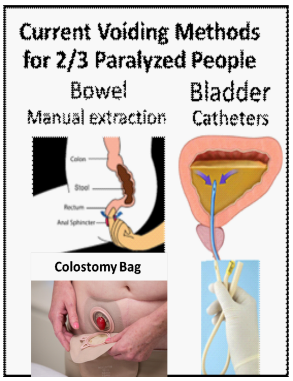
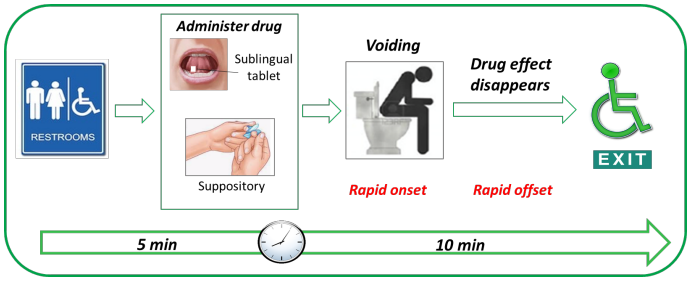
Dignify Therapeutics, LLC
2 Davis Drive
Research Triangle Park, NC 27709

DIGNIFY THERAPEUTICS, LLC

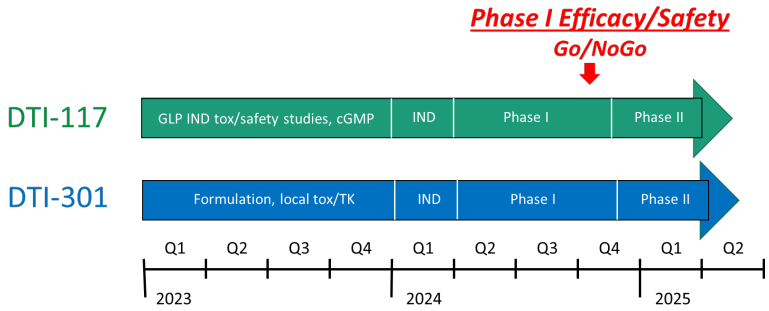
- **Mission statement:** Dignify Therapeutics is focused on developing novel drug and medical device therapies to restore voluntary control of bladder/bowel function and eliminate manual bowel programs, bladder catheters, and adult diapers.



- **Severe, unmet medical need:** The inability to initiate urination or defecation is a terrible problem in people with neurologic injury or disease (2 MM), diabetic neuropathy (4 MM), and institutionalized elderly (1 MM) requiring manual bowel programs, colostomies, and catheters. Loss of control also leads to urinary and fecal incontinence, which are top reasons for institutionalization of the elderly. Urinary and fecal incontinence are largely managed by a $12B adult diapers market with inadequate drug or medical device therapies available.
- **Reimbursement, pricing, and market opportunity:** 3rd party reimbursement analysis indicates Tier 2 placement with a $7-8K/year price point and ~ $1B/ year peak US sales for each Dignify drug program. COGS are ≤ 10% of sale price.
- **Indications:** "On-demand, rapid-onset, short-duration, drug-induced voiding therapy". There are no safe, efficacious, and convenient drug therapies available for inducing urination or defecation. Current management programs include bladder catheterization, manual bowel programs, enemas, laxatives, and diapers. Dignify has two distinct drug programs (DTI-117 – sublingual, DTI-301 - suppository) ready for IND-enabling studies with positive pre-IND meeting outcomes for DTI-117, while DTI-301 will be proposed for a rapid 505(b)(2) path to IND approval. No FDA-approved competition exists for any Dignify program (i.e. all are "first-in-indication" therapies), and Fast-Track FDA designations are expected.



- **Highly de-risked, rapid, inexpensive clinical development:** Dignify's two therapeutic programs (one myogenic, the other neurogenic) are both supported by clinical evidence. Dignify's translational animal models of bladder and bowel dysfunction are highly predictive of clinical responses. For all Dignify therapeutic programs, clinical proof-of-concept (POC) will be established in Phase 1 trials prior to entering Phase 2. Clinical protocols, investigators, sites, and CROs are established through Phase 2a trials planned for Q1 2025. FDA-approved partners are engaged to provide drug substance and product for clinical development. Phase 3 trials are simple to administer and use inexpensive diary and validated QoL questionnaires for efficacy per FDA guidance.



- **IP:** Patents are issued, and auxiliary use and formulation patents are expected for both drug programs.
- **Capital:** $3.4 M seed (Founders, RA Capital, Eshelman Ventures); $>20 M non-dilutive grants (NIH, DoD).
- **Support:** Dignify has strong support from the NIH, Veterans Administration Medical Centers, and patient advocacy groups.
- **Use of Investment Proceeds:** Cover drug development for both through Phase 2a.
- **Team:** Edward Burgard, PhD, President; Karl B. Thor, PhD, Chief Scientific Officer; Anthony Ditonno, Executive Chairman; Dan Ricca, PhD, VP Chemistry; Lesley Marson, PhD, VP Preclinical Research

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