Zacks Equity Research

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Transdel Pharmaceuticals, Inc. (TDLP-OTC)

TDLP: Take A Look At Transdel Pharma...

UPDATE

In June 2010, we initiated coverage of Transdel Pharmaceuticals with an 'Outperform' rating and price target of $2.50 per share. We believe that TDLP-110, currently known as Ketotransdel, has the potential to be a meaning share gainer in the treatment of acute soft tissue pain.

We value Transdel at approximately $2.50 per share. We arrive at this target by conducting a discounted (risk-adjusted) valuation analysis on Ketotransdel to a potential licensing partner. We have used five previous deals for transdermal pain medications as a roadmap for what a potential deal for Ketotransdel may look like.

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	06/07/2010
Current Price (08/13/10)	$1.07
Target Price	**$2.50**

SUMMARY DATA

52-Week High	**$2.20**
52-Week Low	**$0.90**
One-Year Return (%)	**-18.94**
Beta	**-0.08**
Average Daily Volume (sh)	**8,976**
Shares Outstanding (mil)	**16**
Market Capitalization ($mil)	**$17**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2010 Estimate	**N/A**
P/E using 2011 Estimate	**N/A**
Zacks Rank	**3**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**
Zacks Rank in Industry	**54 of 138**

ZACKS ESTIMATES

Revenue

(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2009	0 A	0 A	0 A	0 A	0 A
2010	0 A	0 A	0 E	0 E	0 E
2011					2.5 E
2012					2.5 E

Earnings per Share

(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2009	-$0.10 A	-$0.08 A	-$0.06 A	-$0.05 A	-$0.29 A
2010	-$0.06 A	-$0.03 A	-$0.03 E	-$0.03 E	-$0.14 E
2011					$0.03 E
2012					$0.01 E

Zacks Projected EPS Growth Rate - Next 4 Years % **N/A**

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WHAT'S NEW

Second Quarter Financials…

On August 12, 2010, Transdel Pharma released financial results for the second quarter ended June 30, 2010. The company did not record revenues for the second quarter. Net loss totaled $0.5 million, or 3 cents per share. This was dead-on with our forecast. The company exited the June quarter with approximately $1.0 million in cash and investments. The company is continuing its discussions with potential development and commercialization partners on Ketotransdel. The signing of a collaboration agreement for Ketotransdel remains the key catalyst for the shares over the next year. In the meantime, Transdel's cosmeceutical partners, JMSR and JH Direct, are preparing for the launch of the company's anti-cellulite product (TDLP-310) later this year. Royalties on cosmeceutical sales are expected to extend the current cash balance into 2011.

INVESTMENT THESIS

Ketotransdel The Driving Force…

In June 2010, we initiated coverage of Transdel Pharmaceuticals with an 'Outperform' rating and price target of $2.50 per share. We believe that TDLP-110, currently known as Ketotransdel, has the potential to be a meaning share gainer in the treatment of acute soft tissue pain. We even expect use off-label for the treatment of osteoarthritis (OA) and musculoskeletal pain. Ketotransdel (10% w/w ketoprofen transdermal cream) has significant advantages in the treatment of sight specific pain over traditional oral medications such as Cox-2 inhibitors (Celebrex), oral NSAIDs (ibuprofen, naproxen), and acetaminophen due to the lack of systemic exposure. As such, risk to the heart, the gastrointestinal track, the liver, and the kidneys are substantially reduced.

We see a major catalyst in the shares coming later this month when management plans to present the data from the first phase III trial via an abstract entitled, "Efficacy And Safety Of Ketoprofen 10% Cream In The Treatment Of Pain Associated With Acute Soft Tissue Injuries (Phase 3 Study TDLP-110-001)" at the 13th World Congress on Pain, to be held August 29th to September 2, 2010 in Montreal, Canada.

We see peak sales in the U.S. for soft tissue pain at $200 million. Off-label use, and the potential that a partner eventually conducts a clinical program in OA to attempt to gain an OA-associated pain approval, can bring the peak sales on Ketotransdel to $300 million or above. We expect that management will look to secure a high-teens royalty on sales at the commercial partner. Our financial model assumes cumulative sales from approval to the patent expiration in 2017 are roughly $690 million, meaning the cumulative royalty payment between approval and the launch in 2013 through 2017 to Transdel is in the area of $138 million.

…Cosmeceutical Business Under-Appreciated…

On June 17, 2010, Transdel Pharma and Jan Marini Skin Research (JMSR) entered into a licensing agreement providing JMSR with exclusive U.S. rights to Transdel's transdermal delivery technology for use in an anti-cellulite cosmeceutical product (TDLP-310) for the dermatological market. This exclusive right lasts for one year, after which the right becomes non-exclusive. JMSR also obtained a non-exclusive right to the product outside the U.S. In return, JMSR has agreed to pay Transdel a licensing royalty – we suspect mid-single digits – on the U.S. and worldwide sales of TDLP-310. TDLP-310 is currently in subject trials. Given the limited nature of the exclusive right (expires in June 2011), we expect that JMSR will want to launch the product in the U.S. as soon as possible, most likely before the end of the calendar year. Our financial model assumes these royalty payments begin to accrue in the first quarter of 2011.

The deal with JMSR is on top of the already in-place relationship with JH Direct for TDLP-310 in which JH Direct will be distributing the product through direct response television campaigns, created and managed by JH Direct, followed by an expansion into traditional channels of distribution, such as retail or wholesale channels. We believe the royalty from JH Direct is similar to the JMSR royalty rate at mid-single digits to Transdel.

Transdel's cosmeceutical business remains under-appreciated in our view. The company should begin receiving royalty payments on TDLP-310 by the end of the year. Management's goal is to, in time, use the cosmeceutical business to generate cash to cover the overhead as Transdel continues to develop prescription pharmaceutical products such as Ketotransdel. Beside TDLP-310 (anti-cellulite), the company is conducting formulation work on TDLP-320 (anti-aging) and TDLP-330 (pigmentation). Both products represent additional avenues for licensing to JH Direct, JMSR, or another leading skin care company in 2011.

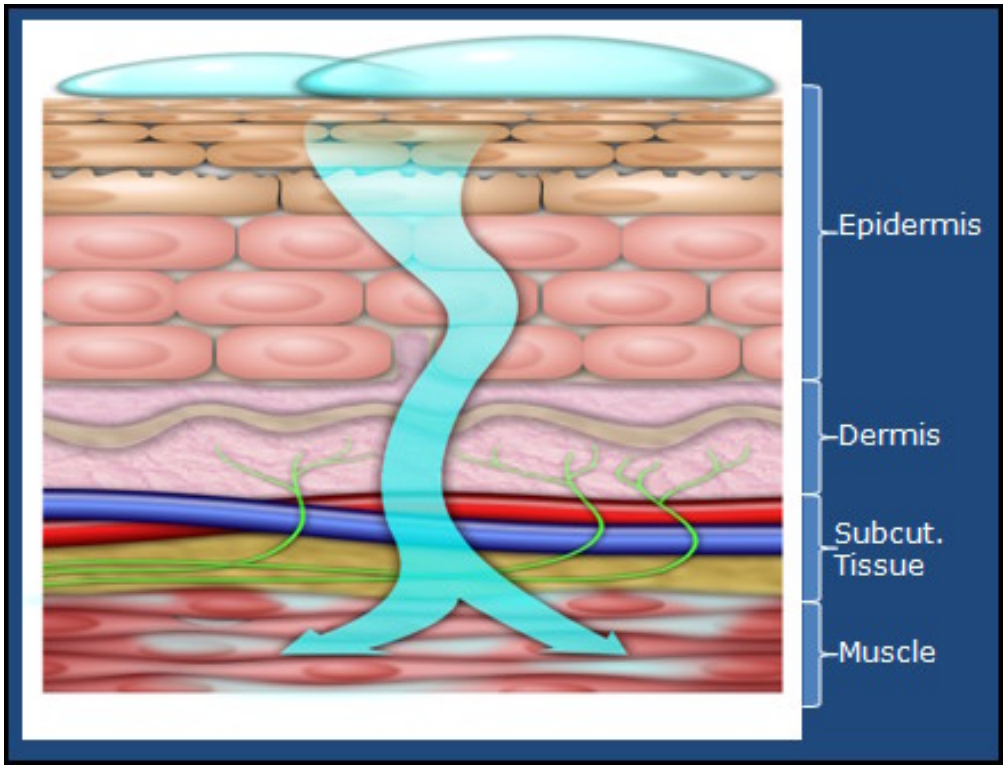
Staying Positive on Transdel Pharma

We value Transdel at approximately $2.50 per share. We arrive at this target by conducting a discounted (risk-adjusted) valuation analysis on Ketotransdel to a potential licensing partner. We have used five previous deals for transdermal pain medications (Astellas and NeurogesX with Qutenza, Covidien and Nuvo Research for Pennsaid, Endo and Novartis for Voltaren Gel, Alpharma and IBSA for Flector Patch, and Alpharma and IDEA AG for Diractin) as a roadmap for what a potential deal for Ketotransdel may look like.

OVERVIEW

Transdel Cream Technology

The company's proprietary drug delivery platform consists of a cream that enables transdermal penetration of drugs avoiding first pass metabolism by the liver and minimizing systemic exposure. Transdel's novel drug delivery technology, developed in-house, facilitates the effective dissolution and delivery of a drug across the skin barrier to reach targeted underlying tissue. The Transdel proprietary cream creates a patented formulation that allows for market approval via the 505(b)(2) pathway, allowing management to move compounds quickly through the clinical development program. Transdel has identified over 500 different drugs in over 60 therapeutic areas, including both approved and established drugs that are small molecules or large biologic peptides.



The Transdel Delivery System (TDS) has several key properties that make it a highly versatile vehicle for topical drug administration. The cream provides the right balance of hydrophilic and hydrophobic characteristics to allow for rapid and efficient partitioning of the drugs into the skin. The cream is biocompatible, and yields no site specific reactions such as pain, drying or irritation. The cream also elicits no immune response or allergenic response.

TDS is biodegradable, thermodynamically stable, insensitive to moisture, and resistant to microbial contamination. Users find the cream's cosmetic presentation to be odorless, easy to apply, with both adhesive and cohesive qualities. These are significant advantages over harsh smelling topical creams that are messy and sticky, or cause irritation while drying. There is minimal alcohol in Transdel's cream. The proprietary cream technology has wide applicability to a number of different medications and injuries or diseases. We also note that Transdel owes no royalties or sub-licenses on pharmaceutical products that utilize the cream. This is a big positive in our view and should help to allow management to approach cash-flow positive operations quickly following the approval of its first prescription product.

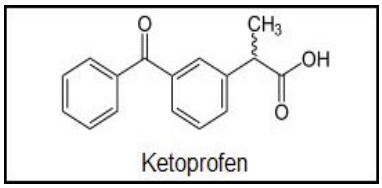
Management is also working to leverage the technology for cosmeceutical applications. The company seeks to develop a new patent protected product by combining well known and established ingredients with its proprietary technology. Targeted cosmeceutical applications include anti-cellulite and anti-aging creams, as well as creams for hyper-pigmentation. Cosmeceutical products can be distributed by prescription or OTC. The company's long-term goal is to develop a cosmeceutical franchise that could potentially cover overhead and contribute funds to the advancement of additional internally-developed ethical products for prescription sale.

KETOTRANSDEL

The company's leading product under clinical stage development is Ketotransdel, which utilizes the proprietary Transdel technology to deliver a non-steroidal anti-inflammatory (NSAID), ketoprofen, to the injured area. Transdel is developing Ketotransdel for the treatment of mild to moderate pain.

Background Info

Ketoprofen is a phenyl propionic acid derivative with the chemical name 2-(3-benzoylphenyl)-propionic acid. The product was first synthesized in 1967, and introduced into clinical practice as an anti-inflammatory treatment for mild to moderate pain in 1973 by Rhone-Poulenc (now part of Sanofi-Aventis). At one time, the drug was available over-the-counter in the U.S. in the form of 12.5mg coated tablets, but manufacturers discontinued these sales due to low product demand relative to more commonly known NSAIDs such as ibuprofen and naproxen. Although recently, Novartis gained U.S. approval for an OTC 12.5mg oral film strip under the brand name Nexcede. The product is also available by prescription in 50, 75, 100, 150, and 220mg capsules as a generic pharmaceutical.



Ketoprofen

Ketoprofen is generally prescribed for arthritis-related inflammatory pain or mild to moderate soft tissue injuries. It is also frequently used in periodontal disease or inflammation of the gums. Topical patches are also extensively used for treatment of musculoskeletal pain. The benefits of the patch is that is has been shown to provide rapid and sustained delivery to underlying tissues without significantly increasing levels of drug concentration in the blood when compared to the traditional oral administration. This greatly reduces the potential gastrointestinal, cardiovascular, and hepatic side effects common with the majority of oral NSAIDs.

Ketoprofen works by inhibiting the production of the enzyme cyclooxygenase in the body. The drug has analgesic, antipyretic, and anti-inflammatory properties that result by its reversible inhibition of the cyclooxygenase-1 and -2 (COX-1 and COX-2) enzymes. Ketoprofen is also used for treatment of nerve pain like sciatica, post-herpetic neuralgia (PHN) and referred pain for radiculopathy. Cyclooxygenase (COX) controls how much of the chemicals known as prostaglandins are produced by the body's immune system. Prostaglandins are released in order to alert the body to the presence of damage caused by injury or disease. The reduction in the amount of prostaglandin biosynthesized correspondingly lowers the amount of pain and inflammation experienced by the patient.

Ketoprofen is metabolized by the liver and excreted by the kidneys and, as such, it is dialyzable. Applying the ketoprofen directly to the site of pain or inflammation through topical gels or creams reduces systemic exposure by eliminating first-pass metabolism by the liver. It also reduces potential gastrointestinal, cardiovascular, and hepatic toxicity. In this way, the ketoprofen is able to treat affected tissue through direct diffusion. This is particularly useful in instances of pain being the result of active or passive movement or additional pressure on the joint. When applied as a gel to a painful skin area, ketoprofen is slowly absorbed by the body. Pain relief starts to occur within 30 minutes after application, with peak plasma concentrations achieved in 30 minutes to two hours. Ketoprofen gel produces plasma levels that are about 60% lower than those experienced after a single oral dose of ketoprofen.

OTC ketoprofen gels at 2.5% w/w are available in 50g and 100g tubes outside the U.S. The products are a clear transparent gel indicated for relief of muscular aches and pains and swelling including sprains, strains, sport injuries and rheumatic pains, and pain of non-serious arthritis. Studies have shown that a 2.5% ketoprofen gel achieves significant pain relief when applied topically to an area of the skin. Clinical testing shows that 2.5% ketoprofen gels compare favorably to methyl salicylate / menthol-based topical OTC gels or creams such as Icy Hot, Aspercreme, and Ben-Gay. Common ketoprofen creams and ointments also contain ketamine and lidocaine as adjuvants potentiators for pain treatment. Intravenous ketoprofen is also available by prescription for veterinary use only. A 10% liquid spray, called Ketospray, is also available outside the U.S. Ketoprofen oral soluble film strips have been recently (December 2009) approved by the U.S. FDA (as Nexcede) and in the EU for OTC use.

A ketoprofen gel with the brand name, Diractin, is approved in Switzerland using German-based IDEA AG's Transfersome proprietary drug delivery technology. Transfersomes are artificial cell vesicle designed to carry a drug through the skin and release the molecule below the skin layer were the inflammation is present. We discuss Diractin in greater detail below.

- Diractin is a 2.3% w/w ketoprofen gel. IDEA AG conducted a clinical program testing Diractin in 866 patients with osteoarthritis (OA) of the knee comparing the effectiveness of three different doses (25mg, 50mg, and 100mg BID) vs. placebo (dummy transfersome gel). The main measure of effectiveness was the change in the severity of pain after 12 weeks of treatment. IDEA filed an MAA for approval of Diractin in the EU in early 2008, but subsequently withdrew the application in August 2008 following conversations with the CHMP in which the agency expressed concerns regarding the effectiveness of the product relative to the control (dummy vehicle). Specifically, the agency did not believe that Diractin sufficiently demonstrated reduced pain levels to an extent that would be relevant for patients. In 2009, IDEA AG released data from two additional programs testing Diractin with and without celecoxib (Pfizer's Celebrex) vs. a dummy transfersome gel. Results failed to show a statistical difference between the control and Diractin. At this point we do not expect Diractin on the market in Europe for several years. Approval in the U.S. is even less likely.

Clinical Development

Management has completed testing of Ketotransdel (ketoprofen 10% w/w) in a double blind, placebo-controlled phase I/II clinical study. The increase in concentration from 2.3% - as tested by IDEA AG with Diractin – to 10% allows for greater efficacy and use in acute and more severe pain conditions that require a visit to the doctor. The study also tested the efficacy and safety of topical Ketotransdel for the treatment of acute pain and soreness in delayed-onset muscle soreness instead of osteoarthritis (OA). The trials were shorter and easier to conduct than the programs discussed above with Diractin.

Transdel also measured level of systemic absorption during the study. Results demonstrated a significant medical benefit from Ketotransdel in terms of relief of pain and muscle soreness. The topical Ketotransdel has approximately 1/100th of the blood levels of ketoprofen found in the circulatory system as compared to a comparable dose of commercially available oral ketoprofen. No adverse reactions to Ketotransdel, such as rash or irritation were reported. As part of a routine requirement to provide safety information in the regulatory submission, the company will conduct studies such as to assess the allergenicity potential and absorption of Ketoprofen during concurrent exercise and heat exposure. These are standard pharmacokinetic (pk) absorption studies required prior to U.S. FDA approval of a new delivery system. These supportive trials will be conducted in healthy subjects concurrent to the second phase III program.

…Phase III…

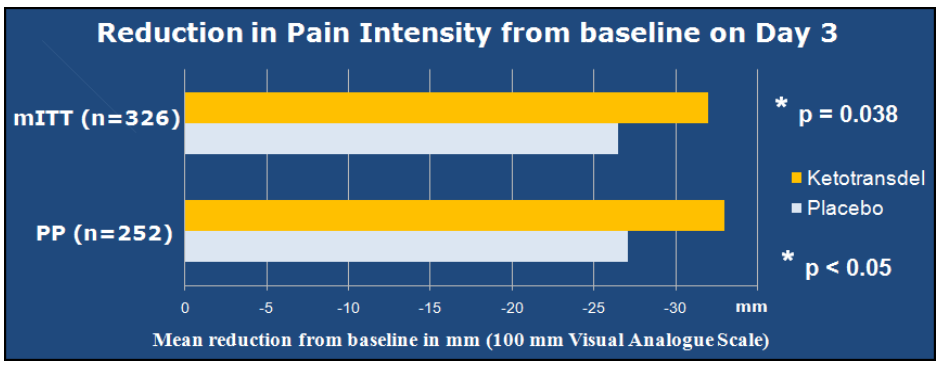
Transdel moved Ketotransdel into a phase III clinical trial (Study-001) in June 2008. Enrollment began in September 2008 and completed in July 2009 at 364 patients randomized at a 1:1 ratio to receive Ketotransdel or placebo vehicle. All patients had acute soft tissue injuries of the upper or lower extremity and were enrolled at 26 centers around the U.S. Patients were instructed to apply 1g of the cream (Ketotransdel or placebo) three times daily over the injured area, for a total of 7 days. 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. The VAS is a well known and validated instrument for pain measurement. Secondary endpoints included safety assessments and other efficacy parameters measured by the VAS.

The company reported top-line the results in October 2009 from 361 or the 364 patients that completed the study. The data demonstrated statistical significance ($p<0.05$) in its primary endpoint in the Per Protocol (PP) analysis (252 patients) and a favorable trend in the full Intent-To-Treat (ITT) analysis (361 patients). In addition, Ketotransdel also demonstrated an excellent safety and tolerability profile. In particular, there were no Ketotransdel treatment-related gastrointestinal, cardiovascular, hepatic or other clinically relevant adverse events reported. 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 results are consistent with previous clinical study findings and support the excellent safety profile.

In January 2010, the company conducted a further in-depth analysis of the full 361 ITT population. In this modified ITT (mITT) population, 35 patients were identified who did not meet study entry criteria at the time of randomization. The majority of the 35 patients tested positive for "recreational drugs" in urine screens conducted prior to randomization. Other participants either improperly used Ketotransdel or used the product in combination with other topical or oral medications that were not allowed during the trial. Unfortunately, the urinalysis took 72 hours to complete and by that time the 35 patients had already been dosed and randomized. Thus, they were included in the original ITT population but were subsequently discontinued from the trial.

According to the International Conference on Harmonization (ICH) E9 guidelines on "Statistical Principles for Clinical Trials", which has been adopted in the U.S., EU, and Japan, exclusion of these 35 patients is acceptable protocol for ITT analysis. Had the urinalysis been completed prior to randomization these participants never would have been dosed. Therefore, the company contracted for a new independent analysis of this modified ITT group. Management reported that excluding these 35 "non-qualifiers", the phase III program would have hit statistical significance for the ITT analysis at ($p<0.038$) on the primary efficacy endpoint. Additionally, the data shows that 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.

…Primary Endpoint…



We believe the market has yet to fully understand the acceptability of the modified ITT population analysis and thus is skeptical of the first phase III program. Our understanding of the ICH-E9 guidelines are that Transdel's exclusion of the 35 "non-qualifiers" is acceptable by the U.S. FDA, and the modified ITT and PP analysis will be validated. This data will be presented at the 13th World Congress on Pain to be held August 29 to September 2, 2010 in Montreal, Canada. We think once the market sees the actual data presentation and begins to understand the company's modified ITT analysis, the stock will react accordingly.

…Safety & Pharmacokinetics…

In the first phase III trial reported above, Ketotransdel demonstrated excellent safety and tolerability. The data below shows the adverse event rate for both Ketotransdel and the placebo. We note that there will half the number of cutaneous (application site) adverse events in the test arm versus the placebo vehicle. This extremely low rate of application site adverse events compares very favorably to FDA approved potential competing products, including King Pharmaceuticals' Flector Patch at roughly 11% (per the package insert) and Novartis / Endo's Voltaren Gel at roughly 7% (per the package insert). Additionally, there were no gastrointestinal, cardiac, liver, or other serious adverse events related to Ketotransdel during the program. Pharmacokinetic analysis shows no clinically relevant changes in blood and urine tests, and only minimal systemic absorption (mean Cmax 39 ng/mL). This low level of systemic absorption equate to only approximately 1 – 2 % of the oral ketoprofen dose.

	Ketotransdel (n-182)	**Placebo (n=182)**
Drug Related Adverse Events:	3.8%	4.4%
Application Site Adverse Events:	1.1%	2.2%

In order to gain approval, the company will need to conduct a second confirmatory phase III clinical study in acute soft tissue pain. Management is currently assessing the design and timing of this second study to support the registration of Ketotransdel in the U.S. We believe it is management's plan to conduct a mirror image study of the first phase III program – which greatly minimizes risk in our view – along with certain modifications to the inclusion criteria (conducing urinalyses prior to randomization) so that non-qualifiers are eliminated prior to the randomization.

The timing of the second phase III 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. The trial will probably cost several million to conduct and should take 9 to 12 months to complete.

Assuming a conservative timeline with relation to a partnership, we believe the company and its partner should be in position to begin this program late 2010 or early 2011. Transdel is doing all the necessary pre-work with the contract research organization (CRO) so that the trial is ready to begin immediately after the funding becomes available. Transdel is currently assessing the necessary steps to gain marketing authorization outside the U.S. as well. At this time, all of our financial models include sales for Ketotransdel in the U.S. only.

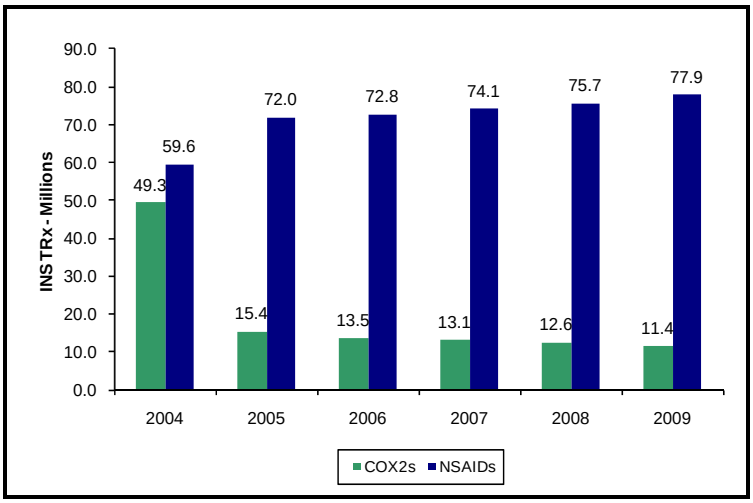
Commercialization & Sales

The potential market opportunity for Ketotransdel is enormous in our view. Pain medications are the third most-prescribed class of drugs in the U.S. Ketotransdel will compete against both oral medications and other topical delivery pain medications.

…Oral Medications…

The market for oral NSAIDs and Cox-2 inhibitors was nearly $8 billion in the U.S. in 2009. Cox-2 drugs such as Vioxx and Celebrex, designed to provide safer gastrointestinal profile, peaked sales at over $7 billion worldwide in 2004 before Vioxx was pulled from the market for cardiovascular risk. OTC products, ibuprofen (Advil) and naproxen (Aleve) have picked up most of the lost Cox-2 share. These drugs provide powerful pain relief, on par with Celebrex, but present the risk for potential gastrointestinal complications, including gastric or esophageal ulcers. According to the American College of Gastroenterology, approximately 60% of the osteoarthritis (OA) patients are at risk for gastrointestinal (GI) damage if they take daily NSAIDs. Several large clinical studies have confirmed that 20-40% of those who take NSAIDs regularly have one or more ulcers in their stomach or intestines. In fact, in the U.S., there are an estimated 16,500 deaths each year due to NSAID-induced GI complications (primarily from GI hemorrhage).

Total Rx (Cox-2 vs. NSAIDs)



Another oral treatment option, Acetaminophen (Tylenol), the most widely used pharmaceutical analgesic and antipyretic agent in the world, also has potential serious side effects. For example, in 2009, the U.S. FDA warned the public about potential acetaminophen-induced hepatotoxicity. The agency has put forth new labeling requirements for nonprescription and prescription products containing the medication.

	Oral			Transdermal
	NSAIDs	Cox-2	Acetaminophen	Ketoprofen
Cardiovascular Safety		X		✓
Gastrointestinal Safety	X			✓
Liver Safety			X	✓
Renal Safety	X	X		✓

We believe a topical (transdermal) delivery system mitigates the risks associated with the oral medications. Transdermal delivery system have been gaining significant market share over the past decade. We estimate this is a $4 billion market in the U.S. in 2010. Plus, as more data becomes available, uptake continues to rise. A research article, *Topical NSAIDs for acute pain: A meta-analysis*, published in the May 2004 (BMC Family Practice 2004, 5:10) concludes that topical NSAIDs were effective and safe in treating acute painful conditions for one week.

The data from 26 double blind placebo controlled trials had information from 2,853 patients for evaluation of efficacy. We note the data showed that local adverse events, systemic adverse events, or withdrawals due to an adverse event were rare, with no different between topical NSAID and placebo. The authors also concluded that different NSAIDs had different efficacy, with ketoprofen being significantly better than all others in an indirect comparison. The work was done at the Pain Research and Nuffield Department of Anaesthetics, University of Oxford, Oxford Radcliffe Hospital, The Churchill, Headington, Oxford, OX3 7LJ, UK.

…Other Topical Medications…

Within the transdermal treatment market, patients and physicians can choose from OTC or prescription products. OTC products include methyl salicylate / menthol-based gels or creams such as Icy Hot, Aspercreme, Biofreeze, and Ben-Gay. An independent analysis of these products conducted by Associated Content found that the German-made Fastum Gel (2.5% ketoprofen gel), available OTC through Home Apteka outside the U.S., proved to be the superior OTC treatment option for acute soft-tissue pain. Delivering an NSAID such as ketoprofen, even at low concentrations provides better pain relief than masking agents such as camphor or menthol gels or creams.

There are three topical NSAIDs on the market in the U.S. in King Pharmaceuticals' Flector Patch (1.3% diclofenac epolamine patch) and Novartis / Endo's Voltaren Gel (1% diclofenac) that give us confidence in the market potential for Ketotransdel. Additionally, there is another FDA approved topical drug, Covidien / Nuvo's Pennsaid (1.5% diclofenac sodium topical solution) that just launched on April 26, 2010. All three, Flector Patch, Voltaren Gel, and Pennsaid, utilize diclofenac as the NSAID.

A journal article published in the Hong Kong Journal of Emergency Medicine by Paulin Ng et al (Hong Kong JEM 2001; Vol. 8:73-77) concluded that ketoprofen and diclofenac are equally effective and safe in the treatment of acute musculoskeletal pain. Another article in the Journal of the Royal Society of Medicine (RSM 1992; Vol. 85:16-18) directly compared controlled release oral ketoprofen to controlled release oral diclofenac and concluded that pain scores in patients on oral ketoprofen were lower than in patients taking oral diclofenac.

King's Flector Patch is the first and only NSAID patch available in the U.S. It is indicated for acute soft tissue (short-term) pain such as minor strains, sprains, and bruises. The benefit of the patch is an easy and convenient application. Downside of the patch is that it can irritate the skin and offers little flexibility in dosing. Most patients and physicians prefer prescribing topical gels and creams to patches. Still, sales of the Flector Patch were $128 million in 2008 and $139 million in 2009. Sales for the first half of 2010 were $69 million. For the full year 2010, we forecast the Flector Patch will deliver sales between $140 and $150 million. Peak sales are $250 million.

Voltaren Gel was the first prescription topical NSAID FDA approved for osteoarthritis (OA) pain. Diclofenac (sold branded as Voltaren) was originally developed by Novartis (Ciba-Geigy) in the mid-1970's and is now widely available generic. Novartis teamed up with Endo Pharmaceuticals to formulate diclofenac into a topical gel. The product posted sales in 2008 of $24 million. In 2009, sales of Voltaren Gel grew to $79 million. Sales for the first half of 2010 were $46 million. For the full year 2010, we forecast Voltaren Gel will post sales between $100 and $120 million. Peak sales are $200 to 250 million.

Nuvo Research received approval for Pennsaid, a 1.5% diclofenac topical solution, in November 2009. It is an odorless and clear solution that is administrated with a dropper 4x daily. The product is approved for the treatment of osteoarthritic pain associated with knee. It is currently marketed in Canada and several European countries. Nuvo's commercial partner, Covidien, launched the product on April 26, 2010. We view Pennsaid as a messy and inconvenient alternative to Voltaren Gel. For 2010, we think sales will be less than $20 million. Peak sales are less than $100 million in our view.



(1.3% diclofenac patch)



(1% diclofenac gel)



(1.5% diclofenac topical solution)

We think that Ketotransdel has the potential to compete effectively with the Flector Patch, Voltaren Gel, and Pennsaid. The initial indication for Ketotransdel will be in acute soft-tissue pain, similar to the Flector Patch. Ketotransdel should be able to capture sizable share from the Flector Patch based on the wider perceived efficacy of 10% ketoprofen vs. 1.3% diclofenac, and the migration of physicians and patient to the more convenient cream. This has been evident in the market share gains with Voltaren Gen over Flector Patch. We think peak sales of Ketotransdel in this indication are $200 million. If Transdel can eventually gain approval for the use of Ketotransdel in OA, the product has total peak sales potential of $300+ million. The significant reduction in application site reaction will also lead to greater uptake for Ketotransdel over Flector and Voltaren in the long-run.

…Partnership Potential…

Management is currently pursuing discussions with U.S. and foreign based potential partners with sales and marketing infrastructures to support Ketotransdel's continued development and eventual commercialization. This could come in the form of a global development collaboration, or regional partnerships that would focus on North America and Europe separately. We think the latter is more likely. We expect that Ketotransdel, when approved by the U.S. FDA, could become the first topical NSAID cream product available by prescription in the U.S. for acute pain management. The initial indication will be in soft tissue pain, but we expect significant off-label use in osteoarthritis (OA) as well.

We do not believe that the U.S. FDA will require Transdel or its partner to conduct an OA trial prior to approval. Precedent has been set with Flector Patch that only a soft tissue program is required for a specific soft tissue label. Eventually approval in OA will require an additional phase III study, but Transdel management plans to leave that decision, and the associated costs, with its commercialization partner. Depending on the off-label sales, outright approval in OA pain may not be necessary. Even without a label for OA, Ketotransdel should have a favorable profile to market to specialists and primary care physicians for the treatment of acute pain:

- ✓ Localized pain relief with well known – and trusted – pharmaceutical product in ketoprofen. Meta-analysis shows that ketoprofen is the superior topical NSAID.
- ✓ Low systemic absorption – leads to low risk of gastrointestinal, cardiovascular, liver, renal or other serious adverse events during use.
- ✓ Transdermal delivery minimized drug-drug interactions and allows for use with medications that are contraindicated for oral NSAIDS, including corticosteroids and anti-coagulants.
- ✓ Transdermal delivery allows for us in patients that are ineligible or unable to take oral medications due to difficulties swallowing.
- ✓ Potential convenience advantage for elderly or children.

Given the favorable characteristics discussed above, we believe management should be able to secure this partnership before year end 2010. We have looked at five previous transactions for similar products to gauge a potential deal value for Ketotransdel.

- In August 2007, Alpharma licensed the rights to the Flector Patch (1.3% diclofenac epolamine topical patch) for the treatment of acute pain due to minor strains, sprains, and contusions from Swiss-based Institute Biochimique SA (IBSA) for the entire U.S. market. The Flector Patch was approved in the U.S. in January 2007. The deal included $100 million upfront. Alpharma also received warrants to purchase common stock in IBSA worth $35 million. Total deal = $100 million + ownership.

- In June 2009, Japanese pharmaceutical company, Astellas, licensed Qutenza (8% *trans*-capsaicin patch) for the treatment of post-herpetic neuralgia (PHN) from small-biotech company, NeurogesX, for all 27 EU member states, plus Iceland, Norway, Liechtenstein, and Switzerland, along with the Middle East and Africa. Qutenza was approved in the EU in May 2009. The deal included $42 million upfront and the potential for $97 million in development and sales related milestones for Qutenza. NeurogesX is also entitled to a mid-teen to mid-20s percent scaling royalty on sales of the product. Total deal = $139 million + royalties.

- In June 2009, Covidien licensed Pennsaid (1.5% diclofenac topical solution) for the treatment of pain associated with osteoarthritis of the knee from small-biotech company, Nuvo Research, for the U.S. market. Pennsaid was eventually approved in the U.S. in November 2009. The deal included $10 million upfront and the potential for $100 million in regulatory ($16 million for approval) and sales related milestones for Pennsaid. Nuvo is also entitled to royalties on sales of the product. Covidien plans to launch Pennsaid in the U.S. around the middle of the year (Covidien guidance was last April 2010). Total deal = $110 million + royalties.

- In May 2008, Endo Pharmaceuticals licensed Voltaren Gel (1% diclofenac) for the treatment of pain associated with OA from Novartis for the entire U.S. market. Voltaren Gel was approved in the U.S. in October 2007. The deal included $85 million upfront and the potential for an additional $25 million in sales-released milestones. Novartis is also entitled to royalties on net sales for the product. Total deal = $110 million + royalties.

- In October 2007, Alpharma licensed the rights to a 2.3% ketoprofen Transfersome Gel for the potential treatment of pain associated with OA, from privately-held IDEA AG, for the entire U.S. market. At the time, Transfersome Gel was in phase III trials in the U.S., and approved in Switzerland as Diractin. The deal included $60 million upfront and the potential for $100 million in development and sales related milestones. Alpharma also purchased an undisclosed stake in IDEA AG. Total deal = $160 million + ownership.

Average Upfront = $60 million

Average Backend = $65 million + ~20% royalty

Flector Patch, Qutenza and Voltaren Gel were all approved at the time of the licensing. Pennsaid and Diractin were under review at the time of their licensing. Plus, management is seeking a development and commercialization deal that will fully fund the second confirmatory phase III program. Thus, the upfront portion of the licensing deal will be less than the $60 million average from the five deals above.

We estimate the costs required on the second phase III trial and to file for approval will be roughly $10 million. It is also clear that an approved drug is worth far more in terms of licensing than a phase III drug, so our best guess is that Transdel will be able to secure an upfront payment in the area of $20 million.

Based on our market analysis, Ketotransdel is a $200 to $300 million product in the U.S., similar to Flector Patch and Voltaren Gel. Thus, the backend portion of the deal should recognize that potential. We expect that the total deal size Transdel should be able to secure is in the area of $100 to $125 million, plus royalties. Although, we note that management has expressed interest in a co-promotional plan, which would limit the backend milestone potential but allow for the company to keep revenues and profits for itself. A specialty pharmaceutical company, seeking to put Ketotransdel in their tier-one marketing position, with 100 to 150 representatives would make an ideal partner for the company.

We place the risk-adjusted discounted present value of this deal between $35 and $40 million (see the valuation section below), meaning that on an outright takeover, we believe Transdel is worth $2.50 per share. This value does not include any potential for the cosmeceutical business.

…Risks…

Based on discussions with the FDA, at least two adequate and well-controlled phase III studies are required in order to obtain regulatory approval to market Ketotransdel. We believe that the first phase III trial will qualify as one adequate and well-controlled trial because there is statistical significance on the primary endpoint in an objectively defined modified ITT population, and statistical significance on secondary endpoints. Above we have outlined why we believe this to be the case. However, we note that there is no assurance that the FDA will accept Transdel's conclusion of the modified ITT data from the first phase III study is sufficient as part of the requirements for regulatory approval. And, Transdel will not be certain of the FDA's stance on this until the new drug application (NDA) has been filed.

PIPELINE

Transdel Pharmaceuticals holds a patent on the Transdel technology that was granted in 1998. The protection around Ketotransdel runs to 2016 through a three layer barrier, including composition of matter around the Ketotransdel formulation, a method of use for transdermal ketoprofen, and manufacturing of Ketotransdel. The potential exists to extend the patent protection of Ketotransdel by an additional six months through pediatric indications for acute soft tissue injury.

Once the patent protection around Ketotransdel expires, we believe it is management's goal to seek to move the product over the counter (OTC), either at 10% ketoprofen w/w or at lower doses similar to what's approved in Europe. This type of life-cycle management allows for added upside to the prescription story and could represent meaningful revenues to Transdel and its partner starting in 2017. We point investors toward the recent move of Zegerid at Santarus to OTC through the company's relationship with Schering-Plough (now part of Merck & Co.) as a roadmap for low-dose Ketotransdel at some point in the future.

In addition, the company has expanded its product development programs to include additional products that utilize the patented Transdel transdermal delivery system (TDS) technology. As noted above, the technology platform is compatible with a board range of drugs and molecular sizes. Potential areas of focus beyond the current pain focus include dermatological, hormonal, cosmetic / cosmeceutical, and nutraceutical applications.

One of the more advanced areas of focus for the company is on anti-cellulite and anti-aging products. The company has conducted clinical programs that demonstrated initial signs of efficacy. In June 2009, the company announced that it had entered into a licensing agreement providing JH Direct, LLC with the exclusive worldwide rights to the company's anti-cellulite cosmeceutical product which utilizes the Transdel patented transdermal delivery system technology. The company anticipates that JH Direct will launch the anti-cellulite product, TDLP-310, through a direct response television campaign during the second half of 2010. Transdel will receive a royalty payment on these direct sales – we suspect mid-single digits.

In June 2010, Transdel Pharma and Jan Marini Skin Research (JMSR) entered into a licensing agreement providing JMSR with exclusive U.S. rights to TDLP-310 for the dermatological market. This exclusive right lasts for one year, after which the right becomes non-exclusive.

JMSR also obtained a non-exclusive right to the product outside the U.S. In return, JMSR has agreed to pay Transdel a licensing royalty – we suspect mid-single digits – on the U.S. and worldwide sales of TDLP-310. Given the limited nature of the exclusive right (expires in June 2011), we expect that JMSR will want to launch the product in the U.S. as soon as possible, most likely before the end of the calendar year. Our financial model assumes these royalty payments begin to accrue in the first quarter of 2011.

Transdel's cosmeceutical business remains under-appreciated in our view. The company should begin receiving royalty payments on TDLP-310 by the end of the year. Management's goal is to, in time, use the cosmeceutical business to generate cash to cover the overhead as Transdel continues to develop prescription pharmaceutical products such as Ketotransdel. Beside TDLP-310 (anti-cellulite), the company is conducting formulation work on TDLP-320 (anti-aging) and TDLP-330 (pigmentation). Both products represent additional avenues for licensing to JH Direct, JMSR, or another leading skin care company in 2011.

FINANCIALS

Transdel exited the second quarter 2010 with $1.042 million in cash and equivalents. The company burned approximately $3.5 million in 2009, over $2 million of which was attributed to the phase III (TDLP-110-001) program. In the first half of 2010, the company burned only $1.1 million. As of June 30, 2010, Transdel had $452k in current liabilities, which include $138k in accrued phase III expenses, $149k in separation expenses, and $164k in accounts payable and payroll liabilities.

In April 2010, Transdel completed a private debt financing of $1 million. The company issued a senior convertible promissory note with an annual interest rate of 7.5% to an existing shareholder. The note has a two-year term. The company has a right to prepay the note at any time upon providing written notice to the holder. At any time prior to the company's repayment of the note, the holder may convert all or any part of the outstanding principal and accrued interest on the note into shares of Transdel common stock at a conversion rate of $1.00 per share.

The liability on the balance sheet as of the end of the second quarter 2010 for the note is $1.018 million, brining the total liabilities as of June 30, 2010 to $1.469 million. Total assets at the end of the second quarter were $1.242 million. As such, the company exited the second quarter with negative shareholder equity of approximately $227k.

The current cash balance of $1.042 million should provide the necessary funding to support operations into the fourth quarter 2010. By that time, we believe management will have finalized plans for the second phase III program on Ketotransdel, and with this path forward management should be able to secure additional funding to fund the development into 2011 or beyond.

We remind investors that once either JH Direct or JMSR launches the anti-cellulite product, Transdel will be in position to collect royalties on sales from both partners. We believe, in time, these cash royalties should grow to the point where they support the companies S&GA line. In the future, the cosmeceutical business could provide meaningful cash flow to Transdel to support additional clinical development or in-licensing opportunities.

VALUATION & RECOMMENDATION

In June 2010, we initiated coverage of Transdel Pharmaceuticals with an 'Outperform' rating and price target of $2.50 per share. We believe that TDLP-110, currently known as Ketotransdel, has the potential to be a meaning share gainer in the treatment of acute soft tissue pain. We even expect use off-label for the treatment of osteoarthritis (OA) and musculoskeletal pain. Ketotransdel (10% w/w ketoprofen transdermal cream) has significant advantages in the treatment of sight specific pain over traditional oral medications such as Cox-2 inhibitors (Celebrex), oral NSAIDs (ibuprofen, naproxen), and acetaminophen due to the lack of systemic exposure. As such, risk to the heart, the gastrointestinal track, the liver, and the kidneys are substantially reduced. Additionally, the company's proprietary transdermal delivery system (TDS), Transdel, offers improved safety and tolerability over currently approved NSAID patches and creams. In our view, Ketotransdel is at least a $200 million product in the U.S., with upside to $300 million or beyond depending upon marketing, distribution, and potential label expansion.

The next step for management is to secure a development and commercialization partner for Ketotransdel. With a clean safety and tolerability profile, and one positive phase III trial in the books, we believe that management will be able to secure this partnership before the end of the year. The product offers significant advantages over competing topical treatments, including King's Flector Patch and Novartis' Voltaren Gel. This should attract a specialty pharmaceutical company interested in pushing Ketotransdel into the second confirmatory phase III program in 2011, with a potential U.S. 505(b)2 application set for 2012.

…Stock Undervalued Due To Lack of Awareness / Misunderstand of the Data…

We value Transdel at approximately $2.50 per share. We arrive at this target by conducting a discounted (risk-adjusted) valuation analysis on Ketotransdel to a potential licensing partner. We have used five previous deals for transdermal pain medications (Astellas and NeurogesX with Qutenza, Covidien and Nuvo Research for Pennsaid, Endo and Novartis for Voltaren Gel, Alpharma and IBSA for Flector Patch, and Alpharma and IDEA AG for Diractin) as a roadmap for what a potential deal for Ketotransdel may look like.

Companies	Product	Stage When Deal Was Signed	Upfront	Milestone	Upside
Alpharma & IBSA	Flector Patch (diclofenac patch)	Approved	$100 million	$0	+Ownership
Astellas & Neurogesx	Qutenza (capsaicin patch)	Approved	$42 million	$97 million	+Royalties
Covidien & Nuvo Research	Pennsaid (diclofenac solution)	Under Review	$10 million	$100 million	+Royalties
Endo Pharma & Novartis AG	Voltaren Gel (diclofenac gel)	Approved	$85 million	$25 million	+Royalties
Alpharma & IDEA AG	Diractin (diclofenac gel)	Phase III	$60 million	$100 million	+Ownership
		Average:	**~$60 million**	**~$65 million**	**+Royalties**

…Setting Expectations For A Deal…

Transdel will require that its potential licensing partner fully-fund the second confirmatory phase III program. As such, we expect the costs of this program, estimated to be $10 to $15 million to reach a new drug application filing, should be backed out of the potential upfront payment. We also believe that the upfront payment will account for the added risk of conducting the second phase III program versus the candidates above, many of which had already cleared regulatory approval. Therefore, we expect that management will be able to secure an upfront payment on Ketotransdel in the area of $15 to $20 million.

Ketotransdel will be under intellectual property protection through 2016. Management can push this into 2017 by filing for pediatric extensions. However, we believe that a potential licensing partner will attempt to negotiate a lower backend payment to Transdel than the average $65 million above due to the patent expiration in 2016 and the fact that the drug will be the fourth topical NSAID on the market behind Flector Patch, Voltaren Gel, and Pennsaid Gel. In our view, a backend payment of $40 to $50 million makes sense.

We see peak sales in the U.S. for soft tissue pain at $200 million. Off-label use, and the potential that a partner eventually conducts a clinical program in OA to attempt to gain an OA-associated pain approval, can bring the peak sales on Ketotransdel to $300 million or above. We expect that management will look to secure a high-teens royalty on sales at the commercial partner. Our financial model assumes cumulative sales from approval to the patent expiration in 2017 are roughly $690 million, meaning the cumulative royalty payment between approval and the launch in 2013 through 2017 to Transdel is in the area of $130 to $140 million.

Conducting a probability and risk-adjusted analysis of these potential cash payments we arrive at a total deal value of approximately $39 million (see below for NPV analysis).

Date	Upfront	Milestones	U.S. Sales	Royalties (~20%)
2010	$15 million	-	-	-
2011	-	-	-	-
2012	-	$10 million (1)	-	-
2013	-	$20 million (2)	$40 million	$8 million
2014	-	$15 million (3)	$90 million	$18 million
2015	-	$15 million (4)	$145 million	$29 million
2016	-	-	$205 million	$41 million
2017	-	-	$210 million (5)	$42 million
Cumulative	**$15 million**	**$60 million**	**$690 million**	**$138 million**
Probability	*~85%*	*~65%*		*~50%*
NPV	**$13 million**	**$16 million**		**$11 million**
			Total NPV for Ketotransdel	**$39 million**

(1) $10 million for U.S. NDA acceptance, (2) $20 million for U.S. Approval, (3) $15 million for cumulative sales >$100 million, (4) $15 million for cumulative sales >$200 million, (5) Assumes pediatric extension of patent protection into 2017

NPV of Ketotransdel at this time equates to a stock price of roughly $2.50 per share. This value does not ascribe any value for the cosmeceutical business, including the deals with JH Direct and JMSR, which we view as upside to the story, especially after either company launches TDLP-310.

PROJECTED FINANCIALS

Transdel Pharmaceuticals, Inc.
Income Statement

	2008 A	2009 A	Q1 A	Q2 A	Q3 E	Q4 E	2010 E	2011 E	2012 E	2013 E
ketotransdel (US Sales)	$0	$0	$0	$0	$0	$0	$0	$0	$0	$40.0
ketotransdel (Ex-US Sales)	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
ketotransdel Royalty	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$8.0**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Collaborations / Milestones	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$2.5**	**$2.5**	**$5.0**
YOY Growth	-	-	-	-	-	-	-	-	*0.0%*	*100.0%*
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$2.5**	**$2.5**	**$13.0**
YOY Growth	-	-	-	-	-	-	-	-	*0.0%*	*420.0%*
Cost of Goods Sold	$0	$0	$0	$0	$0	$0	$0	$0	$0	$2.4
Product Gross Margin	*100.0%*	-	-	-	-	-	-	-	-	*94.1%*
SG&A	$1.8	$1.6	$0.8	$0.4	$0.4	$0.4	$2.0	$1.6	$1.8	$2.0
% SG&A	-	-	-	-	-	-	-	*64.0%*	*72.0%*	*15.4%*
R&D	$2.0	$3.0	$0.1	$0.1	$0.1	$0.1	$0.4	$0.5	$0.8	$1.0
% R&D	-	-	-	-	-	-	-	*20.0%*	*30.0%*	*7.7%*
Operating Income	($3.7)	($4.6)	($0.9)	($0.5)	($0.5)	($0.5)	($2.4)	$0.4	($0.1)	$7.6
Operating Margin	-	-	-	-	-	-	-	*16.0%*	*-2.0%*	*58.8%*
Interest & Other Net	$0.4	$0.0	$0.0	$0.0	$0.0	$0.0	$0.2	$0.3	$0.3	$0.3
Pre-Tax Income	($3.3)	($4.6)	($0.9)	($0.5)	($0.5)	($0.5)	($2.2)	$0.7	$0.3	$7.9
Taxes / Other	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($3.3)	($4.6)	($0.9)	($0.5)	($0.5)	($0.5)	($2.2)	$0.7	$0.3	$7.9
YOY Growth	-	-	-	-	-	-	*-52.4%*	*-132.3%*	*-64.3%*	*3076.0%*
Net Margin	-	-	-	-	-	-	-	*28.0%*	*10.0%*	*61.1%*
Reported EPS	**($0.22)**	**($0.29)**	**($0.06)**	**($0.03)**	**($0.03)**	**($0.03)**	**($0.14)**	**$0.04**	**$0.01**	**$0.35**
YOY Growth	-	-	-	-	-	-	*-52.8%*	*-129.0%*	*-68.8%*	*2723.1%*
Shares Outstanding	14.8	15.6	15.7	15.7	15.8	15.8	15.7	17.5	20.0	22.5

Source: Zacks Investment Research, Inc. *Jason Napodano, CFA*

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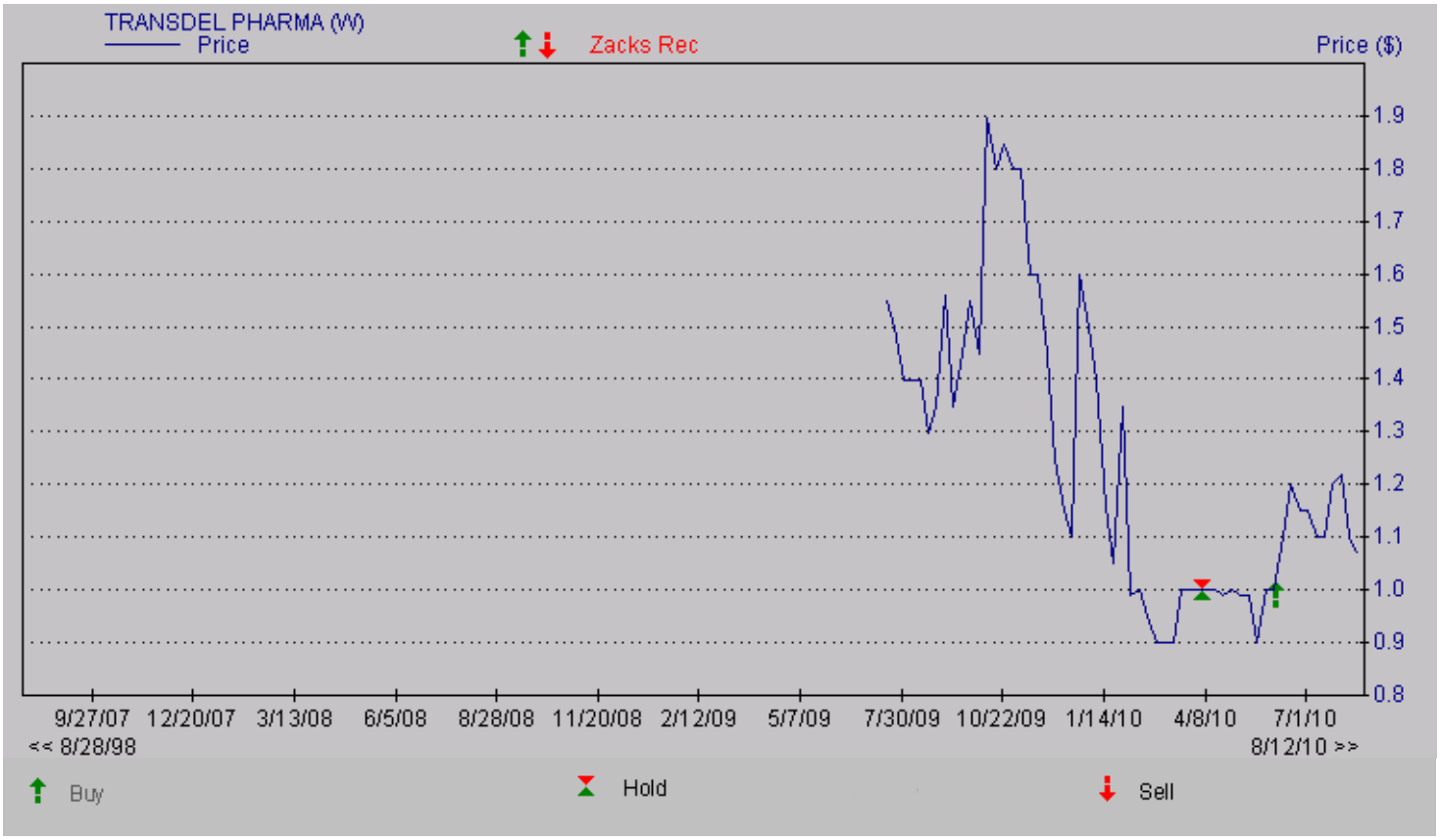
HISTORICAL ZACKS RECOMMENDATIONS



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