

JULY, 2020

# FEMSELECT INVESTOR UPDATE





## **AGENDA**

- 1. High-level Updates
- 2. Round B Progress
- 3. Clinical Update
- 4. Field Update

### COVID-19

### High-Level Update

- ▲ Regulatory: cleared by FDA and CE Mark (not waiting for approvals)
- ▲ <u>Clinical</u>: 1 year data showing EnPlace enables durable repair
- ▲ <u>Clinical</u>: EnPlace considered "COVID-friendly" procedure w/no hospital stay
- ▲ Financial: CLA raise—oversubscribed; extended CLA to \$3M
- ▲ <u>Financial</u>: Small nimble company—remain frugal
- ▲ <u>Commercial</u>: 11 Value Analysis Committee (VAC) Approvals and 9 others in motion; Israeli distributor in place; Sales YTD \$150,000 (Jan-July)
- ▲ Biz Dev: Working toward Round B (VC's and strategics) with Quartz Advisory
- ▲ Biz Dev: Strategic partnering discussions beginning that could lead to acquisition

femselect | confidential 3

# FUNDING STRATEGY LEADING TO ACQUISITION

2018

\$ERIES A \$3 MILLION CLOSED 2020

CLOSE SERIES B \$20 MILLION 2021

STRATEGIC PARTNER SALES PILOT 2022/23

**EXIT** 

CLOSED: FEBRUARY 28, 2018

SECURITIES:
SERIES A PREFERRED SHARES

POST-MONEY VALUATION: \$10 MILLION

# CLA Update: Bridge to Round B

#### 2021 Drive Adoption to Exit

TOTAL RAISED IN CLA = \$2MM+ continuing to raise

CASH BURN = \$120K/month

depending on scenario

MONTHS OF CASH = 10

### RUNWAY/BUDGET

- ► Q3
- ► ELECTIVE PROCEDURES RETURNING
- ► INCREASED BUDGET AS TRAVEL RESTRICTIONS EASE AND ELECTIVE PROCEDURES RESUME
- ► Q4
- ► CLOSE FUNDING/1<sup>ST</sup> TRANCHE

## Actuals v. Budget Q2

P&L Summary	
US K\$	
Revenues	
cos	
Gross profit	
Gross Margin (%)	

R&D
CLINICAL & RA
Physician professional development
S&M
G&A
OPEX Breakdown
EBITDA

Q1.2020		
Actual		
46		
27		
19		
41%		
16		
162		
26		
105		
89		
399		
(380)		

Q2.2020
Actual
56
22
34
60%
26
162
18
82
106
394
(360)

YTD 2020					
Actual	Budget	Variance			
102	186	(85)			
49	67	(17)			
53	120	(67)			
52%	64%				
43	53	10			
324	283	(41)			
44	24	(20)			
188	249	62			
195	186	(9)			
793	795	2			
(741)	(675)	(65)			

- On budget with OPEX
- Revenues lower than anticipated in Q2 due to COVID
  - July trend is strong (see slide 18)

# PROGRESS ROUND B/CLA

### PROGRESS ON ROUND B

### DISCUSSIONS: VENTURES GROUPS

### FEEDBACK & LEARNINGS

- Engaged with Quartz Advisory to improve efficiency of on fundraising/M&A activity
- Quartz has begun reaching out to their contacts
- Several VC's who are in DD (5 actively)
- Capital raise of \$20M necessary to build a commercial organization
- Exit horizon of 2-3 years for more favorable exit valuation than could get now

# COMPARABLE EXITS IN WOMEN'S HEALTH + UROLOGY

ACQUIRER	ACQUIRED COMPANY	DATE	ACQUISITION PRICE
LABORIE	COGENTIX MEDICAL	APR 2018	\$214M*
Scientific	NxTHERA	APR 2018	\$306M
seientific	nVISION	APR 2018	\$275M
7feleflex®	NEOTRACT INC.	SEP 2017	\$725M (\$1.1B + milestones)
<u>©operSurgical</u>	PARAGARD IUD FROM TEVA	SEPT 2017	\$1.1B
<b>AYTU</b> BioScience	NUELLE	MAY 2017	Undisclosed
Medtronic	SMITH & NEPHEW'S GYN BUSINESS	MAY 2016	\$350M

### EXIT OPPORTUNITIES

#### LARGE GLOBAL WOMEN'S HEALTH

Leverage existing sales relationships with minimally invasive













Coloplast

#### **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

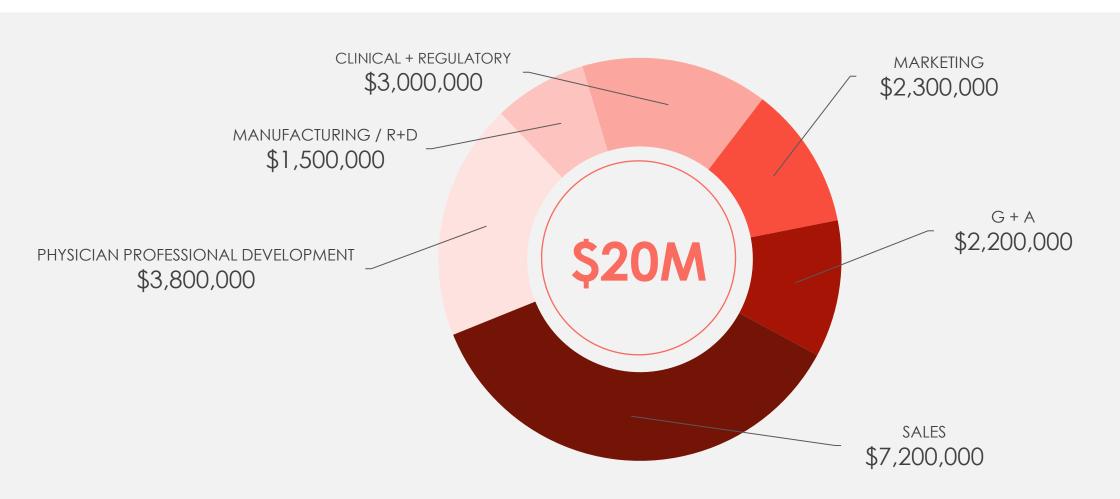




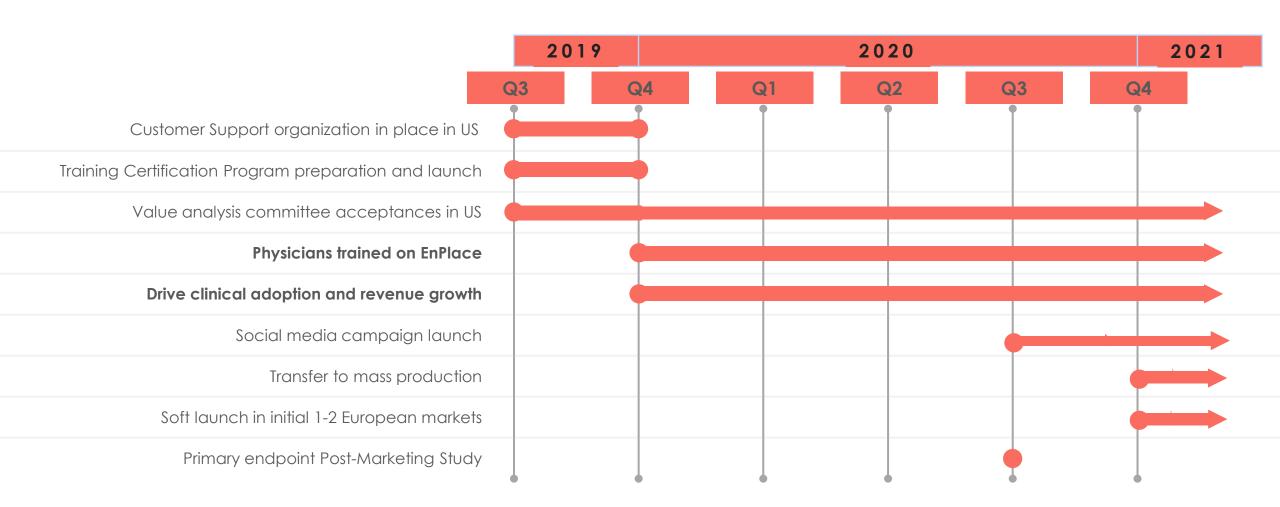


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### ROUND B USE OF PROCEEDS



### KEY COMMERCIAL MILESTONES



### IP UPDATE NEW ALLOWANCES

#### **STRONG IP PORTFOLIO: 4 FAMILIES**



#### FAMILY 1

Method for repairing prolapse while using ultrasound

4 US ISSUED PATENTS
1 ADDITIONAL ALLOWANCE



#### FAMILY 2

Device for tissue anchor delivery

1 US ISSUED PATENT

2ND PATENT ALLOWANCE



#### FAMILY 3

Surgical device for guiding and anchoring - current device

1 JAPANESE ISSUED PATENT
2 ALLOWANCES (SINGAPORE
AND AUSTRALIA)



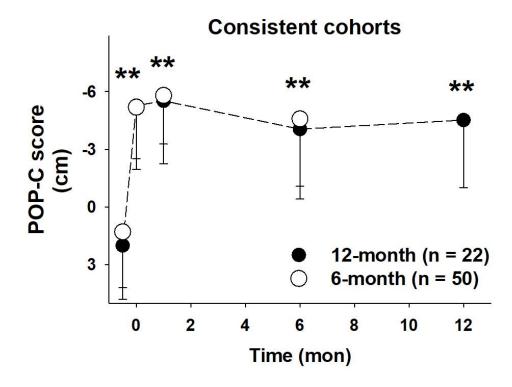
#### FAMILY 4

Anchoring device - current device with latest developments

11 PCT FILINGS IN PROCESS FILING NATIONAL PHASE

# CLINICAL UPDATE

## Durable Repair @ 12 mos (C-Point)

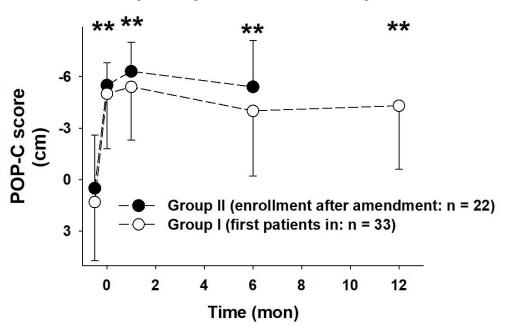


Average (± STD) POP-C point values as a function of time after surgery

- POP-C scores remain significantly above the baseline at both 6- and 12months – the repair is durable.
- The larger 6-month cohort (open symbols) and the 12-month cohort do not differ significantly.
- Treatment with the EnPlace device elevated the apex of the vagina significantly (\*\* p < 0.001)</li>

# Group I (Early Enrollment) versus Group II (Later Enrollment)

#### All participants at each time point



#### Later enrolled patients doing better:

- 1. Learning curve apex seems to be suspended higher in later patients
- 2. Fewer recurrences among patients treated later

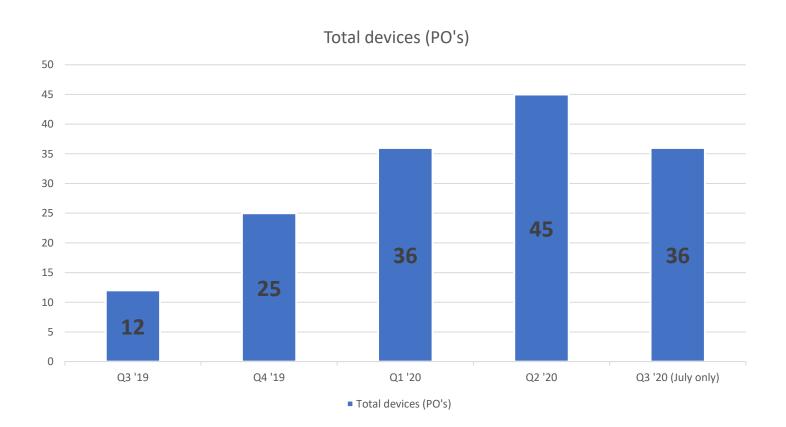
\*\* indicates p < 0.001 different from baseline

No significant changes among 1-month through 12-month C-point measurements in either curve

# FIELD UPDATE

### **US** and Israel sales

# Quarterly Sales



### **US** Commercialization

 Peer-to-peer workshops to observe multiple cases.

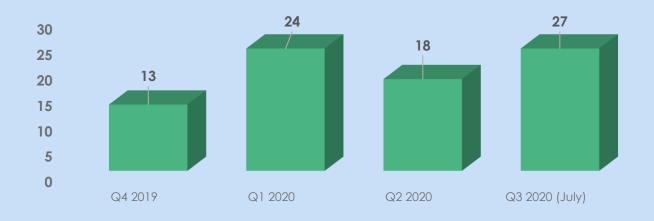
GyneSim™ innovative anatomical
 "wet labs" for physician training.

 Leads from prior shows (AUGS, SGS), relationships & online inquiries

 "Covid approach": webinar & eLearning modules for participation.

### Sales/units update

- Patients: Activity during Covid emphasizes ongoing need & desire for a solution
- ▶ Physicians: Increased comfort & confidence
  - Opportunity to expand within centers:



■ Quarterly Total Units

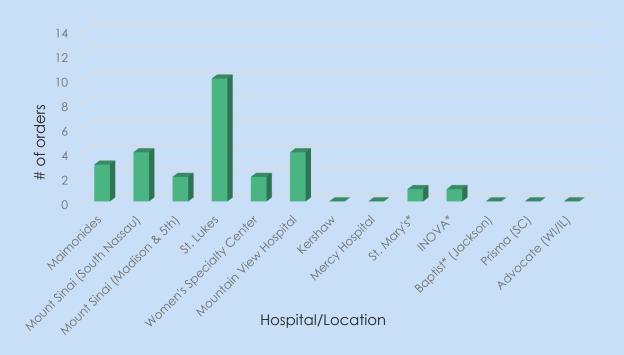
## **Hospital Trends**

- Covid reduced E. Coast activity.
- Several VACs "tabled" as non-critical
- Difficulty "justifying" elective approval
  - e.g. Holy Cross(FL), Prisma(SC)
- Large health systems = >120-day
   approval (\*pre-Covid)
  - Increased focus on small, physician-owned centers!

### **EnPlace™ Center Activity**

- VAC "approved" at 11 locations
- VAC "in review" in 9 additional locations
- ► VAC "proposed" in 3 additional locations
- Customer service/logistics "moving fluidly"





### COMPELLING REASONS TO INVEST

+ CE MARKED



ENPLACETM COMPELLING BRAND INNOVATIVE DEVICE



MINIMALLY INVASIVE \$4B US MARKET



TARGET MARKET IP PORTFOLIO



4 PATENT FAMILIES

CLINICAL ACCEPTANCE



EVIDENCE BASED MEDICINE

FEM SELECT 21



# THANK YOU

### THE FEMSELECT BOARD OF DIRECTORS



### DR. PETER FITZGERALD TRIVENTURES

- Co-Founder & Managing Partner, Triventures
- Director, Center for Cardiovascular Technology, Stanford University



DR. MICHELLE LIN TRANSPACIFIC VENTURES

- Founder and General Partner, TransPacific Ventures, (TPV)
- Director, TSC Bio-venture Inc. and various other start-ups



CARMIZISAPEL
RADBIOMED
COO, Innercore Medical

Former Director of Business
 Development and Portfolio Analysis,
 RAD BioMed Accelerator



BERNIE RUDNICK
MID-ATLANTIC BIO ANGELS (MABA)
AND KEIRETSU ANGEL GROUP

- Founder and Managing Partner of CapGenic Advisors, LLC
- ► Founder MABA and LP in 4 funds Investment Committee of 2
- Director, Atrin Pharmaceuticals, Axxia Pharma, SageMedic, Virion Tx, Co-Founder OtoSense (now ADI)



RENEE SELMAN
FORMER WORLDWIDE PRESIDENT,
ETHICON WOMEN'S HEALTH AND UROLOGY

- 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)



MAX KORENVAES KORENVAES FAMILY FUND

- Director, Double Helix Management, Apollo Laboratories
- and Xhale Asssurance



DR. HAMPTON RICHARDS
KORENVAES FAMILY FUND (OBSERVER)

- OB-GYN Advisor to Korenvaes
- Private practice at Walnut Hill OBGYN

# 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)



MENAHEM NEUMAN MEDICAL DIRECTOR

- Head of Urogynecology, Galilee Medical Center and Bar-Ilan University
- Former Ethicon Women's Health & Urology PFR global trainer and Pelvic Floor Innovation Committee Member



JOEL CHECHIK
CHIEF COMMERCIAL OFFICER

- 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.



BOAZ HARARI VICE PRESIDENT, R + D

- ► 20+ years of experience in the medical device field
- Former CTO VibeMedic Ltd. and Niti Surgical Solutions Ltd.
- Experienced engineer who has developed numerous clinical devices from concept to market

2020 KEY HIRES: CHIEF MEDICAL OFFICER | DIRECTOR OF MARKETING | DIRECT SALES REPS