



# Regenerating Confidence

A NEW PATHWAY FORWARD



FEBRUARY 2018

# Regenerating Confidence | A New Pathway Forward

## A STREAMLINED STRUCTURE



- Reduced expense burn
- Prioritized programs and resources
- Renewed direction and streamlined organization
- The right teams at that right time

## NEW! FINANCING AND MARKET EXPANSION: CHINESE SUBSIDIARY



- Long-term investment horizon with resources
- Establishing a presence in the largest market for esophageal cancer
- Working together, leveraging resources

## SCIENTIFICALLY SOUND AND NOVEL TECHNOLOGY



- Expanded SAB guiding development priorities
- Growing body of data on consistent regeneration
- Novel and new category: bioengineered organ implants with removable scaffold
- New data on mechanisms of action

## THE RIGHT INDICATIONS FOR THE RIGHT CLINICAL AND BUSINESS REASONS



- Learning from experience
- Pediatric Esophageal Atresia (US/China)
- Esophageal Cancer (US/China)
- INDs targeted for filing in 2019

# 2018 Roadmap | Pragmatic Progress

Q1 | 18

First things first;  
re-start operations;  
secure final reports on  
all animal studies;  
IND gap analysis

Expand SAB; actively  
use the SAB to guide  
development (piglet  
studies at CCMC in  
collaboration with  
Dr. Finck

Q2 | 18

Continue to validate  
the science through  
publications and  
3<sup>rd</sup> party review

Review status of  
SBIR Grant:  
non-dilutive financing  
(extend financial  
runway)

Q3 | 18

Broaden operations  
with China subsidiary;  
identify Chinese KOLs  
and investigators;  
update IP

Gain pediatric rare  
disease designation  
for atresia indication

Q4 | 18

Complete piglet  
studies at CCMC;  
continue to engage  
with FDA on  
requirements

Update clinical  
protocols: primary and  
secondary endpoints;  
inclusion and  
exclusion criteria

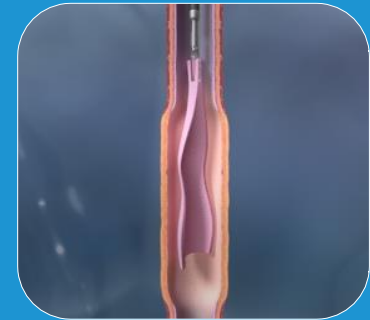
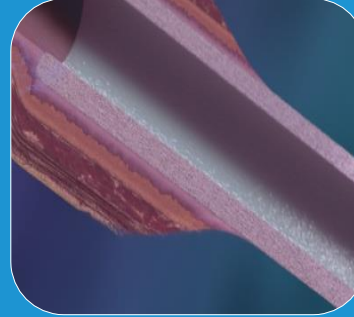


# A Novel Approach | Regenerating Possibilities

Cellspan implant  
is inserted after  
esophageal resection

Rapid healing response  
and initial regeneration  
over the Cellspan Implant

Scaffold is  
removed  
at 21 days



DAY 21



DAY 361



# Partnering for Progress | Biostage & Connecticut Children's Medical Center

Connecticut Children's Medical Center is serving as a pivotal site to advance the Biostage pediatric esophageal atresia program



Active collaboration with  
Connecticut Children's Medical Center

Lead by Christine Finck, MD  
Scientific Advisory Board Member

EVP and Surgeon-in-Chief  
Connecticut Children's Medical Center

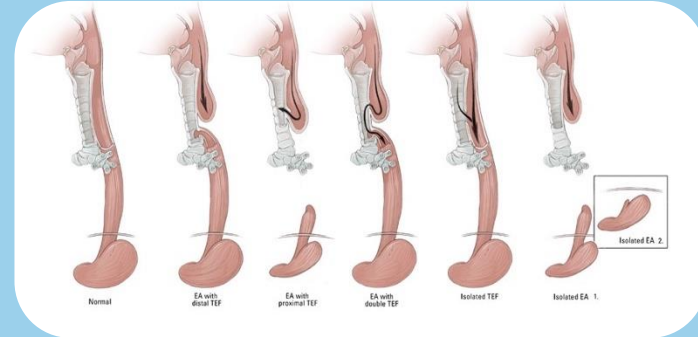
Associate Professor of Pediatrics and Surgery  
UCONN Health

# Pediatric Esophageal Atresia | Life-Threatening and Urgent Need

Approximately 1 in 2,500 infants in the US is born with esophageal atresia

Biostage currently has orphan designation in EA

With long-gap esophageal atresia, on average, infants spend 120 days in the ICU with a cost of \$576k per patient



Infant is born with a gap between the upper and lower esophagus

Esophageal atresia requires immediate surgical intervention

In some cases, the gap is too lengthy to bring the two ends together; this condition is known as long-gap esophageal atresia (LGEA)

With long-gap esophageal atresia there is no consensus on how to correct the defect

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DRIVEN BY THE  
PATIENTS WHO DESERVE  
A BETTER STANDARD  
OF CARE AND THE  
OPPORTUNITY TO  
ACHIEVE BIOSTAGE'S  
FULL POTENTIAL

