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 6, 2009

TRANSDEL PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware (State of Incorporation) **000-52998** (Commission File Number) **45-0567010** (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 8.01 Other Events.

In connection with the announcement by Transdel Pharmaceuticals, Inc. (the "Company") of the top-line results of the Phase 3 clinical study of Ketotransdel®, the Company issued a press release on October 6, 2009. A copy of this press release is included as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibit No. Description

99.1 Press Release of the Company, dated October 6, 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 6, 2009

TRANSDEL PHARMACEUTICALS, INC.

By: /s/ John T. Lomoro

John T. Lomoro Chief Financial Officer Exhibit No. Description

99.1 Press Release of the Company, dated October 6, 2009.





Transdel Pharmaceuticals Announces Positive Phase 3 Study Results for Lead Topical Pain Drug Ketotransdel®

- Primary Efficacy Endpoint Met
- Excellent Safety and Tolerability Profile Demonstrated
- Minimal Systemic Exposure Found in Pharmacokinetic Sub-Study
- Company to Host Conference Call/Webcast Today at 9:00 a.m., (EDT)

LA JOLLA, CA — October 6, 2009 — Transdel Pharmaceuticals, Inc. (OTCBB: TDLP), a specialty pharmaceutical company focused on developing topically administered products using its proprietary transdermal delivery platform, today announced positive top-line clinical results for its lead pain drug Ketotransdel[®] in a Phase 3 trial which evaluated the efficacy and safety of the drug in acute soft tissue injuries of the upper and lower extremities. Ketotransdel[®] is comprised of a transdermal formulation of ketoprofen, an NSAID (Non-Steroidal Anti-inflammatory Drug), and the Company's innovative proprietary Transdel[™] drug delivery system.

Top-Line Results and Trial Design

The double-blind, randomized, placebo-controlled, multi-center Phase 3 study enrolled a total of 364 patients with acute soft tissue injuries 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 Day 3. The VAS is a well known and validated instrument for pain measurement. The study achieved statistical significance in its primary endpoint in the per protocol analysis. The statistical analysis of those patients that complied with the study requirements (the per protocol (PP) population) included a total of 252 patients and showed a positive and statistically significant outcome in the primary efficacy endpoint between Ketotransdel[®] and placebo, reaching a p-value of less than 0.05.

Secondary endpoints included safety assessments and other efficacy parameters.

Ketotransdel[®] demonstrated an excellent safety and tolerability profile similar to the placebo cream. In particular, there were no Ketotransdel[®] treatment related gastrointestinal, cardiovascular or other clinically relevant adverse events reported, which are commonly observed with oral NSAIDs.

Ketotransdel[®] was well absorbed through the skin with minimal blood concentrations of ketoprofen detected in a subset of patients who underwent pharmacokinetic (PK) assessments following multiple exposures during the study. These PK results are consistent with the Company's previous clinical study findings.

Analysis of the Intent-to-Treat (ITT) population of the primary efficacy endpoint (which includes all study patients even if they failed to comply with the protocol and study requirements) favored Ketotransdel[®] compared to placebo but not to a degree that reached statistical significance. We believe that this finding was not due to a lack of effect of Ketotransdel[®], but rather due to patient compliance issues, non-adherence to protocol procedures and other potentially confounding factors (e.g., incorrect use of study drugs and/or concomitant use of unallowed drugs).

"Based on these positive top-line clinical results and the excellent safety profile demonstrated, we believe Ketotransdel[®] is well-positioned to address a critical need in the pain management marketplace. We are committed to continue working closely with the FDA to bring this much needed drug to the marketplace as soon as possible," stated Dr. Juliet Singh, President and Chief Executive Officer of Transdel Pharmaceuticals. "In addition, this clinical study further validates the great potential of our proprietary transdermal drug delivery platform, and we look forward to maximizing the medical and commercial potential of this technology to bring important therapies to patients."

"There is a significant need among healthcare providers and patients for safe and effective therapies for pain management," said lead clinical investigator Evan F. Ekman, M.D. and President of Southern Orthopaedic Sports Medicine and Medical Director of Palmetto Health Parkridge Surgery Center. "The results from this Phase 3 clinical trial are very encouraging. They confirm to me that Ketotransdel® has a valuable role as a potentially safer and effective analgesic and anti-inflammatory treatment compared to available oral pain drugs, including oral NSAIDs, which are associated with gastrointestinal, cardiovascular and other medical problems."

Further detailed analyses are currently ongoing, and the Company intends to present the clinical trial results at upcoming medical conferences and in peerreviewed journals.

The Company expects that Ketotransdel, if and when approved by the United States Food and Drug Administration (FDA), could become the first topical NSAID cream product available by prescription in the United States for acute pain management. Transdel is seeking a commercial partner for Ketotransdel[®], and is actively pursuing discussions with U.S. and foreign based potential partners with sales and marketing infrastructures.

About Ketotransdel

Ketotransdel® is comprised of a transdermal formulation of ketoprofen, an NSAID (Non-Steroidal Anti-inflammatory Drug), and the Company's innovative proprietary Transdel[™] drug delivery system. Ketoprofen was selected as the active ingredient for Ketotransdel® for its proven clinical safety and efficacy track record. In a previous randomized double-blind, placebo controlled Phase 1/2 trial, Ketotransdel® provided effective local delivery of ketoprofen resulting in statistically significant relief of pain and soreness with minimal systemic exposure to the drug. No adverse reactions to Ketotransdel® were reported. The Company also intends to pursue Ketotransdel for other indications, such as osteoarthritis. The drug could address what the Company believes is a significant unmet medical need for patients and physicians seeking a potentially safer alternative to acetaminophen and oral NSAIDS such as ibuprofen and COX-2 inhibitors that have well-known gastrointestinal, cardiac, renal and/or hepatic safety issues.

Acute Musculoskeletal Pain and Pain Market

Acute soft tissue injuries cause musculoskeletal pain that affects the muscles, ligaments, tendons and/or bones. Treatment often includes the administration of oral non-steroidal anti-inflammatory drugs.

The pain market is the third most prescribed class of drugs in the United States. Oral formulations of non-steroidal anti-inflammatory drugs (NSAID) currently are marketed worldwide for the treatment of inflammation and pain, including pain due to musculoskeletal injuries, signs and symptoms of osteoarthritis and rheumatoid arthritis, menstrual cramps, headache and other minor aches and pains. Based on industry estimates, currently more than 30 million people world-wide use NSAIDs daily. 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. While traditional oral NSAIDs are effective, they can cause serious gastrointestinal and cardiovascular adverse events. Further, the withdrawal of some COX—2 inhibitors, a class of NSAIDs, has removed a major therapeutic option for patients with multiple moderate and severe forms of pain, resulting in a significant market opportunity. These developments have created an important need for a locally administered pain product with a strong safety profile. Based on market research reports, the United States transdermal drug delivery market is projected to increase from \$3 billion in 2005 to \$4.5 billion in 2012.

Conference Call/Web Cast Information

Transdel will host a conference call/webcast to discuss matters mentioned in this release. The call is scheduled for today, October 6, 2009, at 9:00 am, Eastern Time. To participate in this call, dial 888—695-0608, or outside of the United States, dial 719-457-2615 and the confirmation code 4282348, shortly before 9:00 a.m., Eastern Time. A replay of the call will be available for a limited period following the call, beginning at 12:00 p.m. Eastern Time today. The replay number is 719-457-0820, confirmation code 4282348. The audio webcast can be accessed at www.transdelpharma.com.

About Transdel Pharmaceuticals, Inc.

Transdel Pharmaceuticals, Inc. (OTCBB: TDLP) is a specialty pharmaceutical company developing non-invasive, topically delivered products. The Company's innovative-patented TransdelTM 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 technology to deliver the active drug, ketoprofen, a non-steroidal anti-inflammatory drug 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 TransdelTM platform technology to expand and create a portfolio of topical products for a variety of indications. The Company is actively pursuing partnerships with companies to expand its product portfolio for pharmaceutical and cosmetic/cosmeceutical products. 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 anti-cellulite cosmeceutical product which utilizes the Company's TransdelTM technology. For more information, please visit <u>http://www.transdelpharma.com</u>.

Forward-Looking Statements

The Company cautions you that the statements included in this press release 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 press release 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®; the third parties upon whom the Company relies to conduct its clinical trials may not perform as expected; 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 press release 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 R eform Act of 1995.

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