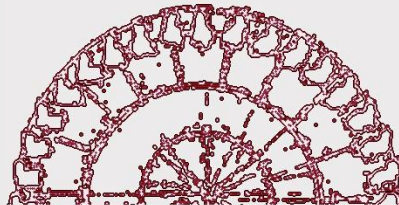


# The Realities of a Start-Up Life Sciences Company

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# Transformative Technologies for Managing Gastrointestinal Disease

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- Focusing on protecting and repairing the gut barrier
- Oral non-absorbable polymer drugs
  - Worldwide exclusive licenses to IP obtained from the Univ. of Chicago
  - Significant European patent has issued
- Multiple \$1 to \$2 billion market opportunities
  - Radiation-induced GI injury, antibiotic-associated colitis (C. difficile), IBD, IBS, NEC in premature infants
- Strong management and advisor network
- Attractive risk-reward profile
  - Solid pre-clinical data, clear path to results

# Initial Product MDY-1001: Preventing Radiation Injury of the GI Tract

- Dose of curative radiation therapy of cancers is limited by injury of normal tissues
- Acute injury occurs in 75% of patients
  - Alters course of radiation therapy in 15-20% of patients
- Chronic injury seen in 5-15% of patients
  - Poorly treatable requiring surgical resection in over 50% of patients
- 1.5 - 2 million cancer survivors suffer from chronic post-radiation intestinal dysfunction



Normal  
Colon



Radiation  
Injury of  
Colon



Oral Mucositis

# Advancing a Start-up Life Sciences Company

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- Follow-on investors **take** risk but don't **like** risk
- Advancement is an exercise in "**de-risking**":
  - Technology & Intellectual property
  - Market opportunity
  - Regulatory barriers
  - Business organization
- Example - Midway
  - Funding sources
    - BioAdvance, Ben Franklin Technology Partners, Univ. of Chicago and Insider Angels
  - Use of Funds
    - Advanced protection of intellectual property
    - Pre-clinical development
    - Preparation for human trials
  - Currently \$2.5M from establishing Proof-of-Concept in humans

# The Dilemma for Start-Ups

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- Financing a multi-year program to reach a series of value-added milestones
- Sources of funds to “de-risk” have contracted
  - Early-stage VC investment has all but disappeared
    - VCs have moved upstream to later-stage “de-risked” opportunities
    - VCs maintaining larger reserves for existing portfolio companies
  - Angels are syndicating and playing a larger role
    - Investment limited to less capital intensive development programs

# The Response by Start-Ups

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- Forced to stay virtual/semi-virtual
- Resorting to less predictable sources of capital
  - Federal grants: NIH, DoD, Pilot programs (e.g. BRG-SPAN grants under ARRA, Tax Grants)
  - Long lead times and low burn-rates are required for this approach
  - SBIR Phase 1 & 2 grants won't get a drug candidate to IND
  - Not all are eligible
- Experienced talent pool is being recruited away to other regions where there is stability of financing
- Example - Midway
  - Midway has remained virtual
  - Midway & its scientific founders have applied for:
    - \$6.7M of NIH translational research grants that include monies for product development.
    - Tax grants under section 48D of the IRS Internal Revenue Code

# Recommendations:

## “De-Risk” the Start-Up Environment in PA

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- Early-stage business models are undergoing a transition providing PA with a unique opportunity
  - Larger companies are downsizing internal R&D
    - Hunting for external assets, earlier in development, to fill their pipelines
- Recommendations
  - Maintain & capitalize on the fertile scientific resources
    - Support systems that facilitate collaborations between institutions
    - Multidisciplinary teams are critical
  - Increase access to predictable capital
    - Support “smart money” programs that are working (e.g. BioAdvance, Ben Franklin Technology Partners)
    - Foster a business climate that encourages:
      - Angel group investment
      - Small VC fund formation and investment
    - Support regulatory predictability at the State and Federal levels
- Access to capital will motivate talent to stay and grow both primary and support companies in PA