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Dermisonics, Inc. (DMSI.OB)

**Ultrasonic patch or injection?
A new drug delivery technology that gets
"under your skin"...**



Rating (12 Month)

Source: <http://www.cortalconsors.de>

Speculative buy

Last rating change: First evaluation
Target price: USD 4.40
Price (16.09.2005, 11:22am ET): USD 0.825
 High/Low 250 days: USD 1.80 / 0.57
 Next analysis : Update

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Basic information

Number of shares (m) :	40.8	Primary exchange:	OTCBB
Market cap USD (m) :	33.7	Reuters symbol:	DMSI.OB
Free floating (%) :	55.9%	Ø daily turnover 3M OTC:	149,443 shares
Major shareholder:	EncSysInc - 44.1%	Frankfurt Stock Ex. Symbol:	FQC.FSE
		ISIN:	US24983U1043
		WKN:	A0DK4Y

Info: <http://www.dermisonics.com>

Business year through December 31.

Dermisonics (DMSI.OB) : A Revolutionary Discovery for Drug Delivery.

In a departure from heretofore unsuccessful "needle-free injections" attempted in the past, Dermisonic's technology is based on the use of **ultrasonic impulses** delivered to and through the drug patch that enlarge pores in the skin to the extent that the active ingredient of the pharmaceutical reaches the bloodstream directly, bypassing the potentially harmful effects of the human digestive system.

By opening the targeted pores and **kinetically motivating** the drug molecules with the ultrasonic signal, larger drug profiles than ever considered before have been made to *dance* their way into patients systems – more than **175 drug therapy compounds qualify** for this technique, offering painless solutions for the chronically ill. Dermisonics could therefore really hold the key to an entire range of new possibilities in *transdermal* active ingredient applications.

Dermisonics' fundamental work is complete: A **US patent** covering the core technology has been **issued**, and 11 others have already been applied for to include further specifications. Studies in human beings with a standard insulin preparation – until now on healthy volunteers – successfully proved high dosing levels. In addition to circles of medical experts, such as the well-known German diabetes researcher **Professor Heinemann** from Neuss, leading pharmaceutical companies have

also begun to intensively study this new technology. Planning of the first pre-clinical testing as a prelude to a human clinical trial with diabetic patients has just been announced (see the company's press release of August 1, 2005), and will take place in a cooperative effort with two insulin manufacturers.

Dermisonics (DMSI.OB) : When is the right time for you to buy this stock?

We have been following the development of Dermisonics for nearly one year, but only now does it seem to us that **right moment has come to get involved**: The basic technology has been secured and the expansion into the *cosmeceuticals* sector, in our opinion, considerably enhances the company's prospects.

Also the company's stock – at least in the USA – has shown clear signs of an **upswing in turnover** in recent weeks, which also reduces risk. Moreover, while Dermisonics is still officially a company in the research and development phase, its **marketing strategies** are already taking shape and dynamic development is anticipated in the coming weeks.

The management is already estimating the probability of success at 80-85%. We are a bit more careful and calculate the chances of success at 25%, which can be considered standard for phase 1b of the clinical trials of a medical technical device.

Nevertheless, even on this basis, a significant under-valuation is indicated for Dermisonics with a price potential of over 300%. The table below clearly shows the earnings value per share that can be anticipated for the U-Strip technology depending on the individual phases of the clinical trials and the FDA approval process:

Dermisonics:		Earnings value of U-Strip technology										
Probability of FDA clearance	10%	20%	25%	30%	40%	50%	60%	70%	80%	90%	100%	
Earnings value per share in USD	1.76	3.52	4.40	5.28	7.05	8.81	10.57	12.33	14.09	15.85	17.62	
Clinical phase:	Ia		Ib					II				

Source: MIDAS Research

The stock markets may also have inaccurate cost concepts colored by the development of medicines. No more than USD 200,000 will be required for the new series of tests. And for the subsequent phase 2 for final market approval, a budget of USD 8-9 million has been set for the 6-week long test with 250 patients at five different locations. **These low costs for market approval will certainly not be a hindrance with the major insulin manufacturers jockeying for position to conclude licensing agreements with Dermisonics.**

What are the prospects for success for the U-Strip technology and what do they mean for the value of Dermisonics?

As can be seen, **SanofiAventis** is attempting to establish its place in the U.S. insulin market, while the old bull *EliLilly* must defend its turf. This is justification enough for one of the two – or even a niche supplier, to help themselves to a larger piece of the pie through an association with Dermisonics. And this is no mere pie in the sky, as is indicated by the fact that **Dermisonics is carrying out the planning of the now upcoming second phase of the human pilot trial - the human trial protocol – in close cooperation with multiple manufacturers.**

In 4-5 weeks we will know for sure. By then, the U-Strip technology will have been successively tested on diabetic patients at the *Dr. Rex Kessler* Research Institute under the supervision of the *State University of Pennsylvania*. Dermisonics hopes that they will be able to prove at least the **equality of its technology with the Minimed pump**. If the dosing results among the diabetes are even nearly as successful as those among the test trial participants, then this data should place Dermisonics in a very promising bargaining position in terms of **licensing agreements with the insulin manufacturers.**

What is diabetes and what benefit does the U-strip technology from Dermisonics offer patients?

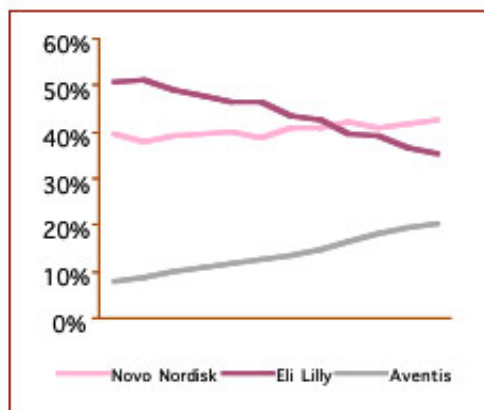
While diabetes is only the fifth most common cause of death in the USA, due to the duration of its treatment, it is the **most expensive chronic disease** there is, currently suffered by around 16 million Americans. This figure is increasing by nearly five percent each year. For diabetics, the body is no longer capable of – or insufficiently capable of – maintaining its blood sugar level (glucose). This is achieved through the natural hormone insulin, which is produced in the pancreas.

In extreme cases, untreated diabetes can lead to lethal shock, and even with consistent treatment, life expectancy decreases by an average of 15 years. In around 10 percent of those afflicted the pancreas is unable to produce any insulin at all from birth (**juvenile diabetes** or diabetes type 1). However, the vast majority of diabetics experience malfunctioning insulin production later in life (**adult diabetes** or diabetes type 2), primarily as a result of improper nutrition or lack of exercise, making it a typical civilization illness. Approximately 25% of this group must regularly inject insulin, while most can rectify the problem with a therapy consisting of a diet regime and pills to sink the blood sugar level. Ultimately, however, it

nearly always leads to the administration of insulin.

Health professionals agree: It would be beneficial to many patients to begin insulin applications earlier, however, most naturally abhor injections and postpone taking this step for as long as possible. An alternative supply option without injections would thus be more than desirable and could establish an additional market beyond the 25% named. Everyone is currently talking about the new insulin drug which can be inhaled as a **spray**. This does not represent competition for Dermisonics because the spray solution is only intended to control blood sugar spikes after meals. There are **two specific applications** to consider for which the various manufacturers offer different insulin preparations: One is for maintaining a constant blood sugar level throughout the day, while the other is for handling blood sugar spikes after meals. Dermisonics is focusing on the long-term supply market.

World market share (Q1/2002 to Q3/2004)



Source: Novo Nordisk; IMS; MIDAS Research

A high degree of mobility is already offered by **insulin pumps**, which like the U-Strip is carried on the body, however, which is connected through a canula. Nevertheless, nearly 5%, or around 200,000 diabetics, have decided for this solution. The leading manufacturer (approx. 70% market share) is Medtronic, Inc. which with its *Minimed* insulin pumps has already written an **extraordinary success story** and in just a few years was able to generate turnover amounting to over USD 1.6 billion in the neurology sector. **The market that Dermisonics intends to enter thus already exists** and could grow even larger, since what is being introduced is a painless solution. In our analysis, we only assumed that the company will manage to also win over 200,000 diabetics to its solution over a period of 5 years, or no more than those currently using insulin pumps.

Skincare Applicator (U-Wand) – a new application with great potential.

If it is possible to use ultrasound to transport active ingredients through the skin to the bloodstream, then it should not be at all difficult to have such ingredients end up in the lower layers of the skin. This slight alteration of the Dermisonic's concept could prove to be extremely effective, because it opens the **door to an entirely new range of applicatory possibilities, cosmeceuticals**, which are a cross between pharmaceutical and cosmetic products. The best known **example is Botox**, a nerve toxin which when injected in low doses just below the skin paralyzes facial nerves and thus makes wrinkles disappear for several months.

Another example is *Collagen*, a structural protein of the connective tissue, which has been used for years in creams or is even injected to fortify the skin and thereby has a smoothing effect. The desire for eternal youth and the increasing societal acceptance of corresponding medical interventions and treatments have led to entirely new growth markets for the cosmetics industry. Although *Botox* was first approved by the *FDA* for cosmetic purposes in 2002, it already generates annual turnover for its manufacturer *Allergan, Inc.* amounting to USD 716 million, and increasing.

The **patent application** for this *SkinCare Applicator*, originally called U-Wand, or ultrasound wand, has already been submitted, and there is no lack of creams which could provide more lasting effects with the *SkinCare Applicator*. We are convinced that Dermisonics will soon be able to announce the **first product partnerships** in this sector. By then, at the very latest, the first economic evaluation of the ultrasound specialist's second main pillar should be possible.

One aspect to be considered, particularly from an investor's point of view, is that creams and similar substances do not need to be approved by the *FDA*; not even internal tolerance tests are required to place such products on store shelves. As a cosmetic product, this should also apply to the *SkinCare Applicator*, as long as it can be ensured that penetration of the substance into the bloodstream can be avoided through the frequency and duration of the ultrasound application. Thus, the "residual *FDA* risk" can be excluded in our opinion in contrast to insulin supply application, while the **market and price potential** seems to actually be at least as large.