

Drug Delivery EXECUTIVE

TransPharma Medical: Unmatched Applications in Transdermal Technology



**DR. DAPHNA
HEFFETZ**
Chief Executive Officer
**TRANSPHARMA
MEDICAL**

“As the company’s core technology evolved into a robust and well anchored transdermal drug delivery product, we recognized that the skills and the knowledge that had developed and accumulated within the company throughout the years now enabled the possibility for independent development of its own product pipeline.”

TransPharma Medical is a biopharmaceutical company focused on the development and commercialization of pharmaceutical products utilizing RF MicroChannel technology, the company’s proprietary active transdermal drug delivery technology developed to address the limitations of current transdermal delivery. Drug Delivery Technology recently interviewed Dr. Daphna Heffetz, TransPharma Medical’s Chief Executive Officer, to learn more about the company and how its RF MicroChannel technology and patch formulation capabilities come together to offer a painless, needle-free platform that improves the delivery of a wide variety of small molecules, proteins, vaccines, and other biotechnological macromolecules.

Q: Please describe your technology and what makes it unique

A: TransPharma’s technology combines the application of RF energy to the skin with unique drug formulations to deliver small molecule and protein therapeutics transdermally in a highly consistent and reproducible manner. Our development group has adapted RF technology in the form of a small, handheld device that, when pressed lightly on the skin, quickly and painlessly creates microscopic channels through the stratum corneum. These channels, which we call RF Microchannels, expand the portfolio of drugs that can be delivered transdermally and have enabled TransPharma to demonstrate, for the first time, the delivery of therapeutically meaningful levels of biologics to the systemic circulation.

By harnessing the unique attributes of RF energy, TransPharma’s technology is unmatched in its ability to precisely define the depth, density, and diameter of the RF Microchannels and, ultimately, the delivery profile of the drug to the target. And, because our device technology stands alone from

the drug, it can be combined with existing patch or topical drug formulations as well as with TransPharma’s proprietary dry protein patch formulations. These unique features of TransPharma’s technology provides for its wide applicability in the areas of systemic drug delivery, both of small molecules and biologics, topical drug administration, and vaccination. We are aware of no other transdermal technology with such wide applicability.

Q: Can you discuss TransPharma Medical’s background and how it evolved from simply licensing its technology to big pharmaceutical companies to develop its own products?

A: In its early years, TransPharma Medical was focused on the strengths of its core transdermal drug delivery platform, and strategically positioned the technology to be incorporated in products collaboratively developed with pharmaceutical companies. As the company’s core technology evolved into a robust and well anchored

Drug Delivery

EXECUTIVE

transdermal drug delivery product, we recognized that the skills and the knowledge that had developed and accumulated within the company throughout the years now enabled the possibility for independent development of its own product pipeline. Through this mix of partnered and proprietary product development, we believe we are capitalizing both on the promise of the technology and growing capabilities of the company.

Q: How proven is the ViaDerm™ technology? What types of products are the most likely candidates to benefit

A: The ViaDerm device is TransPharma's first commercial prototype employing the RF Microchannel technology. As such, TransPharma's RF MicroChannel technology has been validated in a large number of animal models and in four human clinical studies. Validation studies have demonstrated the wide applicability of the technology with small molecules, peptides, and proteins (regardless of size), vaccines, and polynucleic acids. There are many types of drugs that could benefit from TransPharma's technology. TransPharma is focused on those drugs for which our technology will provide clear benefits over the existing therapy. Such benefits could be in the form of improving safety and compliance through the use of a drug patch or enhancing efficacy with the use of sustained-release patch formulations, for example. There are also product candidates, whose ultimate therapeutic use can be enabled with TransPharma's technology, including transcutaneous vaccines, topical peptide or protein-based drugs for dermatologic applications, and product candidates in the area of iRNA therapies.

Q: What is attractive about ViaDerm?

A: The ViaDerm and the additional device designs under development at TransPharma are handheld devices which are pain-free, low cost, extremely portable, and require only a few seconds of simple operation. They are designed to be reusable for more than 1000 applications and are intended for home use by the patient. The underlying device technology makes it applicable for use with a wide variety of patch technologies and topical drug formulations.

From a medical and regulatory perspective, the ViaDerm and future device products are designed to create RF Microchannels consistently and reproducibly within and between patient populations. For the physician, this means patients will benefit from optimal drug delivery within a desired therapeutic range. For the regulator, this means that our technology will allow for minimal variations in drug plasma levels compared to the reference drug. This is also an important consideration in the pursuit of a 505(b)(2) regulatory pathway for approval.

Q: When will ViaDerm be available on the market

A: TransPharma is pursuing its pipeline development along two parallel paths. The first path is through partnerships, and the second path is through independent development. Through this approach, TransPharma can fully exploit the wide applicability of our technology and benefit from early, mid-, and long-term revenue opportunities. In this respect, we expect some of our dermatologic and topical products to enter the market as early as 2007.

Q: Is TransPharma involved in partnering with other pharmaceutical companies?

A: Following its partnership development path, in late 2004, TransPharma entered into a long-term comprehensive development and commercialization agreement with Teva Pharmaceuticals Ltd. Other potential partnerships are underway but are currently in early stages and for strategic reasons may not be disclosed yet.

Q: What are the company's long-term goals?

A: TransPharma's long-term goal is to build a profitable and sustainable business for our technology across multiple products and markets. We believe this is in the best interest of our shareholders and have assembled a top-rate management team to execute on this objective. We recognize the inherent risk in introducing any novel drug delivery technology to the market, and we seek to mitigate this risk through a thoughtful and methodical approach to gaining credibility for our approach with physicians as soon as possible while gaining access to near-term sources of revenue.

TransPharma Medical is at a crossroad as we move from a drug delivery platform company to a product-focused company. This time has its own unique set of challenges, not the least of which is the sourcing of capital for operations. However, we are confident that our technology and business model represent a very attractive investment thesis. ♦