



# Disrupting Convention in Women's Reproductive Health Through Continuous Innovation

Investor presentation  
October 2024

NASDAQ: FEMY



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# Femasys Overview

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## 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® Intrauterine Insemination
- FemVue® Contrast-Generating Device

#### Contraception

- FemBloc® Permanent Birth Control

#### Cancer Diagnostic

- FemCerv® Endocervical Tissue 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., Europe, Japan, and Canada

## Foundation

- Woman-founded and led, experienced leadership team
- Intellectual property portfolio with >180 patents globally
- Cash runway into July 2025
- Six commercial-stage products and one in late-stage clinical trial

## NASDAQ: FEMY (IPO June 2021)

Stock Price (as of 10/28/24)	\$1.33
Share Count	22.2M
Market Capitalization (as of 10/28/24)	\$29.6M
Cash (as of 06/30/24)	\$13.5M

# 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

Collectar Biosciences,  
Akari Therapeutics,  
Lev Pharmaceuticals,  
EpiCept



**James Liu, MD**  
Chief Medical Officer

40+ years of experience

Chair, Dept OB/ GYN  
University Health  
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,  
Cytoc 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

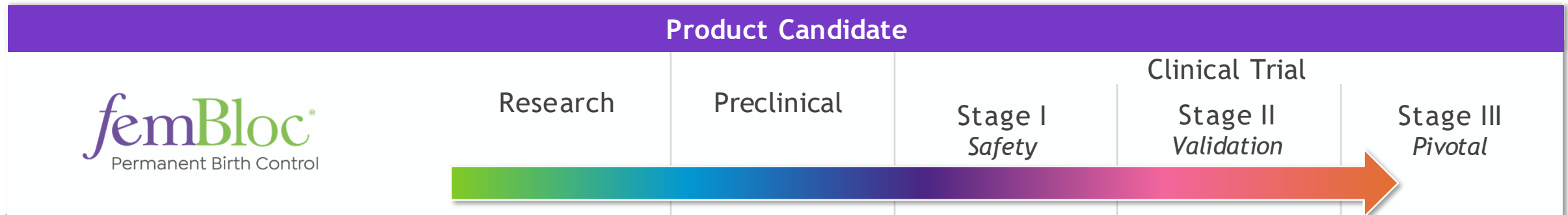
# Solutions for Women Through the Continuum of Care

*Office-based, minimally invasive solutions utilizing shared delivery platforms*

## Commercially Available Products for Infertility

<i>femaSeed</i>	Treatment	Intratubal Insemination
<i>femVue</i>	Diagnostic	Contrast-Generating Device
<i>femCath</i>	Diagnostic	Selective Delivery Catheter
<i>femCerv</i>	Diagnostic	Endocervical Tissue Sampler
<i>femChec</i>	Diagnostic	Controlled Contrast-Generating Device

## Product Candidate



# Infertility-Focused Portfolio

*femaSeed*<sup>®</sup>

## Intratubal Artificial Insemination

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

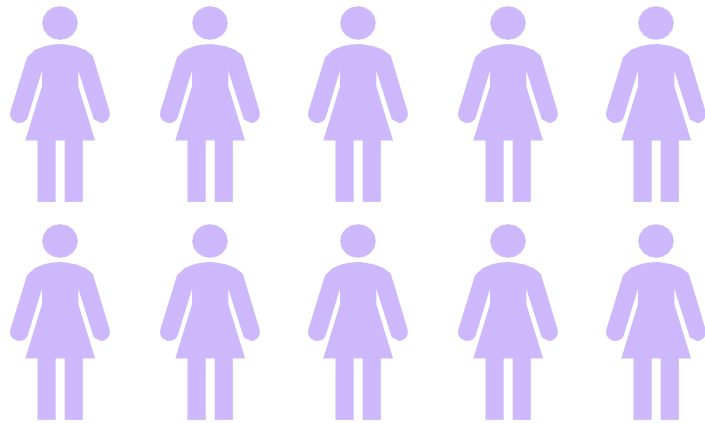
*femVue*<sup>®</sup>

## 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%<sup>3</sup>



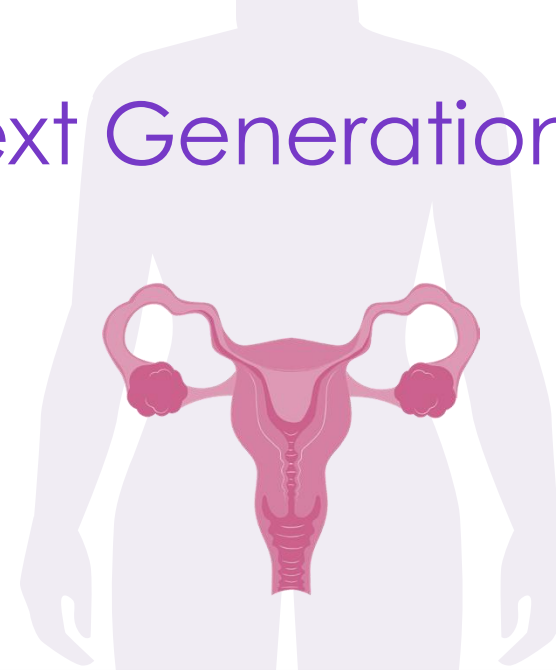
## Key Trends:

- 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>





# FemaSeed and FemVue Provide Next Generation Options



## Patient Journey (U.S.)

**4.3M**  
seek evaluation only



**DISCUSSION**



**DIAGNOSIS**



**DRUGS**



**IUI**



**IVF**

**~1M**  
cycles/ year

**~200k**  
cycles/ year

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

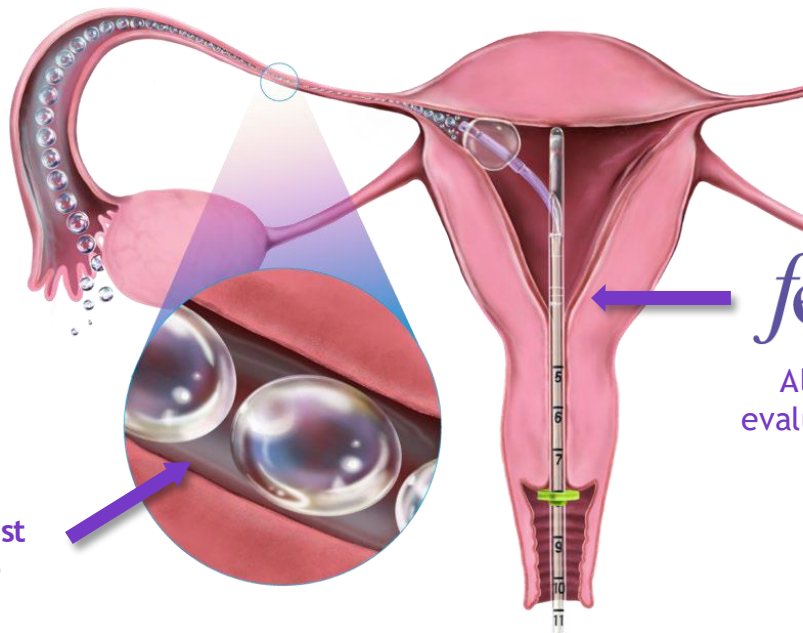
femVue®

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)*



femCath®

Allows for selective evaluation when needed

Natural contrast flows in tube



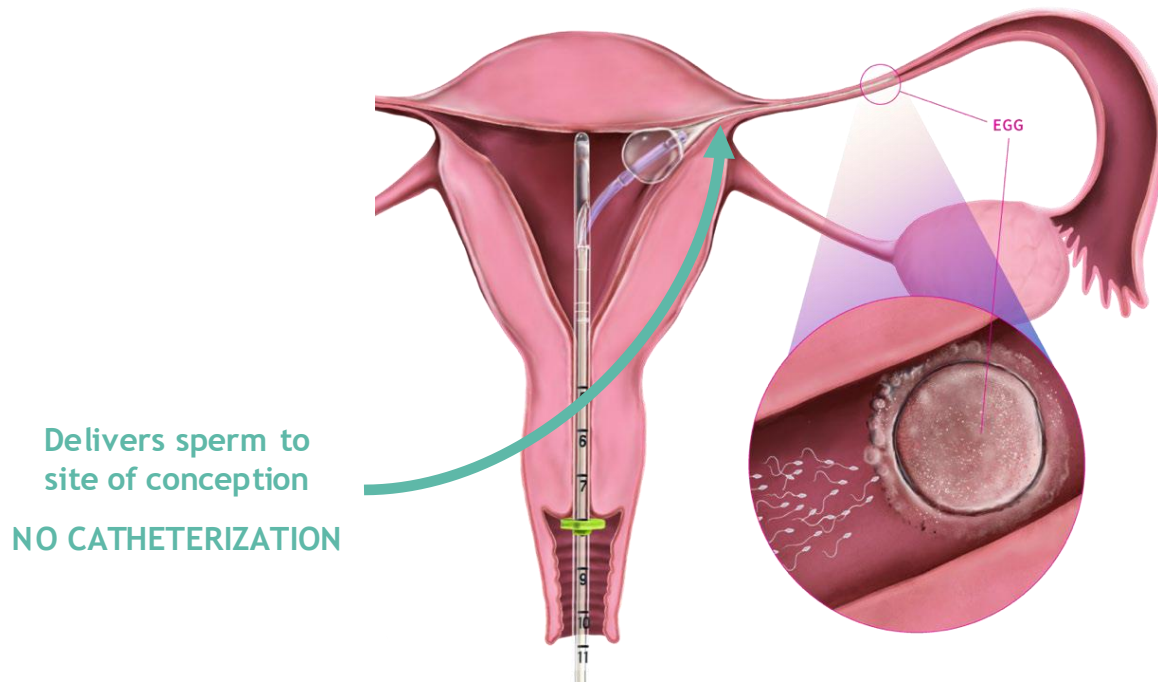
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# Infertility Portfolio: from Diagnosis to *Treatment*

**femaSeed**® Safe • Cost-Effective • Enhance Fertilization

## Intended Population:

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

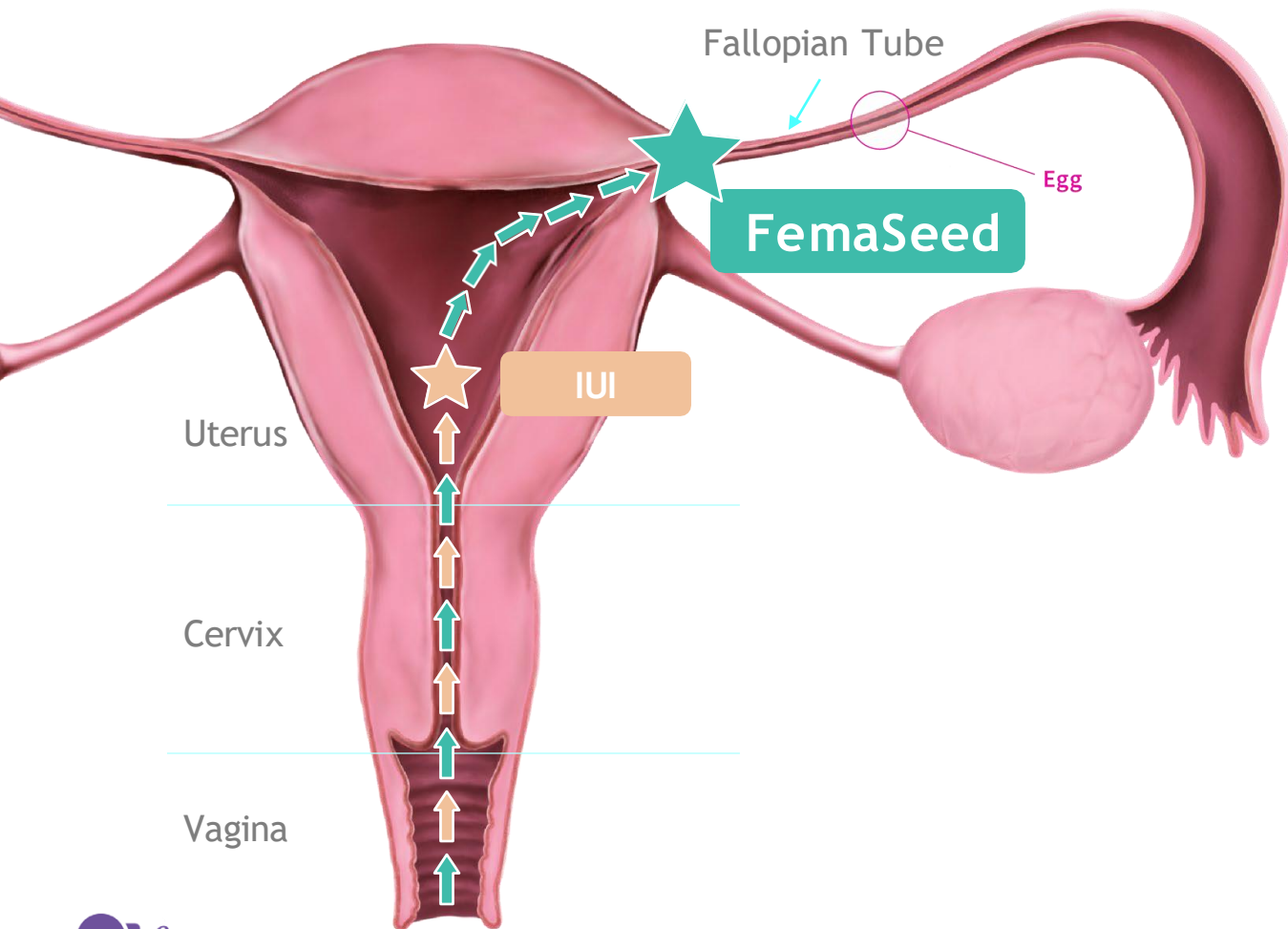


Requires at least one open fallopian tube  
(*FemVue can confirm first*)



Video will open in browser window.

# 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

	femaSeed	Assisted Reproductive Approaches		Artificial Insemination
		IVF	ICSI	IUI
No surgery	✓			✓
No egg retrieval or storage	✓			✓
No required injections	✓			✓
Delivery to fallopian tubes ( <i>site of conception</i> )	✓	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); 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

- ✓ **26.3% pregnancy rate** 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



# Commercialization Strategy in U.S.

## Initial Focus

**~1,700** Infertility Specialists



## Limited Market Release

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

## Expanded Focus

**~40,000** Gynecologists



## 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		Subset of Infertile (After 1-3 IUI cycles or as indicated)
	IUI Intrauterine Insemination	<i>femaSeed</i> Intratubal Insemination	IVF/ICSI In vitro fertilization / intracytoplasmic sperm injection
Average Total Cost	<b>\$500-\$4,000<sup>1</sup></b> total per cycle including ultrasound monitoring, and optional ovulation drugs <sup>2</sup>	<b>+ device</b> per cycle above IUI cost	<b>\$30,000</b> total per cycle, including ultrasound monitoring, ovulation drugs, egg extraction and freezing <sup>3</sup>
Reimbursement	<ul style="list-style-type: none"> <li>Insurance with positive coverage policy typically covers 3-6 cycles</li> <li>Required prior to IVF/ ICSI in many coverage policies</li> </ul>	<ul style="list-style-type: none"> <li>Patient out-of-pocket charge for ITI, If insurance, ancillary services covered under existing codes</li> </ul>	<ul style="list-style-type: none"> <li>14/20 covered states that have fertility insurance coverage, include IVF</li> </ul>
Market Research <sup>4</sup> N=1,000 infertile women	85% of women would have preferred FemaSeed <u>instead of</u> IUI	More than 7 in 10 women were extremely or very likely to consider FemaSeed	88% of women would have preferred FemaSeed <u>prior to</u> 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>.
3. 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





# 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

*fem*Bloc<sup>®</sup>  
Permanent Birth Control

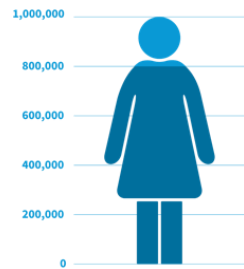
- First and only non-surgical, in-office, permanent birth control option
- In late-stage clinical development with on-going pivotal trial
- Potential to be the safest and most natural approach at substantially less cost than the long-standing surgical alternative

# 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\*

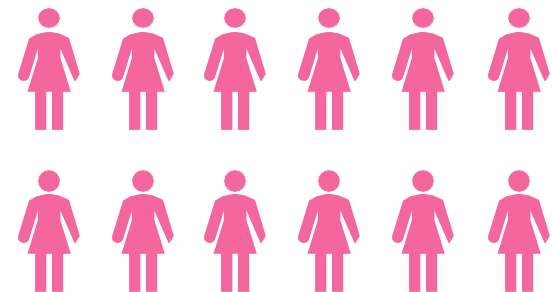


**>13M** Women in the U.S. no longer intend to have children



**\$20B** total market expansion

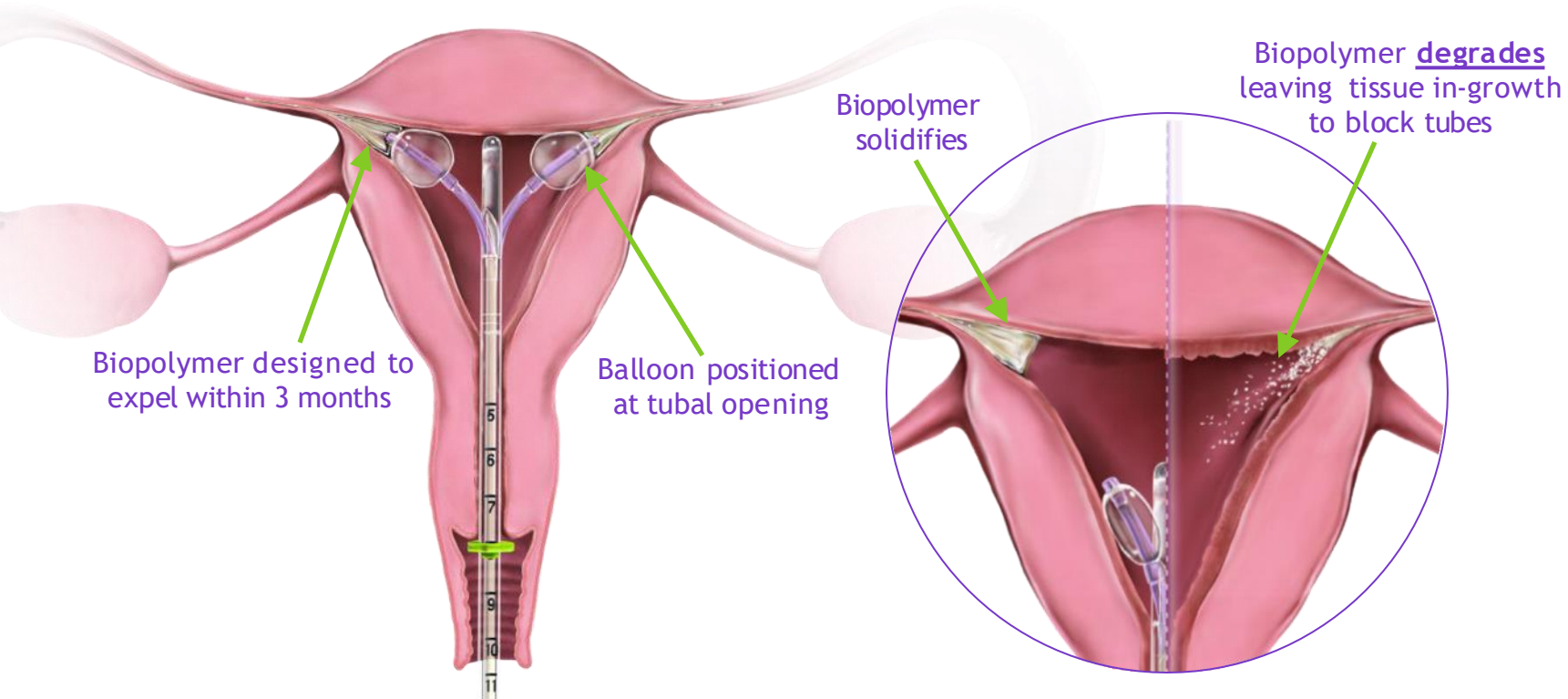
**>12M** use non-permanent birth control long-term



# FemBloc Permanent Birth Control & Confirmation Test

femBloc®

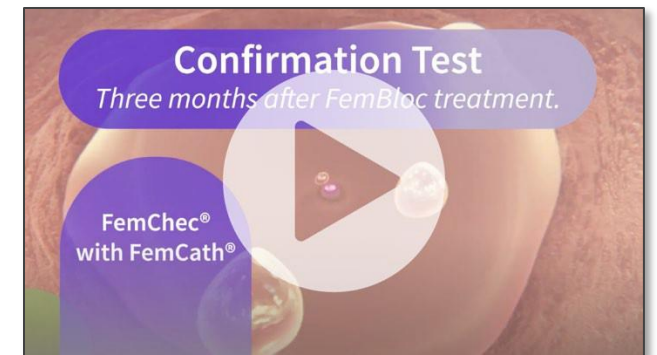
Safe • Convenient In-Office • Lower Cost



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)*

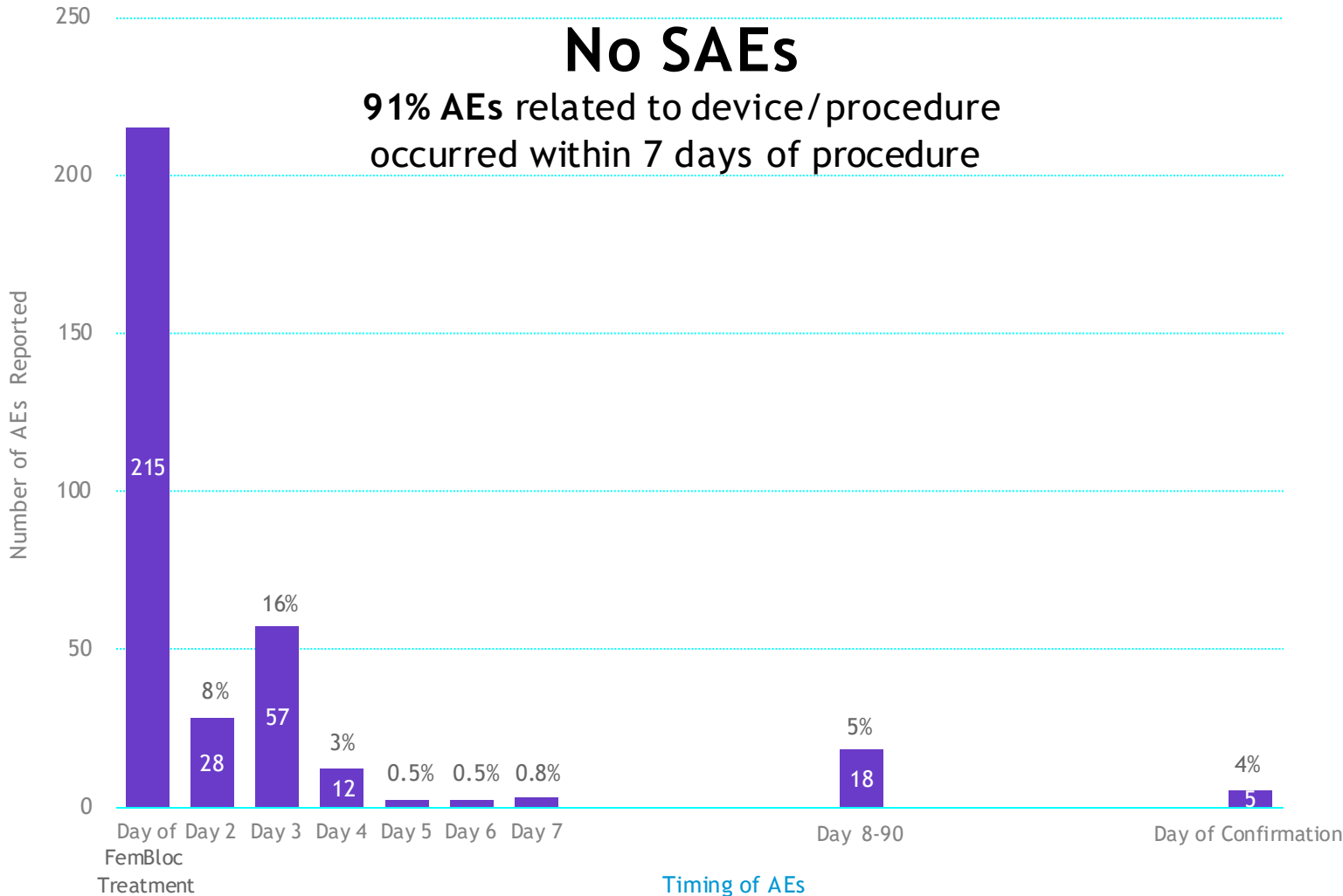
- Prospective, multi-center, open-label, single-arm study
  - Roll-in study design (50 subjects in part A for safety)
  - Endpoints:
    - Primary: pregnancy rate at 1-year after using FemBloc (N=401)
    - Secondary: safety and various in-office assessments
- Additional Analysis:
  - 2-5 years post-market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

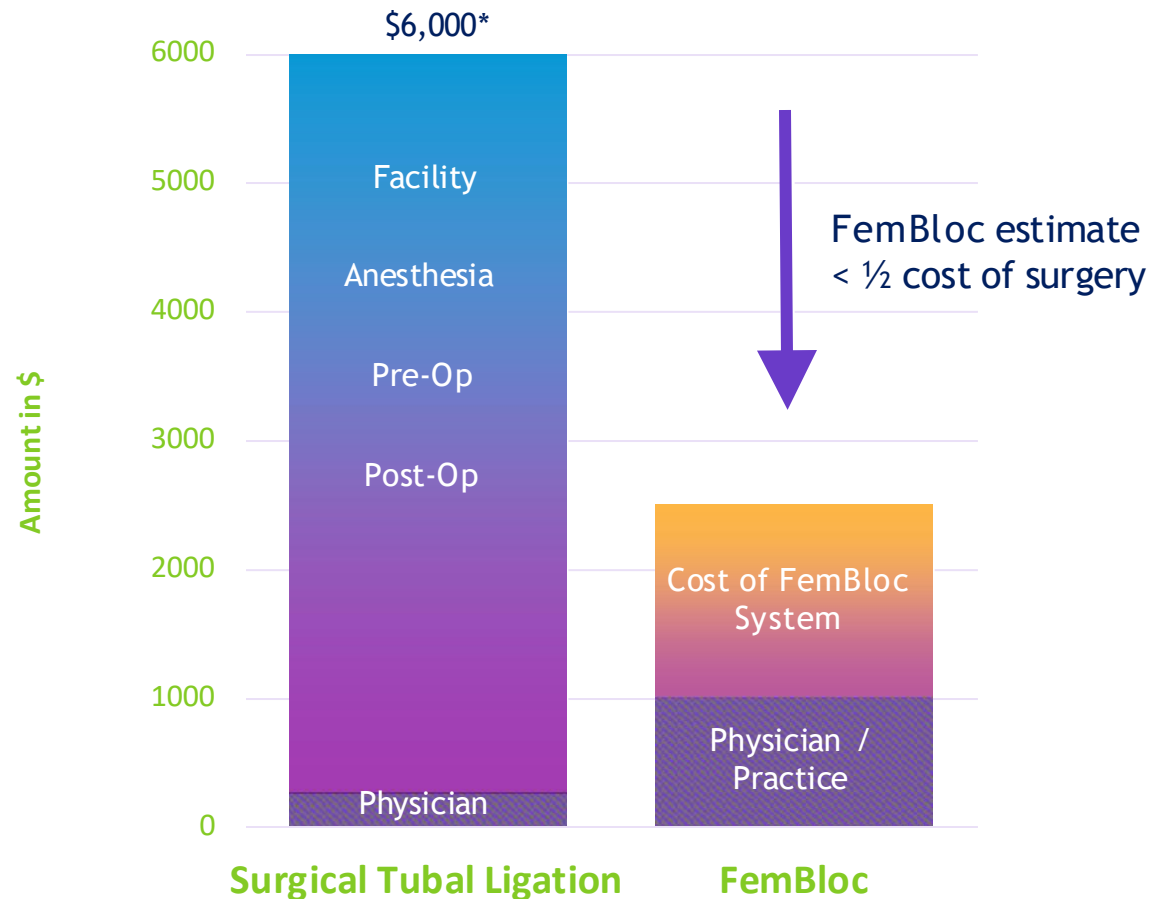


## Other Key Findings:

- **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

	<i>femBloc</i> <sup>®</sup>	Permanent Birth Control		Temporary
		Surgical Sterilization (94% effective*)	Essure <sup>®</sup> <i>No longer marketed</i> (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)



**ACHIEVED**

Initial commercial team on-boarded

Limited market release of infertility product portfolio in North America



**ACHIEVED**

Achieve CE mark for infertility product portfolio



Expand market release of infertility product portfolio to additional regions in North America



# Investment Highlights

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