



Madera Pharmaceuticals



Patented Innovative Platform for Transdermal Drug Delivery



Introduction

Madera Has a Patented Platform for Transdermal Drug Delivery

- **There are large potential therapeutic applications for this patent, including:**
 - Men's Erectile Dysfunction
 - Woman's Sexual Dysfunction
 - Baldness/alopecia
 - Raynaud's syndrome
 - Arthritis
 - Diabetic ulcer treatment
- **We are leveraging our patented discovery and formulation skills to develop transdermal treatments for multiple medical conditions**
 - This enables local delivery of drugs to treat local medical conditions
 - Local delivery enables targeted therapy without systemic side effects
- Madera is focusing on the **erectile dysfunction** application first, because it has a faster FDA regulatory pathway and a large \$4B+ target market with a significant unmet treatment need.



Introduction

Beyond Viagra: The Unmet Need in Erectile Dysfunction Treatment

- **Viagra, Cialis** and similar PDE5 inhibitor medications have become synonymous with the treatment of erectile dysfunction (ED)
- **Underserved patients:** However, these pills only address about half of the available market:
 - The pills don't work in nearly 40% of men
 - The pills can be fatal to the millions of men with heart conditions
 - The pills are not effective on men with nerve damage from prostate cancer surgery
- **FDA approved alternative:** The only other FDA approved drug for ED is **Alprostadil**, which is effective in 90+% of men
 - But it isn't a pill, it is injected into the penis
 - Even so, the injection market is an estimated 6 million doses, a \$200-\$300 million annual market
- **Madera** has patented a method of administering Alprostadil topically, eliminating injections – simply rub on a gel cream



The Problem

The Current Landscape of ED Treatments is Far from Perfect

- **Limited Efficacy:** Viagra and Cialis don't work in 40% of men, take up to 2 hours to have an effect, and are ineffective when there is prostate surgery nerve damage
- **Side Effects:** These oral medications often cause systemic side effects, including headaches, facial flushing and loss of vision, and can be fatal to men with heart conditions
- **Uncomfortable Alternatives:** When pills fail, the next step is Alprostadil, which is administered by penile injections or urethral suppositories



The Madera Solution

Innovative, Patented Non-Invasive Topical Gel Alprostadil

- **Topical Gel Innovation:** Madera offers a needle-free, topical gel application of Alprostadil, a proven ED treatment drug effective in 90+% of men
- **Safe for Heart Patients:** Non-systemic and doesn't reduce blood pressure, making it safe for men with heart conditions who can't use Viagra-type drugs
- **Effective for Prostate Cancer Survivors:** Alprostadil works without the need for arousal, even with nerve damage
- **Fast-Acting:** Works in less than 10 minutes, significantly faster than oral medications



Market Opportunity

\$4 Billion Growing Global Market with Large Unserved Market Needs

- **\$4 Billion Global Market:** The global market for erectile dysfunction treatments is in excess of \$4 billion annually.
- **Significant Unmet Market Needs:**
 - Existing treatments are ineffective for 40+% of men
 - Men with heart conditions cannot take Viagra-type drugs
 - Alprostadil works on men with nerve damage, yet many refuse to use the injection or suppository



Competitive Advantages

Non-Invasive, Safe, Fast-Acting, Patented Solution

- **Topical Formulation:** Madera Gel Cream is the only external topical form of a widely used FDA-approved injected drug. A topical gel cream is a much better alternative to self injection into the penis
- **Effective for Heart Patients:** Unlike Viagra-type PDE5 inhibitors, Madera is safe for men with cardiovascular conditions, broadening its appeal to an underserved market
- **Fast Acting:** Alprostadil is effective in less than 10 minutes
- **Patented Innovation:** Madera's utility patent ensures market exclusivity, providing a significant competitive advantage



Achievements and Next Steps

- **Key Achievements:**
 - US patent granted on innovative skin permeation method for Alprostadil in August 2024
 - Successful skin permeation testing in lab
 - Successful clinical efficacy test in dogs
- **Upcoming Phases – next steps include:**
 - Optimizing the formulation
 - Preparing the FDA submission
 - Conducting clinical trials
- **Estimated 3 years to FDA approval**
 - Streamlined 505(b)(2) regulatory pathway as a new formulation of an existing FDA approved drug
- **After ED, there are other large therapeutic opportunities for Madera's patent, including:**
 - Raynaud's syndrome
 - Arthritis
 - Woman's Sexual Dysfunction
 - Baldness/Alopecia



Financial Projections

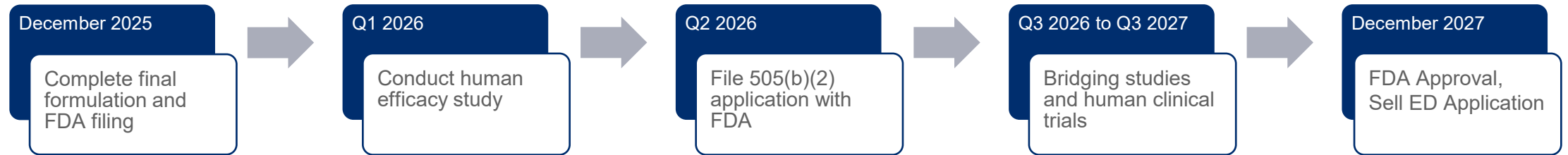
- **Funding Requirements:** The ED project requires a total of \$18 million in funding, to be raised in phases with increasing valuation.
- **Our current raise** of \$3 million will bring us through human efficacy studies within 12 months.
- **Projected Returns:** Based on market size and projected sales, Madera could deliver a return of over 60x invested capital
- **Exit Strategy:** Madera aims to achieve FDA approval within 3 years, positioning the product for acquisition by a major pharmaceutical firm



Timeline and Investor Return

Projected Investor Return of 67x in 3 years

- Our timeline is 3 years to FDA approval & sale



- **Our goal is to bring the ED application to market, and sell upon FDA approval:** Sale of a drug on approval is common in the pharmaceutical industry. Erectile dysfunction drugs Viagra, Cialis and Levitra and injected alprostadil (Advanz), were valued at an average of 3.5x projected peak annual sales.
- **Madera valuation:** Annual sales of the ED injection are estimated at \$200-\$300 million. Management believes Madera will enable a larger unmet market need, but even just replacing the injected sales would imply a value in excess of \$1 billion.
- **Projected Investor Return:**
 - Our current offering is at a valuation cap of \$15 million post-money, with a target value of the ED application of \$1 billion.
 - Investment in this round and a sale at that level would provide a compelling return to the investor.

Our Team

The Madera team are seasoned professionals with deep expertise in pharmaceutical development, regulatory affairs, and commercialization.



Mike Danzi
Founder & CEO

Over 30 years healthcare experience developing, manufacturing and marketing drugs at international pharmaceutical companies; as COO of ICN (NYSE: ICN) and CEO of Legacy Pharma International, with 100's of drug registrations.

Founded US Labs, sold to LabCorp for \$155mm. Founding Chairman and CEO of Biotek from pre-revenue to merger with Ventana Medical, to \$210mm IPO (VMSI)

Harvard Business School MBA
Cornell Engineering BSE
Veteran, US Navy submarine officer



Prof. Marc Brown, PhD
Strategic Partner

Founder of MedPharm, Chair of Scientific Advisory Committee

Academic at Pharmacy Departments at King's College London (KCL) and the University of Hertfordshire; visiting/honorary professorships at the Universities of Reading, Hertfordshire and King's College London.

He has co-supervised over 50 PhD students to success, and has co-authored 2 books, over 200 publications, 30 book chapters and 26 patents describing his research interests which lie mainly in drug delivery to the skin, nail, eye and airways



Charles Evans, PhD
Strategic Partner

Senior Vice President of Pharmaceutical Development at MedPharm Ltd

Named inventor on Madera patent

Expert at formulation development.

Many years of expertise in the successful development of robust commercial products across all types of topical, inhalation and transdermal formulations.

Ph.D. in Pharmaceutics, University of Hertfordshire.



Bob Babilon, MS, MBA
Strategic Partner

President, Prosoft Clinical

35 years in the pharmaceutical industry.

Expert at Regulatory Affairs, Quality Assurance, and Business Development.

MS in Microbiology and Immunology from Temple University and an MBA from St. Joseph's University

Thank You for Considering Madera

- **Patented Transdermal Delivery Platform:** Patented discovery and formulation skills to develop transdermal treatments for multiple medical conditions.
- **Breakthrough Product:** Madera's ED product is an innovative treatment that meets significant unmet market needs.
- **Improve Quality of Life:** This is an opportunity to create a product that will provide life-changing benefits for millions.
- **Multiple Large Potential Therapeutic Markets:** Alprostadil increases blood flow locally. As a topical, it has several large target therapeutic applications.
- **Financial upside:** Madera also has the potential for outstanding financial returns to investors.
- Interested potential investors are invited to visit our data room at <https://docsend.com/view/s/pbw4gwihe8upetcq>

Contact Information:

Mike Danzi, CEO

MikeDanzi@MaderaPharm.com



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