, this Option may be exercised, to the extent of the number of Common Shares with respect to which the Optionee could have exercised it on the date of such termination of employment by the Optionee at any time prior to the earlier of (i) the Expiration Date, or (ii) one year after such termination of service. Any part of the Option that was not exercisable immediately before the Optionee's termination of employment shall terminate at that time.
- 10. <u>Death</u>. If the Optionee dies during his or her service and prior to the Expiration Date, or if the Optionee's service is terminated for any reason (as described in Paragraphs 7, 8 and 9) and the Optionee dies following his or her termination of service but prior to the earlier of the Expiration Date or the expiration of the period determined under Paragraph 7, 8 or 9 (as applicable to the Optionee), this Option may be exercised, to the extent of the number of Common Shares with respect to which the Optionee could have exercised it on the date of his or her death by the Optionee's estate, personal representative or beneficiary who acquired the right to exercise this Option by bequest or inheritance or by reason of the Optionee's death, at any time prior to the earlier of (i) the Expiration Date or (ii) one year after the date of the Optionee's death. Any part of the Option that was not exercisable immediately before the Optionee's death shall terminate at that time.
- 11. <u>Termination for Cause</u>. If the Optionee is removed by the Company for Cause and his or her service with the Company is terminated prior to the Expiration Date, any unexercised portion of this Option shall immediately terminate at that time.
- 12. Change of Control. To the extent the Option is, in connection with a Change of Control, assumed by the acquirer in accordance with the Plan, none of the Common Shares shall vest on an accelerated basis upon the occurrence of the Change of Control, and Optionee shall accordingly continue, over his period of employment following the Change of Control, to vest in the Option Shares in one or more installments in accordance with the provisions of the Option Agreement. However, upon an Involuntary Termination of Optionee's employment within twelve (12) months following a Change of Control, all of the Common Shares at the time subject to the Option shall automatically vest in full on an accelerated basis so that the Option shall immediately become exercisable for all the Common Shares as fully-vested shares and may be exercised for any or all of those Option Shares as vested shares. The Option shall remain so exercisable until the earlier of (i) the Expiration Date or (ii) the expiration of a one year period measured from the date of the Involuntary Termination.

For purposes of this Option Agreement,

- (a) "Cause" shall mean Optionee's: (i) acts of theft, embezzlement, fraud, material dishonesty or misappropriation of any of the Company's (or a surviving entity's following a Change of Control) property, or conviction for, or the entry of a plea of guilty or nolo contendere to, any felony, or to any other crime involving dishonesty, moral turpitude, fraud or embezzlement; (ii) breach of Company's confidentiality agreement, which shall not be subject to any cure; (iii) breach of any material provision of any written agreement between Optionee and the Company (or the surviving entity following a Change of Control), other than a breach as described in subsection (ii) above, and failure of Optionee to cure such beach, if susceptible to cure, within ten (10) days following Optionee's receipt of written notice of such breach; (iv) failure or refusal to perform, or material negligence in the performance of, duties to the Company (or the surviving entity following a Change of Control), or refusal or failure to follow or carry out any reasonable direction of the board of directors of the Company (or of the applicable supervisory personnel of the surviving entity following a Change of Control), which failure or refusal, if susceptible to cure, remains uncured or continues or recurs after ten (10) days following Optionee's receipt of written notice specifying the nature of such failure or refusal; (v) inability to perform the essential functions of Optionee's position, with or without reasonable accommodation, due to a mental or physical disability; or (vi) death.
- (b) "Change of Control" shall mean the occurrence of any of the following: (i) the sale, lease, conveyance or other disposition of all or substantially all of the Company's assets to any "person" (as such term is used in Section 13(d) of the Exchange Act of 1934, as amended), entity or group of persons acting in concert; (ii) any person or group of persons becoming the "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of the Company representing 50% or more of the total voting power represented by the Company's then outstanding voting securities; (iii) a merger, consolidation or other transaction of the Company with or into any other corporation, entity or person, other than a transaction in which the holders of at least 50% of the shares of capital stock of the Company outstanding immediately prior thereto continue to hold (either by voting securities remaining outstanding or by their being converted into voting securities of the surviving entity or its controlling entity) at least 50% of the total voting power represented by the voting securities of the Company or such surviving entity (or its controlling entity) outstanding immediately after such transaction; or (iv) a contest for the election or removal of members of the Board of Directors of the Company that results in the removal from the Board of at least 50% of the incumbent members of the Board; provided, however, in no event shall the securities issued by the Company in connection with a financing transaction (i.e., the primary purpose of which is to raise funds to support the Company's operations) shall be deemed to be a Change of Control.

- (c) "Good Reason" shall mean Optionee's resignation within sixty (60) days after the occurrence of any of the following events without Optionee's consent: (i) a material reduction in the aggregate level of Optionee's base salary and incentive compensation opportunity (other than Company-wide reductions or reductions generally applicable to positions of comparable management authority within the surviving entity following a Change of Control); (ii) a material reduction of Optionee's duties, responsibilities and requirements so that Optionee's duties are no longer consistent with Optionee's position immediately prior to a Change of Control; or (iii) relocation of Optionee's primary place of employment by the Company (or the surviving entity following a Change of Control) to a facility or location more than fifty (50) miles from Optionee's primary place of employment immediately prior to the Change in Control.
- (d) an "Involuntary Termination" shall mean (i) the termination of Optionee's employment by the Company (or the surviving entity following a Change of Control) for reasons other than for Cause or (ii) Optionee's resignation for Good Reason, as those terms are defined herein.

### 13. Securities Matters.

- (a) If, at any time, counsel to the Company shall determine that the listing, registration or qualification of the Common Shares subject to the Option upon any securities exchange or under any state or federal law, or the consent or approval of any governmental or regulatory body, or that the disclosure of non-public information or the satisfaction of any other condition is necessary as a condition of, or in connection with, the issuance or purchase of Common Shares hereunder, such Option may not be exercised, in whole or in part, unless such listing, registration, qualification, consent or approval, or satisfaction of such condition shall have been effected or obtained on conditions acceptable to the Board of Directors. The Company shall be under no obligation to apply for or to obtain such listing, registration or qualification, or to satisfy such condition. The Committee shall inform the Optionee in writing of any decision to defer or prohibit the exercise of an Option. During the period that the effectiveness of the exercise of an Option has been deferred or prohibited, the Optionee may, by written notice, withdraw the Optionee's decision to exercise and obtain a refund of any amount paid with respect thereto.
- (b) The Company may require: (i) the Optionee (or any other person exercising the Option in the case of the Optionee's death or Disability) as a condition of exercising the Option, to give written assurances, in substance and form satisfactory to the Company, to the effect that such person is acquiring the Common Shares subject to the Option for his or her own account for

investment and not with any present intention of selling or otherwise distributing the same, and to make such other representations or covenants; and (ii) that any certificates for Common Shares delivered in connection with the exercise of the Option bear such legends, in each case as the Company deems necessary or appropriate, in order to comply with federal and applicable state securities laws, to comply with covenants or representations made by the Company in connection with any public offering of its Common Shares or otherwise. The Optionee specifically understands and agrees that the Common Shares, if and when issued upon exercise of the Option, may be "restricted securities," as that term is defined in Rule 144 under the Securities Act of 1933 and, accordingly, the Optionee may be required to hold the shares indefinitely unless they are registered under such Securities Act of 1933, as amended, or an exemption from such registration is available.

- (c) The Optionee shall have no rights as a shareholder with respect to any Common Shares covered by the Option (including, without limitation, any rights to receive dividends or non-cash distributions with respect to such shares) until the date of issue of a stock certificate to the Optionee for such Common Shares. No adjustment shall be made for dividends or other rights for which the record date is prior to the date such stock certificate is issued.
- 14. <u>Governing Law</u>. This Option Agreement shall be governed by the applicable Code provisions to the maximum extent possible. Otherwise, the laws of the State of Delaware (without reference to the principles of conflict of laws) shall govern the operation of, and the rights of the Optionee under, the Plan and Options granted thereunder.

IN WITNESS WHEREOF, the Company has caused this Nonqualified Stock Option Agreement to be duly executed by its duly authorized officer, and the Optionee has hereunto set his or her hand and seal, all as of the 20th day of October, 2010.

Transdel Pharmaceuticals, Inc.

By: /s/ John Lomoro

Name: John Lomoro

Title: Chief Financial Officer

/s/ John Bonfiglio

Optionee: John Bonfiglio, Ph.D.

## TRANSDEL PHARMACEUTICALS, INC. 2007 INCENTIVE STOCK AND AWARDS PLAN

# Notice of Exercise of Nonqualified Stock Option

I hereby exercise the nonqualified stock option granted to me pursuant to the Nonqualified Stock Option Agreement dated as of October 20, 2010 by Transdel Pharmaceuticals, Inc. (the "Company"), with respect to the following number of shares of the Company's common stock ("Shares"), par value \$0.001 per Share, covered by said option:

	Number of Shares to be purchased:	
	Purchase price per Share:	\$
	Total purchase price:	\$
— A	. Enclosed is cash or my certified check, bank draft, or postal or express money order in the amount of \$ [circle one] payment for such Shares;	in full/partial
	and/or	
— В	. Enclosed is/are Share(s) with a total fair market value of \$ on the date hereof in full/partial [of such Shares;	circle one] payment
	and/or	
— C.	. I have provided notice to[ insert name of broker], a broker, who will render full/partial [circle one Shares. [Optionee should attach to the notice of exercise provided to such broker a copy of this Notice irrevocable instructions to pay to the Company the full exercise price.]	
	and/or	
— D	. I elect to satisfy the payment for Shares purchased hereunder by having the Company withhold newly acquire to the exercise of the Option.	uired Shares pursuant

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DATED:	 	, 20											
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<sup>\*</sup>Certificates may be registered in the name of the Optionee alone or in the joint names (with right of survivorship) of the Optionee and his or her spouse.

# TRANSDEL PHARMACEUTICALS, INC. RESTRICTED STOCK GRANT NOTICE (2007 INCENTIVE STOCK OPTION AND AWARDS PLAN)

Transdel Pharmaceuticals, Inc. (the "Company"), pursuant to its 2007 Incentive Stock Option and Awards Plan (the "Plan"), hereby awards to Participant the number of shares of the Company's Common Stock set forth below ("Award"). This Award is subject to all of the terms and conditions as set forth herein and in the Restricted Stock Agreement, the Plan, the form of Assignment Separate from Certificate and the form of Joint Escrow Instructions, all of which are attached hereto and incorporated herein in their entirety.

Participant: Dr. John Bonfiglio
Date of Grant: October 20, 2010
Vesting Commencement Date: October 20, 2010
Number of Shares Subject to Award: 50,000

**Vesting Schedule:** The Shares shall vest on and after the following dates, provided the Participant has not terminated his service as of the applicable vesting date:

- (a) 25% of the Common Shares shall vest immediately upon Vesting Commencement Date; and
- (b) the balance of the Common Shares shall vest in equal monthly installments over the next 36 months beginning 30 days after the Vesting Commencement Date;
- (c) provided, however, that Participant shall gain a vested interest in an additional 10% of the Shares upon the closing of a Qualified Transaction.

A "Qualified Transaction" shall mean (i) a debt or equity financing in which the gross proceeds to the Company equals or exceeds \$3 million; or (ii) a corporate partnership transaction that includes gross proceeds to the Company of at least \$3 million to support the Company's general and administrative expenses.

**Additional Terms/Acknowledgements:** The undersigned Participant acknowledges receipt of, and understands and agrees to, this Restricted Stock Grant Notice, the Restricted Stock Agreement and the Plan. Participant further acknowledges that as of the Date of Grant, this Restricted Stock Grant Notice, the Restricted Stock Agreement and the Plan set forth the entire understanding between Participant and the Company regarding the acquisition of stock in the Company and supersede all prior oral and written agreements on that subject.

# TRANSDEL PHARMACEUTICALS, INC.

# PARTICIPANT:

By: /s/ John Lomoro	/s/ John Bonfiglio			
Name: John Lomoro	Signature: Dr. John Bonfiglio			
Title: Chief Financial Officer	Title: Chief Executive Officer			
Date: October 20, 2010	Date: October 20, 2010			

Restricted Stock Agreement, 2007 Incentive Stock Option and Awards Plan, form of Assignment Separate from Certificate and form of Joint Escrow Instructions ATTACHMENTS:

# TRANSDEL PHARMACEUTICALS, INC. 2007 INCENTIVE STOCK OPTION AND AWARDS PLAN Restricted Stock Agreement

Pursuant to the Restricted Stock Grant Notice ("Grant Notice") and this Restricted Stock Agreement (collectively, the "Award") and in consideration of your services as a member of the Board of Directors, Transdel Pharmaceuticals, Inc. (the "Company") has awarded you under its 2007 Incentive Stock Option and Awards Plan (the "Plan") that number of shares of the Company's Common Stock as indicated in the Grant Notice. Defined terms not explicitly defined in this Restricted Stock Agreement but defined in the Plan shall have the same definitions as in the Plan.

The details of your Award are as follows:

#### 1. Vesting.

(a) <u>Normal Vesting</u>. Subject to the limitations contained herein, your Award will vest as provided in the Grant Notice, provided that vesting will cease upon the termination of your Continuous Service.

# (b) Acceleration of Vesting under Certain Circumstances.

- (i) In the event of your death or Disability, then 100% of the shares issued under this Award shall be automatically deemed vested and no longer subject to any Reacquisition Right (as defined below).
- (ii) Upon an Involuntary Termination of Participant's employment within twelve (12) months following a Change of Control, Participant shall automatically gain a vested interest in all then remaining unvested Shares (and the Company's Reacquisition Right shall automatically terminate).

For purposes of this Award,

(a) "Cause" shall mean Participant's: (i) acts of theft, embezzlement, fraud, material dishonesty or misappropriation of any of the Company's (or a surviving entity's following a Change of Control) property, or conviction for, or the entry of a plea of guilty or nolo contendere to, any felony, or to any other crime involving dishonesty, moral turpitude, fraud or embezzlement; (ii) breach of Company's confidentiality agreement, which shall not be subject to any cure; (iii) breach of any material provision of any written agreement between Participant and the Company (or the surviving entity following a Change of Control), other than a breach as described in subsection (ii) above, and failure of Participant to cure such beach, if susceptible to cure, within ten (10) days following Participant's receipt of written notice of such breach; (iv) failure or refusal to perform, or material negligence in the performance of, duties to the Company (or the surviving entity following a Change of Control), or refusal or failure to follow or carry out any reasonable direction of the board of directors of the Company (or of the applicable supervisory personnel of the surviving entity following a Change of Control), which failure or refusal, if susceptible to cure, remains uncured or continues or recurs after ten (10) days following Participant's receipt of written notice specifying the nature of such failure or refusal; (v) inability to perform the essential functions of Participant's position, with or without reasonable accommodation, due to a mental or physical disability; or (vi) death.

- (b) "Change of Control" shall mean the occurrence of any of the following: (i) the sale, lease, conveyance or other disposition of all or substantially all of the Company's assets to any "person" (as such term is used in Section 13(d) of the Exchange Act of 1934, as amended), entity or group of persons acting in concert; (ii) any person or group of persons becoming the "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of the Company representing 50% or more of the total voting power represented by the Company's then outstanding voting securities; (iii) a merger, consolidation or other transaction of the Company with or into any other corporation, entity or person, other than a transaction in which the holders of at least 50% of the shares of capital stock of the Company outstanding immediately prior thereto continue to hold (either by voting securities remaining outstanding or by their being converted into voting securities of the surviving entity or its controlling entity) at least 50% of the total voting power represented by the voting securities of the Company or such surviving entity (or its controlling entity) outstanding immediately after such transaction; or (iv) a contest for the election or removal of members of the Board of Directors of the Company that results in the removal from the Board of at least 50% of the incumbent members of the Board; provided, however, in no event shall the securities issued by the Company in connection with a financing transaction (i.e., the primary purpose of which is to raise funds to support the Company's operations) shall be deemed to be a Change of Control.
- (c) "Good Reason" shall mean Participant's resignation within sixty (60) days after the occurrence of any of the following events without Participant's consent: (i) a material reduction in the aggregate level of Participant's base salary and incentive compensation opportunity (other than Company-wide reductions or reductions generally applicable to positions of comparable management authority within the surviving entity following a Change of Control); (ii) a material reduction of Participant's duties, responsibilities and requirements so that Participant's duties are no longer consistent with Participant's position immediately prior to a Change of Control; or (iii) relocation of Participant's primary place of employment by the Company (or the surviving entity following a Change of Control) to a facility or location more than fifty (50) miles from Participant's primary place of employment immediately prior to the Change in Control.
- (d) "Involuntary Termination" shall mean (i) the termination of Participant's employment by the Company (or the surviving entity following a Change of Control) for reasons other than for Cause or (ii) Participant's resignation for Good Reason, as those terms are defined herein.
- 2. <u>Number of Shares and Consideration</u>. The number of shares subject to your Award is set forth in your Grant Notice and may be adjusted from time to time for capitalization adjustments, as provided in the Plan. As reflected in your Grant Notice, the Award is granted to you in consideration of your services as a member of the Board of Directors. Accordingly, you are not required to make any payment to the Company in order to receive the shares subject to the Award.

3. <u>Securities Law Compliance</u>. You may not be issued any shares under your Award unless the shares are either (i) then registered under the Securities Act or (ii) the Company has determined that such issuance would be exempt from the registration requirements of the Securities Act. Your Award must also comply with other applicable laws and regulations governing the Award, and you will not receive such shares if the Company determines that such receipt would not be in material compliance with such laws and regulations.

## 4. Right of Reacquisition.

- (a) The Company shall have a Reacquisition Right as to the shares you received pursuant to your Award that have not as yet vested in accordance with the Vesting Schedule on the Grant Notice ("Unvested Shares") on the following terms and conditions:
- (i) The Company, shall simultaneously with termination of your Continuous Service automatically reacquire for no consideration (that is, for \$0.00) all of the Unvested Shares, unless the Company agrees to waive its Reacquisition Right as to some or all of the Unvested Shares. Any such waiver shall be exercised by the Company by written notice to you or your representative (with a copy to the Escrow Holder as defined below) within ninety (90) days after the termination of your Continuous Service, and the Escrow Holder may then release to you the number of Unvested Shares not being reacquired by the Company. If the Company does not waive its Reacquisition Right as to all of the Unvested Shares, then upon such termination of your Continuous Service, the Escrow Holder shall transfer to the Company the number of shares the Company is reacquiring.
- (ii) The Company's right to reacquire the shares issued under your Award shall lapse at the rate set forth in your Grant Notice.
- (iii) The shares issued under your Award shall be held in escrow pursuant to the terms of the Joint Escrow Instructions attached to the Grant Notice as Attachment IV. You agree to execute two (2) Assignment Separate From Certificate forms (with date and number of shares blank) substantially in the form attached to the Grant Notice as Attachment III and deliver the same, along with the certificate or certificates evidencing the shares, for use by the escrow agent pursuant to the terms of the Joint Escrow Instructions.
- (iv) Subject to the provisions of your Award, you shall, during the term of your Award, exercise all rights and privileges of a shareholder of the Company with respect to the shares deposited in escrow. You shall be deemed to be the holder of the shares for purposes of receiving any dividends which may be paid with respect to such shares and for purposes of exercising any voting rights relating to such shares, even if some or all of such shares have not yet vested and been released from the Company's Reacquisition Right.
- (v) If, from time to time, there is any stock dividend, stock split or other change in the character or amount of any of the outstanding stock of the corporation the stock of which is subject to the provisions of your Award, then in such event any and all new, substituted or additional securities to which you is entitled by reason of your ownership of the shares acquired under your Award shall be immediately subject to the Reacquisition Right with the same force and effect as the shares subject to this Reacquisition Right immediately before such event.

5. <u>Restrictive Legends</u>. The Company may at any time place legends referencing the Reacquisition Right and any applicable federal, state or foreign securities law restrictions on all certificates representing the shares issued under your Award. You shall, at the request of the Company, promptly present to the Company any and all certificates representing the shares under your Award in your possession in order to carry out the provisions of this Section. Unless otherwise specified by the Company, legends placed on such certificates may include, but shall not be limited to, the following:

"THE SECURITIES REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO RESTRICTIONS SET FORTH IN AN AGREEMENT BETWEEN THIS CORPORATION AND THE REGISTERED HOLDER, OR HIS PREDECESSOR IN INTEREST, A COPY OF WHICH IS ON FILE AT THE PRINCIPAL OFFICE OF THIS CORPORATION."

- 6. <u>Transfers in Violation of Agreement</u>. No shares under your Award may be sold, exchanged, transferred, assigned, pledged, hypothecated or otherwise disposed of, including by operation of law, in any manner that violates any of the provisions of this Award until the date on which such shares are no longer Unvested Shares, and any such attempted disposition shall be void. The Company shall not be required (a) to transfer on its books any shares under your Award that will have been transferred in violation of any of the provisions set forth in this Award or (b) to treat as owner of such shares under your Award or to accord the right to vote as such owner or to pay dividends to any transferee to whom such shares will have been so transferred. In order to enforce its rights under this Section, the Company shall be authorized to give a stop transfer instruction with respect to the shares to the Company's transfer agent.
- 7. Award not a Service Contract. Your Award is not an employment or service contract, and nothing in your Award shall be deemed to create in any way whatsoever any obligation on your part to continue in the employ of the Company or an Affiliate, or on the part of the Company or an Affiliate to continue your employment. In addition, nothing in your Award shall obligate the Company or an Affiliate, their respective shareholders, boards of directors, officers or employees to continue any relationship that you might have as a director or consultant for the Company or an Affiliate.

8. <u>Adjustments for Changes in Capital Structure</u>. Subject to any required action by the stockholders of the Company, in the event of any change in the stock effected without receipt of consideration by the Company, whether through merger, consolidation, reorganization, reincorporation, recapitalization, reclassification, stock dividend, stock split, reverse stock split, split-up, split-off, spin-off, combination of shares, exchange of shares, or similar change in the capital structure of the Company, or in the event of payment of a dividend or distribution to the stockholders of the Company in a form other than stock (excepting normal cash dividends) that has a material effect on the fair market value of shares of stock, appropriate adjustments shall be made in the number and kind of shares subject to this Award, in order to prevent dilution or enlargement of your rights under this Award.

### 9. Withholding Obligations.

- (a) At the time your Award is made, or at any time thereafter as requested by the Company, you hereby authorize withholding from payroll and any other amounts payable to you, and otherwise agree to make adequate provision for any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or an Affiliate, if any, which arise in connection with your Award.
- (b) Unless the tax withholding obligations of the Company and/or any Affiliate are satisfied, the Company shall have no obligation to issue a certificate for such shares or release such shares from any escrow provided for herein.

#### 10. Tax Consequences.

(a) You understand that Section 83 of the Internal Revenue Code, as amended (the "Code") taxes as ordinary income the difference between the amount paid for the shares subject to this Award, if anything, and the fair market value of such shares as of the date on which the shares are "substantially vested," within the meaning of Section 83. In this context, "substantially vested" means that the right of the Company to reacquire the shares pursuant to the Reacquisition Right has lapsed. You understand that you may elect to have your taxable income determined at the time you acquire the shares rather than when and as the Reacquisition Right lapses by filing an election under Section 83(b) of the Code with the Internal Revenue Service attached hereto no later than thirty (30) days after the date of acquisition of the shares. You understand that failure to make a timely filing under Section 83(b) will result in your recognition of ordinary income, as the Reacquisition Right lapses, on the difference between the purchase price, if anything, and the fair market value of the shares issued under the Award at the time such restrictions lapse. You further understand, however, that if such shares with respect to which an election under Section 83(b) has been made are forfeited to the Company pursuant to its Reacquisition Right, such forfeiture will be treated as a sale on which there is realized a loss equal to the excess (if any) of the amount paid (if any) by you for the forfeited shares over the amount realized (if any) upon their forfeiture. If you have paid nothing for the forfeited shares and have received no payment upon their forfeiture, you understand that you will be unable to recognize any loss on the forfeiture of the shares even though you incurred a tax liability by making an election under Section 83(b).

- (b) You understand that you should consult with your tax advisor regarding the advisability of filing with the Internal Revenue Service an election under Section 83(b) of the Code, which must be filed no later than thirty (30) days after the date of the acquisition of the shares issued under this Award. Failure to file an election under Section 83(b), if appropriate, may result in adverse tax consequences to you. You acknowledge that you have been advised to consult with a tax advisor regarding the tax consequences to you of the acquisition of shares hereunder. ANY ELECTION UNDER SECTION 83(b) YOU WISH TO MAKE MUST BE FILED NO LATER THAN 30 DAYS AFTER THE DATE ON WHICH YOU ACQUIRE THE SHARES. THIS TIME PERIOD CANNOT BE EXTENDED. YOU ACKNOWLEDGE THAT TIMELY FILING OF A SECTION 83(b) ELECTION IS YOUR SOLE RESPONSIBILITY, EVEN IF YOU REQUEST THE COMPANY OR ITS REPRESENTATIVE TO FILE SUCH ELECTION ON YOUR BEHALF.
- (c) You will notify the Company in writing if you file an election pursuant to Section 83(b) of the Code. The Company intends, in the event it does not receive your evidence of such filing, to claim a tax deduction for any amount that would otherwise be taxable to you in the absence of such an election.
- 11. <u>Notices</u>. Any notices provided for in your Award or the Plan shall be given in writing and shall be deemed effectively given upon receipt or, in the case of notices delivered by the Company to you, five (5) days after deposit in the United States mail, postage prepaid, addressed to you at the last address you provided to the Company.

#### 12. Miscellaneous.

- (a) The rights and obligations of the Company under your Award shall be transferable to any one or more persons or entities, and all covenants and agreements hereunder shall inure to the benefit of, and be enforceable by the Company's successors and assigns. Your rights and obligations under your Award may only be assigned with the prior written consent of the Company.
- (b) You agree upon request to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent of your Award.
- (c) You acknowledge and agree that you have reviewed your Award in its entirety, have had an opportunity to obtain the advice of counsel prior to executing and accepting your Award and fully understand all provisions of your Award.
- (d) The Company may terminate or amend the Plan or this Award at any time; provided, however, that no such termination or amendment may adversely affect your rights under this Award without your consent unless such termination or amendment is necessary to comply with applicable law or government regulation. No amendment or addition to this Award shall be effective unless in writing.

- (e) By signing this Agreement, you acknowledge that your personal employment information regarding participation in the Plan and information necessary to determine and pay, if applicable, benefits under the Plan must be shared with other entities, including companies related to the Company and persons responsible for certain acts in the administration of the Plan. By signing this Agreement, you consent to such transmission of personal data as the Company believes is appropriate to administer the Plan.
- (f) To the extent not preempted by federal law, this Agreement shall be governed by, and construed in accordance with, the laws of the State of California.
- 13. <u>Governing Plan Document</u>. Your Award is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your Award, and is further subject to all interpretations, amendments, rules and regulations which may from time to time be promulgated and adopted pursuant to the Plan. In the event of any conflict between the provisions of your Award and those of the Plan, the provisions of the Plan shall control.

IN WITNESS WHEREOF, the parties hereto have duly executed this Restricted Stock Agreement as of the $20^{th}$ day of October 2010.				
TRANSDEL PHARMACEUTICALS, INC.	RECIPIENT:			
By: /s/ John Lomoro	/s/ John Bonfiglio Signature: John Bonfiglio, Ph.D.			
Name: John Lomoro	Address:			
Title: Chief Financial Officer				

# FORM OF ASSIGNMENT SEPARATE FROM CERTIFICATE

Dr. John Bonfiglio hereby sells, assigns and transfers unto Trans shares of the common stock of the Assignee, stan represented by Certificate No herewith and do he as attorney-in-fact to transfer the said stock on the the premises. This Assignment may be used only in accordance	f the Corporation issued to the undersigned pursuant to the Award, and
Dated:	DR. JOHN BONFIGLIO
[Instruction: Please do not fill in any blanks other than the sig Company to exercise its Reacquisition Right set forth in the A	, , , , ,

#### JOINT ESCROW INSTRUCTIONS

October 20, 2010

Corporate Secretary Transdel Pharmaceuticals, Inc. 4275 Executive Square, Suite 230 La Jolla, California 92037

Dear Sir/Madam:

As Escrow Agent for both Transdel Pharmaceuticals, Inc., a Delaware corporation (the "Company"), and the undersigned recipient of stock of the Company ("Recipient"), you are hereby authorized and directed to hold the documents delivered to you pursuant to the terms of that certain Restricted Stock Grant Notice (the "Grant Notice"), dated October 20, 2010 to which a copy of these Joint Escrow Instructions is attached as Attachment IV, and pursuant to the terms of that certain Restricted Stock Agreement ("Agreement"), which is Attachment I to the Grant Notice, in accordance with the following instructions:

- 1. In the event Recipient ceases to render services to the Company or an affiliate of the Company during the vesting period set forth in the Grant Notice, the Company or its assignee will give to Recipient and you a written notice specifying that the shares of stock shall be transferred to the Company. Recipient and the Company hereby irrevocably authorize and direct you to close the transaction contemplated by such notice in accordance with the terms of said notice.
- 2. At the closing you are directed (a) to date any stock assignments necessary for the transfer in question, (b) to fill in the number of shares being transferred, and (c) to deliver same, together with the certificate evidencing the shares of stock to be transferred, to the Company.
- 3. Recipient irrevocably authorizes the Company to deposit with you any certificates evidencing shares of stock to be held by you hereunder and any additions and substitutions to said shares as specified in the Grant Notice. Recipient does hereby irrevocably constitute and appoint you as Recipient's attorney-in-fact and agent for the term of this escrow to execute with respect to such securities and other property all documents of assignment and/or transfer and all stock certificates necessary or appropriate to make all securities negotiable and complete any transaction herein contemplated.
  - 4. This escrow shall terminate upon vesting of the shares or upon the earlier return of the shares to the Company.
- 5. If at the time of termination of this escrow you should have in your possession any documents, securities, or other property belonging to Recipient, you shall deliver all of same to any pledgee entitled thereto or, if none, to Recipient and shall be discharged of all further obligations hereunder.

- 6. Your duties hereunder may be altered, amended, modified or revoked only by a writing signed by all of the parties hereto.
- 7. You shall be obligated only for the performance of such duties as are specifically set forth herein and may rely and shall be protected in relying or refraining from acting on any instrument reasonably believed by you to be genuine and to have been signed or presented by the proper party or parties or their assignees. You shall not be personally liable for any act you may do or omit to do hereunder as Escrow Agent or as attorney-in-fact for Recipient while acting in good faith and any act done or omitted by you pursuant to the advice of your own attorneys shall be conclusive evidence of such good faith.
- 8. You are hereby expressly authorized to disregard any and all warnings given by any of the parties hereto or by any other person or corporation, excepting only orders or process of courts of law, and are hereby expressly authorized to comply with and obey orders, judgments or decrees of any court. In case you obey or comply with any such order, judgment or decree of any court, you shall not be liable to any of the parties hereto or to any other person, firm or corporation by reason of such compliance, notwithstanding any such order, judgment or decree being subsequently reversed, modified, annulled, set aside, vacated or found to have been entered without jurisdiction.
- 9. You shall not be liable in any respect on account of the identity, authority or rights of the parties executing or delivering or purporting to execute or deliver the Grant Notice or any documents or papers deposited or called for hereunder.
- 10. You shall not be liable for the outlawing of any rights under any statute of limitations with respect to these Joint Escrow Instructions or any documents deposited with you.
- 11. You shall be entitled to employ such legal counsel, including but not limited to DLA Piper LLP (US), and other experts as you may deem necessary properly to advise you in connection with your obligations hereunder, may rely upon the advice of such counsel, and may pay such counsel reasonable compensation therefor.
- 12. Your responsibilities as Escrow Agent hereunder shall terminate if you shall cease to be Secretary of the Company or if you shall resign by written notice to each party. In the event of any such termination, the Company may appoint any officer or assistant officer of the Company as successor Escrow Agent and Recipient hereby confirms the appointment of such successor or successors as his attorney-in-fact and agent to the full extent of your appointment.
- 13. If you reasonably require other or further instruments in connection with these Joint Escrow Instructions or obligations in respect hereto, the necessary parties hereto shall join in furnishing such instruments.
- 14. It is understood and agreed that should any dispute arise with respect to the delivery and/or ownership or right of possession of the securities, you may (but are not obligated to) retain in your possession without liability to anyone all or any part of said securities until such dispute shall have been settled either by mutual written agreement of the parties concerned or by a final order, decree or judgment of a court of competent jurisdiction after the time for appeal has expired and no appeal has been perfected, but you shall be under no duty whatsoever to institute or defend any such proceedings.

15. Any notice required or permitted hereunder shall be given in writing and shall be deemed effectively given upon personal delivery or upon deposit in any United States Post Box, by registered or certified mail with postage and fees prepaid, addressed to each of the other parties hereunto entitled at the following addresses, or at such other addresses as a party may designate by ten (10) days' written notice to each of the other parties hereto:

COMPANY: Transdel Pharmaceuticals, Inc.

4275 Executive Square, Suite 230 La Jolla, California 92037 Attn: Chief Financial Officer

RECIPIENT: Dr. John Bonfiglio

ESCROW AGENT: Transdel Pharmaceuticals, Inc.

4275 Executive Square, Suite 230

La Jolla, California 92037 Attn: Corporate Secretary

16. By signing these Joint Escrow Instructions you become a party hereto only for the purpose of said Joint Escrow Instructions; you do not become a party to the Grant Notice.

17. This instrument shall be binding upon and inure to the benefit of the parties hereto, and their respective successors and permitted assigns. It is understood and agreed that references to "you" or "your" herein refer to the original Escrow Agent and to any and all successor Escrow Agents. It is understood and agreed that the Company may at any time or from time to time assign its rights under the Grant Notice and these Joint Escrow Instructions in whole or in part.						
	Very truly yours,					
	TRANSDEL PHARMACEUTICALS, INC.					
	By: /s/John Lomoro					
	Name: John Lomoro Title: Chief Financial Officer					
	RECIPIENT					
	/s/ John Bonfiglio					
	Signature					
ESCROW AGENT:						
/s/ John Lomoro						
Signature						

# ELECTION UNDER SECTION 83(b) OF THE INTERNAL REVENUE CODE OF 1986

The undersigned taxpayer hereby elects, pursuant to Section 83(b) of the Internal Revenue Code, to include in taxpayer's gross income or alternative minimum taxable income, as applicable, for the current taxable year, the amount of any income that may be taxable to taxpayer in connection with taxpayer's receipt of the property described below:

1.	The name, address, taxpayer identification number and taxable year of the undersigned are as follows:						
	NAME OF TAXPAYER: Dr. John Bonfiglio						
	NAME OF SPOUSE:						
	ADDRESS:						
	IDENTIFICATION NO. OF TAXPAYER:						
	IDENTIFICATION NO. OF SPOUSE:						
	TAXABLE YEAR: 2010						
2.	The property with respect to which the election is made is described as follows:						
	50,000 shares of the Common Stock of Transdel Pharmaceuticals, Inc., a Delaware corporation (the "Company").						
3.	The date on which the property was transferred is: October 20, 2010						
4.	The property is subject to the following restrictions:						
	Repurchase option at cost in favor of the Company upon termination of taxpayer's employment or consulting relationship.						
5.	The fair market value at the time of transfer, determined without regard to any restriction other than a restriction which by it terms will never lapse, of such property is: <u>\$0.80.</u>						
6.	The amount (if any) paid for such property: <u>none.</u>						
unde	undersigned has submitted a copy of this statement to the person for whom the services were performed in connection with the rsigned's receipt of the above-described property. The transferee of such property is the person performing the services in ection with the transfer of said property.						
The u	undersigned understands that the foregoing election may not be revoked except with the consent of the Commissioner.						
Date	d: Taxpayer						
	• •						
Date	d: Spouse of Taxpayer						

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

- I, John Bonfiglio, Ph.D, President and Chief Executive Officer of Transdel Pharmaceuticals, Inc., certify that:
  - (1) I have reviewed this quarterly report on Form 10-Q of Transdel Pharmaceuticals, Inc.;
  - (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
  - (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
  - (4) I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    - Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    - d) Disclosed in the report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of the annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;
  - (5) I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and registrant's board of directors (or persons performing the equivalent functions):
    - 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 8, 2010 /s/ John Bonfiglio
John Bonfiglio, Ph.D.

President and Chief Executive Officer (Principal Executive Officer)

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

- I, John Lomoro, Chief Financial Officer of Transdel Pharmaceuticals, Inc., certify that:
  - (1) I have reviewed this quarterly report on Form 10-Q of Transdel Pharmaceuticals, Inc.;
  - (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
  - (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
  - (4) I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    - Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our
      conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by
      this report based on such evaluation; and
    - d) Disclosed in the report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of the annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;
  - (5) I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and registrant's board of directors (or persons performing the equivalent functions):
    - 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 8, 2010 /s/ John Lomoro

John 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 September 30, 2010 as filed with the Securities and Exchange Commission on the date hereof (the "Report") pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, John Bonfiglio, 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 8, 2010

/s/ John Bonfiglio

John Bonfiglio, Ph.D. Chief Executive Officer (Principal Executive Officer)

/s/ John T. Lomoro

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