# Sendosurgery

## DDW Update 2022

CHAS MCKHANN, PRESIDENT & CEO May 22, 2022

## Forward Looking Statements & Regulatory Advisory

**Forward Looking Statements**: Certain statements in this presentation are forward-looking statements that are subject to risks and uncertainties that could cause results to be materially different than expectations. In addition, there is uncertainty about the spread of the COVID-19 virus and the impact it may have on the Company's operations, the Company's financial outlook for future periods, the demand for the Company's products, the Company's liquidity position, global supply chains and economic activity in general. Important factors that could cause actual results to differ materially include: reports of adverse events related to our products, outcomes of clinical studies related to our products, development of competitive medical products by competitors, regulatory approvals and extensive regulatory oversight by the FDA or other regulatory authorities, unfavorable media coverage related to our products or related procedures, coverage and reimbursement decisions by private or government payors, Apollo's ability to support the adoption of its products and broaden its product portfolio; the potential size of Apollo's addressable markets; the execution of our gross margin improvement projects; and the availability of cash for Apollo's future operations as well as other factors detailed in Apollo's periodic reports filed with the SEC are posted on Apollo's website and are available from Apollo without charge. These forward-looking statements are not guarantees of future performance and speak only as of the date hereof, and, except as required by law, Apollo disclaims any obligation to update these forward-looking statements to reflect future events or circumstances.

**Non-GAAP Financial Measures:** To supplement the Company's financial statements presented in accordance with U.S. generally accepted accounting principles (GAAP), the Company reports certain non-GAAP financial measures, including non-GAAP operating expenses, which exclude stock-based compensation. These supplemental measures of our performance are not required by, and are not determined in accordance with GAAP. The Company believes that these non-GAAP financial measures provide investors with an additional tool for evaluating the Company's core performance, which management uses in its own evaluation of continuing operating performance, and a baseline for assessing the future earnings potential of the Company. The Company's non-GAAP financial measures may not provide information that is directly comparable to that provided by other companies in the Company's industry, as other companies in the industry may calculate non-GAAP financial results differently. Non-GAAP financial results should be considered in addition to, and not as a substitute for, or superior to, financial measures calculated in accordance with GAAP.

**Product Regulatory Advisory:** This presentation is intended for the investment and financial community and not for the promotion of Apollo products or related procedures. The X-Tack is cleared for approximation of soft tissue in minimally invasive gastroenterology procedures (e.g. closure and healing of ESD/EMR sites, and closing of fistula, perforation or leaks). The Apollo Intragastric Balloon products are approved in the US as a weight loss aid for adults suffering from obesity, with a body mass index (BMI)  $\geq$ 30 and  $\leq$ 40 kg/m2, who have tried other weight loss programs, such as following supervised diet, exercise, and behavior modification programs, but who were unable to lose weight and keep it off. In addition, the Apollo Intragastric balloon has received a Breakthrough Device Designation from the U.S. Food and Drug Administration for use in treating patients with a BMI between 30-40 kg/m2 with noncirrhotic nonalcoholic steatohepatitis (NASH) with liver fibrosis. Outside of the US the indications for Apollo Intragastric Balloon products vary based on product version and local regulatory clearance. The Overstitch is cleared for the endoscopic placement of sutures and the approximation of soft tissue in the GI tract. The Overstitch clearance does not include procedure-specific indications for use. Although Apollo has and continues to obtain clinical data on additional uses for its products, the safety and effectiveness of these uses has not been specifically cleared or approved for commercial purposes by the U.S. Food and Drug Administration.



# Sendosurgery

## **New Endobariatric Opportunities**

### STEVE BOSROCK

VP, Marketing & Medical Education





## **Steve Bosrock**

**VP, MARKETING & MEDICAL EDUCATION** 

**Joined Apollo 2021** 





## **Building Access to Large Untapped Markets**

OBESITY >\$2.98 Estimated Global Addressable Market<sup>1</sup>

+

### REVISIONS

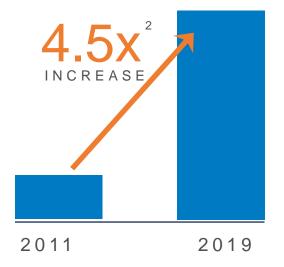
**\$1.0B** Estimated Global Addressable Market<sup>4</sup>

<0.2% Treated surgically<sup>2</sup>

42% of U.S. Adults are obese <sup>2</sup>

UNPENETRATED global obese patient opportunity

**33%** Increase in prevalence expected next 2 decades<sup>3</sup>



U.S. endoscopic bariatric revisions

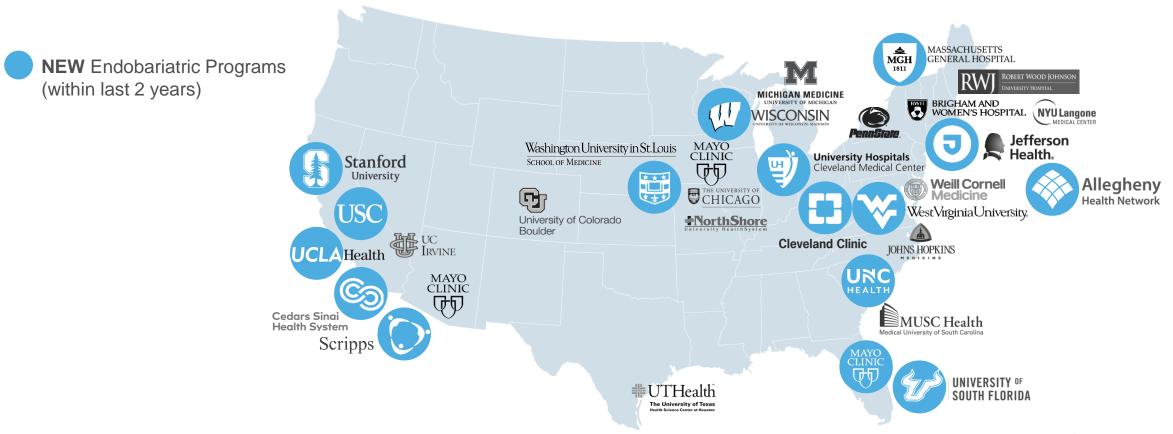


1. NHANES 2017-2018; US Census 2020; ASMBS; management estimates | 2. O'Brien P. Surgical Treatment of Obesity. Endotext (Internet). | 3. Centers for Disease Control and Prevention. | 4. Finkelstein, E; Khavjou, O.; Thompson, H; Obesity and Severe Obesity Forecasts Through 2030. American Journal of Preventive Medicine. June 2012. See Product Regulatory Advisory, slide 2.

## framing our opportunity

SEEK SURGICAL TREATMENT

## >25 and Growing Endobariatric Programs at Leading Academic Centers





## Driving Excitement Around Orbera®

Foundation of our franchise to address growing, global obesity crisis



- Capitalizing on macro recovery & new AGA guidelines
- Significant clinical evidence extending worldwide share leadership as competition expands category
- Increasing physician training and salesforce focus
- Initiating co-marketing programs
- Revitalizing marketing support available to dedicated EBWL practices





## What is the role for ESG?



## Patients Highly Motivated in Search For Weight Loss Help

Arduous journey marred by concerns for physical health, self-image and confidence + social impacts



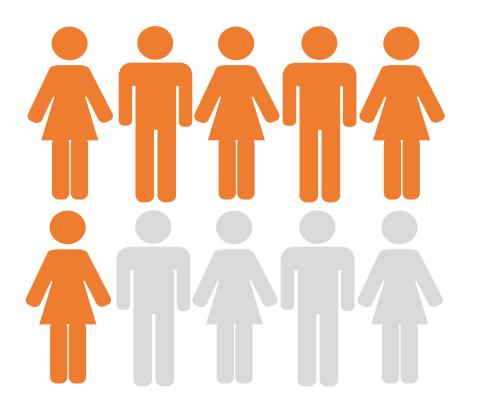
Of patients\* are under the care of a physician for weight loss

Have met with a dietician\*

38%

Have talked with their physician about a weight loss procedure\*

## Patients are Interested in a Less Invasive, Effective & Durable Weight Loss Option



58%

Of patients surveyed have not considered a surgical procedure - leading concerns relate to side effects and complications of surgery\*



## Patients Excited About Less Invasive Treatment

Consideration expands significantly beyond those interested in traditional options

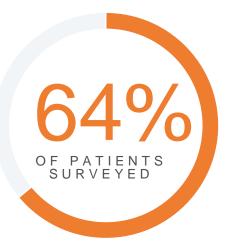
OF PATIENTS

SURVEYED

Likely to see a

doctor to learn

more about ESG



Very interested (34%) or interested in ESG

DRIVERS

46% no surgical cuts44% significant weight loss

43% long lasting loss







Greater preference for **ESG over gastric bypass** 

I like the idea of this. The non-surgical part is very appealing.

I'm ecstatic after reading about it! I would love to know more and with whom I need to speak!?



## Extending Application of OverStitch to **Endoscopic Revisions of Bariatric Surgeries**

are Revisio, Anatomically-driven procedural complications can be addressed following weight loss surgery with endoscopic surgical revision.

1 4 U.S. laparoscopic sleeve & gastric bypasses 2011 to '19<sup>1</sup>

**30-50%** of those will be revision candidates<sup>1</sup>

**43** U.S. revision procedures in 2019<sup>1</sup>

**>70%** of top 100 U.S. Overstitch accounts perform revisions<sup>2</sup>

### ENDOSCOPIC V. SURGICAL REVISION

In a peer-reviewed study<sup>3</sup> that compared results at five years, endoscopic revision demonstrated:

- Equivalent efficacy
- Improved safety profile

	ENDO	SURGICAL	р
Efficacy	<b>11.5%</b>	<b>13.1%</b>	0.67
at 5 years	TBWL	TBWL	
Adverse events	6.5%	29.0%	0.04
Safety	<b>0</b>	<b>19.4%</b>	0.024
profile	SAE rate	SAE rate	



### Marketing & Medical Education

Patient market research Branding & messaging DTP co-marketing (starting with Orbera) Public relations Major conferences (DDW, ASMBS, IFSO, ACG) Peer to peer education programs

### Training

Apollo training courses Physician proctoring Virtual training resources Society-sponsored training (e.g., ASGE, ASMBS)

### **Reimbursement & Market Access**

Dedicated & growing R&MA team Patient access support Engaging key GI and Surgical societies Coding/coverage/payment strategy Health economics/value proposition

## PRODUCT LAUNCH

Pending 510(K) Clearance

### Sales Team Readiness

Learnings from "Wave 1" accounts Dedicated Regional Endobariatric Manager roles Comprehensive account support Sales process and training



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### Sales Team Readiness

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\* Pending FDA Clearance. See Product Regulatory Advisory, slide 2.

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## Outlook for Endobariatric Opportunities

## energize

- Leverage and sustain growth in Orbera®
- MERIT publication
- DeNovo 510(k) clearance for Apollo ESG<sup>™</sup> and Apollo REVISE<sup>™</sup> (in review)
- Comprehensive launch plan
- Learn from initial EBWL practices
- Specialized sales roles

## accelerate

- Launch Apollo ESG<sup>™</sup> & Apollo Revise<sup>™</sup>
- Model training programs after successful academic & private practices
- Continue cadence of supportive clinical evidence
- Support coding, coverage & payment with comprehensive reimbursement program
- Leverage society guidelines

### • Establish ESG and endoscopic revisions as mainstream procedures

- Increase number of experienced practitioners
- Expand awareness of EBWL

lead

Increase EBWL fellowship training & education



# Sendosurgery

## **Commercial Development - US**

KIRK ELLIS

VP, U.S. Sales







## Kirk Ellis

VP, U.S. SALES

Joined Apollo 2021



## Early Innings of Increasing Representation

Perpetuating cycle: growth and revitalized culture attract talent

## accelerating growth

Positioning organization to scale as new opportunities & focus drive faster growth

### infrastructure

Leveraging more sophisticated sales processes, sales training, CRM and sales analytics to prioritize opportunities & increase effectiveness

### service culture

Aligning teams around a winning, service-focused culture

### expertise

Attracting industry-leading, disciplined med-tech professionals

Stryker COOK Medtronic ETHICON



## Expanding Our U.S. Sales Capabilities

Creating strong commercial channel to support growth aspirations

- Rectifying historical underinvestment to create a foundation for growth
- Shifting from "case coverage" focus to physician support and collaboration
- Expanding team from ~30 toward ~40-45 by year end '22





## Advantages of Recent Rep Hires Emerging

>65% of rep team joined under new leadership – meaningful contribution beginning





## Focusing Team to Execute Growth Priorities

Piloting regional endobariatric mgr (REM) roles to facilitate comprehensive patient care



MARKET DEVELOPMENT MANAGERS (MDM)

- Provide product education, training and procedural expertise across all three product lines
- Support case coverage and help clinicians advance through the learning curve
- Identify new growth opportunities and qualify leads



- Strengthen EBWL customer relationships
- Identify & develop new EBWL accounts
- Provide best practices in supporting patients
   through continuum of care
- Support practice marketing (e.g., Orbera<sup>®</sup> comarketing program)



## U.S. Sales Outlook

## energize

- Infusing team with high-caliber talent
- Creating new service culture throughout organization
- Building sales infrastructure: sales processes, sales training, CRM, sales analytics
- Piloting new Regional Endobariatric Manager roles

## accelerate

- Continue to build breadth and depth of sales organization
- Adjust mix of MDMs & REMs based on market learnings

## lead

- Establish a best-in-class selling organization
- Leverage for future product introductions and expansion opportunities



# Sendosurgery

## **Commercial Development - International**

### MIKE GUTTERIDGE

VP, International Sales



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## Mike Gutteridge

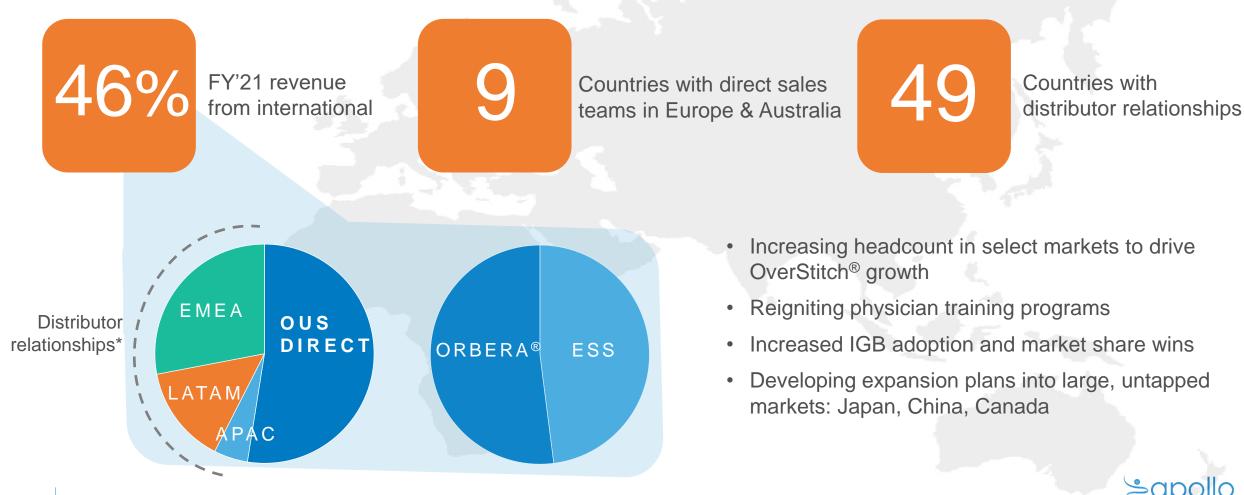
VP, INTERNATIONAL SALES

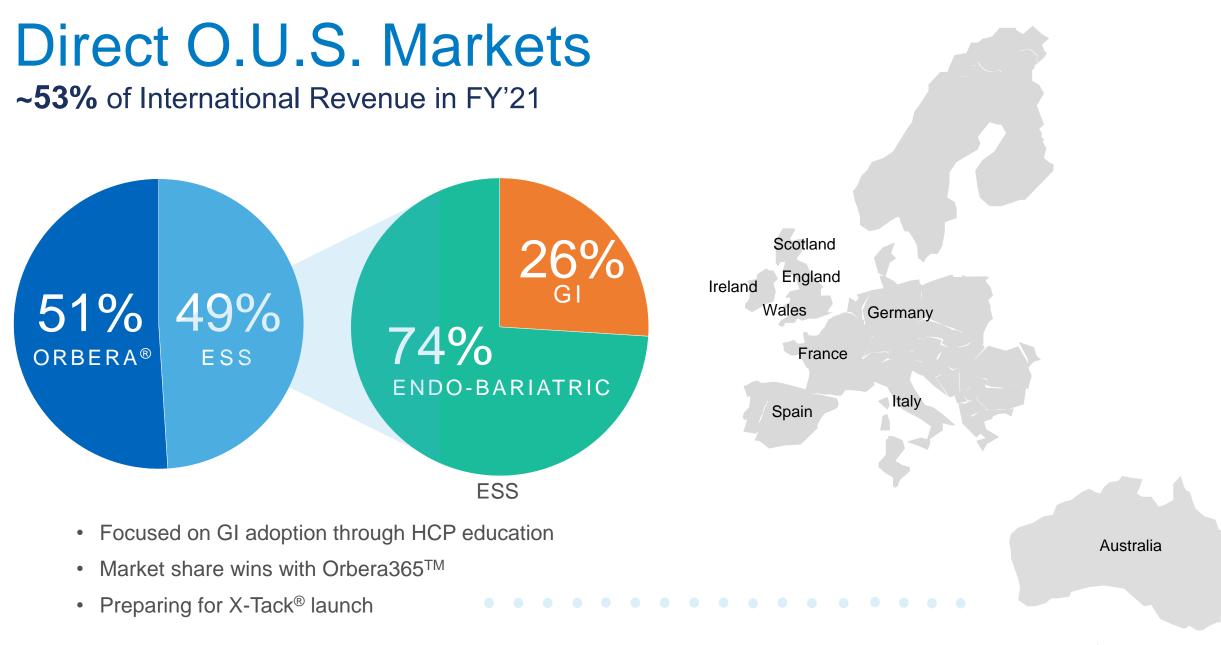
**Joined Apollo 2016** 

Smith&nephew ArthroCare NHS

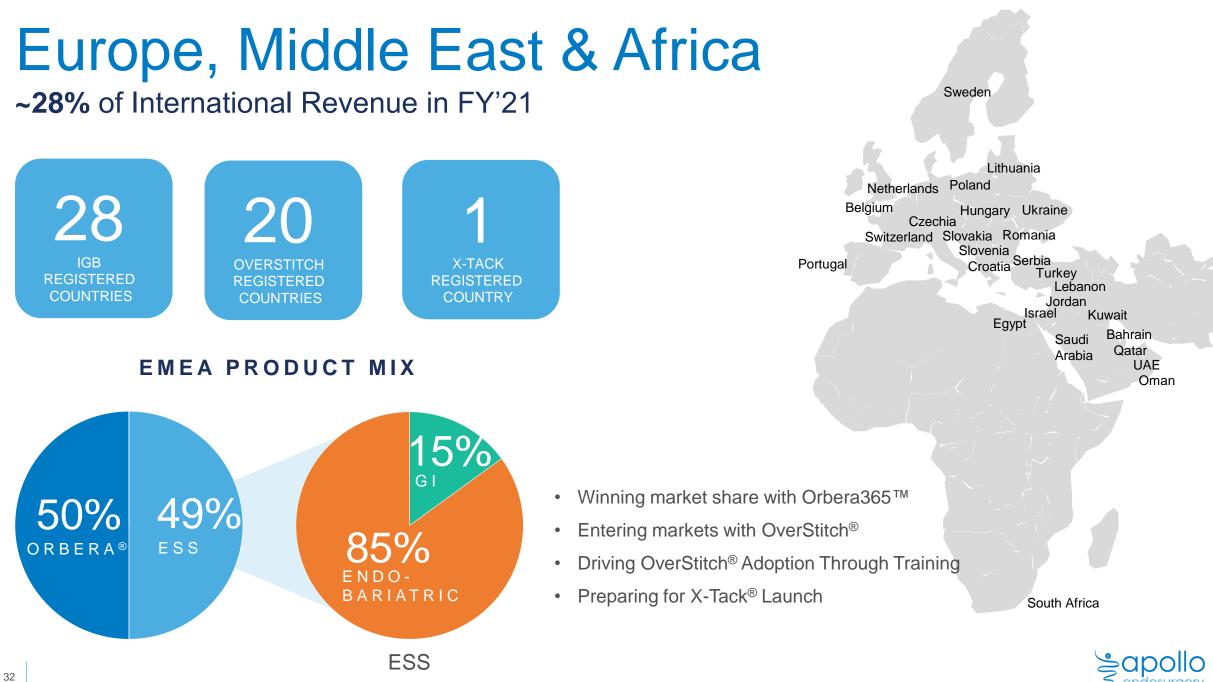
## Well- Established O.U.S. Network

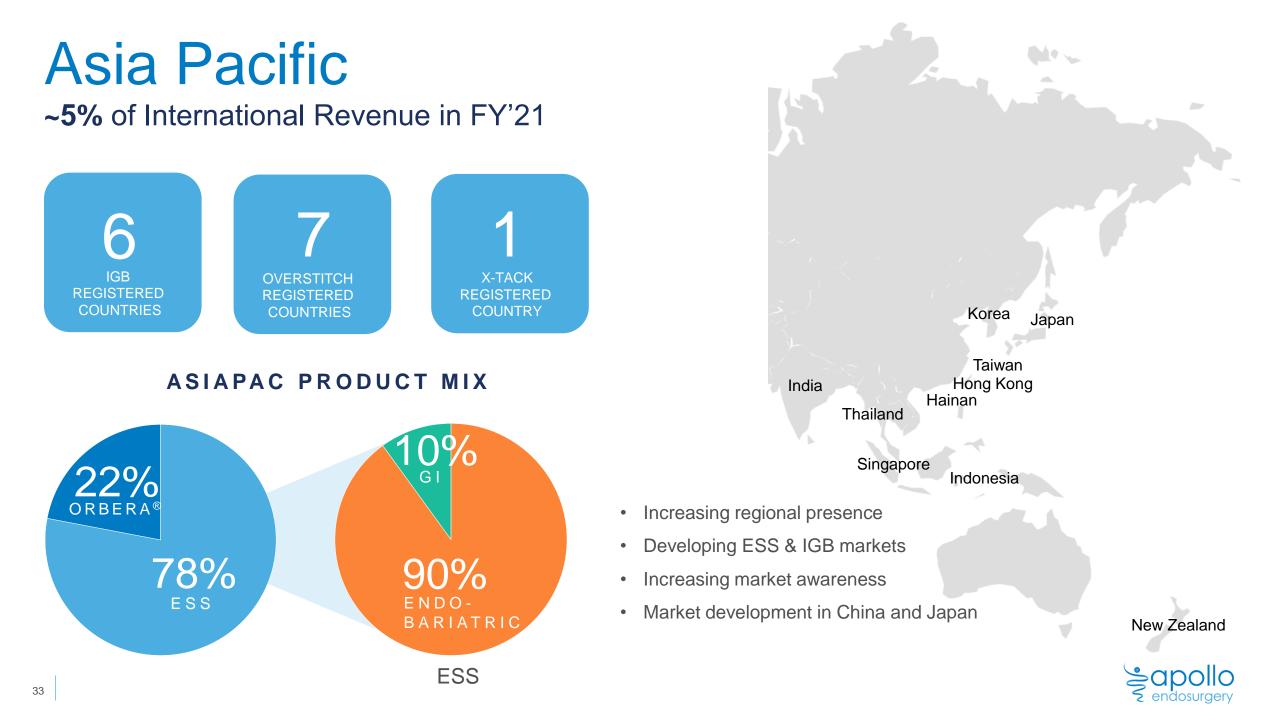
Cultivating international infrastructure to support accelerated growth

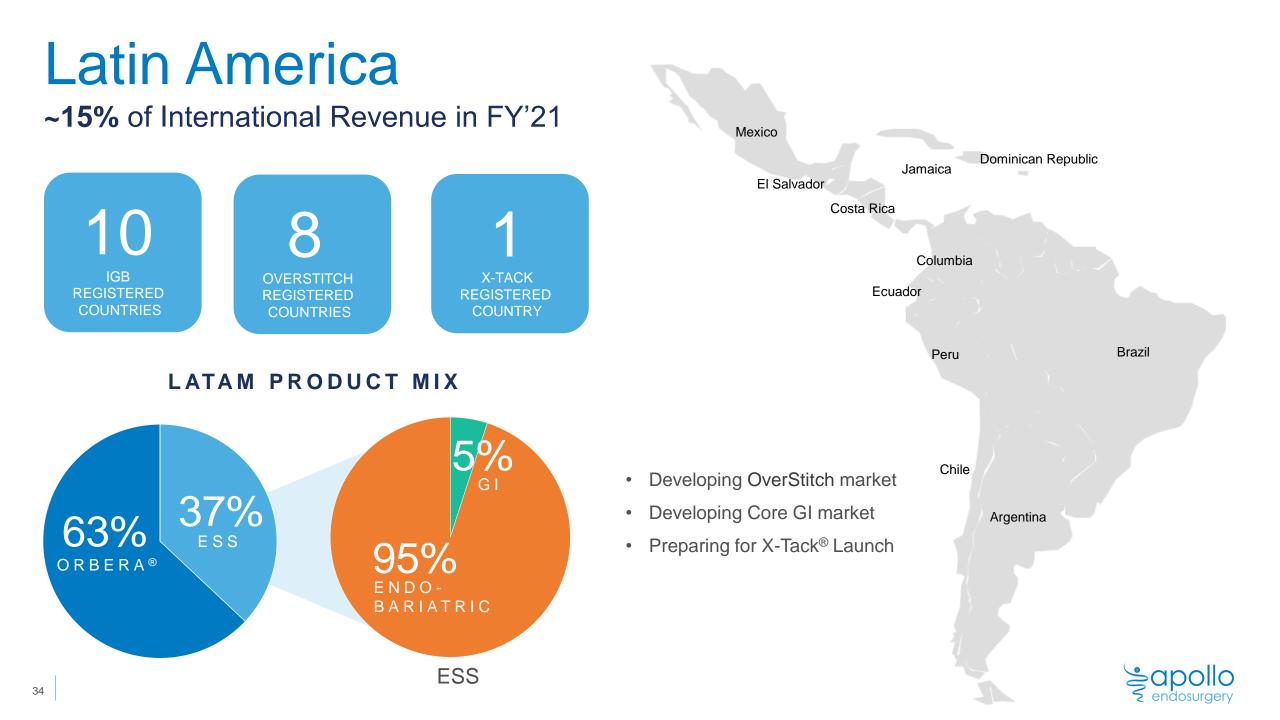












## O.U.S. Sales Outlook

## accelerate

### lead

- Increasing headcount in select markets to drive OverStitch<sup>®</sup> growth
- Reigniting physician training programs

energize

- Increasing IGB adoption & share wins
- Preparing for X-Tack<sup>®</sup> launch
- Developing expansion plans in large, untapped markets: Japan, China, Canada

- Establish X-Tack<sup>®</sup> as a new standard in GI defect closure
- Leverage MERIT trial publication to support reimbursement efforts in key countries
- Continue to drive clinical data collection supporting utilization of OverStitch<sup>®</sup>, Orbera<sup>®</sup>, and X-Tack<sup>®</sup>

- Well-established infrastructure scales to support broad O.U.S. presence
- Work with physician societies to train next generation of doctors



# Sendosurgery

## **Clinical Strategies**

### TIFFANIE GILBRETH

VP, Clinical and Medical Affairs







# Tiffanie Gilbreth

VP, CLINICAL & MEDICAL AFFAIRS

Joined Apollo 2012

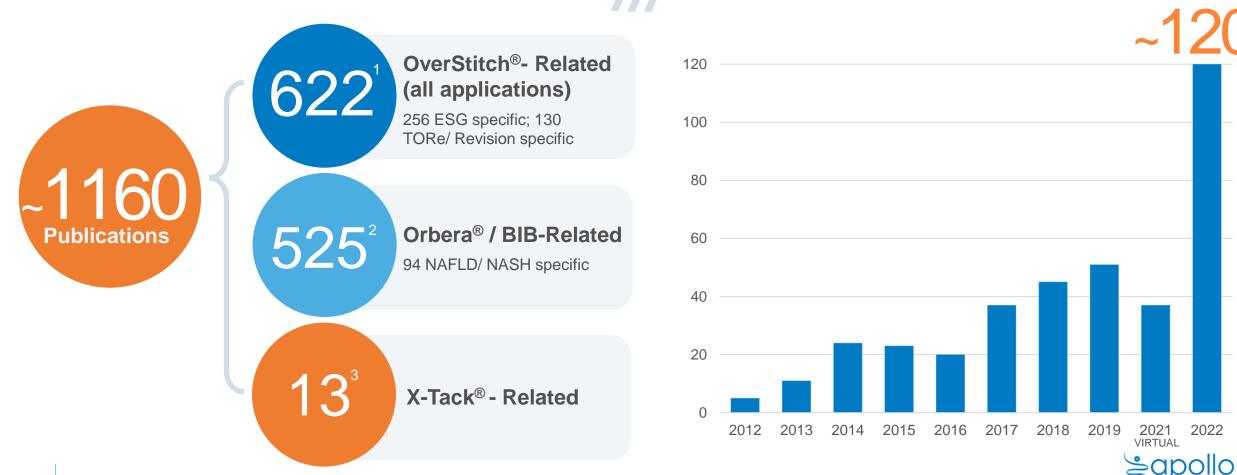


# **Changing Practice with Clinical Validation**

Massive inflection at DDW strengthens significant clinical library

#### significant clinical library

#### **DDW Presentations/Posters/Cases**



# **OverStitch® for Defect Closure / Fixation**

#### previous

## new developments @ DDW

~270 Peer-reviewed clinical publications<sup>1</sup>

50 Different clinical applications<sup>1</sup>

Prospective study of utility of OverStitch Sx endoscopic suturing system to close large defects after endoscopic submucosal dissection (Othman)

Endoscopic management of very-delayed-onset tracheoesophageal fistula and esophagocutaneous fistula after neonatal colonic interposition for esophageal atresia (Lin)

Limitless! treatment of giant gastric lesion(41cm) with endoscopic submucosal dissection (Aslan)

Endoscopic ultrasound-directed transgastric ercp (edge): a multicenter US study on long term follow-up and fistula closure (Shah-Khan)



# X-Tack<sup>®</sup> for Defect Closure / Fixation

#### previous

## new developments @ DDW

Peer-reviewed clinical publications<sup>1</sup>

>20 Different clinical applications<sup>1</sup>

US multi-society task force (AGA, ACG, ASGE) recommends prophylactic closure for lesions >20mm, right colon<sup>2</sup> Efficacy, feasibility and safety of the X-Tack endoscopic helix tacking system: a multicenter experience (Sharaiha)

"Holey moly": comprehensive management of an eroded aortic prosthetic graft (Hu)

Complicated gastro-cutaneous fistula closure with x-tack endoscopic helix tacking system (Sultan)

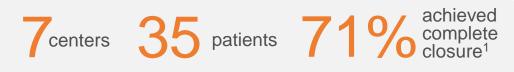
Novel through-the-scope suture closure of colonic EMR defects (Bi)

Through-the-scope suture closure of non-ampullary duodenal EMR defects (Almario)



# X-Tack<sup>®</sup> - DDW Clinical Highlights

#### THROUGH-THE-SCOPE SUTURE CLOSURE OF NON-AMPULLARY DUODENAL EMR DEFECTS (Almario)



- Large post EMR defect (36 ± 23mm)
- High rate of antithrombotic use (22.9%)
- Complete closure achieved (71.4%)
- Only 1 TTSS system used on average (range 1-3)
- 1 Intraprocedural bleeding event (managed endoscopically)
- TTSS is an effective tool for closure of mucosal defects after EMR of large non-ampullary duodenal defects.

#### NOVEL THROUGH-THE-SCOPE SUTURE CLOSURE OF COLONIC EMR DEFECTS (Bi)

- 13 centers 100 patients 73% achieved complete closure<sup>1</sup>
- Over 50% of the defects were >40mm
- Complete closure achieved (73%)
- 1 TTSS system used on average (range 1-2)
- Delayed bleeding occurred in 1 case (managed endoscopically using 2 XTack systems)
- **TTSS** was effective in achieving complete closure of large post-EMR defect sites, despite large lesion size.





#### previous

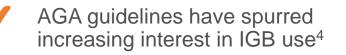
## new developments @ DDW

~525 Peer-reviewed clinical publications<sup>1</sup>

>32K Patients included in studies<sup>2</sup>

Intragastric balloon outcomes on diabetes, hypertension and dyslipidemia at 6 months: a systematic review and meta-analysis (Shah)

Intragastric balloon placement prior to bariatric surgery does not lead to an increased risk of adverse events following surgery (Platt)





# Suturing for ESG

#### previous

## new developments @ DDW

>250 Peer-reviewed clinical publications<sup>1</sup>

>6.50

Patients included in studies<sup>1</sup>

>5 year Follow-up data available<sup>2</sup>

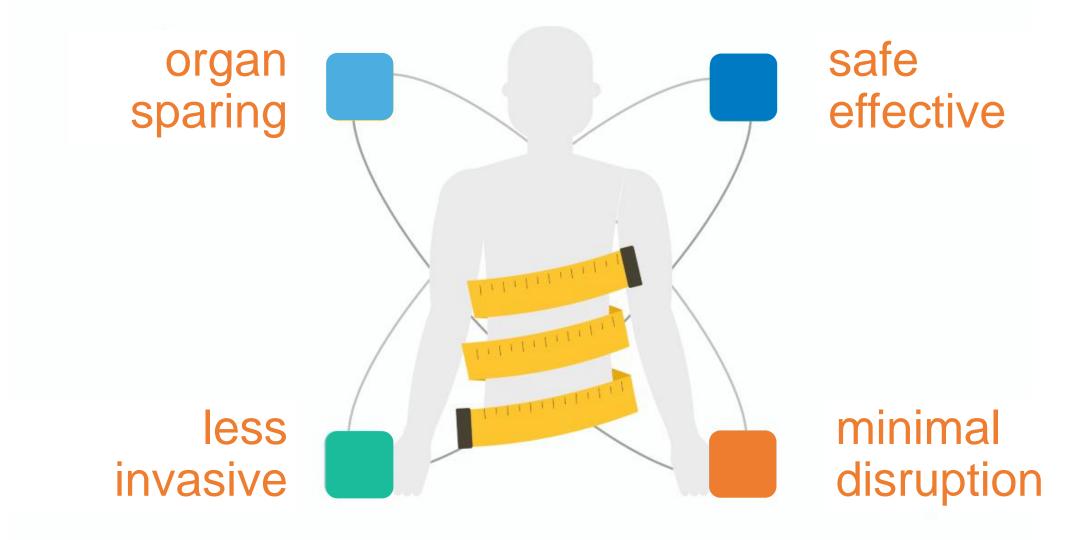
Endoscopic sleeve gastroplasty in class III obesity: weight loss and metabolic outcomes in 339 consecutive patients (McGowan)

Metabolic and anthropometric changes after endoscopic sleeve gastroplasty (Sarkar)

Endoscopic sleeve gastroplasty significantly reduces the comorbidities of the metabolic syndrome at 5-year follow-up (Westerveld)

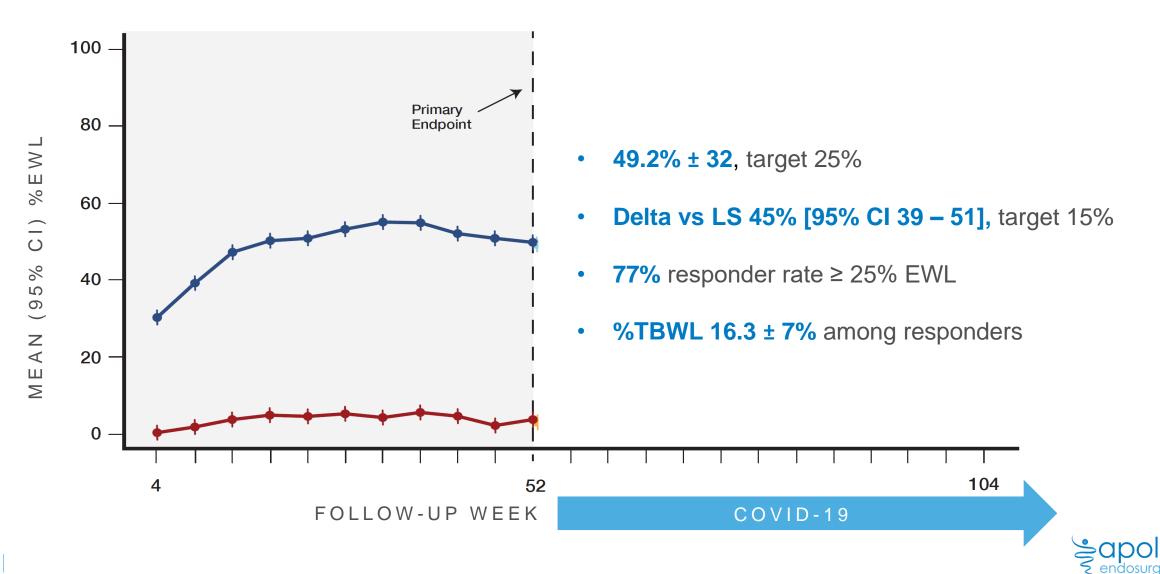
Direct comparative efficacy and safety of endoscopic sleeve gastroplasty vs. Laparoscopic sleeve gastrectomy: a systematic review and metaanalysis (Beran)

## ESG Can Meet Unmet Clinical Needs





## MERIT Results: Efficacy & Durability



## MERIT Results: Significant Impact on Comorbidities

#### ESG compared to standard of care

	ESG		SoC		р
	Improve	Worsen	Improve	Worsen	
Diabetes Mellitus Type II (DMII)	93%	0%	15%	44%	<0.001
Metabolic Syndrome + NAFLD + Inflammation	83%	0%	35%	38%	<0.001
Hypertension (HTN)	67%	6%	40%	23%	=0.01

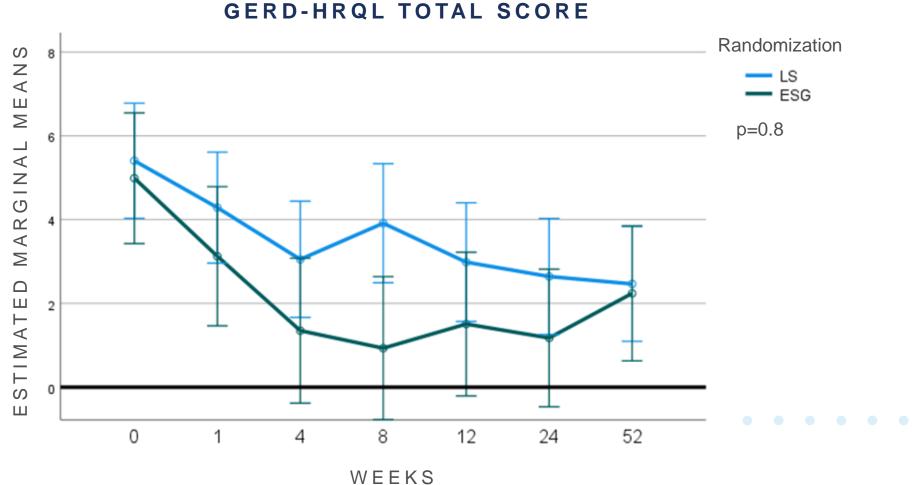
#### diabetes mellitus type II (DMII)

#### metabolic syndrome + nafld + inflammation

ESG	Improve	Worsen	р	ESG	Improve	Worsen	р
HOMA-IR	-3 (SD 6.354)	+1.35 (SD 3.2)	P=0.01	Hepatic Steatosis Index (HSII)	-2.24 (SD 3.075)	-0.61 (SD 3.409)	P=0.01
HgA1c (Diabetics)	-0.87 (SD 1.1)	+0.39 (SD 0.7)	P<0.001	CRP	-1.78 (SD 4.04)	+0.51 (SD 3.525)	P<0.01
HgA1c (baseline>7)	-1.77 (SD 0.755)	+0.16 (SD 0.635)	p<0.001	Waist/ Hip Ratio (% Change)	-2.91 (SD 8.5188)	-0.36 (SD 7.2852)	P=0.02



## MERIT Results: GERD Improved





## Suturing for Revision of Previous Bariatric Procedures

### previous

## new developments @ DDW

>130 Peer-reviewed clinical publications<sup>1</sup>

>3000 Patients included in studies<sup>1</sup>

>7 year Follow-up data available<sup>2</sup>

Transoral gastric outlet reduction for post-prandial hypoglycemia after rouxen-y gastric bypass (Dunn)

Medium term efficacy of the endoscopic transoral outlet reduction for weight regain and dumping syndrome after gastric bypass (Pentecorvi)

Factors associated with weight loss after endoscopic transoral outlet reduction (TORE); (Meyers)

GLP-1 analogues in combination with revisional endoscopic sleeve gastroplasty: 24-month follow-up (Hoff)

Combination therapy yields improved safety and similar efficacy compared to surgical revision for the management of weight regain following roux-en-y gastric bypass (Jirapinyo)



# Sendosurgery

# Closing

# **Our Priorities**

Initiatives to accelerate growth across products & geographies

#### Expand Core GI Defect Closure & Fixation

continuing to drive OverStitch adoption & X-Tack<sup>™</sup> penetration; OUS expansion

#### Leverage Orbera<sup>®</sup> Resurgence

creating sustainable growth in endobariatric practices

#### Prepare for Apollo ESG<sup>™</sup> & Apollo Revise<sup>™</sup>

laying groundwork for successful commercial releases

# Advance the Organization

investing to create a worldclass foundation for growth



# Growth Outlook

#### • • • • • • • • • • • • • • • • •



# energize accelerate lead Invest to build a Leverage new clinical Become the

foundation for growth

Leverage new clinical indications and applications

Become the standard of care

