

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

# **Opportunity Overview**

Non-Confidential

Arstat Pharmaceuticals, Inc.





# 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:



**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



The first and only oral contraceptive explicitly designed for women with high BMI. With a unique, highly beneficial label for >50% of the market, projected sales >\$2B/year.



First-in-category medicated vaginal ring for uterine fibroids and endometriosis. Optimal use of the best class of drugs; >\$1B/year.



**ENHANTA** TM Phase IIb asset **First-in-category non-hormonal therapy** for painful, heavy menstrual periods. Potential first-line for a prevalent disorder.



First oral contraceptive meeting the consensus criteria of an ideal hormonal combination. The safest pill for normal-weight women.



## **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®**, 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



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**

Andrea S. Lukes, MD, FACOG Lead Clinical Advisor	Barbara Levy, MD, FACOG. FACS Medical Affairs Advisor	Karen Drexler, BSE, MBA Corporate Development Advisor
Agis Kydonieus, PhD Drug Delivery Advisor		Russell Barrans, MBA Commercial Strategy Advisor
Akifa Khattak, JD, MHA, MS Biotech Strategy Advisor	Sarita Stefani, MS Corporate Strategy Advisor	Marina Ness, MPH Social Media Advisor



## 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 disproportionally impacts women with high BMI

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

<sup>\*</sup> The rates are for reproductive-age US women. Body Mass Index (BMI) categories: - Obese - BMI ≥ 30 kg/m²; Overweight - BMI 25 - 29.9 kg/m².

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



# **NUVOCEPT<sup>TM</sup> - 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-billiondollar 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**<sup>TM</sup>



# **NUVOCEPT<sup>™</sup> – 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<sup>TM</sup> 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.
- Unrivaled efficacy and safety permit comfortable long-term treatment (not an option for other hormonal medications), drastically reducing the need for hysterectomies.

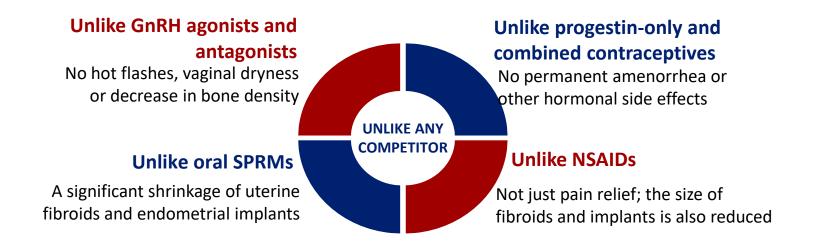
A breakthrough solution for highly prevalent and undertreated conditions.

<sup>\*</sup> Prevalence among women aged 15-49 years



# PREMRING<sup>TM</sup>: Valuable Asset in Fast-Growing Markets

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



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**<sup>TM</sup>

- 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<sup>TM</sup>**

- 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

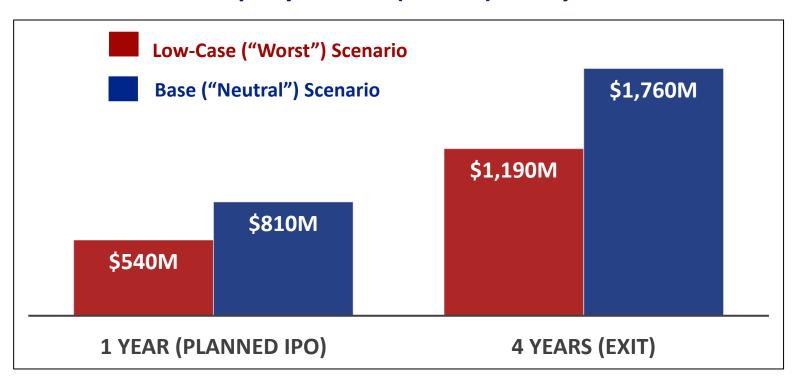
The Sole Inventor and Owner, Founder - Arkady Rubin, PhD





## **Arstat Pharmaceuticals: Valuation\***

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



<sup>\*</sup> 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 PREMRING and ENHANTA R&D). A 49-page report is available.

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



# **Exit Opportunities and ROI Targets**





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

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



## **Arstat Pharmaceuticals: 4-5 Year Plan**



Private Placement and an IPO\*

2 2024-2025

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

1 2024 Bridge Financing (\$1M)

<sup>\*</sup> 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) ahead of a private placement and an IPO

SAFE Notes

\$20M Valuation Cap (Post-Money)

**Closing: 7/2024** 

## The investors of this round are expected to own 5% of the public company

## **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**

- A \$5M private placement by a broker-dealer
- Target closing: November 2024

- Firm-commitment IPO\* (Q1/Q2 2025)
- At least \$120M pre-money valuation

<sup>\*</sup>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
- Validated by two engagement offers for valuable firm-commitment IPOs
- 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

<sup>\*</sup> 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 ≈ 1 year)



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8

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