



FEMSelect

February 2021

Introducing EnPlace

A breakthrough approach for
pelvic organ prolapse

CLEARED BY FDA AND CE MARKED



ENPLACE™

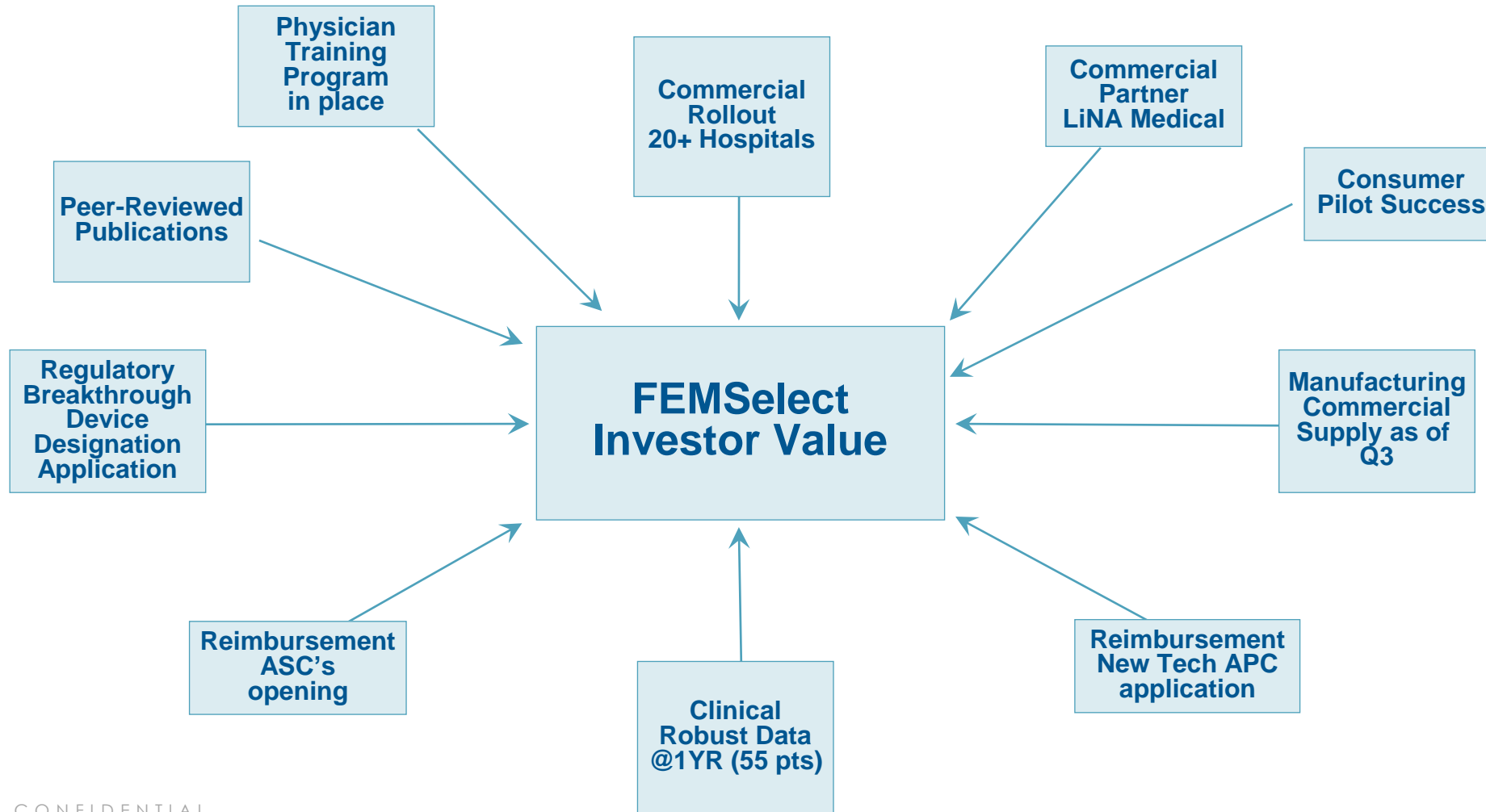
*ligament fixation system
for prolapse procedures*

First and only of its kind.

**Minimal Dissection
Minimally invasive**

- ▶ Large addressable market (**\$4B+ US market**)
- ▶ Commercial traction (17 VAC's approved with 20+ in process)
- ▶ Reimbursement pathway in the US
- ▶ Clinical results demonstrated **safety and effectiveness at 1 year—new data release 55 patients @ 1 yr**
- ▶ **Cleared by FDA** and received **CE Mark**

Multiply our Value with Commercial Capability



Commercial and Financial Summary 2020

- **2020 Global sales \$300,000 with 1 sales rep in field during a global pandemic**
- **2020 CLA Oversubscribed and raised \$3M in total**
- **US Market Highlights**
 - ▶ VAC “approved” at 17 locations
 - ▶ VAC “in review” at 20 additional locations
 - ▶ LiNA Medical pilot in place
- ▶ **Israel Market Highlights**
 - ▶ Clalit (largest) Sick Fund approved EnPlace on Dec 2
 - ▶ Additional 5 physicians trained
- **Continuing Strategic Interest**

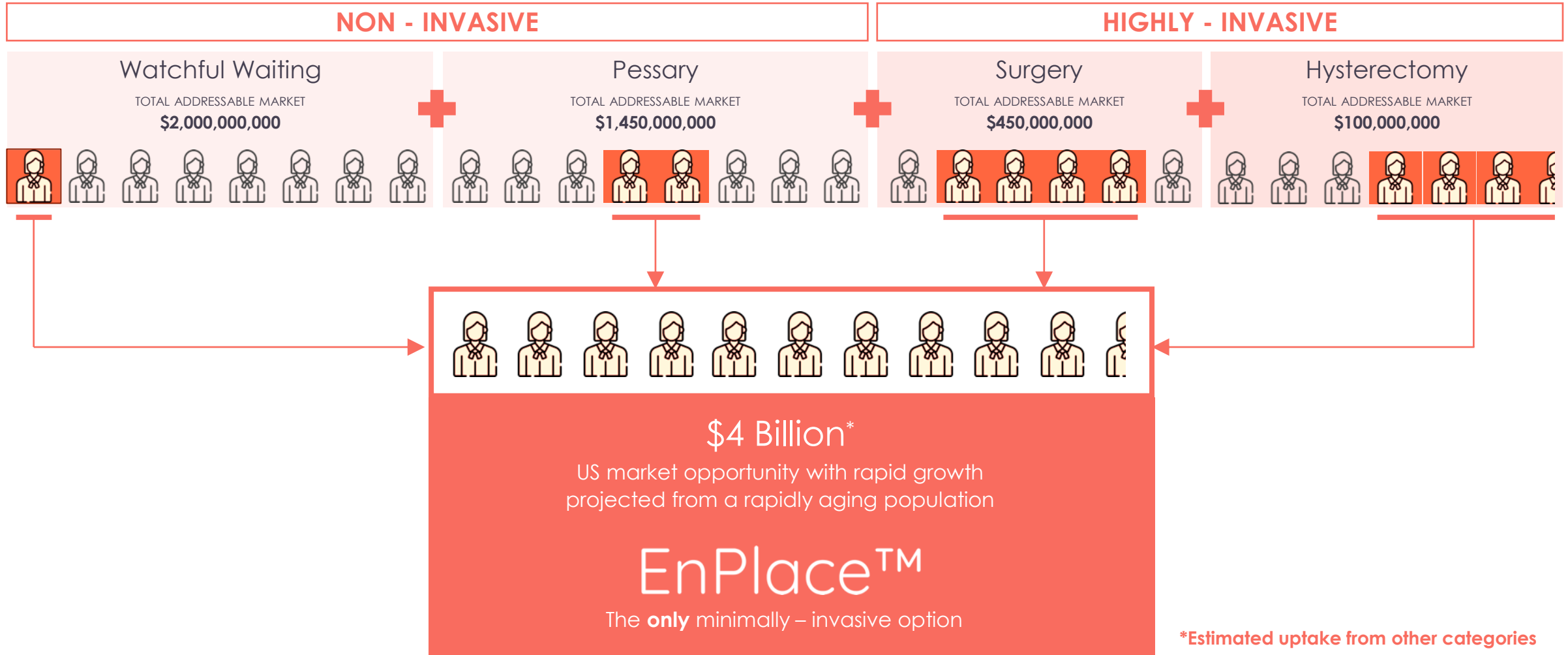
THE ONLY TRULY MINIMALLY INVASIVE APPROACH

- ▶ 4 year data showing durable repair and minimal AE's
- ▶ Minimal dissection – vaginal approach
- ▶ NO mesh implant
- ▶ Finger guide for accurate placement of anchor
- ▶ QUICK return to activities
- ▶ Cleared by FDA / CE Mark



4mm wide
10x shorter than an IUD
6x smaller than the diameter of a dime

A **NEW** MARKET OPPORTUNITY



*Estimated uptake from other categories

ACTUAL VS. BUDGET

YEAR-END 2020

P&L Summary	Q1.2020	Q2.2020	Q3.2020	Q4.2020	YTD 2020		
	Actual	Actual	Actual	Actual	Actual	Budget	Variance
US K\$							
Revenues	46	56	108	92	302	467	(165)
COS	28	24	52	35	138	191	(52)
Gross profit	18	32	57	57	163	276	(113)
Gross Margin (%)	39%	56%	52%	62%	54%	59%	
R&D	16	26	21	55	118	138	20
CLINICAL & RA	161	160	113	164	598	629	31
Physician professional development	26	18	16	24	85	84	(1)
Marketing	105	82	92	88	368	389	21
Sales				2	2		(2)
G&A	89	106	129	141	466	429	(37)
OPEX Breakdown	398	392	372	474	1,637	1,669	33
EBITDA	(380)	(360)	(316)	(417)	(1,473)	(1,393)	(80)

FUNDING STRATEGY LEADING TO **ACQUISITION**



EXIT OPPORTUNITIES

LARGE GLOBAL WOMEN'S HEALTH

Leverage existing sales relationships with minimally invasive



REGIONAL (US AND EU) PLAYERS

Expand into new territories with disruptive technology



SURGICAL SUPPLY AND ENDOSCOPY

Leverage customer relationships and knowledge of OR environment



WOMEN'S HEALTH COMPANIES

GYN customer base with adjacent products



URODYNAMICS

Leverage sales relationships in customer base with new product

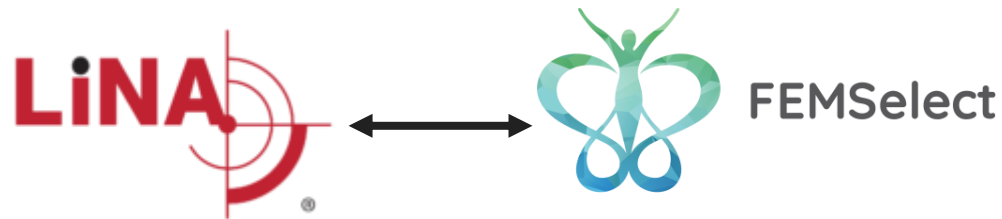


WOMEN'S HEALTH COMPANIES

Leverage end-user brand+ advertising spend with synergistic products



Sales Partnership



LiNA Medical

**Global leader in
minimally-invasive
gynecology**

- ▶ 8 Reps trained
- ▶ Excitement in the field from physician response
- ▶ 5 VACs approved and 3 more in process
- ▶ Partnership expansion discussions are ongoing for Q2 and beyond

LiNA/FEMSelect “pilot” KPI Dashboard (A + B Leads)



Physician (name/state)	Facility	Lead Rating	VAC Approval/ Can order? (Y/N)	Scheduled Patients (“X” or date)	Completed EnPlace cases (“X” or date)	Reorder? (Y/N)
Dr. Lucente, PA	St. Luke’s Hospital	A	Y	X	X	Y
Dr. Pelekanos, PA	Highland Hospital	A	Y	X	X	Y
Dr. Garely, NY	Mt. Sinai S. Naussau	A	Y	X	X	Y
Dr. Shobeiri, VA	Inova Fairfax	A	Y	X	X	Y
Dr. Wisemann, PA	Guthrie Clinic	A	Y	X	X	Pending
Dr. Ellerkman, MD	Mercy Medical Center	A	Y	X	X	Pending
Dr. Davila, FL	Holy Cross Hospital	A	Y	Pending	X	Pending
Dr. Chaikin, PA	Franklin Surgery Center	A	Y	X	Pending	
Dr. Kumar, NY	Mt. Sinai Hospital	A	Y	Pending		
Dr. Shah, NY	Mt. Sinai Beth Israel	A	Y	Pending		
Dr. Molden, PA	St. Mary’s	A	Y	Pending		
Dr. Espillat, PA	Grandview Hospital	A	Y	Pending		
Dr. Michelewski, NJ	St. Barnabas	B	N			
Dr. Pelekanos, PA	Allegheny Forbes	B	N			
Dr. Duenos, WV	Ruby Memorial	B	N			
Dr. Raders, FL	Health First	B	N			
Dr. Bailey, FL	N. Florida Regional	B	N			
Dr. Adelowo, MA	Reliant Medical Group	B	N			
Dr. Wakamatsu, MA	Mass General	B	N			
Dr. Illanes, MA	Tuft’s Medical Center	B	N			

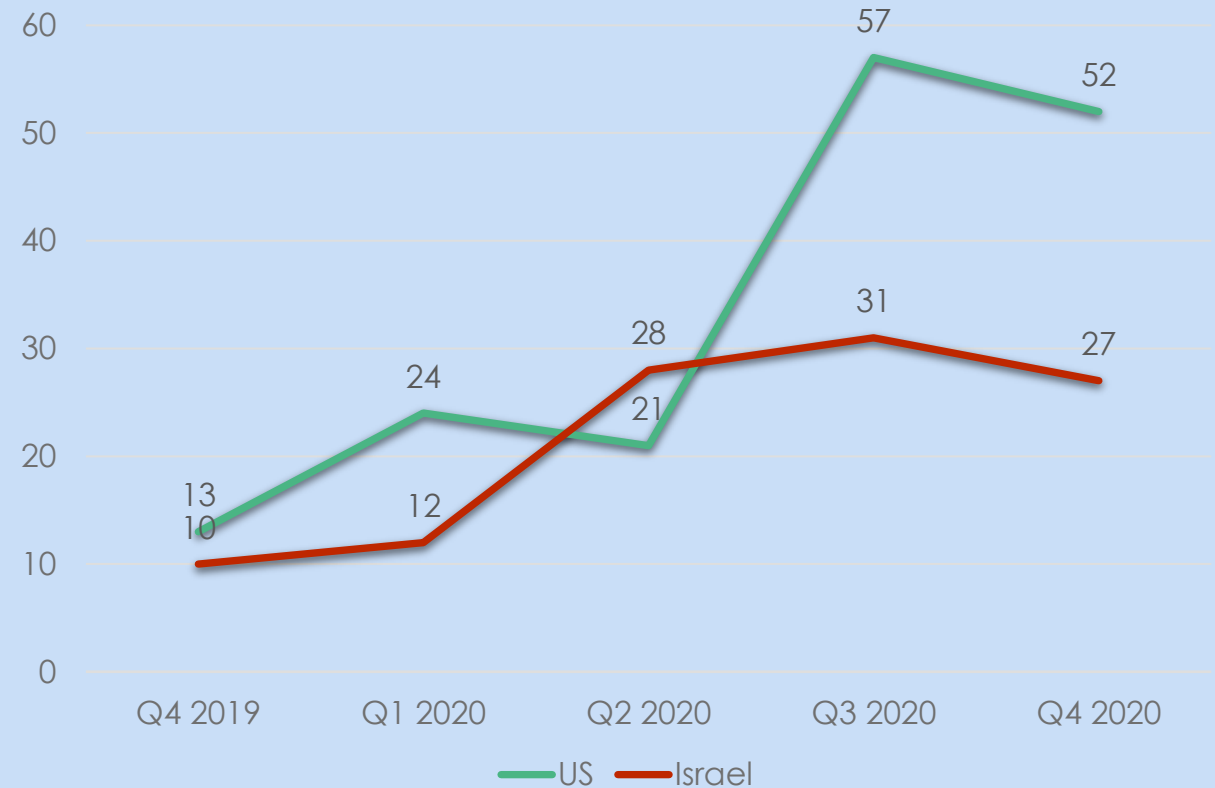
Lead Rating:
 A. Ordering site or VAC approval
 B. High interest => willing to submit/submitted to VAC

NOTES:
 The LiNA “pilot” territories continue to expand w/new, interested FPMRS-focused physicians/centers.
 Covid-19 “stalled” some of the progress since Q42020, yet several sites will reconvene for VAC/NPR.

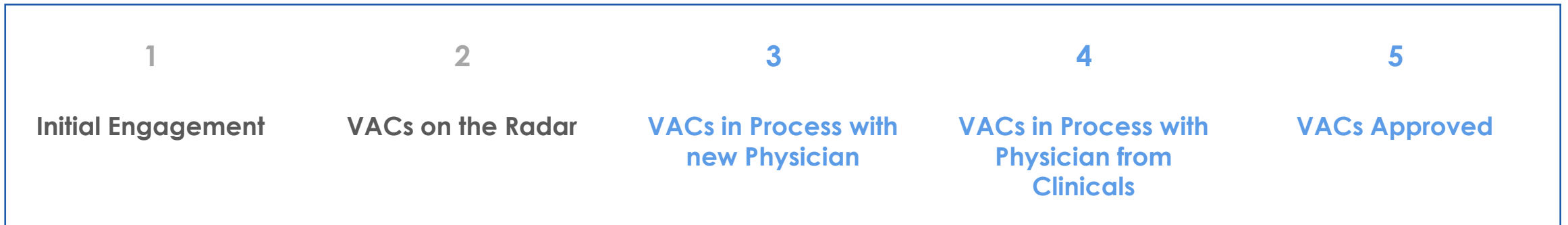
Commercialization

- 17 VACs approved and more on the way
 - 20+ in motion
- GyneSim™ innovative anatomical “wet labs” for physician training.
- LiNA Sales Partnership
 - Enables multiplier effect as we expand from 1 rep to 8 reps

US/Israel Sales per Quarter







VALUE ANALYSIS COMMITTEE (VAC) SUBMISSIONS **FILL SALES PIPELINE** FOR Q2/Q3



- VAC submissions generate pipeline of future sales
- 17 approved VAC's (hospitals purchasing already)
- 20+ VAC's in phases 3-5 of the process which will generate increased sales in Q2/Q3

PROFESSIONAL EDUCATION STRATEGY PROVING STRONG

ONLINE MODULE CERTIFICATION	TABLETOP/SIMULATOR MODEL	WET LAB	LIVE OR REMOTE PROCTORED SESSIONS
	<ul style="list-style-type: none"> ▶ Custom FEMSelect model ▶ Dr. Miyazaki Model 	<ul style="list-style-type: none"> ▶ Develop an anatomical model using animal tissue to simulate actual procedure <p style="text-align: center;">GYNESIM</p> 	<ul style="list-style-type: none"> ▶ “Train the trainer” with post-marketing study physicians ▶ Celebration Hospital’s “Beehive” system, remote proctoring within the OR 

Market Developments and Strategic Planning

➤ Reimbursement:

- CMS enabled prolapse repair procedures to be reimbursed in ASC (ambulatory surgery center) as of 1/1/2021
- FEMSelect is working with key centers to understand impact on reimbursement
- Seems promising that this will open up usage in ASC that was previously blocked

➤ Regulatory

- FEMSelect has engaged former head of FDA Breakthrough Device Designation program to draft and submit application for EnPlace as breakthrough
- Will get response with 60 days
- If successful, could potentially (legislation-dependent) lead to 4 years automatic coverage by CMS
- Can pave the way for an expanded indication for EnPlace

Manufacturing Update

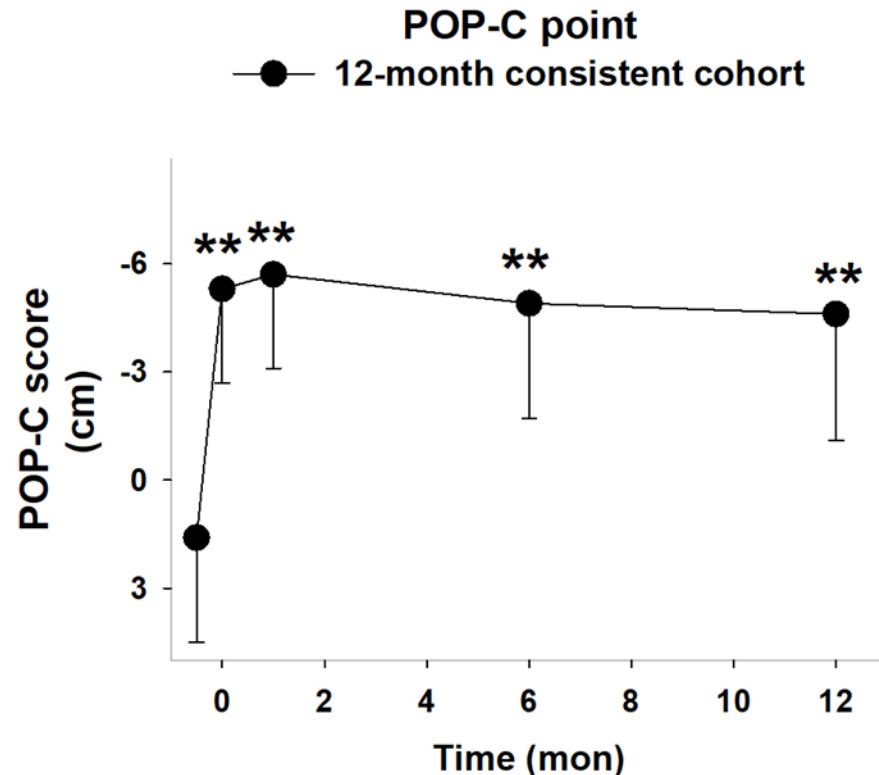
- Design phase and mold production complete for mass production (mold produced in China and transferred to Israel)
- Process of Verification & Validation (V&V) testing to begin by early March
- Pricing of 1,000 devices in negotiation currently
- **At initial stage, will be approx. 60% off of initial COGS**
- Further efficiencies and higher volumes will bring further savings
- Goal: transfer to mass production to be complete by end of June, 2021
- First batch of commercial supply to be produced in July

Clinical Data Accumulates

Showing Durable Repair/Minimal Side Effects

- 4 year First in Woman data submitted for publication and under final review with prestigious peer-review urogynecology journal
- Initial Post-Marketing Study results accepted for **Oral Presentation** at Society of Gynecologic Surgeons in May
- Post-Marketing Study **1 year data shows durable repair at 1 year**
 - Predictable anatomical response based on symptom relief questionnaire
 - Data was easily projected for women who didn't come due to COVID

Durable Repair @ 12 mos (C-Point)



Average (\pm STD) POP-C point values as a function of time after surgery

- POP-C scores remain significantly above the baseline at both 6- and 12-months – the repair is durable. (55 patients @ 1 year)
- Treatment with the EnPlace device elevated the apex of the vagina significantly (** $p < 0.001$)

Summary

- LiNA relationship strong and anticipate expansion of partnership
- Cash position fair but need cushion to strengthen our position
- Strategic interest is strong
- Clinical results continue to show durability of repair
- Enthusiasm of physicians increasing particularly with ASC coding changes
- Qualified leads inbound through targeted online marketing

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THANK YOU