



June 1, 2023

# Q2 Investor Update

A breakthrough approach for  
**pelvic organ prolapse**

CLEARED BY FDA AND CE MARKED



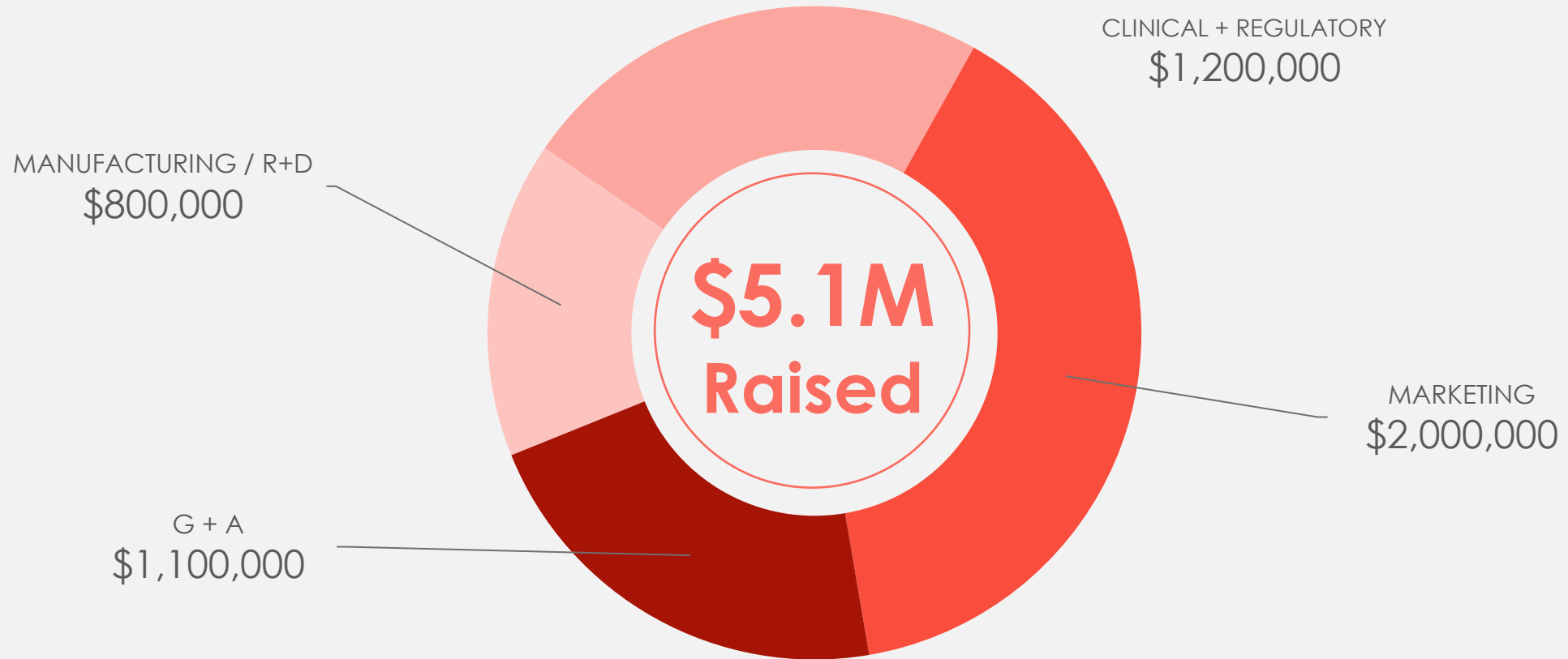
# Agenda

1. 2022 Round B Commitments
2. 2023 Q1 Overview—on Track for Value Creation
3. KPI's and Financial Overview
4. Strategic Overview 2-5 Year Plan to Exit

# EnPlace Pitch

- ❖ EnPlace is the **only** minimally invasive platform for pelvic floor fixation with FDA clearance and commercial traction.
- ❖ Successfully designed by a Urogynecologist and an experienced medical device engineer to include safety and OR efficiency with optimal, reproducible results.
- ❖ EnPlace requires NO DISSECTION for fixation, which may reduce blood loss, risk of infection and injury (i.e., nerve entrapment) and contributes to rapid patient recovery (2-3 days with minimal post-op pain).
- ❖ EnPlace is used in a same-day outpatient procedure (<30 mins), commonly done under light sedation and was recently awarded its own C-Code providing economic efficiency in the ASC or Outpatient setting.
- ❖ EnPlace offers patients (AND SURGEONS) a desirable surgical approach to treat prolapse.

# ROUND B USE OF PROCEEDS: Accelerating commercial efforts



# Strategic Milestones for 2025

- EnPlace brand
  - Minimum of \$15-20MM in Sales
  - Network effect from consumers generating referrals
  - “Standard of care” for 10% of FPMRS physicians
  - LiNA/1099 indirect sales force + FEMSelect direct sales force (65%) + OUS Sales (23%)
- Product
  - 400+ [physicians educated and doing cases](#)
  - 150 [physicians with 6 per month \(US\)](#)
  - KOL support
  - [Prof Ed and VAC processes smooth](#)
  - OUS markets: 3-4 markets opened outside US generating sales
- Clinicals
  - Clinical data with 5 Year efficacy and safety data
  - [Registry data](#) with additional QoL and safety endpoints
- Manufacturing
  - Sufficient inventory
  - 2<sup>nd</sup> Contract Manufacturer Certified

# Value Driving Milestones Already Achieved

## **Product Brand**

- Unique, minimally invasive pelvic ligament fixation device
- Meets growing trend in ambulatory solutions (<1hr procedure)
- Patent protected– 4 families >10 issued already
- FDA cleared & CE mark obtained
- Reimbursement code established
  - CMS HCPCS C9778 (Colpopexy, Minimally Invasive, Extraperitoneal)

## **Market**

- 25M women US-based
- \$10B+ market worldwide
- Limited competition in minimally invasive devices field
- Growing unmet need due to termination of mesh products

## **Team**

- Experienced women's healthcare executive leadership
- Experienced field staff:
  - Medical Director
  - Internal Sales Representatives
- Leading National, minimally-invasive device distributor contract
- Leading global manufacturer partnership

## **Capitalization**

- Tight knit investor group <50
- \$14M equity financing raised to date
- Simple cap structure
- 20% FD option pool
- No debt

## **Operations**

- First commercial sale early 2020
- FY 2022 \$1.0M gross revenues
- FY 2023 \$5.0M gross revenue forecasted
- Manufacturing partnership yielding low CoGS, high-margin finished product
- 70+ hospitals approved/onboarded
- 90+ trained physicians in market
- US and Israel commercial operations

## **Sales Process**

- Established Value Analysis Committee (VAC) kit, physician training and hospital onboard processes in place
- Contracted Professional Education Trainers
- Multiple education methods available (Miyazaki model, Gynesim model, Live Surgery)

# Q1 Off to a Great Start

+ **Hired 2 more FS specialist & smoothly transition to Hybrid model**

+ **Hired Chief Medical Officer in US**

+ Sales tools in place: Targeting w/**Acuity tool** and **SalesForce** to track progress

+ **Sales above plan** based on early impact from EnPlace specialists in field

+ **On track with budget and cash flow**

+ **FS generating buzz & leads at clinical conferences**

+ Social media campaign designed and ready to go at end of June

- Optimizing LiNA relationship continues as key focus
  - Shorten VAC timelines
  - Early case coverage crucial
  - High follow-up post 4-6 cases to establish habit

# THE FEMSELECT TEAM, OVER 100 YEARS OF DIVERSE EXPERIENCE



**DEBBIE GARNER**  
CO – CHIEF EXECUTIVE OFFICER

- ▶ 20+ years of experience in commercialization roles in pharma and medical device companies including Eli Lilly and Co. and iMDsoft
- ▶ MBA, Wharton School of Business, University of Pennsylvania and BA, Harvard College



**RENEE SELMAN**  
CO – CHIEF EXECUTIVE OFFICER

- ▶ Industry expert and Angel investor, Robin Hood Ventures
- ▶ Former Interim Chief Commercial Officer of Agile Therapeutics (women's health)
- ▶ Former Worldwide President of Ethicon Women's Health and Urology (division of J&J)



**MICHAEL ADOMIAK**  
MARKET DEVELOPMENT  
DIRECTOR

- ▶ 20 years of experience in Sales and Marketing roles for Coloplast and Johnson & Johnson (Ethicon and Ortho-McNeil)
- ▶ Achieved top sales consistently throughout his career.
- ▶ Regional Trainer in Urogynecology.



**MENAHEM NEUMAN**  
MEDICAL DIRECTOR

- ▶ Urogynecology & Pelvic Floor Medicine, Faculty of Health Sciences, Ben Gurion University of the Negev
- ▶ President of the International Society of Pelviperineology
- ▶ Former Ethicon Women's Health & Urology Global Trainer



- ▶ **KARLA F. LOKEN DO**  
OBGYN F A C O O G  
CHIEF MEDICAL OFFICER US  
Board Certified OBGYN , over 20 years of women's health experience in private practice, academics, medical education, and proctoring.



**BOAZ HARARI**  
VICE PRESIDENT, R + D

- ▶ 20 years of experience in Sales and Marketing roles for Coloplast, Medtronic and, most recently, NeoTract
- ▶ Led targeted marketing and sales expansion initiatives for a variety of minimally invasive, cardiac and urologic implantable technologies



**SHERWYN DAVIDSON**  
VICE PRESIDENT, QUALITY &  
REGULATORY AFFAIRS

- ▶ 20+ years interacting with regulatory authorities, establishing and maintaining a Quality Management System
- ▶ Former Senior Project Manager at Mediscense Ltd.
- ▶ B.Sc. in Industrial Engineering from Ben-Gurion University



▶ **FRANK GALLAGI**  
CHIEF FINANCIAL OFFICER

- ▶ 15+ years in finance and operational executive role within medical device and food ingredient companies.
- ▶ 20+ years in venture capital private equity leadership roles managing deal diligence, structuring and management.
- ▶ Certified Public Accountant





# Medical Affairs & Research

**SUFU** Presentation Dr. Gold abstract  
Dinner Presentation Dr. Biggs, Lucente and Pezzella

**SGS** Abstract by Dr. Lucente 24 mo data  
Developed two new KOLs in Tucson and NM

**AUGS submission** Video abstract submission  
Planning Surgical Expo room w/KOL

**Value Dossier** completed for Hospital Value proposition to be leveraged for White Paper

**Publications**- 1 article accepted; 2<sup>nd</sup> submitted (pending)

**LINA** – Planned support of webinar series with KOL May, July, Sept

**Registry Plan in place**; to be kicked off Q3 '23

**Goals:** Real World Data

**Patient Claims:** Satisfaction, Refer a friend

Symptom relief

Return to work

**Surgeon:** Ease of use, Scheduling Efficiency

Adoption time

Safety and durability

Discussions with several KOL over **Investigator Initiated Studies**

# Sales Process –Lessons Learned

- LiNA partnership excellent in certain instances and proving more challenging in others
- With a dedicated focus, processes initially bottle-necked can now be effectively relieved
  - Value Proposition package now demonstrating value across multiple constituents (Hospital, Physician, Customer)
  - Trained Surgeon Champion a “Must Have”
- Physician learning curve is 4-6 cases
  - Follow up is key/ New habits take time
  - Patient/Consumer feedback fuels adoption
- Physician targeting is crucial-FPMRS trained best targets
- Sales Rep Profile - device skill set preferred, this is an OR sale
- Launching during COVID was difficult ☹️

# Value Proposition- Clinical/Economic/Customer

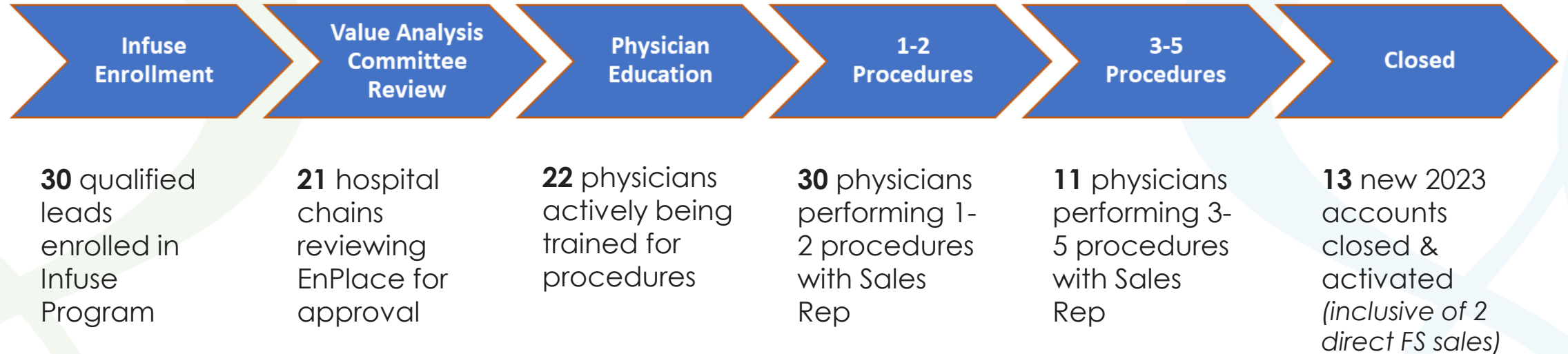
EnPlace was provided a new HCPCS code (C9778 – Colpopexy, Minimally invasive, extraperitoneal) by the Centers for Medicare and Medicaid Services (CMS) on 11/10/21.

As such, our device is positioned for reimbursement as a Level 5 GYN procedure as well as designated as device-intensive, enabling broader access to EnPlace for women in the ambulatory surgery center (ASC)

Clinical Value	Economic Value	Ambulatory Surgical Center	Hospital Outpatient	Economic Benefit
<ul style="list-style-type: none"><li>• Increased safety &amp; fewer complications</li><li>• Less invasive procedure</li><li>• Permits concomitant surgery (if needed) such as Anterior and posterior colporrhaphy repairs</li></ul>	Reimbursement	\$2,486.16	\$4,503.49	<ul style="list-style-type: none"><li>• Shorter operation time</li><li>• Higher throughput</li><li>• Potential reduction of complications and reoperation rates</li></ul>
	EnPlace ASP	\$1,560.00	\$1,560.00	
	Economic Value	\$926.16	\$2,943.49	
	Plus:	Shorter operation time Higher throughput Potential reduction of complications and reoperation rates Potential to drive increased patient volume by offering innovative procedure		

# Validation of Market Assumptions

FEMSelect EnPlace specialists bringing physicians into the funnel and tracking each step of process in Salesforce



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- Dr. Pezzella webinar clip 8:37 to 10:14

[The EnPlace® System Webinar - Dr. Andrea Pezzella \(May 2023\)](#)



# On Track Toward 2025

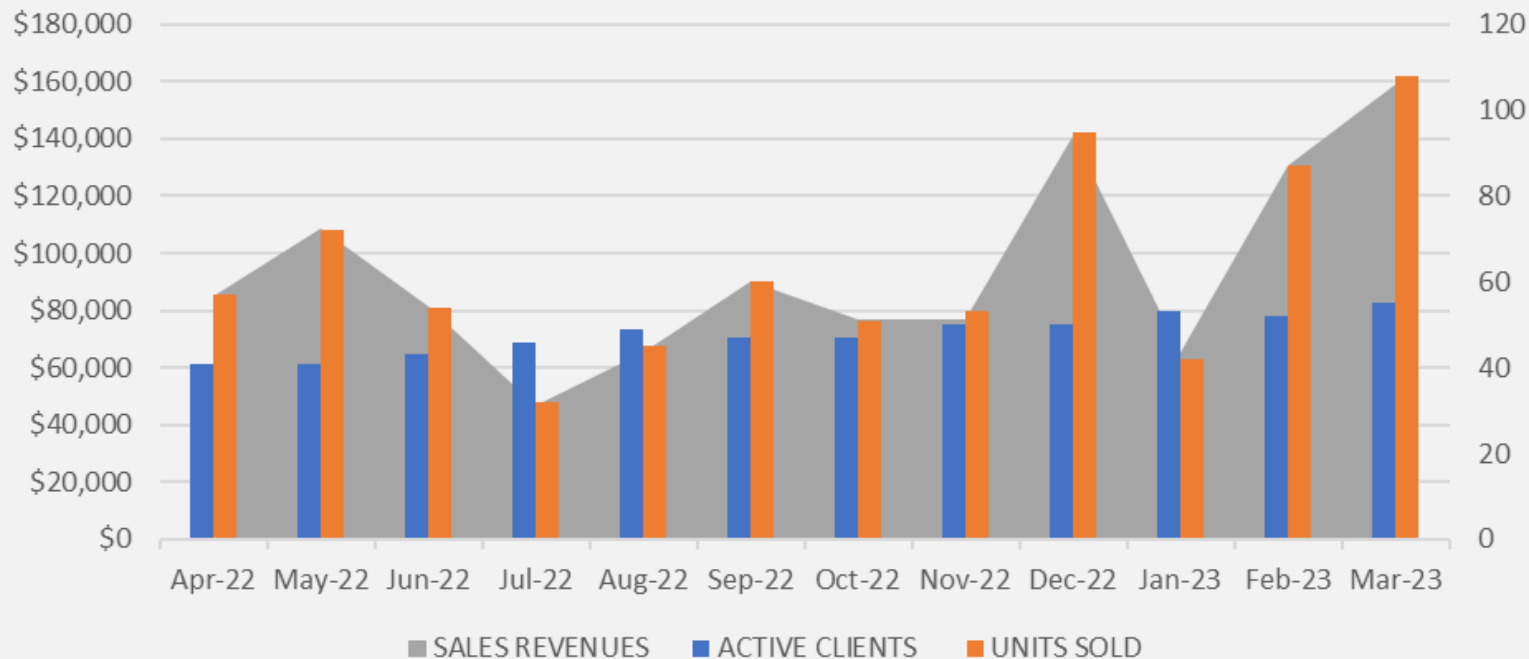
**Q1 UNITS SOLD**  
237A v 138F  
+170%

**ASP**  
\$1,499A v \$1,509F  
-0.68%

**Q1 SALES REVENUES**  
\$355,320A v \$208,317F  
+171%

**CASH ON HAND (\$000s)**  
\$4.239A v \$4.301F  
-1.46%

## 12 MONTH U.S. SALES REVENUES



## Avg Monthly Units per Physician

### Q1 '23

53 active physicians  
80 mo. avg units purchased  
1.51 units p physician/ p mo.

### Q1 '22

41 active physicians  
52 mo. avg units purchased  
0.79 units p physician / p mo.

### Forecast '23

123 active physicians  
246 mo. avg units purchased  
2.0 units p physician/ p. mo.

# Q1 Client Level Unit Sales

	'23 Forecast	Q1 Forecast	Q1 Actual	Q1 Variance
<b>Client Level Units Sold</b>				
LiNA hybrid channel	2,356	138	228	90
FEMSelect direct channel	496	0	9	9
OUS channel	438	87	117	30
<b>Total client level units sold</b>	<b>3,290</b>	<b>225</b>	<b>354</b>	<b>129</b>
<b>Retail ASP</b>				
Existing portfolio business	\$1,509	\$1,509	\$1,502	-\$7
New business prospects	\$1,500	\$1,500	\$1,430	-\$70
OUS channel	\$907	\$907	\$907	\$0
<b>Gross Revenues</b>				
LiNA hybrid channel	\$3,556,456	\$208,317	\$342,450	\$134,133
FEMSelect direct channel	\$743,355	\$0	\$12,870	\$12,870
OUS channel	\$396,900	\$79,200	\$106,119	\$26,919
<b>Total gross revenues</b>	<b>\$4,696,711</b>	<b>\$287,517</b>	<b>\$461,439</b>	<b>\$173,922</b>

## CFO Comments:

Exceptional quarter as the Company successfully launched its direct sales initiatives and continued harvesting of client base.

The Company sold through 354 units generating roughly \$461k in gross revenues at client level. These results exceeded expectations by 129 units and \$174k gross revenues.

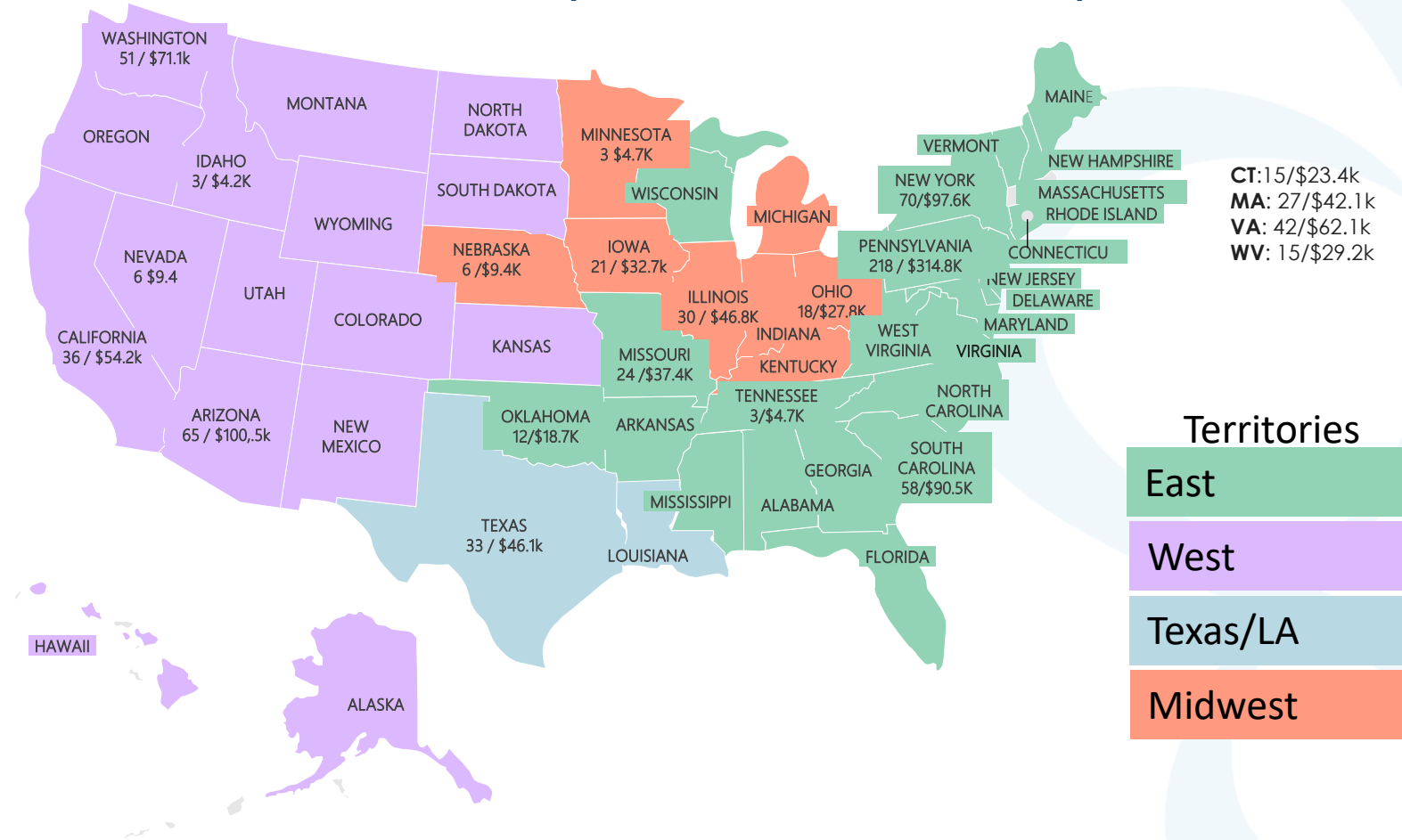
# Territory Focus = High Volume Sales

A top priority of 2023 was the assignment of specific territories to FEMSelect W-2 Reps in hopes of optimizing LiNA sales leads while generating new opportunities in carved-out territories.

Since launching in Q4 '22 we have seen increased physician monthly volumes and more consistency in our top-tier hospital networks.

Top tiered customers averaging 9 units per month over TTM.

12 MONTH TERRITORY REVENUES (TTM UNITS 756 / REVENUES \$1.128MM)



**Direct FEMSelect territories:** New Jersey, Upstate NY, Philadelphia, Maryland, Delaware, Indiana, Kentucky, Ohio (excl. Cleveland), South Texas (Houston & Austin) Louisiana, Colorado



## Demonstrating Market Demand: Social Media Marketing Messages

### TOP 6 MESSAGES FROM MARKET RESEARCH

1. Nearly one-half of all women between ages 50 and 79 have some degree of uterine or vaginal vault prolapse or some other form of pelvic organ prolapse
2. Factors that increase your risk of uterine prolapse include childbirth, age, obesity, chronic constipation, genetic conditions, and having a hysterectomy
3. Pelvic organ prolapse can make you feel like your “insides are out”
4. EnPlace<sup>®</sup> is used in a same-day procedure and does not require an overnight stay
5. EnPlace<sup>®</sup> requires minimal incisions with less scarring than traditional surgery and allows for quick patient recovery
6. EnPlace<sup>®</sup> is cleared by the FDA

# Demonstrating Market Demand: Social Media Marketing Pilot to Kick-off end of June

## Target Audience

- W45-54
- W55-69

## Markets

- Derby, CT
- Tucson, AZ
- Detroit, MI
- Columbia, SC

## GEO-TARGETED MEDIA TACTICS

Digital	<ul style="list-style-type: none"> <li>• Paid Search</li> <li>• Programmatic</li> <li>• Native</li> </ul>	<ul style="list-style-type: none"> <li>• Facebook</li> <li>• Instagram</li> <li>• Organic Social</li> </ul>
Audio	<ul style="list-style-type: none"> <li>• Pandora</li> </ul>	
Alternative Out of Home (OOH)	<ul style="list-style-type: none"> <li>• Gyms – in-club screens &amp; women's locker rooms</li> </ul>	
PR & Social	<ul style="list-style-type: none"> <li>• Press Releases</li> <li>• Media Relations &amp; Outreach</li> <li>• Media Monitoring, Social Listening &amp; Newsjacking</li> </ul>	<ul style="list-style-type: none"> <li>• Social Posts Across Channels</li> </ul>

Creative and Media Plan Review

Revised Media Plan

HCP Doctor Approval

Pilot Assets (Creative/Social/PR)

Campaign Live

Approved

April 19

April 20 - 24

April 26

May 1

April 26 - May 5

May 5

May - June

June 12

June 26 - Sept 24

July - Sept

PR/Social Plan

Message Testing Round 2

Media Plan Approval

Creative Approval

Web Development

Media Reporting

# POTENTIAL EXIT PARTNERS

## 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 Roll Up Possibilities

Leverage end-user brand+ advertising spend with synergistic products

*Telehealth platform  
OAB technology  
SUI technology  
Pelvic trainer/pessary*

# 2023-2025 Proforma/Modified Forecast

	Actual	Forecast		
	2022	2023	2024	2025
<b>KPI's</b>				
# of US physicians activated	65	123	210	338
Monthly avg physician purchases	0.78	2.00	2.50	3.00
Client-level units sold US)	609	2,952	6,300	12,185
Client-level units sold (OUS)	230	468	1,303	4,260
LINA Inventory purchases	1,600	3,222	7,069	13,760
<b>Financial Results (000's)</b>				
<b>Gross Revenues</b>				
US	\$2,424	\$4,200	\$10,667	\$16,742
OUS	\$224	\$424	\$1,173	\$3,924
Total gross revenues	\$2,648	\$4,624	\$11,840	\$20,666
<b>Net Revenues</b>				
US	\$1,444	\$2,698	\$7,131	\$14,359
OUS	\$153	\$294	\$821	\$2,684
Total net revenues	\$1,597	\$2,992	\$7,952	\$17,043
	60%	65%	67%	82%
<b>Cost of Revenues</b>	\$579	\$850	\$2,038	\$3,306
Gross profit	\$1,018	\$2,142	\$5,914	\$13,737
Gross margin (gross%)	38%	46%	50%	66%
Gross margin (net%)	64%	72%	74%	81%
<b>Operating expenses</b>	\$1,673	\$4,534	\$6,028	\$8,428
<b>Operating profit / (loss)</b>	-\$655	-\$2,392	-\$114	\$5,309
<b>Cash @ end of period</b>	\$5,222	\$2,331	\$1,966	\$6,694

# Strategic Discussions

- Updates at clinical conferences & industry conferences:
  - Clinical:
    - Society of Urodynamics and Female Pelvic Medicine & Urogenital Reconstruction (SUFU)
    - Society of Gynecologic Surgeons (SGS)
    - American College of Obstetricians and Gynecologists (ACOG)
  - Industry:
    - MedFemtech (Paris) (Debbie)
    - BioMed (Tel Aviv) (Debbie)
  - High-level updates
  - Meet new strategics and engage
- Women's-health roll-up conversation
  - Understand competitive landscape
  - Meet other femtech companies in pelvic floor arena
- How can you help?
  - Follow us on social media
  - Keep in touch with us as you interact with others in med device or femtech space

# Summary

- ▶ Round B resources enabling build of value creation
- ▶ Lessons learned from 2022 have shaped 2023 early success with EnPlace specialists
- ▶ On track for value creation metrics
- ▶ Gaining visibility for the brand in the industry

# FEMSELECT

a one of a kind opportunity for **pelvic health**

## LARGE UNMET NEED

- ▶ 25 million American women deal with symptoms
- ▶ Only 3 million diagnosed
- ▶ Fewer than 400,000 are treated surgically
- ▶ Minimally invasive options needed & preferred by physicians & consumers
- ▶ Uterus preservation for benign uteri, Hysteropexy vs. vaginal hysterectomy ideal
- ▶ Non-Surgical interventions like pessaries are not meeting the need, high discontinuation rates

## 1<sup>st</sup> MINIMALLY INVASIVE MESHLESS SOLUTION

- ▶ < 30 minute procedure
- ▶ Return to daily activity within 2-3 days and Minimal post op pain
- ▶ Physician confidence demonstrated after 5 procedures
- ▶ Done under MAC /LMA anesthesia reducing procedural risk
- ▶ 1 year Post Marketing Study publication submitted and pending JMIG approval
- ▶ 4 years data published showing durable repair

## COMMERCIAL TRACTION

- ▶ LiNA Strategic Partnership goes to next level with EnPlace Specialty Sales Team added as support
- ▶ Positive upward trend in sales
- ▶ EnPlace-specific Reimbursement Outpatient Hospital and ASC
- ▶ Nearly 70 hospitals approved, 30 more pending
- ▶ 90 trained docs and gaining traction
- ▶ Highly engaged KOLS for proctoring

## EXPERIENCED TEAM CAPITAL EFFICIENT

- ▶ Significant Women's Health experience
- ▶ Completion of \$5.1M Round B gives runway until breakeven (Raised \$14M to date)
- ▶ Continue to see Issuances of PCTs; 15 patents issued + 2 allowances
- ▶ Transfer to commercial supply complete. COGS reduced by 45%
- ▶ Continued evidence generation and marketing plan
- ▶ Clinical Evidence presentations at all major congresses (SGS, AUGS, SUFU 2023)