

Sector: Pharmaceutical Technology

Area: Transdermal Drug Delivery.

Description

Company is advancing the science of transdermal drug delivery with a spray-on delivery system to deliver medications directly through the skin, for systemic or localized application. Products spray onto intact skin, rub in and are completely absorbed almost immediately.

Clinical Need

Many drugs cannot reach their intended target because they cannot successfully reach the area of need. Pills may create GI problems or require higher dosing (resulting in, for example, high likelihood of liver & kidney toxicity). This delivery approach enables clinical success for compounds too toxic for oral dosage. Relief expected to be equivalent to or better than oral meds with much faster onset. Spray delivery has additional appeal in pediatric and geriatric applications where swallowing can be problematic.

Scope of Problem/Opportunity. Company believes its initial target market exceeds \$300 Million in annual sales. This include Hormone Replacement Therapy ("HRT"), Pain Management, Alzheimer's and anti-infectives (anti-malarial). The technology opens up the potential transdermal drug universe to potentially 4,000 drugs (from the current 17).



A simple spray can deliver small molecule drugs, such as pain treatments, avoiding side effects and delivering a higher dose locally with near immediate results vs. 20-30 minutes.

Present: Painful needle use for kids, oral drug toxicity for internal organs, delay in activity onset with pain medications.

Future: Patchless, efficient, safe, spray-on drug delivery methodology

Spray-on drug absorbs within a few minutes and delivers a rapid medical relief equivalent to injection.

Evidence

Company's technology has been employed with safe and efficacious results in 17 trials, including 5 clinical trials that support its unique aspects and potential for the topical delivery of drugs more safely and effectively than existing gel products. These results have been published in peer-reviewed, medical journals. We have seen evidence of near-immediate relief of localized muscle pain.

Current Status

Currently raising capital to fund a pivotal 150 patient study planned for 2nd quarter of 2016. Submitting applications to begin developing strategic partnerships with leading pharma companies.

Milestones Catalysts

Intellectual Property: Patents issued in 2002, 2004, 2007

Regulatory: Blue Letters releasing trials under EMA rules issued March 2016. Expecting to File US IND based on these studies in the 2nd quarter of 2017

Major Challenges

Must raise capital to complete trials and to fund their development efforts.

Marketplace Dynamics

Customers will be existing pharmaceutical companies that can license this technology to enhance the competitive position of their products. Direct sales effort to these organizations through a corporate organization and business development partnerships. Additionally, they have an internally- controlled program to manufacture generic pharmaceuticals themselves for distribution through normal channels.

Competitors. There are several other transdermal delivery methodologies mostly involving a skin patch and gel approach. Company is unaware of competing technologies in transdermal drug delivery via a spray or lotion.

Finance. \$5.8 Million has been invested in the company to date. Seeking a minimum of \$5 million and up to \$30M at an estimated ~\$50 million pre-money valuation. Funds will be used to bring the first products to market.

Ownership. Company is 60% owned by founders/management. Remaining by a diverse group of shareholders.

Exit timeline. Liquidity outlook. Company via an exit through the sale of the firm to a large pharma company or through an IPO, the occurrence of which is anticipated by 2019.

X Factor. We have a 10 x on the company at the current valuation if successful.

History and Origins

The technology was conceptualized by current CEO in the mid-90's at the request of an inquirer who became a collaborator/co-inventor. The state of transdermal art was analyzed and key parameters controlling transdermal flux identified and system to modulate these characteristics composed of GRAS-listed substances developed.

Intellectual Property

The Company's technology is protected by three (3) broad patents in the United States and twenty (20) additional patents issued in the EU, Canada, Mexico and Japan.

Organization

The company was founded in 2012 and is located in Southeastern US.

It has 5 FTE and recently engaged investment banking to assist in the capital raise. Management team has long history in pharmaceutical sector.

Key Takeaways

The company can provide a safer and faster delivery of drugs combined with a billion-dollar market potential at a low incremental cost.

In addition to providing immediate delivery, it provides a more direct means to deliver a much smaller, but equally effective dose of drugs.

Management has very good understanding of the pharma market and should be able to secure licensing and partnerships.