

Disrupting Convention in Women's Reproductive Health Through Continuous Innovation

Investor presentation February 2025

**NASDAQ: FEMY** 



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## Femasys Overview

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

Technological advancements in female reproductive health are long overdue, driving our focus to develop in-office, accessible, safe and innovative options as true solutions.

# MAIN AREAS OF FOCUS Infertility

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

## Contraception

FemBloc® Permanent Birth Control

## **Cancer Diagnostic**

FemCerv® Endocervical Tissue Sampler





## Investment Highlights

#### Mission

- · Develop disruptive broad portfolio of women's health products
- Address multi-billion-dollar global market opportunities
- Improve patient care and health economics

#### **Differentiator**

- Minimal competition with well defined reimbursement strategies
- Commercial-readiness with in-house CMC and device manufacturing
- Global regulatory approvals (U.S., Europe, Canada, Japan & Israel)

#### **Foundation**

- · Woman-founded and led, experienced leadership team
- Intellectual property portfolio with ~200 patents globally issued
- 6 commercial-stage products and 1 late-stage candidate

NASDAQ: FEMY (IPO June 2021)				
Stock Price (as of 01/31/25)	\$1.18			
Share Count	23.8M			
Market Capitalization (as of 01/31/25)	\$28.1M			
Cash (as of 09/30/24)	\$7.6M			



## 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

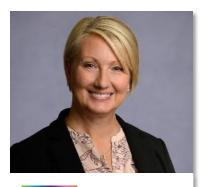
Chair, Dept OB/ GYN
University Heath
System, Chair Dept
Reproductive Biology at
Case Western, and
Division Head
University of Cincinnati



**Dan Currie**Chief Operating Officer

30+ years of experience

Ciba Vision, Novoste, Salumedica



Christine Thomas
Chief Regulatory &
Clinical Officer

20+ years of experience

GE Healthcare, Boston Scientific, Smiths Medical, RTI Surgical



## Solutions for Women Through the Continuum of Care

Commercially Available Products (U.S., Europe & Canada)			
femaSeed	Intratubal Insemination for first-line infertility treatment		
femvue	Contrast-Generating Device for fallopian tube diagnosis		
<i>f</i> emCath <sup>°</sup>	Delivery Catheter for selective fallopian tube evaluation		
<i>f</i> emCerv°	Endocervical Tissue Sampler for cervical cancer diagnosis		
femChec*	Controlled Contrast-Generating Device for fallopian tube diagnosis		

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



## Commercialization Strategy

#### **Initial Focus**

Infertility Specialists & Gynecologists performing infertility



#### **Initial Market Release**

- U.S. direct sales team
  - conglomerates (Boston IVF & HRC Fertility)
- Spain distribution partnership
  - private and public centers





#### **Expanded Market Release**

- Wider distribution and geographical expansion pending country specific requirements
- Activate patient awareness campaigns
- Additional product offerings will accelerate

# Fertility Portfolio femaSeed Intratubal Insemination

- Innovative first-line insemination option; enhances natural fertilization
- Completed pivotal trial supports safety & efficacy
- Substantially less cost and less risk than the long-standing IVF alternative



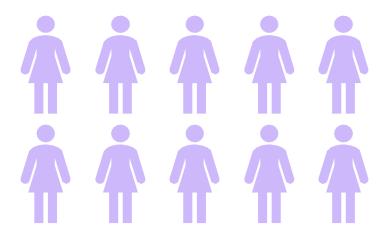
First in-office ultrasound evaluation of fallopian tubes





## 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%<sup>3</sup>



#### **Key Trends:**

- 43 U.S. states have recorded lowest fertility rate in last three decades<sup>4</sup>
- 9.14 million women have received infertility services at some time in their lives<sup>5</sup>



NOTES:

https://www.cdc.gov/nchs/nsfg/kev\_statistics/i-kevstat.htm.

1. https://www.cuc.gov/htths/fisig/key\_statistics/i-

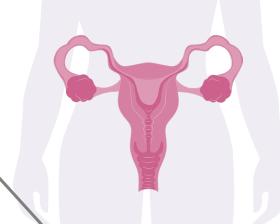
Levine H. et al. (2023)

4 Centers for Disease Control and Prevention (2019)

Chandra A, et al. (2014)

## Significant Need for Next Generation Options

>\$1B Annual market opportunity



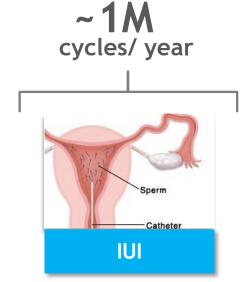
## **Patient Journey**

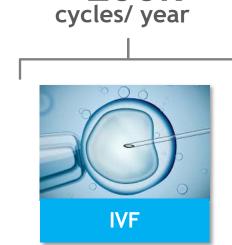
4.3M seek evaluation only









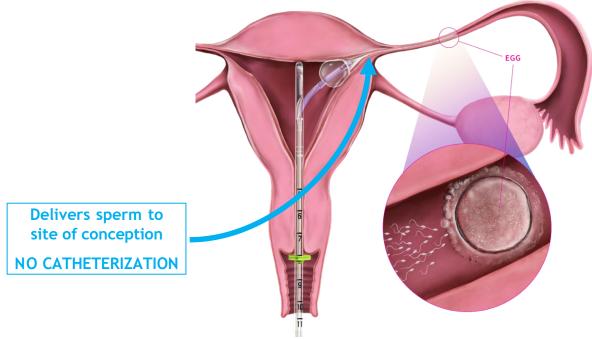


~200k



## Infertility Portfolio: from Diagnosis to Treatment

# femaSeed Safe • Cost-Effective • Enhance Fertilization



Requires at least one open fallopian tube

(FemVue diagnosis performed first)

#### **Intended Population:**

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



Video will open in browser window.



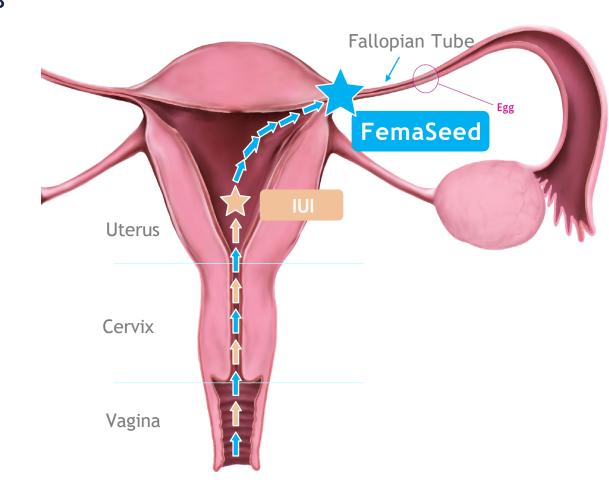
## FemaSeed Top Line Data from Pivotal Trial Demonstrates Significant Progress in Fertility Treatment

#### Trial Design (NCT 04966847); enrollment completed Q4 2023

- Prospective, unblinded pivotal trial evaluating the safety and efficacy of FemaSeed
- Primary endpoint: 3 -week pregnancy rate
- Safety: 7-week follow-up period post FemaSeed

#### Trial Results\*

- ✓ <u>26.3% pregnancy rate</u> for women with male factor/ unexplained infertility
- ✓ More than double pregnancy rate when compared to historic intrauterine insemination (IUI) for similar patient population (17.5% FemaSeed vs 6.7% IUI per cycle)
- Majority of women who became pregnant did so after first FemaSeed procedure
- ✓ No new safety concerns; all AEs consistent with IUI





## FemaSeed Offers Significant Competitive Advantages

		Assisted Reproductive Approaches		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 Priced to Support First-Line Treatment Option

Population

Infertile Women/Couples Seeking Treatment

IUI

femaSeed

+device

Average Total Cost \$500-\$4,0001

total per cycle depending on ultrasound monitoring and use of ovulation drugs<sup>2</sup>

- 3-6 cycles covered
- Required prior to IVF in many coverage policies

- per cycle above IUI cost
- Patient out-of-pocket charge
- Ancillary services covered under existing codes

#### **Subset of Infertile**

(After 1-3 IUI cycles or as indicated)

**IVF** 

\$30,000

total per cycle, including ultrasound monitoring, ovulation drugs, egg extraction, freezing<sup>3</sup>
Genetic testing optional; monthly storage fees extra.

14/20 covered states have IVF fertility insurance coverage

Market Research<sup>4</sup> N=1,000 infertile women

Reimbursement

85% of women would have preferred FemaSeed <u>instead of</u> IUI

Most indicated extremely or very likely to consider FemaSeed

88% of women would have preferred FemaSeed prior to IVF

#### NOTES

- 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.

4. Data on file with Femasys

# In-Office Sterilization



- First and only non-surgical, in-office, permanent birth control option
- In late-stage clinical development with on-going pivotal trial in U.S.
- 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

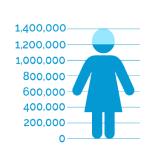
U.S. Market Information

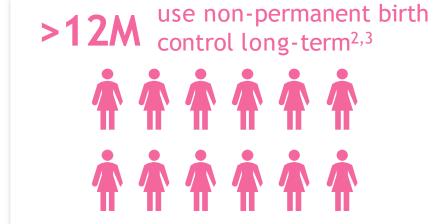
\$3B annual market opportunity

\$20B total market expansion

1.2M

women choose surgical tubal ligation as a form of permanent birth control every year<sup>2,4</sup>







<sup>1</sup> Jones et. al, Current contraceptive use in the United States, 2006–2010, and changes in patterns of use since 1995. National health statistics reports; no 60. Hyattsville, MD: National Center for Health Statistics. 2012.

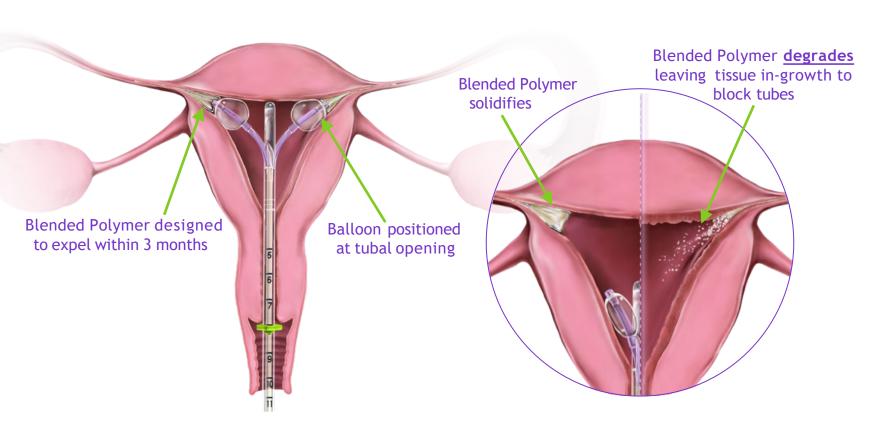
<sup>&</sup>lt;sup>2</sup> Daniels et. al, Current contraceptive status among women aged 15-49: United States, 2017–2019. NCHS Data Brief, no 388. Hyattsville, MD: National Center for Health Statistics. 2020.

<sup>&</sup>lt;sup>3</sup> National health statistics reports; no 60. Hyattsville, MD: National Center for Health Statistics. 2012.

<sup>4</sup> Martinez GM. Receipt of family planning services in the United States: 2022–2023. NCHS Data Brief, no 520. Hyattsville, MD: National Center for Health Statistics. 2024. DOI: https://dx.doi.org/10.15620/cdc/169629

## FemBloc Permanent Birth Control & Confirmation Test

# femBloc Safe • Convenient In-Office • Lower Cost

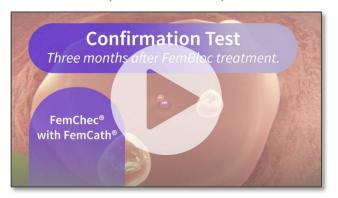




Video will open in browser window.



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



Video will open in browser window.



## FemBloc Clinical Studies for U.S. FDA Approval (PMA)

#### Stage III: FINALE Pivotal Clinical Trial

#### Trial Design (IDE approved June 2023; currently enrolling in U.S.)

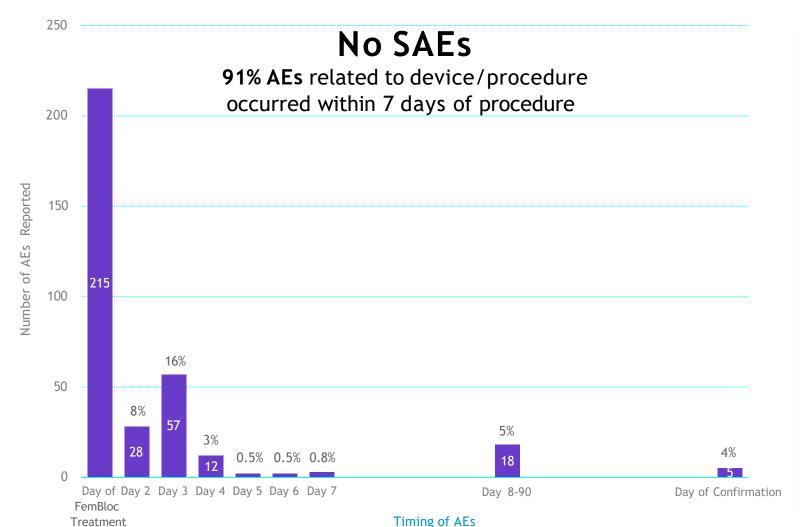
- Prospective, multi-center, open-label, single-arm study with historical control
  - Roll-in study design (50 subjects in part A for safety)
  - Primary Endpoint: pregnancy rate at 1-year after using FemBloc (N=401)
- Additional Analysis:
  - Safety, including 2-5 years post-market
  - Interim analysis: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

Completed Earlier FemBloc Clinical Studies (N=321)			
Early Clinical (N=93)	Stage I: Safety (N=183); IDE approved	Stage II: Validation (N=45); IDE approved	
Evaluated delivery system and blended polymer	No serious AEs reported; 5-year follow-up for safety	Selection of confirmation test for pivotal trial; 5-year follow-up for safety	



## FemBloc Safety Profile

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

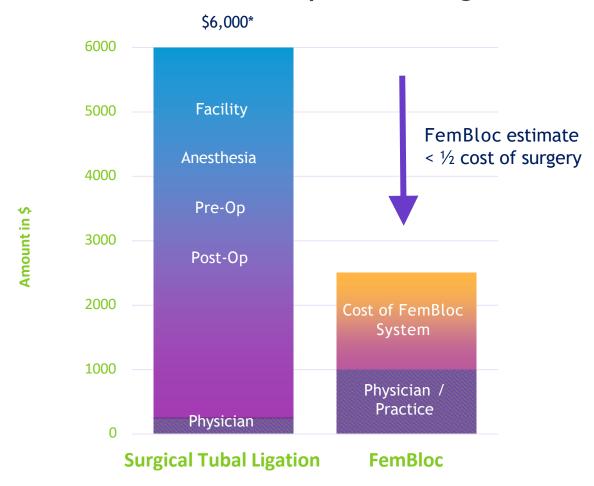


#### Other Key Findings:

- 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

#### U.S. Cost Breakdown Compared to Surgical 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 Birth Control		Temporary
	femBloc°	Surgical Sterilization ( <u>94% effective</u> *)	Essure® No longer marketed ( <u>95% effective</u> *)	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

Broaden market release of infertility product portfolio in U.S. & Spain Increase regulatory country approvals/ registrations for product portfolio Progress FemBloc U.S. pivotal trial to Part B Expand GYN product offerings with new product initiative(s)



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