# SECURITIES AND EXCHANGE COMMISSION WASHINGTON, DC 20549

### FORM 8-K

Current Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): October 26, 2009

# TRANSDEL PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Charter)

**Delaware** (State of Incorporation)

000-52998

45-0567010

(Commission File Number)

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

4225 Executive Square, Suite 485, La Jolla, California

(Address of Principal Executive Offices)

**92037** (Zip Code)

Registrant's telephone number, including area code: (858) 457-5300

### **Not Applicable**

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

### Item 7.01. Regulation FD Disclosure.

On Monday, October 26, 2009, Dr. Juliet Singh, Transdel Pharmaceutical, Inc.'s President and Chief Executive Officer, will be presenting at the 4th Annual BIOCOM Investor Conference held at the Hyatt Regency Hotel in La Jolla, California. Dr. Singh will also be presenting at the 8th Annual BIO Investor Forum held at the Palace Hotel in San Francisco, California on Thursday, October 29, 2009. A copy of Dr. Singh's presentation, which provides information regarding Transdel's Phase 3 clinical trial results for its lead topical pain drug Ketotransdel®, is attached as Exhibit 99.1 to this Current Report on Form 8-K and will be shown at both conferences.

### Item 9.01. Financial Statements and Exhibits

### (d) Exhibits

Exhibit No. Description

99.1 Presentation for both the 4th Annual BIOCOM Investor Conference, to be held at the Hyatt Regency Hotel in La Jolla, California on October 26, 2009 and the 8th Annual Bio Investors Forum, to be held at the Palace Hotel in San Francisco, California on October 29, 2009.

### **SIGNATURE**

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.

Dated: October 26, 2009

TRANSDEL PHARMACEUTICALS, INC.

By: <u>/s/ John T. L</u>omoro

John T. Lomoro Chief Financial Officer

### EXHIBIT INDEX

Exhibit No. Description

99.1 Presentation for both the 4th Annual BIOCOM Investor Conference, to be held at the Hyatt Regency Hotel in La Jolla, California on October 26, 2009 and the 8th Annual Bio Investors Forum, to be held at the Palace Hotel in San Francisco, California on October 29, 2009.

# Transdel Pharmaceuticals, Inc.



Symbol: TDLP.OB

October 2009

### Safe Harbor Statement

The Company cautions you that the statements included in this presentation that are not a description of historical facts are forward-looking statements. These include statements regarding: the Company's interpretation of the results of its Phase 3 clinical trial for Ketotransdel\*; whether the results from the clinical trial, along with any other clinical trials that may be required by the FDA, will be sufficient to support a 505(b)2 New Drug Approval (NDA) submission; the potential indications for use for Ketotransdel®; the market opportunity for the Company's products; and the Company's ability to complete additional development activities for products utilizing its proprietary transdermal delivery platform. Actual results may differ materially from those set forth in this presentation due to the risks and uncertainties inherent in the Company's business, including, without limitation: the outcome of the final analyses of the data from the Phase 3 clinical trial may vary from the Company's initial conclusions; the FDA may not agree with the Company's interpretation of such results or may challenge the adequacy of the Company's clinical trial design or the execution of the clinical trial; the FDA may continue to require the Company to complete additional clinical trials for Ketotransdel® before the Company can submit a 505(b)2 NDA application; the results of any future clinical trials may not be favorable and the Company may never receive regulatory approval for Ketotransdel®; technological changes or competitive products or pricing may prevent the Company from successfully commercializing its products; and the Company's current need to raise additional funding to complete its product development plans. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements is set forth in the Company's filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K and its Quarterly Reports on Form 10-Q filed with the SEC. Such documents may be read free of charge on the SEC's web site at www.sec.gov. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement and the Company undertakes no obligation to revise or update this presentation to reflect events or circumstances after the date hereof. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.



# Company Overview

# □ Specialty pharmaceutical company

- Focused on the development and commercialization of topically delivered medications
- Products based on proprietary transdermal delivery technology
- Lead pain program, Ketotransdel®, has successfully completed a Phase 3 trial demonstrating significant efficacy and safety
- Expanding co-development opportunities for other programs



# Transdel Investment Highlights

### ☐ Positive Phase 3 results for lead pain drug, Ketotransdel

- Reported statistically significant efficacy results and excellent safety in Phase 3 trial
- Minimal blood concentrations of ketoprofen in pharmacokinetic studies

### Large market opportunity for Ketotransdel

U.S. market for NSAIDs and Cox-2 inhibitors is in excess of \$6 billion per year

### ☐ Partnership/collaboration opportunity

- Ketotransdel® positive data expected to increase partnering interest
- Discussions underway on co-development opportunities for other programs

### □ Novel transdermal delivery platform applicable to a broad range of drugs

- Proprietary technology provides opportunity to generate additional pipeline candidates using existing or novel drugs
- Opportunity to leverage technology for cosmeceutical applications (e.g. JH Direct partnership for anti-cellulite product)
- ☐ Highly qualified team with significant industry experience

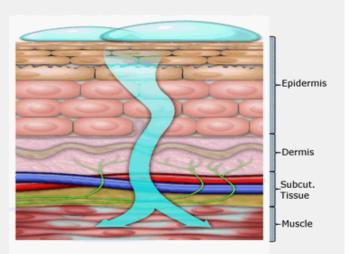


# Transdel Transdermal Delivery System (TDS)

# Transdel's Transdermal Delivery System (TDS)

TDS is a nanoparticulate matrix topical cream

- □ Transdel's proprietary cream formulation enables active drug to penetrate the skin and reach targeted underlying tissue
- ☐ Components generally regarded as safe (GRAS)
- Delivery system uses synergistic mechanisms to enhance penetration
- ☐ Thermodynamic stable properties allow solubilization of drug and then promote release of drug

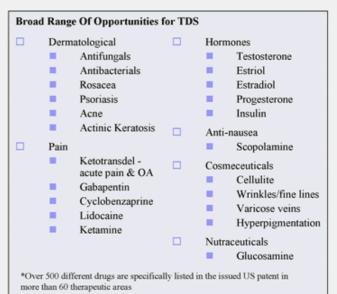




# Transdermal Delivery System (TDS)

### TDS platform provides significant benefits

- Compatible with broad range of drugs and molecular sizes
- Maximizes solubilization of drugs (lipophilic, hydrophilic and amphiphilic)
- Broad patented technology platform with issued IP covering composition of matter, methods of use and methods of manufacture





# **Ketotransdel®**

# Ketotransdel: Product Profile

- □ Ketotransdel is comprised of a transdermal cream formulation of ketoprofen, and our proprietary patented Transdel drug delivery system
- Ketoprofen is a non-steroidal anti-inflammatory drug (NSAID) that has been found to be among the most efficacious topical NSAIDs
- ☐ Delivers 100mg of ketoprofen per 1g of cream
  - Same dosage as oral ketoprofen when used in recommended dosage of 3x per day
- ☐ Completed Phase 1/2 and Phase 3 trials demonstrated:
  - Statistically significant efficacy
  - Excellent safety and tolerability
  - Minimal blood concentrations



# Ketotransdel Market Opportunity

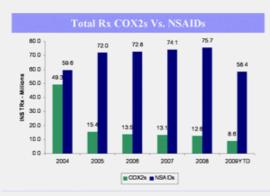
Pain treatments are the third most-prescribed class of drugs in the U.S.
According to market research firm BCC Research the global market for pain relievers was worth \$19.1 billion in 2008, and is expected to grow to \$32.8 billion by 2013
Market for NSAIDs and Cox-2 inhibitors exceeds \$6 billion in the U.S. per year
<ul> <li>Oral NSAIDs are associated with serious gastro-intestinal, cardiac, renal and liver side effects</li> </ul>
<ul> <li>Withdrawal of Bextra and Vioxx leaves multi-billion dollar market largely replaced by oral NSAIDs</li> </ul>
Everyday OTC painkillers such as aspirin, acetaminophen (Tylenol) and Advil may result in safety concerns and may not be potent or efficacious for acute musculoskeletal pain of moderate intensity
Physicians and patients are continuing to seek alternative options for effective and safe pain medications
Ketotransdel, if approved by the FDA, could become the first topical NSAID cream product in the U.S. for acute pain management
The U.S. transdermal drug delivery market is projected to increase to \$4.5 billion in 2012*

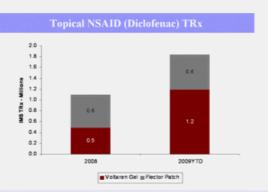
\*Source: U.S. Transdermal Drug Delivery Markets, Frost and Sullivan, August 2006.



# Pain Therapeutic Market Dynamics

- The withdrawal of Vioxx and Bextra has resulted in a significant decline in COX-2 prescriptions and a significant increase in NSAID prescriptions
  - After an increase in 2005 when the COX-2's were withdrawn, NSAID TRx's have continued to post steady year-over-year growth
- Since the introduction of Flector Patch and Voltaren Gel in late 2007 / early 2008, prescriptions for these two topical medications have increased substantially
  - In 2009, Voltaren Gel prescriptions have surpassed Flector Patch prescriptions





Note: Graphs denote total prescriptions, per IMS data. 2009YTD figures include monthly IMS TRx through September 2009.



# Ketotransdel Phase 3 Trial

Clinical Design: Randomized, double-blind, placebo controlled

Study Population: 364 patients

Indication: Acute soft tissue injuries (sprains & strains)

Dosing Regimen: Ketoprofen vs. Placebo (Vehicle) cream, 1g three times daily

over 7 days

Primary Endpoint: Change from baseline in pain intensity on Day 3 (VAS)

Secondary Endpoints: Safety assessments, various other efficacy variables

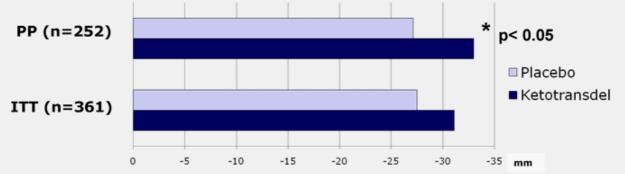
Pharmacokinetics in subset of patients

Clinical Sites: 26 (USA)



# **Primary Efficacy Results**

### Change from Baseline in Pain Intensity on Day 3



Mean reduction from baseline in mm (100 mm Visual Analogue Scale)

Ketotransdel demonstrated statistically significant higher reduction in pain intensity from baseline in the Per Protocol (PP) analysis and a favorable treatment effect in the Intent-To-Treat (ITT) analysis

PP population included:

Pre-specified minimum use of study medication; Valid Day 3 Pain Assessments; No unallowed drug use.



# Safety and Pharmacokinetics

	Ketotransdel (n= 182)	Placebo (n=182)
All potentially related		
Adverse Events (AEs): 15 (4.1%)	7 (3.8%)	8 (4.4%)

- ✓ Ketotransdel demonstrated excellent safety and tolerability
- ✓ Low overall incidence of AEs
- ✓ No related gastrointestinal, cardiac, liver, kidney or other serious AEs
- ✓ Few potentially related adverse events (mainly cutaneous)
- ✓ No clinically relevant changes in blood and urine tests
- ✓ Minimal systemic absorption (mean Cmax 39 ng/mL) consistent with previous findings (approximately 1 2 % of oral ketoprofen dose)



# Conclusions - Ketotransdel Phase 3

- $\square$  Ketotransdel achieved statistical significance in its Primary Efficacy Endpoint in the Per Protocol population (p < 0.05)
- ☐ Ketotransdel demonstrated excellent safety and tolerability
- No treatment related gastrointestinal, cardiac, liver, kidney or other serious adverse events
- □ No clinically relevant changes in blood and urine tests
- Minimal blood concentrations of ketoprofen in pharmacokinetic study, consistent with previous findings
- Estimated systemic absorption about 1 2 % of a comparable oral ketoprofen dose, consistent with previous findings



# Patients Who May Benefit From a Topical NSAID

- Healthy patients with localized pain
- History of gastrointestinal symptoms / gastrointestinal ulceration
- History of heart, liver, kidney disease or other serious medical conditions
- Elderly and Children
- Intake of multiple drugs for other conditions (minimize drug-to-drug interactions)
  - Corticosteroid use with oral NSAIDs increases adverse risks 15-times
  - Anti-coagulants with oral NSAIDs increase mortality by 12times
- Cannot take drugs orally / have swallowing difficulties



# Ketotransdel Competitive Advantages

- Provides alternative to address the significant safety concerns associated with oral COX-2 inhibitors / nonselective oral NSAIDs and acetaminophen
- Broad technology platform that is patent protected
- Less invasive delivery
- ☐ Faster delivers drugs in few minutes with no residue
- Large and growing market opportunity
- □ Void in pain management market due to withdrawal of Vioxx and Bextra
- Excellent safety profile
- Potential for multiple indications
- Rx path with the FDA

Ketotransdel® could address significant unmet medical need for pain management



# Ketotransdel Next Steps

- ☐ Finalize registration strategy
- Continue partnering discussions
  - Discussions underway with several potential sales and marketing partners



# Cosmeceutical Applications of TDS

- Lead product anti-cellulite formulation
- In June 2009, the Company announced that it entered into a license agreement with JH Direct, LLC for the exclusive worldwide rights to Transdel's anticellulite cosmeceutical product which utilizes the Company's Transdel technology
- Anticipated expansion of cosmetic/cosmeceuticals pipeline to include the following formulations:
  - Anti-aging
  - Hyperpigmentation
  - Varicose veins
- Pursuing discussions with potential sales and marketing partners for these cosmetic/cosmeceutical products



# Transdel Management Team

### Juliet Singh, Ph.D., Chief Executive Officer/President

- Over 20 years of pharmaceutical management experience: Allergan; Baxter Healthcare; and, Collateral Therapeutics
- Corporate Officer responsible for Regulatory Affairs & Quality Assurance
- Managed worldwide regulatory submissions of BOTOX® and recombinant factor VIII

### John Lomoro, Chief Financial Officer

- Over 15 years of financial experience with public and private organizations, including 5 years with Ernst & Young LLP
- Director, North America Accounting, Carl Zeiss Vision Inc.
- Certified Public Accountant

### Joachim P. H. Schupp, M.D., Chief Medical Officer

- Over 24 years of leadership experience in strategic design and execution of international clinical development projects, cross-functional project management and post-marketing surveillance in the pharmaceutical industry
- Senior management positions at Ciba-Geigy, Novartis, ProSanos Inc., Adventrx Pharmaceuticals
- Significantly contributed to the successful development, registration and launch of new and life cycle products (Voltaren, Cataflam, Apligraf, Sandoglobulin, Femara, Exjade)



# Select Financials

Key Statistics						
Symbol:	TDLP.OB	Fiscal Year End:	December 31st			
Current Price (10/23/09):	\$1.85	Shares Outstanding:	15.6 million			
Market Cap:	\$28.9 million	Cash (as of 6/30/09)	\$2.9 million			



# Transdel Investment Highlights

### ☐ Positive Phase 3 results for lead pain drug, Ketotransdel

- Reported statistically significant efficacy results and excellent safety in Phase 3 trial
- Minimal blood concentrations of ketoprofen in pharmacokinetic studies

### Large market opportunity for Ketotransdel

- U.S. market for NSAIDs and Cox-2 inhibitors is in excess of \$6 billion per year
- Ketotransdel® may have advantages over recently launched topical pain medications

### □ Partnership/collaboration opportunity

- Ketotransdel® positive data expected to increase partnering interest
- Discussions underway on co-development opportunities for other programs

### □ Novel transdermal delivery platform applicable to a broad range of drugs

- Proprietary technology provides opportunity to generate additional pipeline candidates using existing or novel drugs
- Opportunity to leverage technology for cosmeceutical applications (e.g. JH Direct partnership for anti-cellulite product)
- Highly qualified team with significant industry experience



# Contact Us

### **Corporate Headquarters**

Transdel Pharmaceuticals, Inc. (OTC BB: TDLP.OB)

4225 Executive Square

Suite 485

La Jolla, CA 92037

### **Investor Contact**

John Lomoro Chief Financial Officer (858) 457-5300 johnl@transdelpharma.com

Please visit www.transdelpharma.com for more information.

