

# *Developing Transformational Products for Tens of Millions of US Women (Hundreds of Millions Worldwide)*

## Opportunity Overview

Non-Confidential

**Arstat Pharmaceuticals, Inc.**

March 18, 2024



# Why Arstat Pharmaceuticals is a Great Investment

## 1 For the first time, addressing huge public health priorities:

Reliable birth control for 20 million US contraceptive users with overweight and obesity

Decrease in harmful radical surgeries in 15 million US women with uterine fibroids and endometriosis

2 Two Phase III-ready assets (confirmed by the FDA); two likely blockbusters

3 14 patents from a co-inventor of the best-selling US oral contraceptive

4 Strong Management Team, Stellar Advisory Board





5 Exceptional exit opportunities:

 **A Likely IPO (~ 1 year)**  
**ROI Target: 5-6x**

 **EXIT (3.5 - 4 years)**  
**ROI Target: 25-30x**

# Advancing One of the Best Pipelines in Women's Health

- ❖ *First-in-category, transformational products for critical unmet needs*
- ❖ *Strong supporting data; a low-risk, rapid 505(b)(2) NDA pathway*

 <p><b>NUVOCEPT™</b> <i>Phase III-ready</i></p>	<p>The first and only oral contraceptive explicitly designed for women with high BMI. <b>With a unique, highly beneficial label for &gt;50% of the market, projected sales &gt;\$2B/year.</b></p>
 <p><b>PREMRING™</b> <i>Phase IIb asset</i></p>	<p>First-in-category medicated vaginal ring for uterine fibroids and endometriosis. <b>Optimal use of the best class of drugs; &gt;\$1B/year.</b></p>
 <p><b>ENHANTA™</b> <i>Phase IIb asset</i></p>	<p>First-in-category non-hormonal therapy for painful, heavy menstrual periods. <b>Potential first-line for a prevalent disorder.</b></p>
 <p><b>DUACEPT™</b> <i>Phase III-ready</i></p>	<p>First oral contraceptive meeting the consensus criteria of an ideal hormonal combination. <b>The safest pill for normal-weight women.</b></p>

# Team (Management/Advisors)

120+ years of working with leading women's health brands




## Management


**Arkady Rubin, PhD**  
**Founder, Inventor, President/Chief Scientific Officer**  
 An industry veteran (J&J, Pfizer) who designed and executed numerous clinical studies and majorly contributed to the development and FDA approval of top women's health products. **A co-inventor\* of Ortho Tri-Cyclen Lo<sup>®</sup>, one of the best US pills.** Its 9% market share is translated into \$1.8B/year in today's market.



**Wendy J. Weiser**  
**Chief Operating Officer**  
 A founder of one of the largest medical association management firms; an experienced COO



**Jason Spitz, MBA**  
**Chief Commercial Officer**  
 Executive who was responsible for corporate communications in a public women's health company



***We are looking for executives (including a CEO and a Chairman of the Board)***

## Advisory Board

<b>Andrea S. Lukes, MD, FACOG</b> Lead Clinical Advisor	<b>Barbara Levy, MD, FACOG. FACS</b> Medical Affairs Advisor	<b>Agis Kydonieus, PhD</b> Drug Delivery Advisor
<b>Linda Shapiro Manning, MD, PhD</b> Clinical Development Advisor	<b>Russell Barrans, MBA</b> Commercial Strategy Advisor	<b>Sarita Stefani, MS</b> Corporate Strategy Advisor
<b>Marina Ness, MPH</b> Social Media Advisor		

\*Patents: EP1140109, AU765153, CA2356747, and many others

# For the First Time, Addressing a Major Public Health Challenge

## Safe and Effective Hormonal Contraception for Women with High BMI



≈ 40% of US women have obesity\*



≈ 25% women are overweight\*

**20 million of US women with overweight and obesity search for reliable birth control**  
— with common choices (hormonal pills, patches, and rings) performing poorly in this population



**Women with obesity have up to 4.3 times greater chance of an unintended pregnancy\*\***



**Women with obesity have up to 3.7 times greater odds of terminating a pregnancy\*\***

**The overruling of Roe disproportionately impacts women with high BMI**

**It is exceptional, if not historic, timing to develop Nuvocept™**

\* The rates are for reproductive-age US women. Body Mass Index (BMI) categories: - Obese - BMI  $\geq 30$  kg/m<sup>2</sup>; Overweight - BMI 25 - 29.9 kg/m<sup>2</sup>.

\*\* Daskoch P. Obesity linked to elevated risk of unintended pregnancy, abortion, STDs. *Perspectives on Sexual and Reproductive Health*. 2010;42:276.

# NUVOCEPT™ - A Truly Powerful Asset

The first and only oral contraceptive explicitly designed for women with high BMI

## 1 Unprecedented Label

New indication and unique claims for a lasting competitive advantage

## 2 Phase III-Ready

Successful meeting with the FDA; an abbreviated program is finalized

## 3 Projected Sales >\$2B/year

It will likely dominate a multi-billion-dollar segment of the US market



## 4 Rapid, Low-Cost R&D

< \$20M in total costs and <3.5 years to the FDA approval

## 5 Low-Risk

Validated by the FDA acceptance of safety and efficacy projections

## 6 Strong IP Portfolio

Seven US patents and an EU patent covering major European markets

The FDA approved the first-ever contraceptive clinical program dedicated to women with overweight and obesity

# NUVOCEPT™ – Exciting Market Opportunity

## Benefits for Lasting Competitive Advantage

- 1 Unique indication and labeling claims
- 2 Unprecedented database for women with high BMI
- 3 Reduced risk of pregnancy and serious side effects
- 4 No contraindications or limitations of use



Will likely be accepted as the 1<sup>st</sup> line oral contraceptive for women with high BMI (≈ 60% of the market)

## According to top experts, US gross sales may exceed \$2B/year

- At a branded price, the value of the US market is **\$20B (\$200M for each % of total Rx)**.
- With the only label for women with obesity, NUVOCEPT will dominate a \$6B segment.
- With overweight women (≈30% of users) excluded, this assessment is very conservative.

# Why PREMRING™ for Uterine Fibroids and Endometriosis?

*To fight severe reproductive disorders that destroy millions of lives*

- **25%\*** of US women (>20 million) have symptomatic uterine fibroids
- **10%\*** of US women (>10 million) suffer from endometriosis
- Terrible menstrual cramps, pelvic pain, heavy menstrual bleeding, infertility
- **400,000 hysterectomies/year; at least 13 million US women had their uterus removed because of uterine fibroids and endometriosis**

*Unlike other treatments, designed as an alternative to radical surgeries*

- Low doses of a well-studied SPRM\* are delivered by a novel route directly to affected tissues.
- **Unrivalled efficacy and safety permit comfortable long-term treatment** (not an option for other hormonal medications), **drastically reducing the need for hysterectomies.**

**A breakthrough solution** for highly prevalent and undertreated conditions.

\* Prevalence among women aged 15-49 years



# PREMRING™: Valuable Asset in Fast-Growing Markets

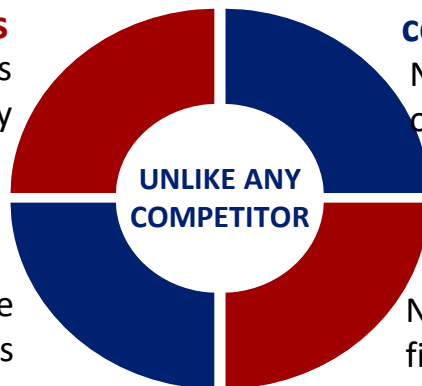
*Expected US gross sales - \$1.33B/year; >\$1B in each indication (worldwide)*

**Unlike GnRH agonists and antagonists**

No hot flashes, vaginal dryness or decrease in bone density

**Unlike progestin-only and combined contraceptives**

No permanent amenorrhea or other hormonal side effects



**Unlike oral SPRMs**

A significant shrinkage of uterine fibroids and endometrial implants

**Unlike NSAIDs**

Not just pain relief; the size of fibroids and implants is also reduced

Competitors focus on the symptoms.  
**PREMRING is designed as a curative option.**

**Compelling supporting data greatly reduces the R&D risks and ensures a high probability of PREMRING approval**

# Arstat Pipeline: Additional Details

## Other Products: Highlights

### ENHANTA™

- **First single non-hormonal therapy for painful, heavy menstrual periods** (>25 million US women)
- **Novel drug combination (Rx and OTC)**, with no competition.
- **Phase IIb asset**; could be ready for Phase III (FDA confirmation needed)
- **Projected US Gross Sales -\$520M**

### DUACEPT™

- **An improved version of the world-leading oral contraceptive** for 3 million normal-weight users
- **Phase III-ready**: \$5M in total costs if developed in parallel with NUVOCEPT.
- **In some countries, it may be approved with no new clinical data.**
- **Projected US Gross Sales -\$140M**

## Large and growing IP portfolio (13 granted US patents and an EU patent)

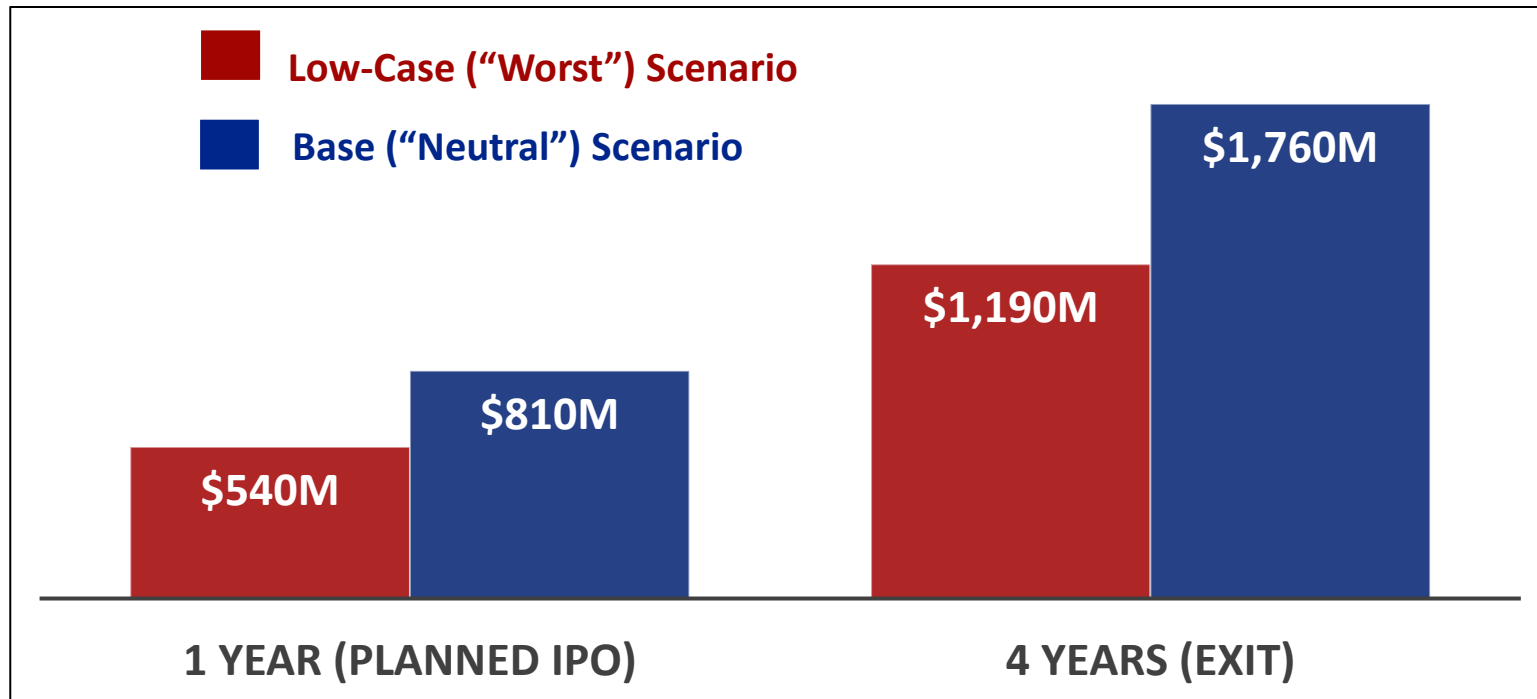
**13 US Patents:** 9,675,622; 9,925,199; 10,111,887; 10,463,678; 10,537,582; 11,103,515; 11,717,527; 10,251,836; 11,116,718; 10,532,037; 10,709,679; 11,351,132; 11,833,126; **10+ more US patents planned**; **European (EU) Patent:** EP 2790688 B1.

Issued and new US patents and regulatory exclusivity are expected to **protect the products until at least 2037**, possibly much longer

*The Sole Inventor and Owner, Founder - Arkady Rubin, PhD* 

# Arstat Pharmaceuticals: Valuation\*

The fair company's value (NPV\*\*) at key milestones



\* In collaboration with **Bio-strategy Analytics**, ARSTAT determined the portfolio value in 1 year and 4 years (after the approval of NUVOCEPT/DUACEPT and the completion of PREMIRING and ENHANTA R&D). A 49-page report is available.

\*\*The NPV (Net Present Value) is calculated using the Discounted Cash Flow (DCF) and Risk-Adjusted (eNPV) methods.

# Exit Opportunities and ROI Targets

 **~ 1 year**

**IPO**  
(subject to market conditions)

**ROI Target: 5-6x\***

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 **3.5 - 4 years**

**EXIT**

**ROI Target: 25-30x\*\***

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 **Acquisition**

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**OR**

**A Valuable Public Company** 

With a projected market cap of > \$1.2B

\***Conservative estimate:** assuming the IPO valuation is < 30% of the low-case portfolio value. See slide 11.

\*\***Conservative estimate:** assuming the low-case valuation scenario at the exit. See slide 11.

# Arstat Pharmaceuticals: 4-5 Year Plan

Exit: Company Sold or Reaches  
a Market Cap of > \$1.2B

4 2028

3 2027-2028



NUVOCEPT - FDA Approval  
DUACEPT - FDA Approval  
ENHANTA - nearing FDA Approval  
PREMRING – sold or in Phase III

Private Placement  
and an IPO\*

2 2024-2025

1 2024 Bridge Financing (\$1M)

\* Subject to market conditions; otherwise, a reverse merger or Series B round



# Arstat Pharmaceuticals: The Ask and Action Plan

**ARSTAT is raising \$1M (Bridge Financing)** to continue R&D and corporate development activities in preparation for a \$5M private placement followed by an IPO

- **SAFE Notes**
- **\$20M Valuation Cap (Post-Money)**
- **20% Discount**

*Target Closing: July 2024*

## Major Tasks

- Finalize executive team and assemble a well-connected board of directors
- Conduct one more pre-IND meeting with the FDA (ENHANTA)
- Prepare the IND application (NUVOCEPT/DUACEPT); select vendors for the Phase III study
- Expand an outreach to potential partners and support the private placement

## Pending Next Steps

- **Private placement by a broker-dealer**
- \$5M preferred equity (“qualified financing”)
- Target Closing: November 2024

- **Firm-commitment IPO\***
- At least \$120M pre-money valuation
- Timing: Q1 or Q2 of 2025

*\*If market is not supportive, a reverse merger may be considered*

# A Likely IPO (Q1 or Q2 of 2025): Strategic Considerations

- 1 Investment bankers consider Arstat a potentially great public company**
  - rapid, low-risk, low-cost R&D, huge markets, clear and achievable strategic goals
- 2 Validated by two engagement offers for valuable firm-commitment IPOs**
- 3 Impeccable market timing**
  - the overruling of Roe v. Wade makes NUVOCEPT a precious opportunity for IPO investors
- 4 More advanced pipeline vs. 2/3 of biopharma IPOs\***
- 5 A notable precedent: Myovant Sciences**
  - a women's health pharma company had the largest biotech IPO of 2016, eight months after its launch, with a few employees\*\*
  - with a pipeline arguably comparable to ARSTAT's
  - from the initial funding round (\$7M) to a \$2.9B exit in  $\approx$  6 years



\* [www.mtspartners.com/wp-content/uploads/sites/2/2016/08/Early-Stage-IPOs-2012-2018-August-2018.pdf](http://www.mtspartners.com/wp-content/uploads/sites/2/2016/08/Early-Stage-IPOs-2012-2018-August-2018.pdf)

# Summary of the Investment and Partnership Opportunity

- ✓ **For the first time, addressing huge public health priorities**
  - reliable contraception for women with high BMI
  - comfortable long-term therapy for uterine fibroids and endometriosis
- ✓ **A 4-product pipeline includes two Phase III assets and two likely blockbusters**
- ✓ **14 patents from a co-inventor of the best-selling US oral contraceptive**
- ✓ **Strong supporting data; expertise to deliver (120+ years with leading brands)**
- ✓ **Looking for senior executives (including a CEO and a Chairman of the Board)**
- ✓ **An exceptional near-term exit option (a likely IPO in  $\approx$  1 year)**



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