



Flexible Surgical Devices for Gastrointestinal Cancers

**CPRIT Conference Company
Showcase Oct 2012**

Defining the Future
of Flexible Surgery™

Agenda

- Corporate overview
- How Apollo is using its CPRIT Award
- Progress made with the CPRIT funding
- Next Steps with additional funding

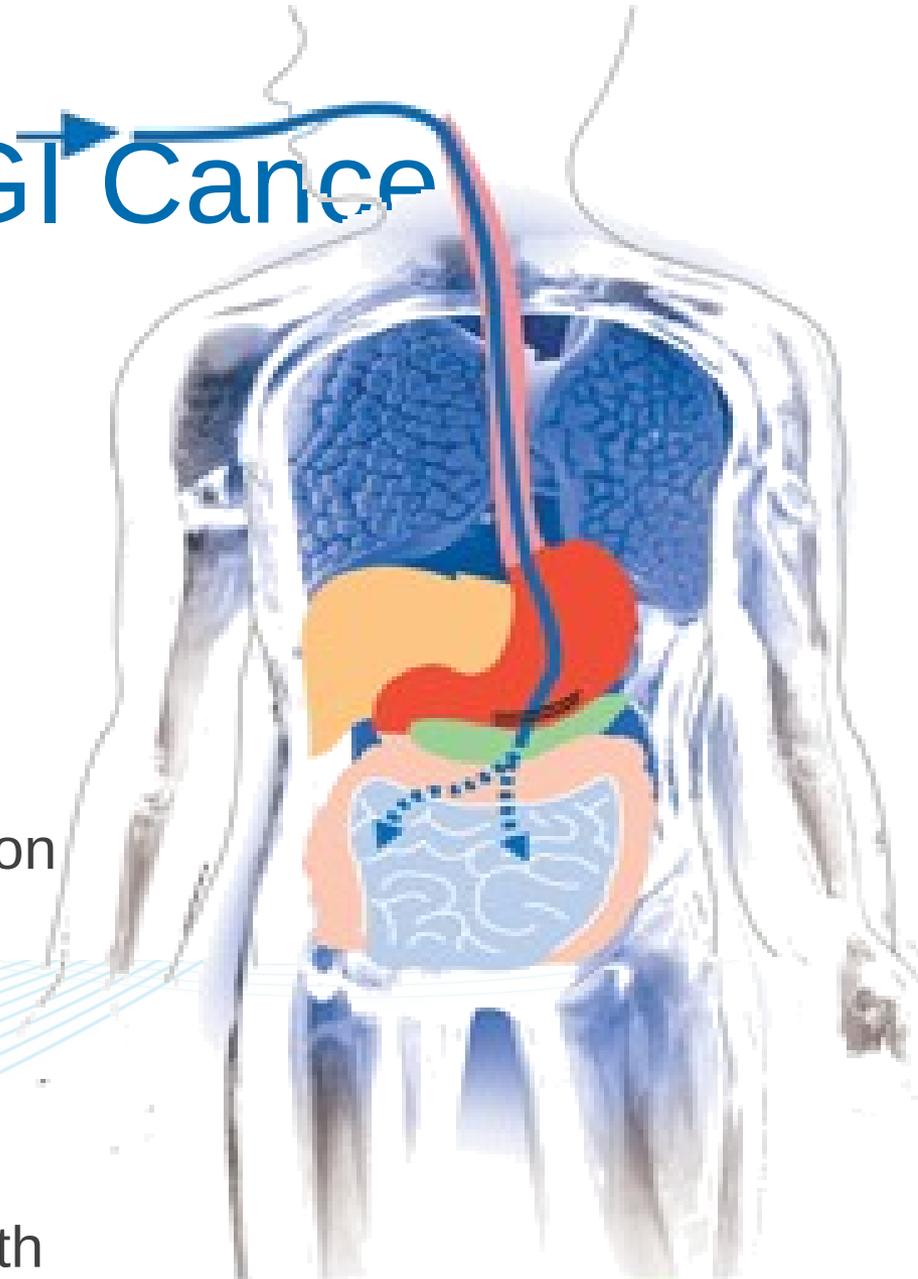
Apollo Endo Company

Summary

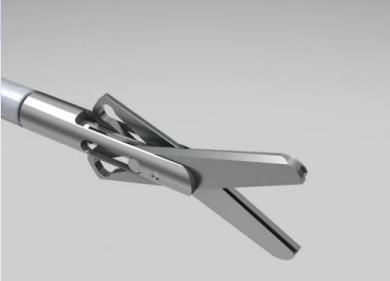
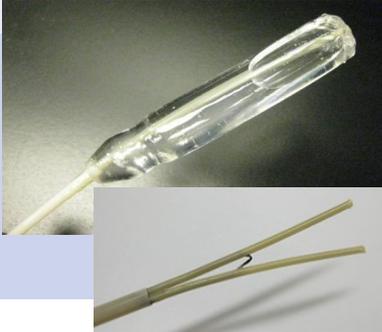
- FDA cleared endoscopic surgical devices targeted at GI cancers and other GI disorders
- Strong physician, society, and strategic partner relationships
- Multiple products with multiple clinical applications
- Seasoned team with commercialization, M&A, and IPO experience
- 5 Months of US sales >\$500k revenue and >1000 patients successfully treated to date

Impact of GI Cancer

- Esophageal cancer is the 8th most common malignancy and **6th** most common cause of cancer deaths worldwide
- Gastric cancer is the **most common malignancy in the world** and second most common cause of death worldwide
- Colorectal cancer is the **3rd most commonly diagnosed cancer** and the **2nd most common cause** of cancer death in the United States



Apollo Product Portfolio Mix

		Functional Purpose	Mkt.
OverStitch™ Endoscopic Suturing System with Tissue Helix™		True surgical suturing on a fully flexible platform. Allows minimally invasive closure of resected GI cancers	\$1.8B
FlexSheers™ Endoscopic Scissors		Robust surgical style cutting of tissue. Minimally invasive removal of suspect tissue.	\$200M
SuMO™ System for Mucosal Lesions		Enables en-bloc surgical resection of pre-cancerous mucosal GI Lesions	\$1.4B

Apollo CPRIT History

- Approved for \$5M pilot commercialization grant in first round of applications
- Leveraged **\$13.7M** in external capital
- Primary goals:
 - OverStitch - First proof of concept in humans
 - SuMO – POC in preclinical, US FDA submission, ready for human POC

Apollo/CPRIT

Commercialization “Firsts”

- First commercialization grant to hit all project milestones (all ahead of schedule)
- First funded product to gain US FDA clearance
- First funded product to treat cancer patients
- **Supported 30 high quality medical device jobs in Austin**

High Impact Results

- “Revolutionary cases like this one begin to reveal the potential of new flexible surgery techniques and tools designed to remove early stage lesions from the colon, esophagus, and stomach,” says Jay Redan, MD, Medical Director of Minimally Invasive Surgery at Florida Hospital Celebration Health.

Key OverStitch Clinical Procedures

- Validation of colonic suturing:
 - Jeffrey Marks, MD, Case Western University
 - 6 patient pilot
 - “Treat and resect” protocol in colon
- Endoscopic removal of stomach cancers
 - Dr. Jay Redan, MD, Celebration Hospital
 - First removal of GIST cancer (stomach

SuMO POC Clinical Trial Q4 2011

- AMC Medical Research B.V in the Netherlands lead by Professor Dr Paul Fockens
- “Treat and resect” protocol
- Two discrete arms:
 - 1) adjacent healthy tissue, multiple locations
 - 2) diseased tissue
- Study recently expanded to include stomach

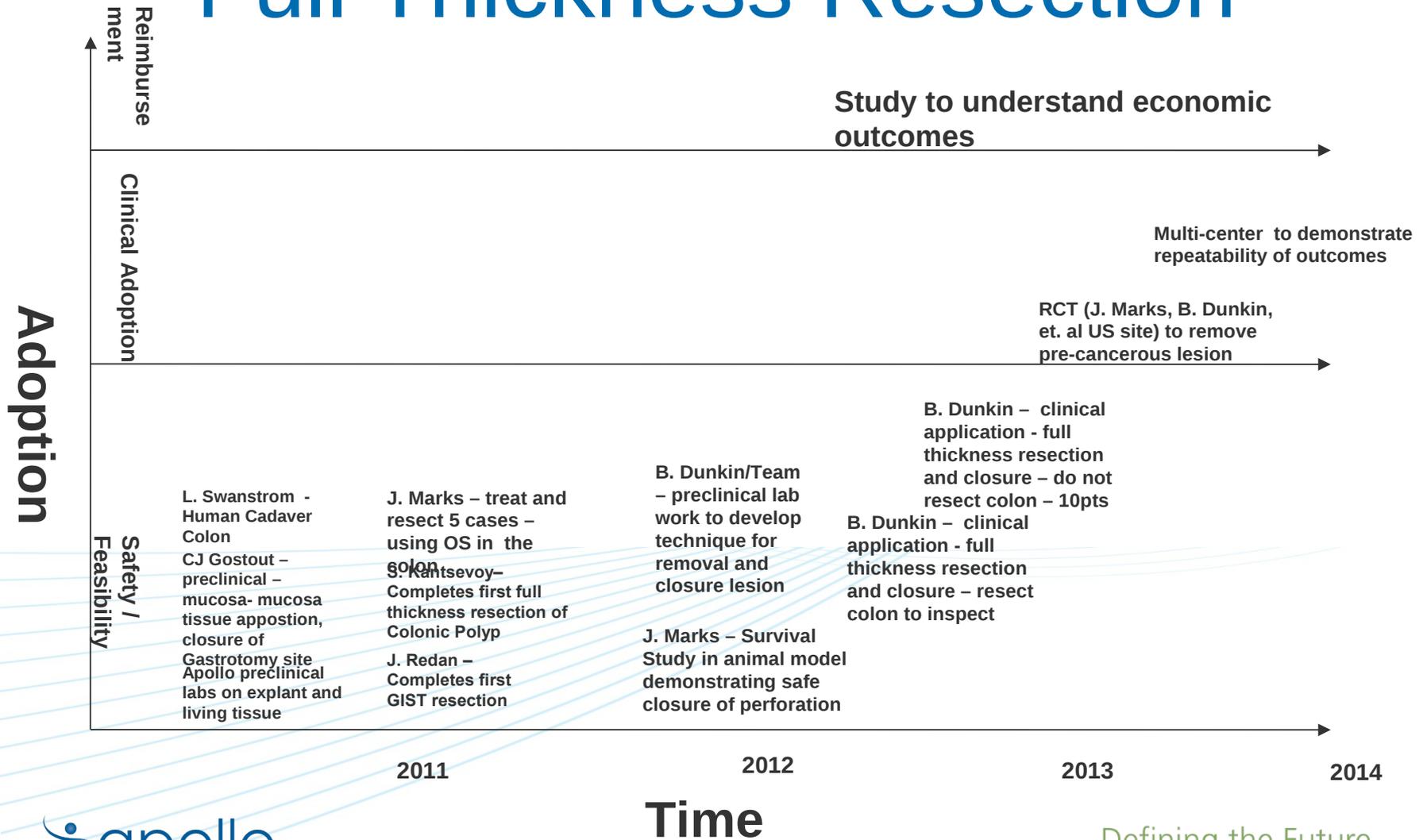
Slide/Video

- SuMO animation
- Kantsevov FTR

Next Steps with Additional Funding

- Continue success of previous phase and drive adoption of OverStitch and SuMO for GI cancer treatment
- OverStitch:
 - Refine procedure for full thickness resection
 - Expand full thickness resection clinical registry

Evidence Generation – Full Thickness Resection



Apollo Endo CPRIT Summary

- Company with proven success translating CPRIT funding to tangible patient results
- FDA cleared endoscopic surgical devices targeted at GI cancers and other GI disorders
- Strong physician, society, and strategic partner relationships
- Seasoned team with commercialization, M&A, and IPO experience
- Further funding will allow continued focus on colorectal and cancer related applications

Backup slides

Co-Founders and Innovation Partners



Peter Benjamin Cotton, M.D.: Professor of Medicine, and Director of the Digestive Disease Center, at the Medical University of South Carolina in Charleston.



Christopher J. Gostout, M.D.: Professor of Medicine in the Mayo Clinic College of Medicine and the Director of the Developmental Endoscopy and Research Unit in the Mayo Division of Gastroenterology and Hepatology, Rochester, Minnesota.



Robert Hawes, M.D.: Professor of Medicine at the Medical University of South Carolina in Charleston, USA, and is an adjunct Professor of Bioengineering at Clemson University.



Sergey Kantsevov, M.D. Assistant



Anthony K. Hood, M.D.: Associate Professor of Medicine at Johns Hopkins Hospital, Division of Gastroenterology. He is the Director of Gastrointestinal Endoscopy with special interests in therapeutic endoscopy and sphincter of Oddi dysfunction.



Pankaj Jay Pasricha, M.D.: Chief, Gastroenterology & Endoscopy, Stanford University. Significant research in obesity, motility disorders, and inflammatory bowel disease. Prolific inventor and entrepreneur.



Sydney Shum, M.D.: Member of the Board of the Hospital Authority of Hong Kong; a member of the Medical Council of Hong Kong; the current president of the Endoscopic and Laparoscopic Surgeons of Asia (ELSA). *Flexible Surgery™*



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Inter-institutional agreement pools intellectual property created by the Apollo Group under a single framework, licensed to Apollo Endosurgery

Apollo Endosurgery Surgical Advisory Board Members



Santiago Horgan, M.D.: Professor of Surgery at the University of California, San Diego. He is the director of Minimally Invasive Surgery and Director of the Center for Treatment of Obesity at the University of California, San Diego with interests in minimally invasive, bariatric, robotic and esophageal surgeries. First transgastric appendectomy in US.



Jeffrey Marks, M.D.: Associate Professor, Case Western Reserve University School of Medicine, Cleveland. Dr. Marks focuses on Minimally invasive surgery, gastrointestinal surgery, and endoscopy and is well published in the field of endoluminal surgery and NOTES..



Steve McCarus, M.D.: Chief, Division of Gynecologic Surgery and Medical Director at the Center for Pelvic Health, Florida Hospital Celebration Health in Orlando, Florida. Dr. McCarus is nationally renown obstetrics and gynecology surgeon that has widely lectured and published on gynecologic endoscopy and gynecologic surgery.



Adrian Park M.D., F.R.C.S., F.A.C.S.: Professor and Chief of General Surgery at the University of Maryland Medical Center in Baltimore, Maryland. Dr. Park is a focused on developing and applying new minimally invasive surgical techniques and technologies. He has authored over 150 scientific articles and book chapters.



Jay A. Redan, M.D.: Director of General Surgery and the Surgical Training Institute Florida Hospital Celebration Health in Orlando, Florida. He has over 15 years experience in laparoscopic and thoracoscopic surgery. His clinical interests are in minimally invasive surgery and general surgery (bariatrics and esophageal).



Mark A. Talamo, M.D.: Chairman in the Department of Surgery at the University of California, San Diego School of Medicine with a surgical focus on gastrointestinal surgery and an emphasis on minimally invasive technology to minimize pain and scarring. Current President of SAGES.



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Defining the Future
of Flexible Surgery™

Apollo Endosurgery



- Austin based, 45 person private company
- Venture backed
- In-house pilot manufacturing capability in place
- On site clean-room with 4 cell setup
- Full machining capability in house, including CNC, injection molding, and rapid prototyping printers
- Robust electronic quality system implemented

Defining the Future
of Flexible Surgery™

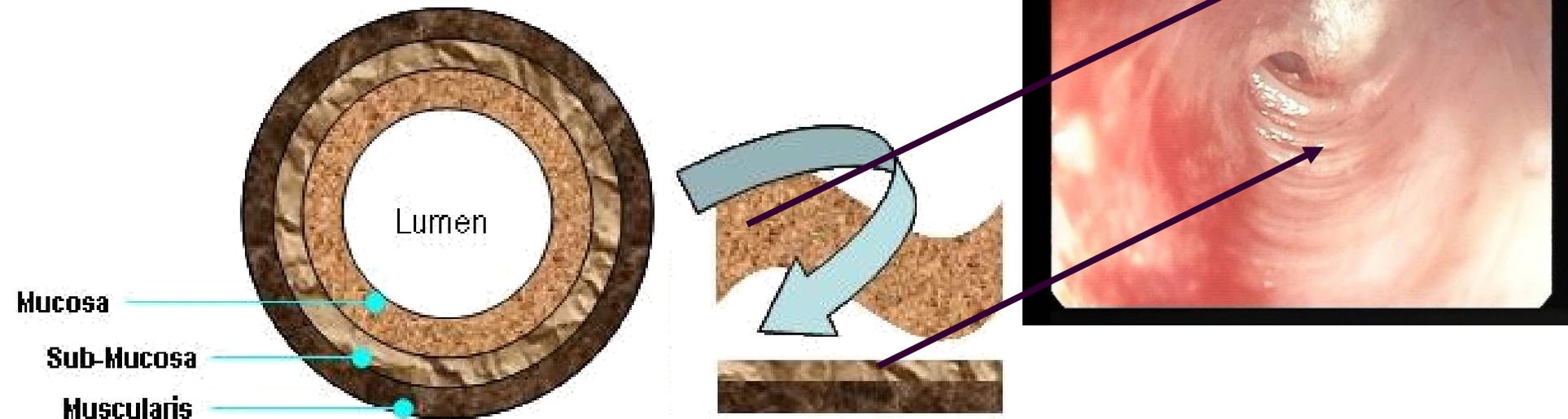
Incidence of GI Cancers

	UNITED STATES			TEXAS	
	Prev	Inc	Mort	Inc	Mort
Colorectal Cancer	1.1 million	147k	55k	45,182	16,329
Esophageal Cancer	24k	17k	15k	4,147	3,556
Gastric Cancer	59,853	21,130	10,620	6,899	4,072

Apollo Relevance to CPRIT

- Apollo is targeting colorectal, esophageal, and gastric cancers, which rank as the 2nd most common cause of cancer death in the United States
- Apollo has a 510(k) device-based approach, translating to faster time to market and greater near term impact
- Our devices and techniques have been confirmed in multiple clinical and preclinical studies, by the top institutions and surgeons around the world
- Our company has a proven track record of performance and success

SuMO Concept



- The GI tract is comprised of multiple layers. SuMO creates a new operative space underneath lesions in the mucosa, allowing for safe, quick surgical resection with an endoscope

SuMO System 510k Claims

- The **SuMO™ Access and Tissue Resection System** is intended to access, dissect, and resect soft tissue in endoscopic gastrointestinal procedures such as removal of flat polyps.
- The **Injection Needle** is intended for endoscopic injection of solutions such as saline as a procedural aid in endoscopic procedures.

- The **Tunneling Balloon** is intended for

Apollo OverStitch Platform



[Click for System Animation](#)

**Approved
510(k) FDA
Claim**

**The Apollo Endosurgery
OverStitch Endoscopic Suture
System is intended for
endoscopic placement of
suture(s) and approximation of
soft tissue.**

Cost

**\$599 (base system), ~\$270 sutures
per procedure, single use**

Uniqueness:

- **True surgical suturing anywhere
you can get a standard endoscope**

**Commercial
Status:**

- **Completing market pilot (300
cases)**
- **Launching GEN II Q4 2011**

Overstitch for Cancer Therapy-

Summary of cancer related cases – July 2012

Cancer	#	Procedure	Physician(s)
Esophageal Cancer	1	Palliative: Stent Fixation	Kantsevov
Lung Cancer	1	Palliative: Tracheo- esophageal fistula covered with Stent	kKntsevov
Esophageal stricture	1	Palliative: Recurrent Stricture	Kantsevov
Colon Cancer	3	Palliative: Closure of fistula after cancer treatment	Thompson, Locke, Marks
Colon Cancer	5	Therapeutic, POC: Closure of defect created in colon	Marks / Delaney
Gastric	1	Therapeutic: GIST tumor	Redan
Rectum	1	Therapeutic: Closure of rectal defect from rectal tumor removal (TEMS)	Redan
Colon cancer	1	Therapeutic: Full thickness removal and closure of colonic lesion	Kantsevov