

# *Transforming Care for Critical Women's Health Needs*

## **Opportunity Overview**

Non-Confidential

**Arstat Pharmaceuticals, Inc.**

May 19, 2025



## ***Arstat Pharmaceuticals - Executive Summary***

***For the first time, addressing high women's health priorities:***

**Reliable birth control for 20 million US  
contraceptive users with high BMI  
(overweight and obese)**

**Significant decrease in harmful surgeries  
in 15 million US women with uterine  
fibroids and endometriosis**

- **A world-class, advanced four-product pipeline for ~62 million US women**
- **Two Phase III-ready assets (confirmed by the FDA); two likely blockbusters**
- **15 US and EU patents** from a co-inventor of the best-selling US oral contraceptive
- **A team of distinguished women's health experts and advocates**
- **A profitable exit strategy for investors**



**A Likely IPO (~ 1 year)**

**ROI Target: 5-6x**




**EXIT (3.5 - 4 years)**


**ROI Target: 25-30x**

## One of the best pipelines in women's health

- *First-to-market, clinically differentiated 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 designed for women with high BMI (&gt;50% of the market); <b>projected sales - \$1-2B/year.</b></p>
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 <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>
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 <p><b>ENHANTA™</b> <i>Phase IIb asset*</i></p>	<p>First-in-category single non-hormonal therapy for painful, heavy menstrual periods. <b>Potential first-line for a prevalent disorder.</b></p>
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 <p><b>DUACEPT™</b> <i>Phase III-ready</i></p>	<p>The first oral contraceptive for women with cardiovascular risk factors. <b>The safest option for normal-weight pill users.</b></p>
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\* The clinical development stage after the completion of pre-clinical activities

## Summary of Markets and Projected Sales

- **Across the entire portfolio:**
  - *an addressable market: ≈ 62 million US women (> 800 million worldwide)*
  - *projected peak annual gross sales (US): at least \$2.9B, could be close to 4.8B*
- **NUVOCEPT & PREMRING are potential leaders in multi-billion-dollar markets**

Product	Addressable US Market	Peak Gross Annual Sales (US Only)*	
		“Base” Scenario	“Upside” Scenario
NUVOCEPT	≈ 20 million	\$1,070M	\$2.260M
DUACEPT	≈ 3 million	\$140M	\$180M
PREMRING - Uterine Fibroids	≈ 9 million	\$570M	\$800M
PREMRING - Endometriosis	≈ 5 million	\$760M	\$890M
ENHANTA (Rx)	>25 million	\$430M	\$650M
<b>Total</b>	<b>≈ 62 million</b>	<b>\$2,970M</b>	<b>\$4,780M</b>

 **\*All assessments utilize very conservative market share and pricing assumptions**

# Arstat Pharmaceuticals: Leadership

## Arkady Rubin, PhD, Founder, Inventor, President/CSO



- Industry veteran (J&J, Pfizer) who designed and executed numerous clinical studies and contributed to the development and FDA approval of top women's health products
- Co-inventor\* of Ortho Tri-Cyclen Lo<sup>®</sup>, one of the best US oral contraceptives (\$1.8B/year in current market conditions). Authored 20+ patents and multiple publications

## Jon Stelzmler, Acting CEO, Prospective Board Member



- A proven business leader with 4 decades of achievements in specialty markets, including women's health. A builder of high-performing teams and innovative market solutions.
- Career highlights: President of US Specialty Business (Lupin); Senior VP & General Manager of a \$1B Women's Healthcare Franchise (Bayer); Vice President (Pfizer)

## Andrea S. Lukes, MD, MHSc, FACOG, Chief Medical Officer



- For 8 years, served as a Chief Medical Officer at Health Decisions, a leading women's health CRO (sold to Premier Research); Owner of a private practice/research center
- A well-published principal investigator in over 150 clinical trials; Consultant to major women's health companies (e.g. Myovant, Bayer, Abbvie), presenter at FDA meetings.

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

# Advisory Board

120+ years of developing leading women's health brands



## Elite Group of Women's Health Leaders and Advocates (Past and Current Advisors)

<p><b>Elizabeth Garner, MD, MPH</b> A Past President of the American Medical Women's Association</p>	<p><b>Barbara Levy, MD, FACOG. FACS</b> A health care access expert, a previous ACOG's VP for health policy</p>	<p><b>Jeffrey M. Cohen</b> Founder &amp; CEO of 3 life sciences companies with successful exits.</p>
<p><b>Karen Drexler, BSE, MBA</b> A former CEO, recipient of the Female Entrepreneur of the Year Award</p>	<p><b>Linda Shapiro Manning, MD, PhD</b> Physician scientist, executive, and a prominent obesity expert</p>	<p><b>Russell Barrans, MBA</b> A commercial expert who introduced widely known contraceptive brands.</p>
<p><b>Agis Kydonieus, PhD</b> A founder of the Controlled Release Society, 10 books on drug delivery</p>	<p><b>Sarita Stefani, MS</b> Women's rights advocate, a CEO of Amilis, an exceptional startup</p>	<p><b>Marina Ness, MPH</b> Public health professional in patient-centric market research</p>

*We are seeking senior executives, advisors, and Company's Board members*

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

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



≈ 40% of US women have obesity\*



≈ 25% women are overweight\*

### 20 million US women with high BMI need reliable birth control

— with common choices (hormonal pills, patches, and rings) performing poorly in this population



Obese women have up to **4.3x greater** chance of an unintended pregnancy\*\*



Obese women have up to **3.7x greater** odds of terminating a pregnancy\*\*

The overruling of Roe disproportionately impacts women with high BMI, making their need for dependable contraception more urgent than ever.

\* 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<sup>1</sup> with the FDA; an abbreviated program is finalized

### **3 Projected Sales - \$1-2B/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 overweight and obese women.**

<sup>1</sup> While the meeting was formally classified as a pre-IND meeting, it accomplished all objectives of a pre-Phase III meeting



## ***Problem: Marketed Contraceptives are Not Intended for Women with High BMI***

**Excluding from pivotal trials**

Most Phase III trials excluded women with high BMI, and many approved contraceptives are marketed to an unstudied population

**Delivering suboptimal doses**

Due to poor drug absorption, women with high BMI receive 70-80% of the nominal dose<sup>1,2,3,4,5</sup>, with unsatisfactory pregnancy prevention

**Increasing cardiovascular risks**

Modern contraceptive formulations are not suitable to women with high BMI due to a higher rate of serious cardiovascular events<sup>6,7,8</sup>



### **Unacceptable performance of All Recently Approved Combined Hormonal Contraceptives:**

- **Generess®(2011): Risk of pregnancy increases by 72% for women with obesity<sup>9</sup>**
- **Quartette®(2013): Pregnancy rates greater by 86% for women with obesity<sup>10</sup>**
- **Annovera®(2018): Due to safety risks, clinical testing of women with obesity was terminated<sup>11</sup>**
- **Twirla®(2020): Contraindicated in women with obesity; a limitation of use in overweight women<sup>12</sup>**
- **Nextstellis®(2022): Due to decreasing effectiveness, limitation of use in women with obesity<sup>13</sup>**

Selected Sources: <sup>1</sup>Edelman (2009), <sup>2</sup>Edelman (2014), <sup>3</sup>Westhoff (2010), <sup>4</sup>Evra (2001), <sup>5</sup>Robinson (2013), <sup>6</sup>Arstat Pharmaceuticals, Inc. (Data on file), <sup>7</sup>Abdollahi (2003), <sup>8</sup>FDA (2011), <sup>9</sup>Yamazaki (2015), <sup>10</sup>NDA 204061 (2013), <sup>11</sup>Annovera (2018), <sup>12</sup>Twirla (2020), <sup>13</sup>Nextstellis (2021)

# **Our Solution: FDA-Endorsed NUVOCEPT™**

**Novel oral contraceptive uniquely formulated for women with high BMI**

<b>Highly Effective</b>
<b>Up to 3 times lower pregnancy rates vs. leading brands</b>

<b>Very Safe</b>
<b>2 – 3-fold reduced risk of serious side effects vs. modern pills</b>

**The FDA has recognized the importance of NUVOCEPT and allowed its move to Phase III**


<b><i>“Women will LOVE it”</i></b>
<b>(Andrea S. Lukes, MD, MHSc FACOG)</b>
Dr. Lukes conducted >80 trials of women’s health products.

- ✓ **NUVOCEPT efficacy and safety projections accepted**
  - no need for Phase I or Phase II data\*
  - the FDA has agreed with the immediate dosing of 1,500+ women
- ✓ **NUVOCEPT’s unprecedented label is conceptually endorsed**
  - Beneficial claims for overweight and obese women
  - No contraindications or limitations of use
- ✓ **The first-ever program entirely dedicated to women with high BMI is finalized**

\*At least seven other approved oral contraceptives also started clinical testing in Phase III

## NUVOCEPT – Projected Peak Sales: \$1-2B/year (US Only)

Valuation Scenarios	Market Share*	Rebates	Gross Sales	Net Sales
“Base”	10%	50%	\$1,070M	\$963M
“Upside”	15%	30%	\$2,260M	\$2,034M

 \*With exclusive label and superior safety and efficacy, NUVOCEPT will likely be accepted as the 1<sup>st</sup> line oral contraceptive for women with high BMI (≈ 60% of the market)

**Conservative Marketing Assumptions** 

Sales Forecasting Metrics	“Base”	“Upside”
Market Size, Monthly TRx (m)	100	100
Market Share at Peak	10%	15%
Filled Prescriptions at Peak (m)	10	15
Gross (AWP**) Price (\$)	215	215
Gross Revenue (m)	2,150	3,225
Rebates and discounts	50%	30%
Net selling price per monthly Rx (\$)	107	150
Net Revenue (m)	1,070	2,260
COGS Ratio	10%	10%
Gross Profit (m)	963	2,034

\*\*AWP = Average Wholesale Price; from Information for Vermont Prescribers of Prescription Drugs: [https://www.compliance.bayerweb.com/AWP/Bayer\\_2025M01\\_VermontShortForm\\_NATAZIA.pdf](https://www.compliance.bayerweb.com/AWP/Bayer_2025M01_VermontShortForm_NATAZIA.pdf)

## *Why PREMURING™ 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 harmful 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™ - Differentiation and Market Opportunity

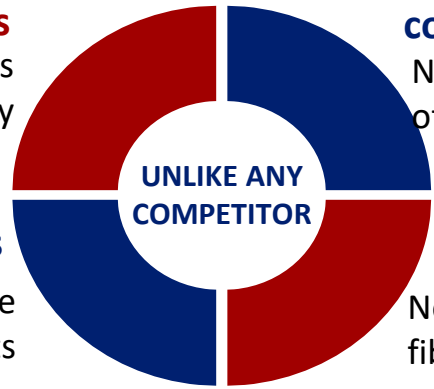
Expected US gross sales - \$1.33B/year; >\$1B in each indication (worldwide)

**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™

- **Novel non-hormonal therapy for painful, heavy menstrual periods** (>25 million US women)
- **Proprietary 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™

- **Novel oral contraceptive** for 3 million normal-weight women with cardiovascular risk factors.
- **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 (15 granted US and EU patents)

**14 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; 12,005,138

**10+ more US patents planned;**  
European (EU) Patent: EP 2790688 B1.

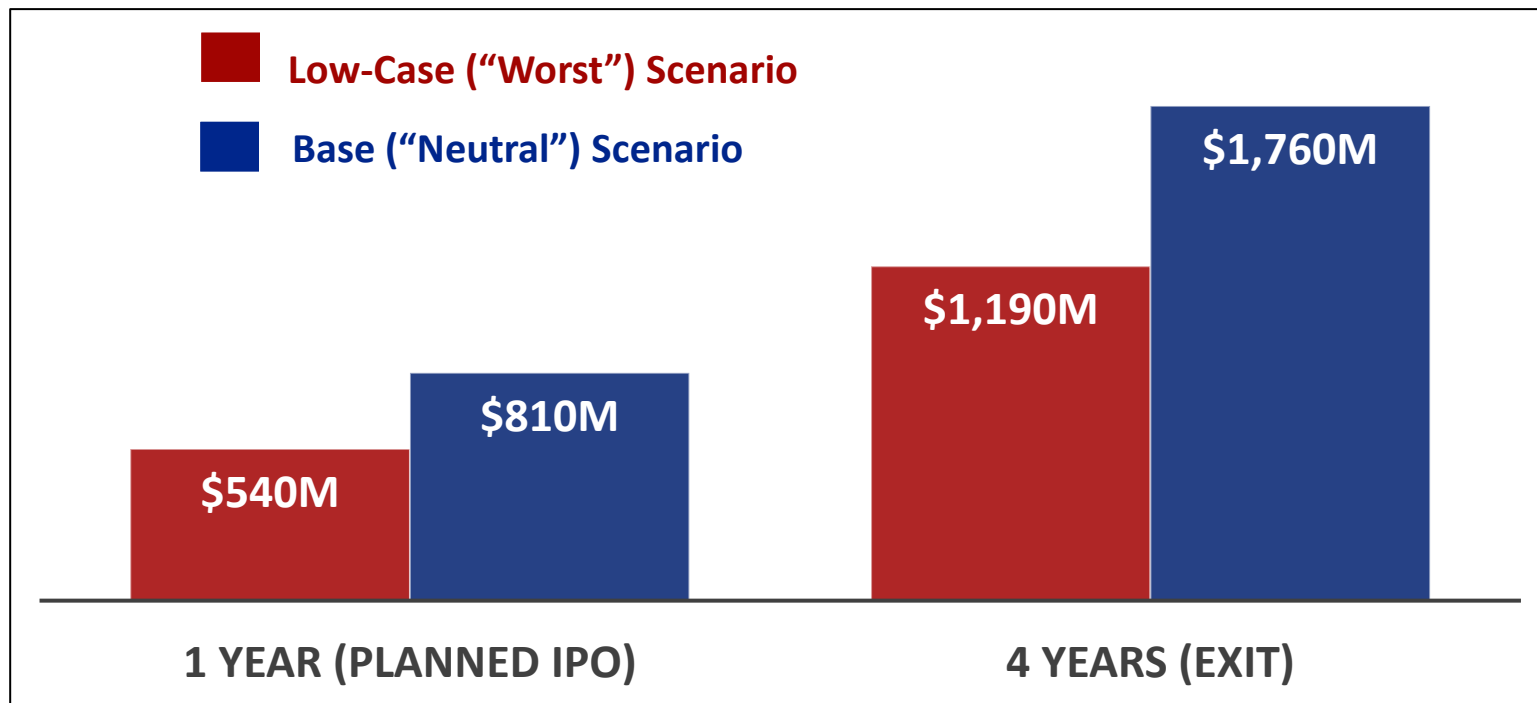
Issued and new US patents and regulatory exclusivity are expected to protect the products until at least 2037, possibly much longer

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



## Company Valuation\*

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



\* In collaboration with **Bio-strategy Analytics**, Arstat determined the portfolio value at 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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**Product Out-Licensing or Company Sale**

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**OR**

**A Valuable Public Company** 

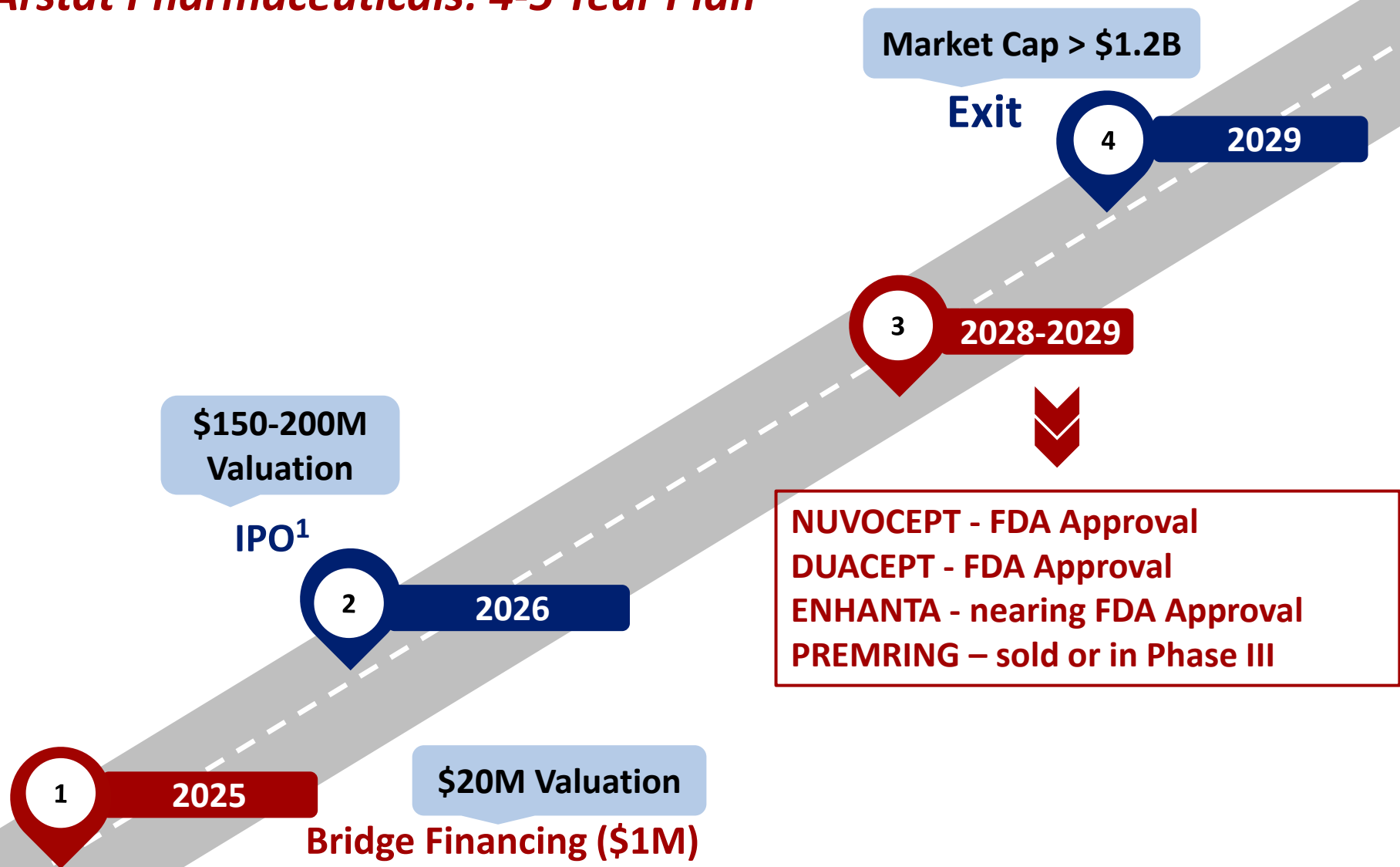
With a projected market cap of > \$1.2B

\***Conservative estimate:** assuming the IPO valuation is <30% of the low-case portfolio value. See slide 15.

\*\***Conservative estimate:** assuming the low-case valuation scenario at the exit. See slide 15.



# Arstat Pharmaceuticals: 4-5 Year Plan



<sup>1</sup>Subject to market conditions; otherwise, a reverse merger or Series B round

## ***A Likely IPO (around Q1 of 2026): Strategic Considerations***

- **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 due to the overruling of Roe v. Wade**
- **More advanced pipeline than 2/3 of biopharma IPOs\***

### **A notable precedent: Myovant Sciences**

- 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 A's
- From the initial funding round (\$7M) to a \$2.9B exit in ≈ 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)

## ***IPO Comparables – Arstat targets are very conservative***

***Valuable recent IPOs with a lead asset in Phase III (no revenues)\****

<b>Company</b>	<b>Symbol</b>	<b>IPO Date</b>	<b>Money Raised</b>	<b>Market Cap</b>	<b>Percent Equity</b>	<b>Stage</b>
<b>Alumis, Inc.</b>	ALMS	6/28/2024	<b>\$300M</b>	<b>\$958M</b>	31%	<b>Phase III</b>
<b>Fractyl Health, Inc.</b>	GUTS	2/2/2024	<b>\$110M</b>	<b>\$714M</b>	15%	<b>Phase III</b>
<b>ArriVent BioPharma, Inc.</b>	AVBP	1/26/2024	<b>\$175M</b>	<b>\$575M</b>	30%	<b>Phase III</b>
<b>CG Oncology Inc.</b>	CGON	1/25/2024	<b>\$380M</b>	<b>\$1.206M</b>	32%	<b>Phase III</b>
<b>Adlai Nortye Ltd.</b>	ANL	9/29/2023	<b>\$50M</b>	<b>\$720M</b>	8%	<b>Phase III</b>
<b>Neumora Therapeutics, Inc.</b>	NMRA	9/15/2023	<b>\$250M</b>	<b>\$2.585M</b>	10%	<b>Phase III</b>
<b>RayzeBio, Inc.</b>	RYZB	9/15/2023	<b>\$311M</b>	<b>\$940M</b>	33%	<b>Phase III</b>

**Arstat’s IPO targets (\$30-50M raised; \$150-200M market cap) are very conservative**

— 20-25% of median values calculated from the above table

**A possible fast-track IPO: 7-8 months to public market**

— if market conditions not favorable, the company may consider a fast-track IPO initially focusing on the lead asset (NUVOCEPT) with a fund-raising target reduced to \$15-20M.

\* <https://www.iposcoop.com/last-100-ipos/>

## ***Arstat Pharmaceuticals: The Ask and Action Plan***

**Arstat is raising \$1M (Bridge Financing)** ahead of an optional private placement and an IPO

**\$20M Valuation Cap  
(Post-Money)**

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

### **Major Tasks and Next Steps**

- Finalize the senior executive team and assemble a well-connected board of directors
- Conduct pre-IND meeting with the FDA (ENHANTA); Prepare the IND (NUVOCEPT/DUACEPT)
- Expand outreach to potential partners and support private placement
- ***An engagement letter (an optional private placement followed by the IPO) (June 2025)***
- ***\$3-5M optional private placement (target closing October 2025)***
- ***\$30-50M IPO\* at Post IPO valuation \$150-200M\*\* (around Q1 of 2026)***

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

*\*\*Committed IPO targets*

## ***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**
- **15 patents from a co-inventor of the best-selling US oral contraceptive**
- **Strong supporting data; expertise to deliver (120+ years with leading brands)**
- **Seeking senior executives and Board members**
- **An exceptional near-term exit option (a likely IPO in  $\approx$  1 year)**



### **Contact:**

**Arkady Rubin, PhD**

**Founder, President, Chief Scientific Officer**



**+1 347-385-0878**



**[arubin@arstatinc.com](mailto:arubin@arstatinc.com)**



**[www.arstatinfo.com](http://www.arstatinfo.com)**