

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		



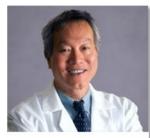
## Key Leadership



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



SVP, Regulatory & Clinical 20+ years of experience GE Healthcare, Boston Scientific, Smiths Medical, RTI Surgical

**Christine Thomas** 



## Solutions for Women Through the Continuum of Care

Office-based, minimally invasive solutions utilizing shared delivery platforms

	Commer	rcially Available I	Products				
femaSeed"		Treatment			Intratubal Insemination		
fem Vue		Diagnostic		Contrast-Generating Device			
<i>f</i> emCath	1	Diagnostic		Selective Delivery Catheter			
femCerv*	I	Diagnostic		Endocervical Tissue Sampler			
		Product Candidate	9				
femBloc'	Research	Preclinical	Stage I Safety	Clinical Trial Stage II Validation	Stage III Pivotal		
Permanent Birth Control							



# Infertility-Focused Portfolio



#### Intratubal Artificial Insemination

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



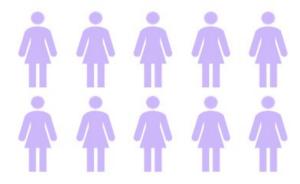
## Tubal Diagnosis with Ultrasound

 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>





## FemaSeed and FemVue Provide Next Generation Options





4.3M seek evaluation only





DIAGNOSIS

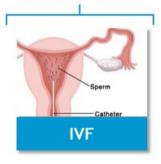


1M cycles/ year



200k

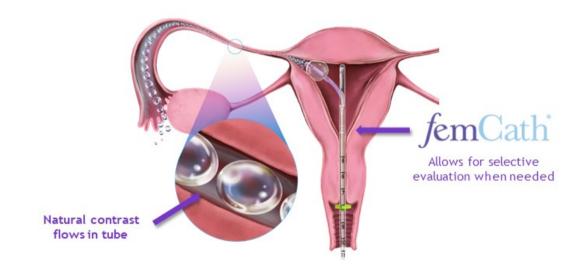
cycles/year





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

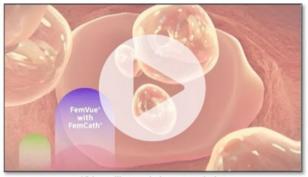




#### Intended Population:

 Baseline diagnostic test for infertility and prior to insemination

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



Video will open in browser window.



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

# femaSeed Safe • Cost-Effective • Enhance Fertilization

# Delivers sperm to site of conception NO CATHETERIZATION

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



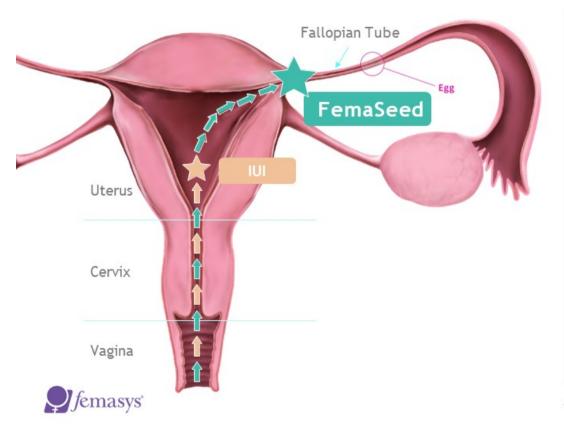
#### Intended Population:

- 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 Reproductive Approaches		Artificial Insemination
	femaSeed	IVF	ICSI	IUI
No surgery	<b>/</b>			<b>/</b>
No egg retrievalor storage	<b>/</b>			<b>/</b>
No required injections	<b>/</b>			<b>/</b>
Delivery to fallopian tubes (site of conception)	<b>~</b>	NA	NA	
Cost-effective	<b>/</b>			<b>/</b>
Minimal safety risks	<b>/</b>			<b>/</b>
Low male sperm count efficacy	<b>/</b>	<b>/</b>	<b>/</b>	
Single fallopian tube solution	<b>/</b>	NA	NA	
Widespread accessibility	<b>/</b>	Varies	Varies	<b>/</b>



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

#### Infertile Women/ Couples Seeking Treatment Population femaSeed" Intrauterine Insemination Intratubal Insemination \$500-\$4,0001 +device Average total per cycle including per cycle above IUI cost Total Cost ultrasound monitoring, and optional ovulation drugs2 If insurance, covered under IUI codes (service, sperm washing) Insurance with positive coverage policy typically covers 3-6 Reimbursement 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 freezing3

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

**lemasys** 







## FemaSeed has Significant Potential Revenue Opportunity

Immediate addressable market

> 1 million\*

IUI cycles/ yr

~\$1 B

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



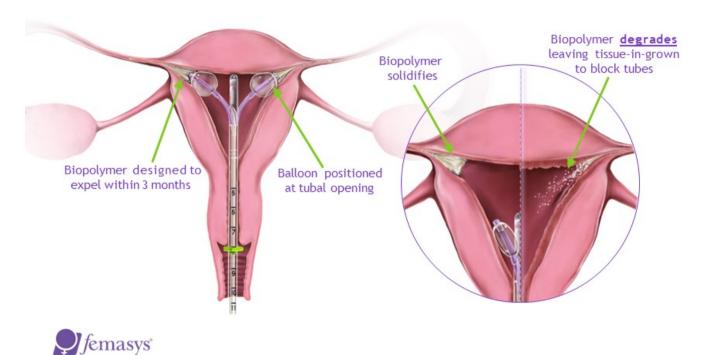


\*Frattarelli 2007

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## 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 Pre-Market Approval (PMA)

#### Stage III: FINALE Pivotal Clinical Trial

Trial Design (IDE approved June 2023; currently enrolling)

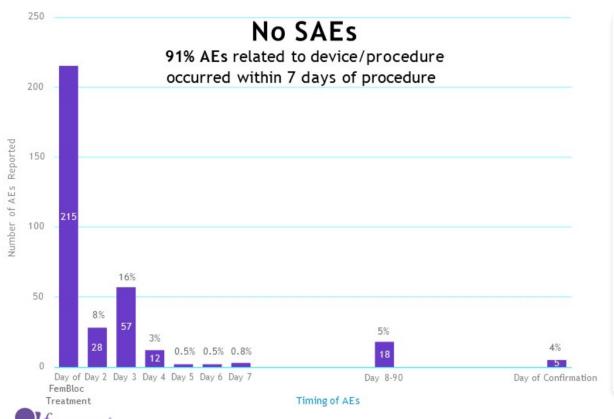
- Prospective, multi-center, open-label, single-arm study
  - Roll-in study design (50 subjects in part A for safety)
  - Endpoints:
    - o Primary: pregnancy rate at 1-year after using FemBloc (N=401)
    - Secondary: safety and various in-office assessments
- Additional Analysis:
  - 2-5 years post-market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

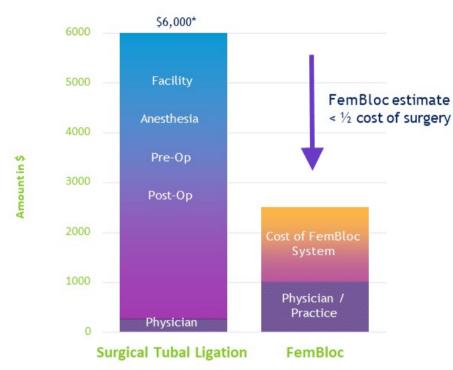


## Other Key Findings:

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



## Milestones

## Inflection points that create value for investors





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**Contact Details** 

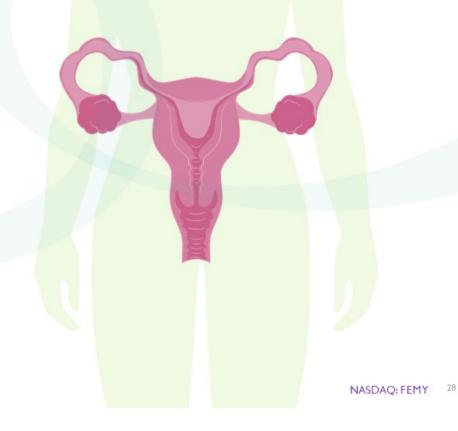
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# **APPENDIX**





## Strategic Commercial Priorities



## Market Positioning & Differentiation

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



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



**I**femasys

## 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

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