Dignify Therapeutics, LLC



Profile

- **Novel Bowel and Bladder Therapies**
- Repositioning **Existing Compounds**
- **Expedited** development
- **Out-licensing**

Severe Unmet Need

- Solution to restore bladder and bowel function
- **Patient friendly**
- More predictable
- **Eliminate catheters** and diapers

Solution

- "On demand" patient controlled functionality
- **Reduced healthcare**
- Improved quality of life

Target Markets

- **Spinal Cord Injuries**
- Spina Bifida
- MS
- Stroke
- **Diabetes**
- **Elderly**

Dignify Therapeutics, a Research Triangle Park, NC based virtual drug development company, is focused on developing novel bladder and bowel therapies for spinal cord injured (SCI), spina bifida, multiple sclerosis and similar populations with voiding dysfunction. The development strategy is to reposition existing compounds and access expedited development and regulatory programs to minimize the time through clinical trials. The business strategy is to out-license products to large pharmaceutical companies after the completion of clinical requirements through phase II proof-of-concept. These partnerships can be a source of funding for subsequent products and potential return for investors. The Company plans to fund most of the development activities through non-dilutive institutional grants and loans but is seeking \$1.5 million from initial investors to perform the pre-clinical activities to enable the IND approval to allow for i.v. proof-of-concept study in humans in 1H'15.

Restoring the voluntary control of excretory function

The inability to efficiently empty the bladder and/or bowel is a common problem in people with SCI, spina bifida, multiple sclerosis, stroke, Parkinson's disease and the elderly. Current therapies include urinary catheters or adult diapers which are inadequate. The majority of SCI patients must perform multiple daily bladder catheterizations and each year almost one in four requires hospitalization for catheter-related infections and urinary retention complications costing the healthcare system over \$350M. Bladder and/or bowel dysfunction affects virtually all SCI patients, and for most patients the ability to regain bladder/bowel control is equally as important as regaining mobility.

A convenient and effective method of managing excretory function

Our lead product DTI-100 will enable patients to empty their bladder and/or bowel when convenient for them



Novel pharmaceutical treatments to offer features and benefits including:

- 1) Ability of patients to regain voluntary bladder/bowel control;
- 2) Reduction or elimination of bladder catheters and associated complications;
- Overall healthcare costs savings by reducing bladder infections and hospitalization; and,
- 4) Reduction in caregiver time needed to assist patients and increased productivity for patients. Currently, there are no effective and tolerable marketed drugs to treat urinary retention disorders.

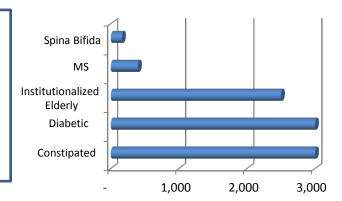
SCI initial focus, strong rationale for expanded large patient populations

People with spinal cord injury, spina bifida, multiple sclerosis, stroke, Parkinson's disease and the elderly have virtually no pharmaceutical options to manage their symptoms. Our initial focus is on treating a subset of the SCI population which will provide favorable regulatory consideration, positive marketing opportunity, non-dilutive funding opportunity and motivated patient population. Assuming 110,000 eligible SCI patients, premium pricing supported by managed care organizations, and a conservative 40% worldwide sales penetration, the estimated annual peak sales for the lead candidate, DTI-100, would be approximately \$400M. Regulatory approvals for additional indications would provide significantly higher revenue and potential value for investors.

US Patient Populations (000s)

SCI Value (WW)

110,000 **Treatable Patients** 40% Penetration Rate 44,000 Patients Treated \$10,160 Annual Cost to Treat \$447 Million Annual Peak Sales



Development programs

- 1. DTI-100: bowel and bladder therapy (see next page for details)
- 2. DTI-200: bowel and bladder therapy (totally different mechanism from DTI-100)
- 3. DTI-300: bowel therapy (totally different mechanism from DTI-100 and DTI-200)

Multiple Shots on Goal

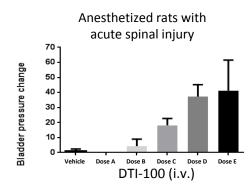
Dignify Therapeutics, LLC



DTI-100: Potent and efficacious with favorable clinical safety profile for drug target

DTI-100 data summary

- Potent (nM) and efficacious in vitro contraction of human bladder and bowel (100% of "gold standard")
- Potent and efficacious in vivo contraction of bladder in anesthetized control rats and rats with acute spinal injury (see graph to right)
- Potent and efficacious drug-induced voiding of urine in awake rats with chronic (4 week) spinal injury and anesthetized rats with diabetic cystopathy (12 week)
- Clinical data on DTI-100 analog (> 100 subjects) demonstrates robust pharmacodynamic response and favorable adverse event profile for DTI-100's target receptor



DTI-100: Intellectual Property

- No Barrier to Entry
- Continued
 Enablement

Management Team

Large/Small

Proven track record

Pharma Companies

Experts in drug

development

DTI-100 patent summary

- Extensive patent freedom-to-operate search completed
- Provisional patent filed (Aug 2013)
 - Methods of use and administration
 - Rapid onset formulations
 - · Drug combinations

Majority of team has worked together over multiple decades

- Benny Ward, Chief Executive Officer:
 - Closure Medical (acuired by JNJ), InnerPulse, BioDelivery Sciences International
- Karl B. Thor, PhD, President, Chief Scientific Officer:
 - Eli Lilly, GenuPro (partnered with JNJ), Dynogen; 2 first-ever NDAs for urology
- Eboo Versi, MD, PhD, Chief Medical Officer:
 - Eli Lilly, Pfizer, Yamanouchi; Urogynecologist, Oxford, Cambridge, Harvard
- Dan Ricca, PhD, VP, Chemistry:
 - Glaxo, SARCO (acquired by PPD), Dynogen

Exceptional and Enthusiastic Scientific Advisory Board

- Michael Kennelly, MD, FACS: Clinical investigator, Carolinas Rehabilitation, Charlotte, NC
- · John Lavelle, MD: Clinical investigator, Veterans Affairs Medical Center, Palo Alto, CA
- · Bradley Kropp, MD: Clinical investigator, U. of Oklahoma, Oklahoma City, OK

Exit Strategy

Dignify is a limited liability corporation which allows returns to be efficiently distributed to investors. Proceeds from the out-licensing, including up fronts, milestones, and sales royalties, of DTI-100 and subsequent programs can be distributed to investors and/or retained for future product development.

Dividend Payments to Investors

Investment Opportunity

The Company is seeking \$1.5M for 2014 development activities to initiate IND-enabling preclinical studies to enable patent claims and to file the IND for lead candidate, DTI-100, in Q4 2014. IND approval will allow DTI-100 "POC" trials in SCI patients, which is currently planned to be funded by non-dilutive grants and loans, to commence Q1 2015. Founders have funded \$100K thus far and own ~ 97% of the equity.

Investor Financing

Funding & Milestones

- \$1.5M Equity
- \$12M Non-dilutive Grants and Loans

Non-dilutive grants and loans To Date 2015 2014 2016 2017 \$100K by Mgmt. \$3.4M \$3.6M \$1.5M \$5.0M Outlicense Product File IND \$50K NCBIO POC i.v. Formulation **POC Final** Potential Investor i.v. Formulation Loan Initiate Final Formulation Return Formulation

Contact: