Zacks Equity Research

January 17, 2011
Jason Napodano, CFA
312-265-9421
jnapodano@zacks.com

www.zacks.com
111 North Canal Street, Chicago, IL 60606

Transdel Pharmaceuticals, Inc. (TDLP-OTC)

TDLP: Transdel Looks Far Under-Valued…

UPDATE

On September 2, 2010, Transdel presented the full data from the company's phase III program studying Ketotransdel vs. placebo in 364 patients with acute soft tissue pain. Results demonstrate a statistically significant advantage for the company's drug, as well as excellent safety and pharmaco-kinetics. Next up for the company is to conduct a second and third phase 3 program in 2011.

We value Transdel at approximately $2 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 (01/17/11)	$0.60
Target Price	**$2.00**

SUMMARY DATA

52-Week High	**$1.49**
52-Week Low	**$0.54**
One-Year Return (%)	**-48.28**
Beta	**-0.04**
Average Daily Volume (sh)	**3,717**
Shares Outstanding (mil)	**16**
Market Capitalization ($mil)	**$10**
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	**58 of 92**

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 A	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	-$0.05 A	-$0.04 E	-$0.16 E
2011					$0.04 E
2012					$0.01 E

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

© Copyright 2011, Zacks Investment Research. All Rights Reserved.

INVESTMENT THESIS

Ketotransdel The Driving Force…

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 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 $250 million. 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 in 2013 to the patent expiration in 2017 are roughly $550 million, meaning the cumulative royalty payment between approval and the launch in 2013 through 2017 to Transdel is in the area of $110 million.

…Cosmeceutical Business Under-Appreciated…

In June 2009, Transdel Pharmaceuticals and JH Direct, LLC announced they have entered into a licensing agreement providing JH Direct with the exclusive worldwide rights to Transdel's anti-cellulite cosmeceutical product, TDLP-310. The product utilizes Transdel's patented transdermal delivery system technology. Under the terms of the agreement, JH Direct paid Transdel initial royalty advances and will pay future licensing royalty on the worldwide sales of the anti-cellulite product. The product will be launched 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 are particularly excited about this opportunity for Transdel. JH Direct is among the best direct marketing firms in the country, with significant experience and prior success with products such as the Shake Weight and several other cosmeceutical products. The anti-cellulite market is a very attractive opportunity for the company. An estimated 85% to 90% of women develop cellulite following puberty. Sales of anti-cellulite products total have created a $3 billion cosmeceutical market as of 2010. Teaming-up with JH Direct also presents an opportunity for Transdel to expand its pipeline to include formulations for anti-aging, varicose vein and hyperpigmentation.

TDLP-310 is currently in subject trials. We expect that JH Direct will be in position to launch the product by the end of the first quarter 2011. We figure that Transdel is entitled to low single digit royalties on product sales. We estimate that TDLP-310 can be a $150 million product based on obtaining 5% share in the anti-cellulite market. This should provide Transdel non-dilutive cash to fund the SG&A line in 2011 and beyond.

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 the anti-cellulite cosmeceutical product (TDLP-310) for the professional dermatological market. This includes potential sale into spas, medical-spas, and dermatologists offices. This exclusive right lasts for one year after the direct to consumer launch from JH Direct. After the one year 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.

Transdel's cosmeceutical business remains under-appreciated in our view. The company should begin receiving royalty payments on TDLP-310 shortly. 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.

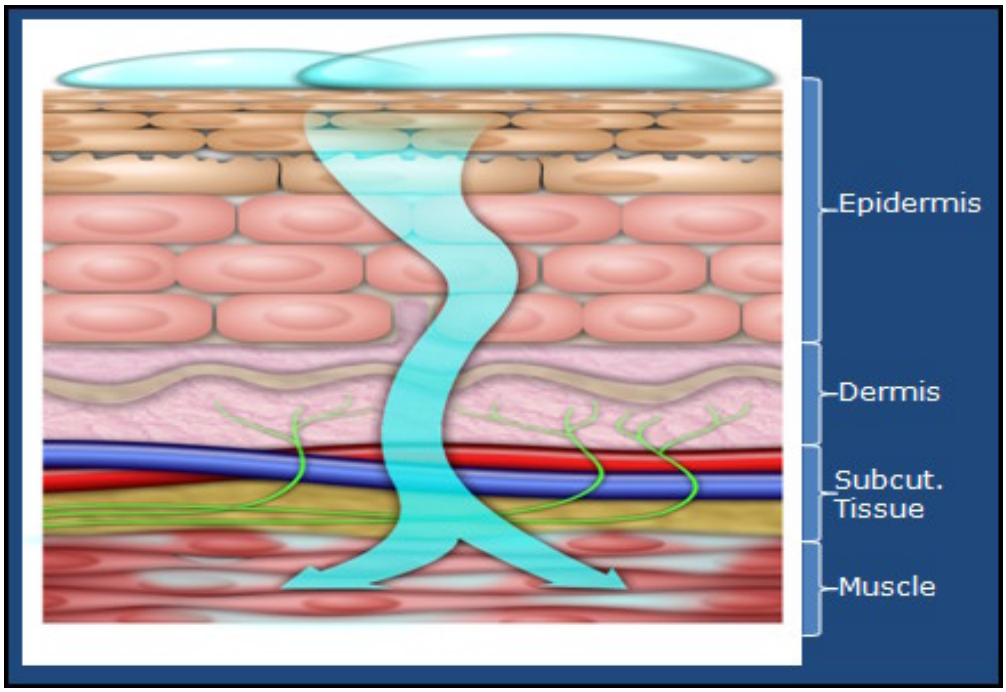
Staying Positive on Transdel Pharma

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.

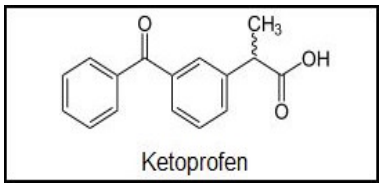
Management is also working to leverage the technology for cosmeceutical applications. The company seeks to develop a new patent protected product by combining well known and established ingredients with its proprietary technology. Targeted cosmeceutical applications include anti-cellulite and anti-aging 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

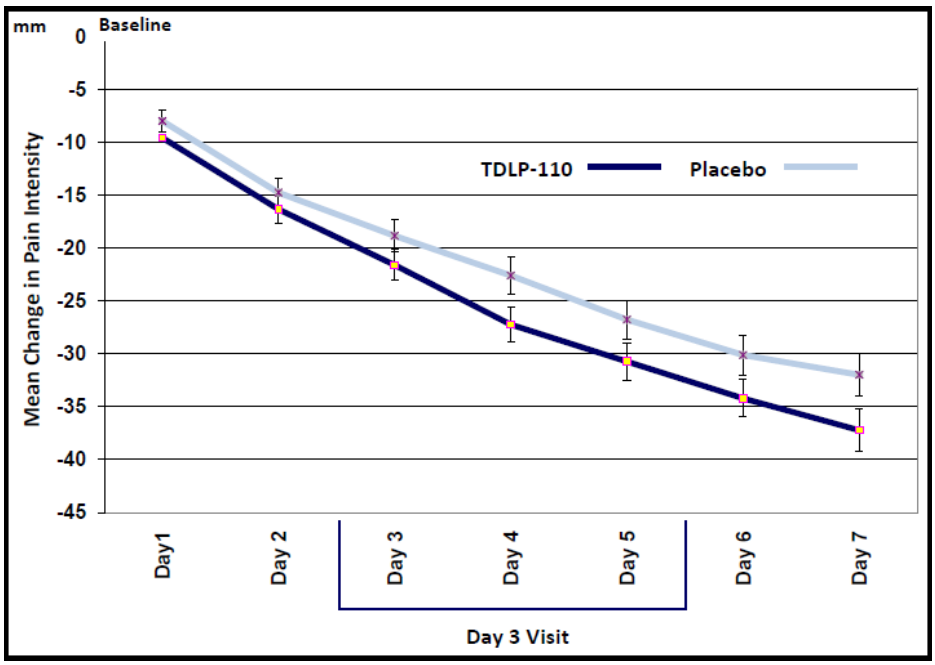
Management has completed testing of Ketotransdel (ketoprofen 10% w/w) in a double blind, placebo-controlled phase III clinical study. The trial enrolled 364 patients with acute soft tissue injuries (sprains & strains) randomized at 26 clinical sites in the U.S. Subjects received TDLP-110 (Ketoprofen 10% cream), called Ketotransdel, 1g 3x daily, or placebo, over a 7 day period. The primary endpoint was the change from baseline in pain intensity as measured by the 100mm visual analog scale (VAS) during daily activities on the Day 3 visit. Other secondary endpoints included safety assessments, various efficacy variables, and stead-state pharmacokinetics (pk) analysis. The data was recently presented at the 13th World Congress on Pain, held in Montreal, in September 2010.

The trial met the primary endpoint in reduction in pain intensity during daily activities over a 24 hour period on Day 3 visit (modified ITT population) using the 100mm VAS.

Phase III TDLP-110-001	TDLP-110 (n=159)	Placebo (n=167)	
…Baseline (Day-0) Mean	77.0	76.1	
…Day-3 Mean	47.8	51.2	
… Change in Baseline (Actual)	-29.2	-24.9	
…Change in Baseline (Percent)	-37.9%	-32.7%	*p=0.038*

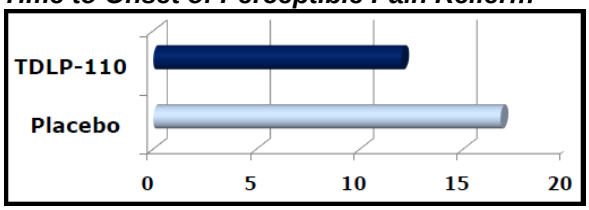
Results show that Ketotransdel treated patients had statistically significant greater reductions in pain intensity than placebo treated patients. During the trial, Ketotransdel demonstrated excellent safety and tolerability, with no treatment related gastrointestinal, cardiac, liver or other serious adverse events. Pharmacokinetic analysis revealed no clinically relevant changes in blood and urine tests, and very low blood concentrations (mean Cmax) of ketoprofen following topical application when compared to comparable doses of oral ketoprofen.

The chart below shows the mean change in pain intensity from baseline over 7 days of treatment. Results show consistent separation between TDLP-110 (Ketotransdel) and placebo over time, with statistical significance between the two groups on Day-4 (p=0.041) and Day-7 (p=0.047).

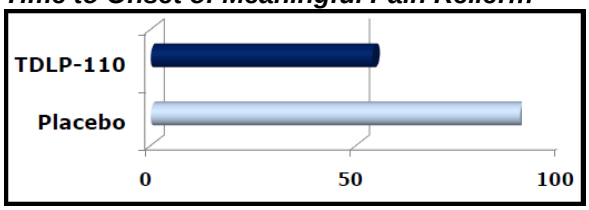


Patient satisfaction on achieving moderate to high pain relief, as measured by the 7 point Likert Scale, showed a statistically significant advantage on Day-3 (p=0.023) for the Ketotransdel treated group. Also, pain relief assessment using the 5-item Pain Relief Scale (PRS-5) showed a statistically significant advantage on Day-7 (p=0.042) for the Ketotransdel treated group. Other secondary efficacy endpoints, including Time to Onset of Perceptible Pain Relief and Time to Onset of Meaningful Pain Relief, also demonstrated an advantage for the Ketotransdel group over placebo.

Time to Onset of Perceptible Pain Relief…



Time to Onset of Meaningful Pain Relief…



During the program, 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.

	TDLP-110 (n-182)	**Placebo (n=182)**
All Adverse Events:	18.1%	20.3%
Drug Related Adverse Events:	3.8%	4.4%
Application Site Adverse Events:	1.1%	2.2%

Moving Forward…

In order to gain approval, the company will need to conduct a second confirmatory phase III clinical study in acute soft tissue pain. We assume the trial will include roughly 360 patients with all soft tissue injuries. 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. This trial must hit statistical significance on the full ITT population.

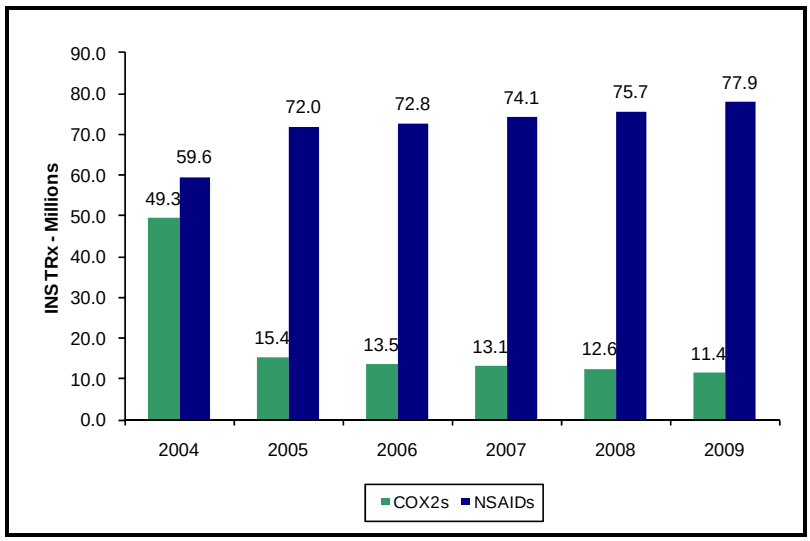
The FDA will also require a phase IIIb program in just muscle strains prior to approval. Transdel will probably seek to enroll a 200 patient program in ankle strains to start once the second confirmatory phase III program is up and running. Data from two supportive "pk" programs will also be required. Management must conduct these phase I/II programs to show no allergenicity or exercise-induced heat effects on the formulation. Nothing here is significantly time or cost prohibitive in our view.

The timing of the second and third phase III trials, along with the pk supporting programs, will be dependent on obtaining adequate financing to support the execution of these activities and for other working capital expenditures. We estimate the cost of the confirmatory phase III program is in the area of $7 million. The phase IIb program will cost roughly $4 million, with another $1 million necessary for the pk studies. In total, Transdel requires roughly $12 million to fund Ketotransdel to NDA filing. 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. We are anticipating that management can get a deal done in the second or third quarter of 2011. 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.

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 Ketoprofen
	NSAIDs	Cox-2	Acetaminophen	
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.

…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.



(1.3% diclofenac patch)



(1% diclofenac gel)



(1.5% diclofenac topical solution)

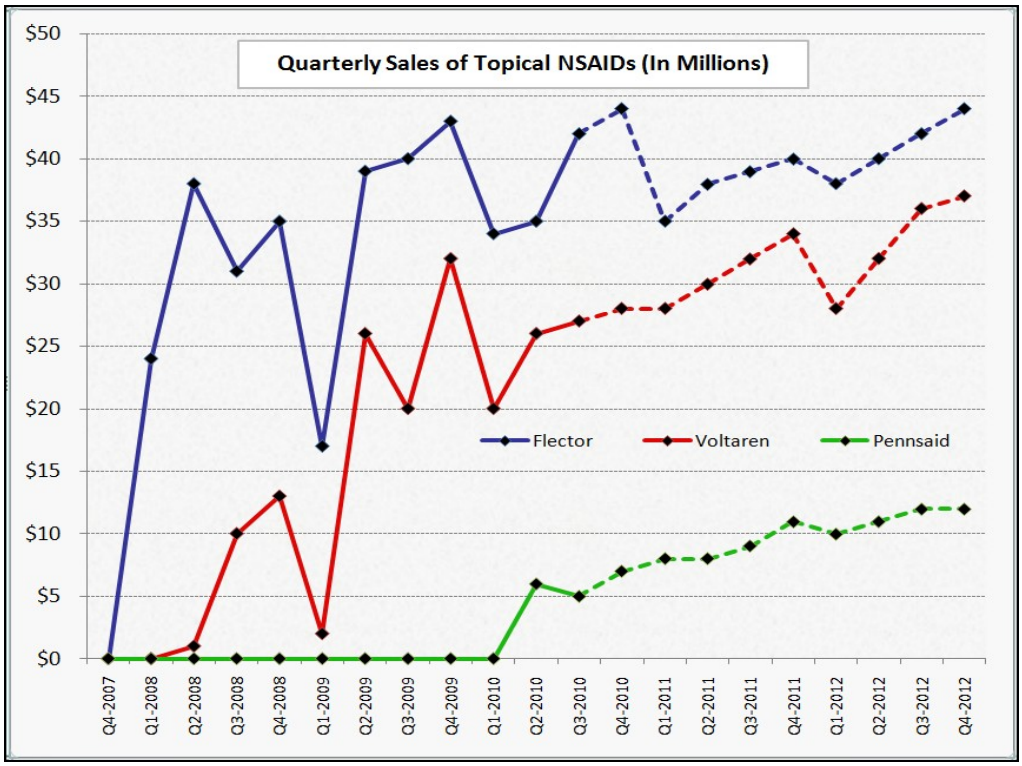
King's Flector Patch is the first and only NSAID patch available in the U.S. It is indicated for acute soft tissue (short-term) pain such as minor strains, sprains, and bruises. The benefit of the patch is an easy and convenient application. Downside of the patch is that it can irritate the skin and offers little flexibility in dosing. Most patients and physicians prefer prescribing topical gels and creams to patches. Flector patch costs approximately $180 for a 20-day application. Still, sales of the Flector Patch were $128 million in 2008 and $139 million in 2009. Sales for the first three quarters of 2010 were $111 million. For the full year 2010, we forecast the Flector Patch will deliver sales of $155 million. Peak sales are $200 to 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. Voltaren Gel costs approximately $80 for a 20-day application. The product is messy and smells rather harsh. Still, Voltaren Gel did sales in 2008 of $24 million. In 2009, sales of Voltaren Gel grew to $79 million. Sales for the first three quarters of 2010 were $74 million. For the full year 2010, we forecast Voltaren Gel will post sales of $102 million. Peak sales are $150 to 200 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 at $180 for a 20-day application. We view Pennsaid as a messy and inconvenient alternative to Voltaren Gel. However, Nuvo and Covidien are working on a next-generation Pennsaid Gel that will compete more effectively with Voltaren. For 2010, we think sales will be $10 million. Peak sales for Pennsaid liquid are only $30 million in our view.

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 $250 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.

On January 12, 2011 we sat down with Transdel's Chief Business Officer, Terry Nida, and the company's Chief Financial Officer, John Lomoro. We think the marketing message for Ketotransdel is clear:

- ✓ 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 in the next several months. 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 to fund development to approval, including Transdel's operating burn, will be roughly $15-20 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 $10-15 million.

Based on our market analysis, Ketotransdel is a $200+ 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 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 $30 and $35 million (see the valuation section below), meaning that on an outright takeover, we believe Transdel is worth $2 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. Transdel has excellent proof-of-concept with the first phase III program, but two more programs that hit statistical significance on the entire ITT population are necessary. This presents future development risk.

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 within the next several months. 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 the JH Direct launch, 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, we expect that JMSR will want to launch the product in the U.S. as soon as possible after JH Direct.

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 third quarter 2010 with $0.467million 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 $1.6 million. As of September 30, 2010, Transdel had $363k in current liabilities, which include $135k in accrued phase III expenses, $91k in separation expenses, and $137k in accounts payable and payroll liabilities.

In April 2010, Transdel completed a private debt financing of $1 million through an issued a senior convertible promissory note at 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. The liability on the balance sheet as of the end of the third quarter 2010 for the note is $1.036 million, bringing the total liabilities as of September 30, 2010 to $1.4 million. Total assets at the end of the third quarter were $0.579 million. As such, the company exited the second quarter with negative shareholder equity of approximately $0.820 million.

On November 1, 2010, Transdel received a Federal grant in the amount of approximately $244,000 under the Qualifying Therapeutic Discovery Project (QTDP) that is part of the Patient Protection and Affordable Care Act. The funds were awarded in support of Ketotransdel. We expect that Transdel will receive the funds by the end of 2010.

The current cash balance of $0.47 million plus the $0.24 million from the QTDP should provide the necessary funding to support operations into 2011. 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.

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. 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 $250 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 large-scale proof-of-concept program in the books, we believe that management will be able to secure this partnership shortly. 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 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, the phase IIIb program, and two smaller pk supportive studies. As such, we expect the cost of developing Ketotransdel to a NDA filing is an estimated to be $15 million. This amount should be backed out of the potential upfront payment. We also believe that the upfront payment will account for the added risk of conducting these programs 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 $10-15 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 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 $250 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 $550 million, meaning the cumulative royalty payment between approval and the launch in 2013 through 2017 to Transdel is in the area of $100 to $120 million.

Conducting a probability and risk-adjusted analysis of these potential cash payments we arrive at a total deal value of approximately $30 million (see below for NPV analysis).

Date	Upfront	Milestones	U.S. Sales	Royalties (~20%)
2011	$10 million	-	-	-
2012	-	-	-	-
2013	-	$5 million (1)	-	-
2014	-	$15 million (2)	$35 million	$7 million
2015	-	$10 million (3)	$80 million	$16 million
2016	-	$10 million (4)	$125 million	$25 million
2017	-	-	$145 million(5)	$29 million
2018	-	-	$165 million	$33 million
Cumulative	**$10 million**	**$40 million**	**$550 million**	**$110 million**
Probability	*~85%*	*~65%*		*~50%*
NPV	**$10 million**	**$10 million**		**$10 million**
			Total NPV for Ketotransdel	**$30 million**

(1) $5 million for U.S. NDA acceptance, (2) $15 million for U.S. Approval, (3) $10 million for cumulative sales >$100 million, (4) $10 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 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

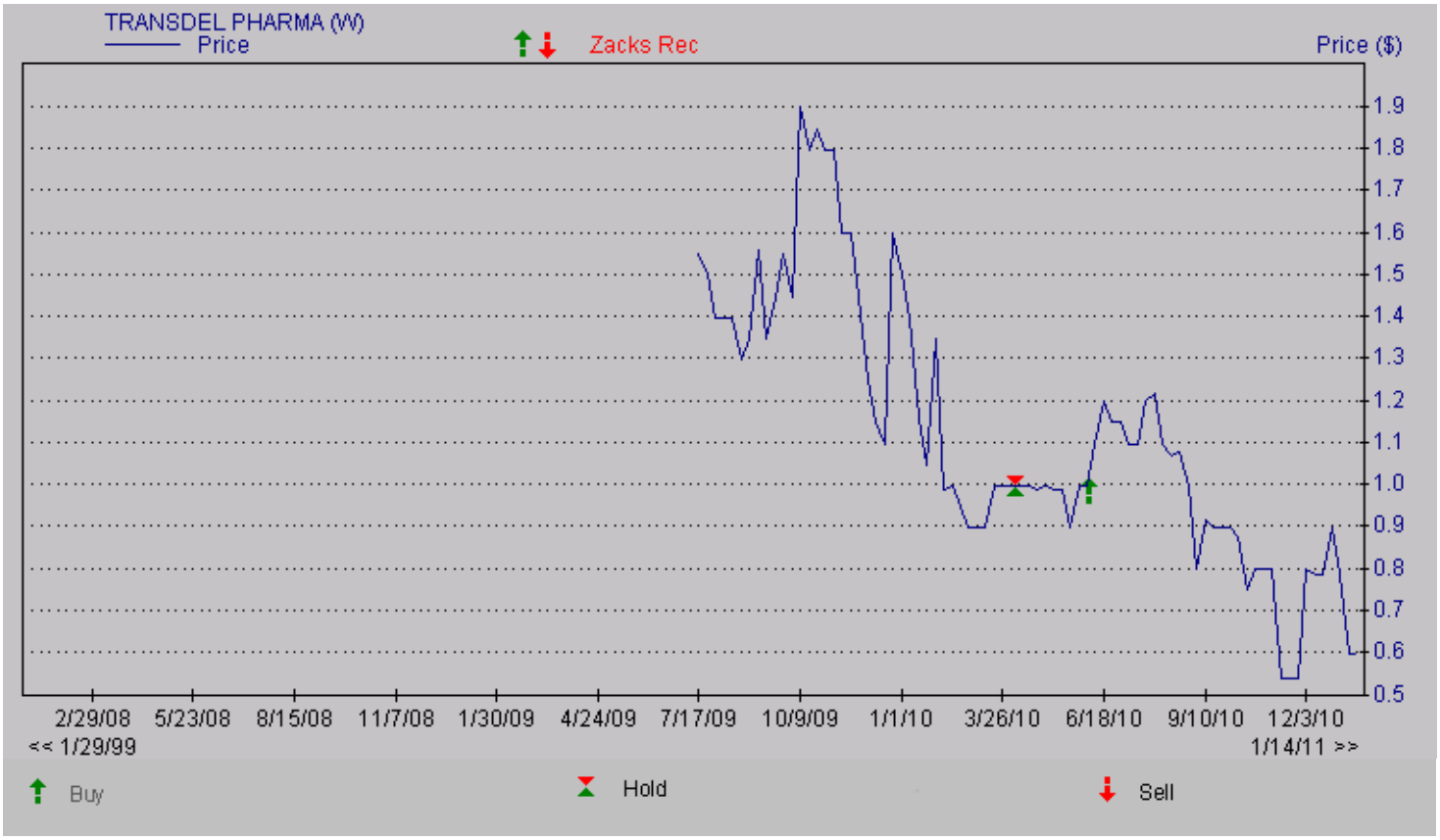
Transdel Pharmaceuticals, Inc.
Income Statement

	2009 A	Q1 A	Q2 A	Q3 A	Q4 E	2010 E	2011 E	2012 E	2013 E
ketotransdel (US Sales)	$0	$0	$0	$0	$0	$0	$0	$0	$40.0
ketotransdel (Ex-US Sales)	$0	$0	$0	$0	$0	$0	$0	$0	$0
ketotransdel Royalty	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$8.0**
YOY Growth	-	-	-	-	-	-	-	-	-
Collaborations / Milestones	**$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**	**$2.5**	**$2.5**	**$13.0**
YOY Growth	-	-	-	-	-	-	-	*0.0%*	*420.0%*
Cost of Goods Sold	$0	$0	$0	$0	$0	$0	$0	$0	$2.4
Product Gross Margin	-	-	-	-	-	-	-	-	*94.1%*
SG&A	$1.6	$0.8	$0.4	$0.6	$0.5	$2.3	$1.6	$1.8	$2.0
% SG&A	-	-	-	-	-	-	*64.0%*	*72.0%*	*15.4%*
R&D	$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	($4.6)	($0.9)	($0.5)	($0.7)	($0.6)	($2.7)	$0.4	($0.1)	$7.6
Operating Margin	-	-	-	-	-	-	*16.0%*	*-2.0%*	*58.8%*
Interest & Other Net	$0.0	$0.0	$0.0	$0.0	$0.0	$0.2	$0.3	$0.3	$0.3
Pre-Tax Income	($4.6)	($0.9)	($0.5)	($0.7)	($0.6)	($2.5)	$0.7	$0.3	$7.9
Taxes / Other	$0	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($4.6)	($0.9)	($0.5)	($0.7)	($0.6)	($2.5)	$0.7	$0.3	$7.9
YOY Growth	-	-	-	-	-	*-45.2%*	*-128.1%*	*-64.3%*	*3076.0%*
Net Margin	-	-	-	-	-	-	*28.0%*	*10.0%*	*61.1%*
Reported EPS	**($0.29)**	**($0.06)**	**($0.03)**	**($0.05)**	**($0.04)**	**($0.16)**	**$0.04**	**$0.01**	**$0.35**
YOY Growth	-	-	-	-	-	*-45.9%*	*-125.3%*	*-68.8%*	*2723.1%*
Shares Outstanding	15.6	15.7	15.7	15.9	16.0	15.8	17.5	20.0	22.5

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

© Copyright 2011, Zacks Investment Research. All Rights Reserved.

HISTORICAL ZACKS RECOMMENDATIONS



DISCLOSURES

Zacks SCR certifies that all of the views expressed in our reports or blogs accurately reflect the personal views of the analyst or analysts contributing to the report or blog about the subject company or companies and its or their securities. We also certify that no part of an analysts' compensation was, is or will be, directly or indirectly, related to the specific recommendations or views expressed in any report or blog.

The following disclosures relate to relationships between Zacks Investment Research ("ZIR") and Zacks Small-Cap Research ("Zacks SCR") and the companies covered by the Zacks SCR analysts in the Small-Cap Universe.

ZIR or Zacks SCR Analysts do not hold shares in the companies in which they cover. Each analyst has full discretion on the rating and price target based on their own due diligence. Analysts are paid in part based on the profitability of Zacks SCR, which includes payments received for non-investment banking revenues and services.

ZIR and Zacks SCR do not make a market in any stock. Zacks SCR has never received compensation for investment banking services on the small-cap universe. Zacks SCR does not expect received compensation for investment banking services on the small-cap universe. Zacks SCR has received compensation for non-investment banking services on the small-cap universe. Zacks SCR expects to receive additional compensation for non-investment banking services on the small-cap universe. Non-investment banking services include investor relations services and software, financial database analysis, advertising services, brokerage services, advisory services, investment research, and investment management.

Additional information is available upon request. Zacks SCR reports are based on data obtained from sources we believe to be reliable, but is not guaranteed as to accuracy and does not purport to be complete. Because of individual objectives, the report should not be construed as advice designed to meet the particular investment needs of any investor. Any opinions expressed by Zacks SCR Analysts are subject to change. Reports are not to be construed as an offer or the solicitation of an offer to buy or sell the securities herein mentioned. Zacks SCR uses the following rating system for the securities it covers. Buy/Outperform: The analyst expects that the subject company will outperform the broader U.S. equity market over the next one to two quarters. Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters. Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

The current distribution of Zacks Ratings is as follows on the 1017 companies covered: Buy/Outperform- 15.4%, Hold/Neutral- 78.8%, Sell/Underperform – 5.3%. Data is as of midnight on the business day immediately prior to this publication.

© Copyright 2011, Zacks Investment Research. All Rights Reserved.