

Disrupting Convention in Women's Reproductive Health Through Continuous Innovation

Investor presentation
April 2024

**NASDAQ: FEMY** 



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# Femasys Overview

### **Empowering Women & Enabling Choice**

Femasys is committed to providing women with revolutionary products as they seek solutions throughout their reproductive journey. Technological advancements in female reproductive health are long overdue, driving our focus to develop in-office, accessible, and innovative options.

#### MAIN AREAS OF FOCUS

### Infertility

- FemaSeed® Intratubal Targeted Insemination
- FemVue® Contrast Generating Device

### **Contraception**

FemBloc® Permanent Birth Control

### **Cancer Diagnostic**

FemCerv® Endocervical Sampler



# Investment Highlights

#### **Mission**

- Develop disruptive broad portfolio of products for women's health
- Address multi-billion-dollar global market opportunities
  - Infertility therapeutic and diagnostic
  - Permanent birth control
- Improve patient care and health economics

#### **Differentiator**

- Minimal competition with well defined reimbursement strategies
- Commercial-readiness with in-house CMC and device manufacturing
- Achieved global regulatory approvals, including U.S., Japan, and Canada

#### **Foundation**

- · Woman-founded and led, experienced leadership team
- Intellectual property portfolio with >150 patents globally
- Cash runway into 2H 2025
- Four commercial-stage products and one in late-stage clinical trial

NASDAQ: FEMY (IPO June 2021)				
Stock Price (as of 04/01/24)	\$1.72			
Share Count	22.1M			
Market Capitalization (as of 04/01/24)	\$38.0M			
Cash (as of 12/31/23)	\$21.7M			



# Key Leadership



Kathy Lee-Sepsick
President, CEO, Founder

30+ years of experience

Terumo Medical, Novoste, Salumedica



**Dov Elefant**Chief Financial Officer

30+ years of experience

Cellectar Biosciences, Akari Therapeutics, Lev Pharmaceuticals, EpiCept



James Liu, MD
Chief Medical Officer

40+ years of experience

Chair, Dept OB/ GYN
University Heath
System, Chair Dept
Reproductive Biology at
Case Western, and
Division Head
University of Cincinnati



Richard Spector
Chief Commercial Officer

25+ years of experience

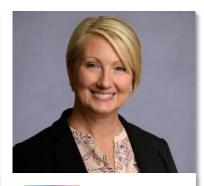
Quilibrium, Insulet,
OvaScience, NeoMatrix,
Cytyc Surgical



**Dan Currie**Chief Operating Officer

30+ years of experience

Ciba Vision, Novoste, Salumedica



Christine Thomas

SVP, Regulatory & Clinical

20+ years of experience

GE Healthcare, Boston Scientific, Smiths Medical, RTI Surgical



# Solutions for Women Through the Continuum of Care

Office-based, minimally invasive solutions utilizing shared delivery platforms

Commercially Available Products				
femaSeed	Treatment	Intratubal Insemination		
femVue	Diagnostic	Contrast-Generating Device		
<i>f</i> emCath <sup>°</sup>	Diagnostic	Selective Delivery Catheter		
<i>f</i> emCerv°	Diagnostic	Endocervical Tissue Sampler		

Product Candidate					
		Preclinical	Clinical Trial		
femBloc® Permanent Birth Control	Research		Stage I Safety	Stage II Validation	Stage III Pivotal



# Infertility-Focused Portfolio



### **Intratubal Artificial Insemination**

- FDA-cleared, innovative first-line infertility treatment for directed sperm delivery
- Positive topline results announced



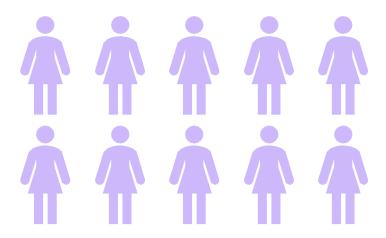
### Tubal Diagnosis with Ultrasound

• FDA-cleared, first in-office ultrasound evaluation of fallopian tubes



No Affordable Infertility Options Introduced in Decades

> 10M women in the U.S. struggle with infertility<sup>1</sup>



~50% due to male factor<sup>2</sup>

Sperm counts worldwide have declined by >50%3



### **Key Trends:**

- 43 U.S. states have recorded lowest fertility rate in last three decades4
- 9.14 million women have received infertility services at some time in their lives<sup>5</sup>





/www.cdc.gov/nchs/nsfg/key\_statistics/i-keystat.htm

Centers for Disease Control and Prevention (2019)

# FemaSeed and FemVue Provide Next Generation Options



### Patient Journey (U.S.)

4.3M seek evaluation only

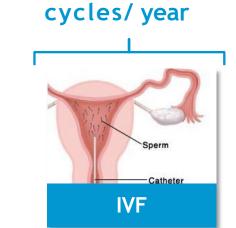








**1**M

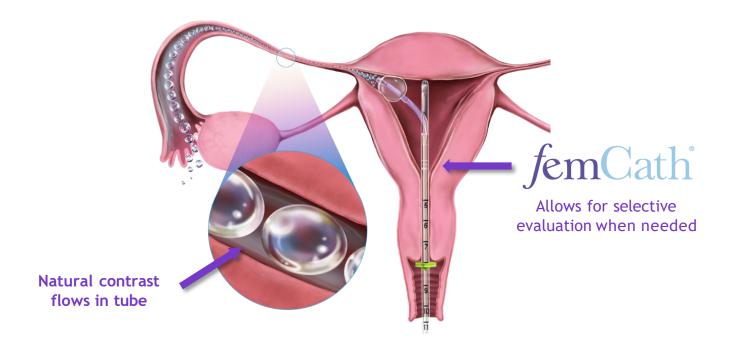


200k

# Infertility Portfolio: from **Diagnosis** to Treatment



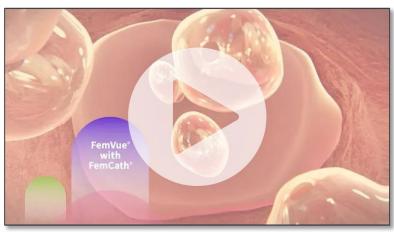
Safe • Cost-Effective • Time Saving



#### **Intended Population:**

 Baseline diagnostic test for infertility and prior to insemination

(Note: blocked tubes are a silent factor affecting 1 in 3 infertile women)

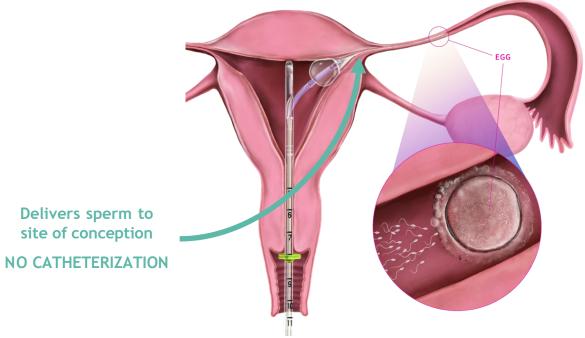


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# Infertility Portfolio: from Diagnosis to Treatment

# femaSeed Safe • Cost-Effective • Enhance Fertilization



Requires at least one open fallopian tube (FemVue can confirm first)

### **Intended Population:**

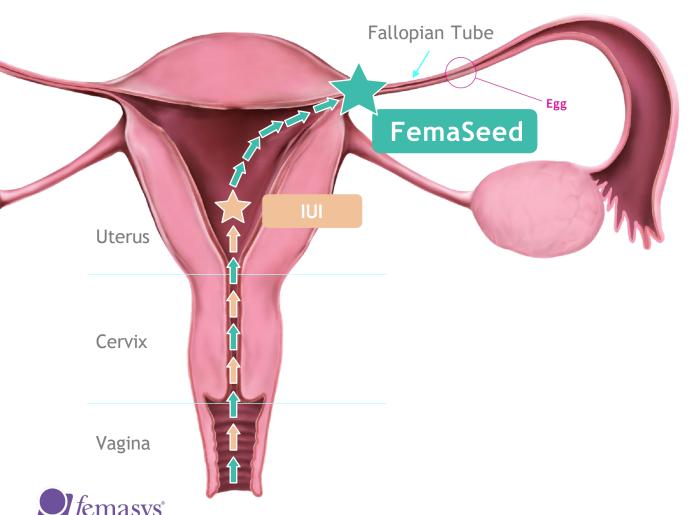
- Infertile women/ couples
- Patients desiring insemination, including same sex couples & single women



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### FemaSeed Overcomes the Last Barrier to Natural Fertilization



### Advantages from Market Research

- 92% of Survey Respondents had Favorable Impression of FemaSeed\*
- It's angle toward the opening (ostia) is the most critical finding that I am impressed with that allows sperm to be the closest to the egg.
  - Reproductive Endocrinologist HCP\*
- Delivery to fallopian tube makes sense with low count [sperm] cases to improve efficacy.
  - Reproductive Endocrinologist HCP\*
- It's an interesting concept for women who have unilateral disease [blocked tube].
  - Reproductive Endocrinologist HCP\*

# FemaSeed Offers Significant Competitive Advantages

		Assisted Reproduc	Artificial Insemination	
	femaSeed <sup>*</sup>	IVF	ICSI	IUI
No surgery				
No egg retrieval or storage				
No required injections				
Delivery to fallopian tubes (site of conception)		NA	NA	
Cost-effective				
Minimal safety risks				
Low male sperm count efficacy				
Single fallopian tube solution		NA	NA	
Widespread accessibility		Varies	Varies	



FemaSeed Top Line Data from Pivotal Trial Demonstrates Significant Progress in Fertility Treatment

#### Trial Design (NCT 04966847)

- Prospective, unblinded pivotal trial evaluating the safety and efficacy of FemaSeed
- Primary endpoint: pregnancy rate
- Safety: 7-week follow-up period post FemaSeed

#### **Trial Results**

- 24% pregnancy rate for male factor infertility following FemaSeed
- More than double pregnancy rate when compared to historic intrauterine insemination (IUI) for similar patient population
- Majority of women who became pregnant did so after first FemaSeed procedure
- No new safety concerns reported, and all AEs consistent with IUI





# Commercialization Strategy in U.S.



#### Limited Market Release

- Focused regions and targeted audience
- Focused sales and marketing efforts
- Monitoring, evaluation and iterative improvement



### **Expanded Market Release**

- Wider distribution and geographical expansion
- Targeted marketing and sales strategies
- Education and training
- Expanded product offerings
- Customer support, feedback collection, and monitoring market performance



# FemaSeed Priced to Support First-Line Treatment Option

#### Population

#### Infertile Women/ Couples Seeking Treatment

## IUI

Intrauterine Insemination

femaSeed

Intratubal Insemination

#### Average Total Cost

\$500-\$4,0001

total per cycle including ultrasound monitoring, and optional ovulation drugs<sup>2</sup>

### +device

per cycle above IUI cost

#### Reimbursement

- If insurance, covered under IUI codes (service, sperm washing)
- Insurance with positive coverage policy typically covers 3-6 cycles
- Required prior to IVF/ ICSI in many coverage policies

#### Subset of Infertile

(After 1-3 IUI cycles or as indicated)

## **IVF/ICSI**

In vitro fertilization / intracytoplasmic sperm injection

\$30,000

total per cycle, including ultrasound monitoring, ovulation drugs, egg extraction and freezing<sup>3</sup>

 14/20 covered states that have fertility insurance coverage, include IVF

#### NOTE

- 1. https://www.fertilityiq.com/iui-or-artificial-insemination/the-cost-of-iui
- 2. Parenthood, Planned. "What Is Intrauterine Insemination (IUI)?" Planned Parenthood, https://www.plannedparenthood.org/learn/pregnancy/fertility-treatments/what-iui.
- Ravitsky, et al. The forgotten men: rising rates of male infertility urgently require new approaches for its prevention, diagnosis and treatment. Biology of Reproduction, 2019, 101(5), 872-874.

# FemaSeed has Significant Potential Revenue Opportunity

Immediate addressable market

> 1 million\*

IUI cycles/ yr

~\$1B market opportunity

Immediate expansion

4.8 million

women seek evaluation & treatment

**Expansion** opportunity

**Future expansion** 

4.3 million

women seek evaluation only



# In-Office Sterilization



- First and only non-surgical, in-office, permanent birth control option
- In late-stage clinical development with on-going pivotal trial
- Potential to be the safest and most natural approach at substantially less cost than the long-standing surgical alternative





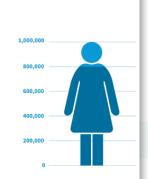
# Lack of Innovation in Last Century for Permanent Birth Control



\$2B annual market opportunity

800,000

women choose surgical tubal ligation as a form of permanent birth control every year\*

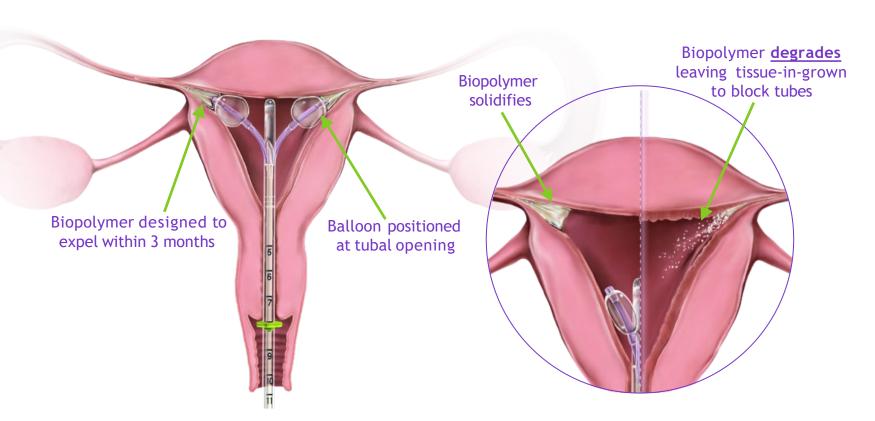


\$20B total market expansion



## FemBloc Permanent Birth Control & Confirmation Test

# femBloc Safe • Convenient In - Office • Lower Cost





Video will open in browser window.



#### **Ultrasound-Based Confirmation Test** (to ensure success)



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# FemBloc Clinical Studies for Pre-Market Approval (PMA)

#### Stage III: FINALE Pivotal Clinical Trial

#### Trial Design (IDE approved June 2023; currently enrolling)

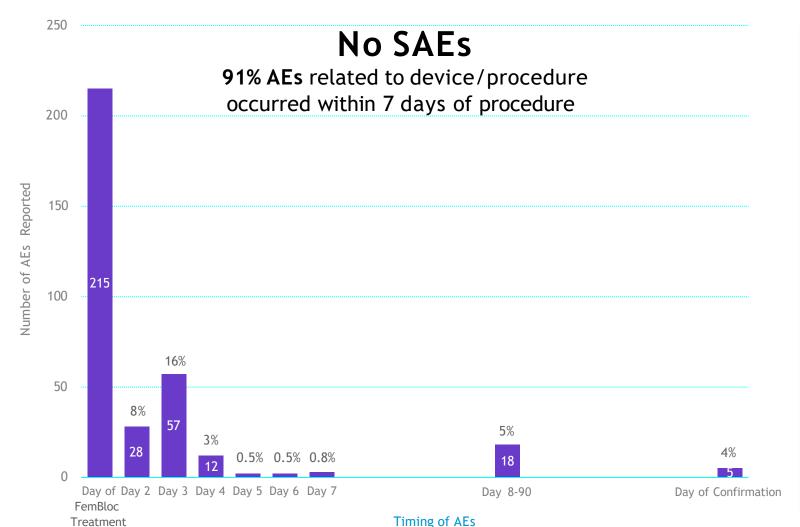
- Prospective, multi-center, open-label, single-arm study
  - Roll-in study design (50 subjects in part A for safety)
  - Endpoints:
    - Primary: pregnancy rate at 1-year after using FemBloc (N=401)
    - Secondary: safety and various in-office assessments
- Additional Analysis:
  - 2-5 years post-market for safety
  - Interim analysis: after 300 women have relied on FemBloc for 1-year

Completed Earlier FemBloc Supportive Studies (N=321)					
Early Clinical (N=93)	ical (N=93) Stage I: Safety (N=183); IDE approved Stage II: Validation (N=45); IDE approved				
Evaluated Delivery & Biopolymer	No Serious AEs Reported; 5-year follow-up for safety	Selection of Confirmation Test for Pivotal; 5-year follow-up for safety			



# FemBloc Safety Profile

(N = 228 subjects from Stage I & II; 5-year follow-up on-going)

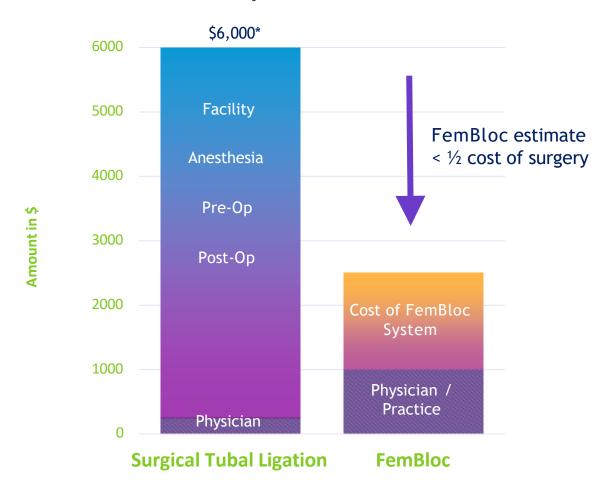


### Other Key Findings:

- Investigator Rating:
  - 96% extremely or very satisfied with FemBloc
- Most common AEs:
  - 59% bleeding/ spotting
  - 55% pain/ cramps
- Mean pain score per visual analog scale (0-10):
  - 4.6 FemBloc
  - 3.4 confirmation test

# FemBloc Improves Health Economics

### Cost Breakdown Compared to Alternative



NO COST TO PATIENT (covered under Affordable Care Act)

#### FemBloc Efficiencies

- In-office procedure expands practice services
- Can perform multiple procedures in same room
- Quick to perform; ease of room turnover
- Patient immediately resumes normal activities

\*Planned Parenthood 2019, https://www.plannedparenthood.org/learn/birth-control; Doximity 2019; U.S. Bureau of Labor Statistics, 2019.



# FemBloc Offers Significant Competitive Advantages

		Permanent E	Temporary	
	femBloc*	Surgical Sterilization (94% effective*)	Essure® No longer marketed (95% effective*)	IUD
Permanent				
Office procedure			Some	
No special capital equipment				
No anesthesia				
No implant (coil/clip)				
No surgery (risks/cost)				
No hormones				
Coverage in place/anticipated				
Worldwide accessibility		Varies	Off Market	



## Milestones

### Inflection points that create value for investors

**ACHIEVED** 

Top line data for FemaSeed pivotal clinical trial (LOCAL)

Initial commercial team on-boarded

Limited market release of infertility product portfolio in North America Achieve CE mark for infertility product portfolio Expand market release of infertility product portfolio to additional regions in North America

Q1)









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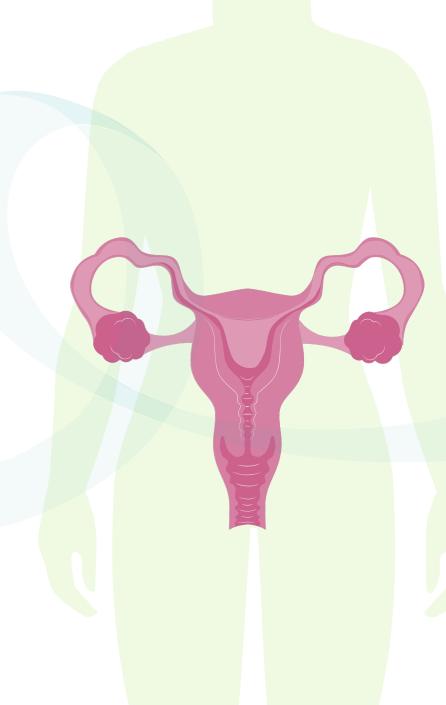
**Contact Details** 

Investor Relations: IR@femasys.com

Media Inquiries: PR@femasys.com



# APPENDIX





## Strategic Commercial Priorities



#### **Market Positioning** & Differentiation

- Market Research & Analysis
- Product Positioning & Messaging
- Performance Measurement & Optimization
- Omni-Channel Engagement



#### **Targeted Customer** Engagement

- Targeted Marketing & Outreach
- Personalized Messaging
- Follow-Up & Persistence
- Value Proposition Demonstration
- Direct to Consumer Outreach



#### **Focused Consumer** Outreach



- **Identify Targets and Segmentation**
- Tailored Messaging
- **Multi-channel Communication**
- Clinical Thought Leader Campaign

#### Corporate Synergy & Branding



- Improving Revenue
- **Cost Optimization**
- Streamline Brand Products
- **Boosting Brand Value**



#### Training & **Support Initiatives**

- **Educational Initiatives**
- Sales Enablement & Support
- **Evidence-Based Education**
- Feedback & Adaptation



#### Strategic Partnerships & Alliances

- **Key IVF Groups**
- **Medical Societies**
- Advocacy Groups
- Social Influencers
- Partnerships with Healthcare Providers

#### **Patient** Education



- Patient Focused Education Materials
- Online Resources & Webinars
- **Community Events**
- Workshops & Forums
- Social Media Campaigns

