



ARSTAT Pharmaceuticals

*Advancing Transformational Products
for Tens of Millions of US Women*

Introductory Presentation

July 28, 2022

Arkady Rubin, PhD
Chief Scientific Officer and Acting CEO



Vision: One of the Best Pipelines in Women's Health

Two Phase III-ready products (confirmed by the FDA)



Addressing a high public health priority in a post-Roe world

The first and only oral contraceptive designed explicitly for **overweight and obese women** (≈6 million US pill users). The FDA has recognized a major need and endorsed unprecedented testing and labeling for women with high BMI. **A \$2B/year US opportunity** (< \$20M in total costs and <3.5 years to market)



First brand that meets the criteria of an ideal oral contraceptive (the safest progestin and a low estrogen dose). A great option for >2 million US pill users with normal weight

Two other candidates are ready for Phase IIb



First-in-class vaginal ring for **uterine fibroids and endometriosis** (≈14 million US women). Ultra-low doses of the promising drug are delivered directly to affected tissues for unmatched efficacy and safety. **Potential US blockbuster**



First-in-class **non-hormonal therapy** for **painful and heavy menstrual periods** (>25 million US women). Likely first-line for a common, undertreated disorder

Mission: To Build a High-Growth Pharmaceutical Company



Clinically and Commercially Strong Products

- Likely first-line therapies in areas of high medical needs
- Across the entire portfolio, annual US sales in billions of dollars

Rapid, Low-Risk Development

- Proven efficacy and safety; straightforward clinical programs
- A highly experienced management and advisory team

Early Return on Investment (ROI)

- A powerful pipeline is expected to support an appealing IPO
- An initial ROI is projected in 1 year or less

Strong, Large and Growing IP Portfolio (11 Granted US Patents)

NUVOCEPT/DUACEPT

US Patents:

- US 9,675,622
- US 9,925,199
- US 10,111,887
- US 10,463,678
- US 10,537,582
- US 11,103,515

Ex-US Patents:

- **European (EU):** EP 2790688 B1
- German 20 2012 012 822.1

Pending:

- US application 17,385,330
- 2 more US patents planned

PREMRING

US Patents:

- US 10,251,836
- US 11,116,718

Ex-US Patents:

- German 20 2011 110 356.4
- German 20 2011 110 355.6

Pending:

- US application 16,295,577
- US application 17,401,964
- 4 more US patents planned

ENHANTA

US Patents:

- US 10,532,037
- US 10,709,679
- US 11,351,132

Ex-US Patents:

- German 20 2011 110 392.0

Pending:

- US application 17,661,678
- 3 more US patents planned

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

Inventor, Founder

All patents were developed by Arkady Rubin, PhD - a 30-year pharma industry veteran (J&J, Pfizer). Dr. Rubin designed pivotal trials of leading women's health brands and was a co-inventor* of Ortho Tri-Cyclen Lo[®], a top US oral contraceptive with peak annual sales over \$500 million

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

Our Innovation and Supporting Data: A Top-Line Overview



NUVOCEPT/DUACEPT

Novel Oral Contraceptive *New Multiphasic Dosing Regimen*

- An oral contraceptive with gradually increasing hormonal amounts and a constant progestin-to-estrogen ratio has never been considered.
- A calibrated dose increase greatly improves efficacy, while a constant ratio reduces unwanted side effects.
- When combined with a shorter drug-free interval, the safest progestin, and low overall drug exposure, it is an optimal regimen for overweight and obese women (NUVOCEPT)
- Supported by historical data from multiple efficacy and safety studies and PK/PD modeling of the impact of body weight on the drug absorption



PREMRING

Novel Drug/Device Combo *First-in-Class Vaginal Ring*

- Targeted, controlled delivery of SPRM was never applied to treating uterine fibroids and endometriosis.
- Multiple data sources position this option as the optimal use of SPRMs - increasingly appealing R&D candidates for these disorders.
- Supported by:
 - (a) an established mechanism of vagina-to-uterus drug transport (“first uterine pass effect.”);
 - (b) proven efficacy of oral SPRMs;
 - (c) desirable PD effects of the intravaginal delivery of SPRM for contraceptive purposes;
 - (d) pre-clinical and in-vitro studies



ENHANTA

Novel Oral Drug Formulation *First-in-Class Drug Combination*

- Heavy and painful menstrual periods were never treated with an NSAID in combination with a very low dose of antifibrinolytic (tranexamic acid). Such a low-dose supplement was never considered or tested.
- Known mechanism of menstrual blood-reducing action of each component and historical data from dose-response studies support the superiority of ENHANTA over an NSAID monotherapy (a primary endpoint in a pivotal Phase III study)
- Historical clinical data also suggest an improvement in quality of life that is unachievable with other therapies



Very Large Markets, Great Commercial Potential

- Across the entire portfolio:
 - An addressable US market is near 50 million women (> 800 million women worldwide)
 - Projected peak annual gross sales (US): at least \$3.4 Billion; could be close to \$4.8 Billion
- NUVOCEPT & PREMRING are potential leaders in multi-billion-dollar markets

Product	Addressable US Market	Peak Annual Gross Sales* (US)	
		"Most Likely" Scenario	"Best" Scenario
NUVOCEPT	≈ 6 million	\$1,440M	\$2,200M
DUACEPT	>2 million	\$140M	\$180M
PREMRING - Uterine Fibroids	≈9 million	\$570M	\$800M
PREMRING - Endometriosis	≈5 million	\$760M	\$890M
ENHANTA (Rx & OTC)	>25 million	\$520M	\$740M
Total	>47 million	\$3,430M	\$4,810M

* Conservative projections verified by top commercial experts; validated by multiple benchmarks

Significant worldwide sales, particularly in the EU, are also expected

Our Major Asset - NUVOCEPT™

Addressing a High Unmet Contraceptive Need and Public Health Priority

The first oral contraceptive formulated explicitly for overweight and obese women (~60% of US pill users)

1 Highly Profitable

- It will likely dominate a multi-billion-dollar segment of the US contraceptive market
- Favorable market access & coverage

4 Phase III-Ready

- Favorable meeting with the FDA; clinical program is finalized
- Abbreviated 505(b)(2) NDA



2 Rapid, Low-Cost R&D

- < \$20M in total costs
- < 3.5 years to the US market

3 Low-Risk

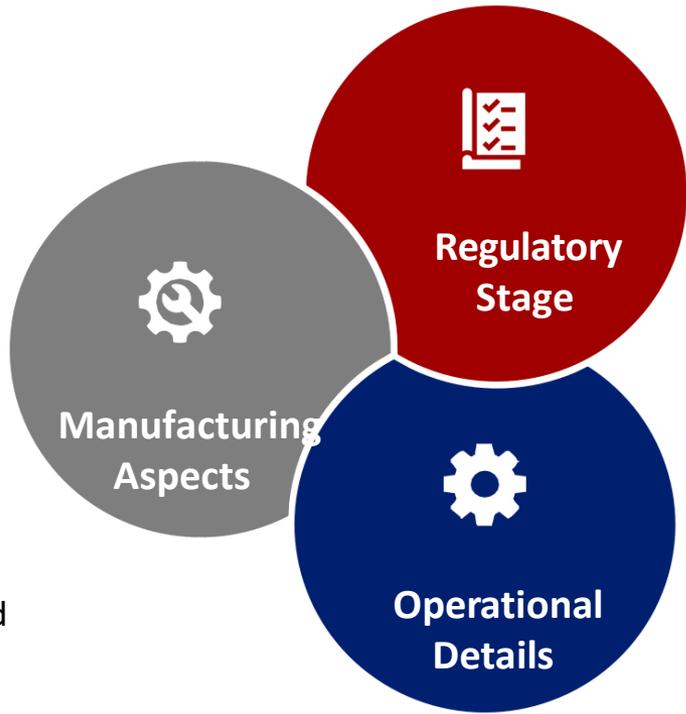
- Confirmed by the FDA review of supporting efficacy and PK/PD data
- Validated by six granted US patents

➤ The first and only contraceptive endorsed by the FDA for the exclusive clinical testing and labeling in women with high BMI

NUVOCEPT™: Poised To Start Phase III

Straightforward Manufacturing

- NUVOCEPT components are out of patent and available at low cost from multiple suppliers (manufacturers of generic LNG/EE pills)^{1,2}
- Stability and other CMC details will be easily addressed



FDA Pre-Phase III Meeting³: Major Outcomes

- Phase III study can start immediately after the opening of the IND
- The FDA has outlined key features of a Phase III study design and endorsed a unique product label

Program Logistics are being Finalized

- Detailed cost and time estimates are received from multiple CROs
- Potential clinical study vendors are being evaluated

¹ There are at least 10 generic manufacturers of LNG/EE pills with active drug files (e.g., Mayne Pharma, Aurobindo Pharma, Lupin, Mylan Labs, Sun Pharm, Novast Labs, etc.)

² The costs of drug supplies for the entire Nuvocept clinical program are estimated at \$150K

³ While the meeting was formally classified as a pre-IND meeting, it accomplished all objectives of a pre-Phase III meeting

Why NUVOCEPT™?



2 in 3
reproductive-age US women
are **overweight or obese**¹

With unintended pregnancies
very distressing due to
maternal and child health hazards²



Marketed oral contraceptives do not work well for this population due to
an increased risk of pregnancy and serious side effects



A MAJOR UNMET NEED - A reliable oral contraceptive for overweight and obese women



**Recent Roe v. Wade developments make the need for
effective birth control more urgent than ever**



Marketed Contraceptives are Not Intended for Obese Women

Excluding from pivotal trials	<ul style="list-style-type: none"> Most of Phase III efficacy trials excluded women with high BMI and approved contraceptives were often marketed to an unstudied population
Delivering suboptimal doses	<ul style="list-style-type: none"> Due to reduced drug absorption, obese women receive 70-80% of the intended (nominal) dose^{1,2,3,4,5} with totally unacceptable protection from pregnancy
Increasing cardiovascular risks	<ul style="list-style-type: none"> Most of modern contraceptives cannot be recommended to obese women due to a troubling incidence of serious cardiovascular events^{6,7,8}

➤ Unacceptable Performance of All FDA-Approved Combined Hormonal Contraceptives in the Last Decade:

Generess®	Quartette®	Annovera®	Twirla®	Nextstellis®
Risk of pregnancy increases by 72% for obese women ⁹	Pregnancy rates greater by 31% and 86% for overweight and obese women ¹⁰	Due to a higher VTE risk, clinical testing of obese women was terminated ¹¹	Contraindicated in obese women; a limitation of use in overweight women ¹²	Due to a decreasing effectiveness, limitation of use in obese women ¹³
2011	2013	2018	2020	2021

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

NUVOCEPT™: A Better Way



Gold Standard in Oral Contraception

Hormonal components tested by tens of millions of women



Highly Effective

Up to 3 times lower pregnancy rates versus leading brands



Very Safe

2 – 3-fold reduced risk of serious side effects vs. competitors



“Women will LOVE it”

(Andrea S. Lukes, MD, MHSc FACOG)

Dr. Lukes is our Lead Clinical Advisor. She has conducted or overseen >80 trials of women’s health products.

The FDA has recognized the importance of NUVOCEPT

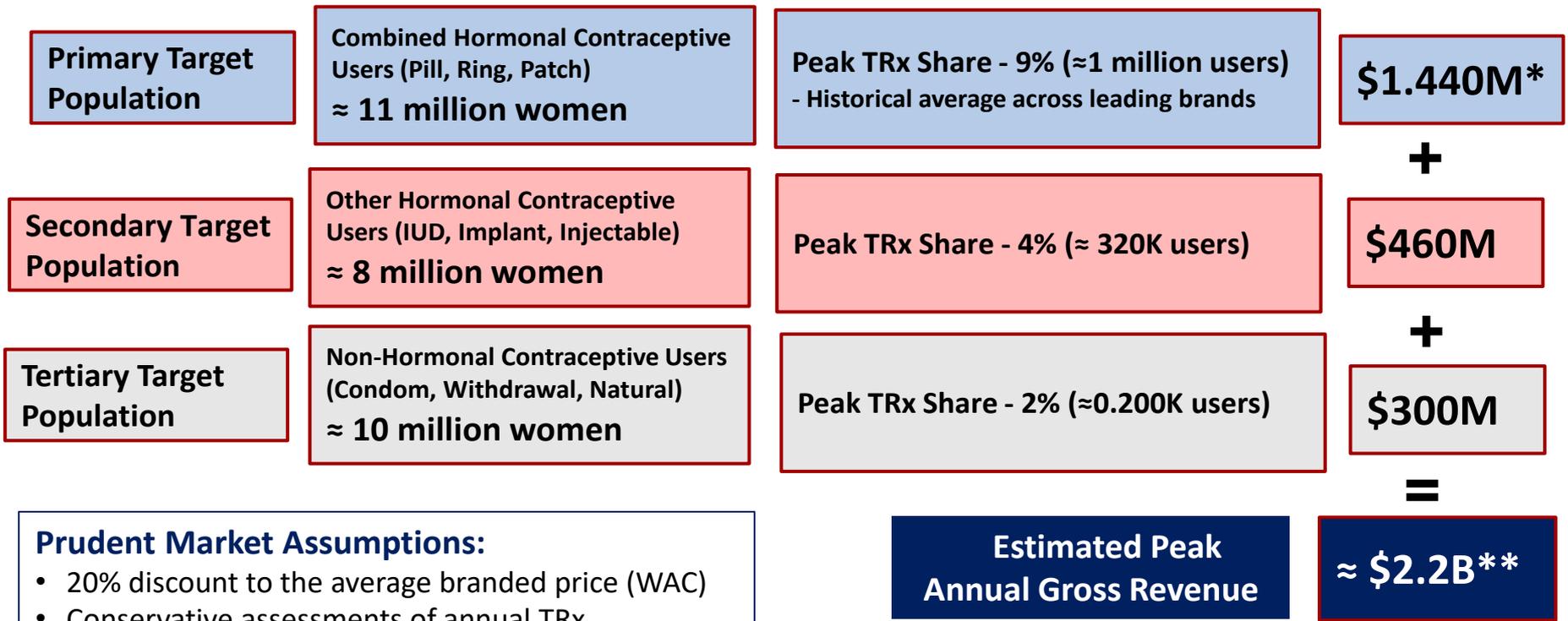
- ✓ **NUVOCEPT efficacy and safety projections accepted**
— the FDA has approved the dosing of 1,500+ women
- ✓ **After the pre-IND meeting, a new FDA guidance was Issued**
— the impact of obesity on contraceptive efficacy is emphasized



Establishing Effectiveness and Safety for Hormonal Drug Products Intended to Prevent Pregnancy
Guidance for Industry

NUVOCEPT™ – US Gross Sales May Exceed \$2B/year

Very large commercial opportunity for ≈ 30 million US women who are seeking safe and reliable contraceptive method. Roughly 20 million of these women are overweight or obese.



Prudent Market Assumptions:

- 20% discount to the average branded price (WAC)
- Conservative assessments of annual TRx
- Very conservative market share projections

* “Most Likely” Scenario
** “Best Case” Scenario

Sources: ¹IMS NPA (2019), ²MediSpan Price Rx Select (2019), ³Call Transcript (2020), ⁴ARSTAT Inc. (Data on file), ⁵Guttmacher (2021)

NUVOCEPT™ Exclusivity: a Pillar of Commercial Success

- 1 The most attractive (if not the only) option for women and their physicians** due to an exclusive contraceptive indication for overweight and obese women
- 2 Unprecedented efficacy and safety labeling claims** based on a unique clinical program
- 3 The safest solution** when overweight women desire the pill **for non-contraceptive reasons** (>30% of US users)



Take a risk with inferior or untested contraceptives
OR
prescribe NUVOCEPT

Projected Nuvocept Labeling Benefits:

- ✓ Unlike all recently brands, no contraindications or limitations of use in obese and overweight women
- ✓ The most sizeable and comprehensive efficacy and safety database in women with high BMI
- ✓ Reduced risk of pregnancy and VTE in obese women (Phase III data and historical comparisons*)

Favorable Market Access & Coverage:

➤ New US Government Guidance (2022) requires to cover ALL FDA-approved contraceptives (irrespective of the availability of generics or similar brands) with no out-of-pocket costs

*To be confirmed after the NDA filing

Other ARSTAT Products: Highlights

PREMRING™

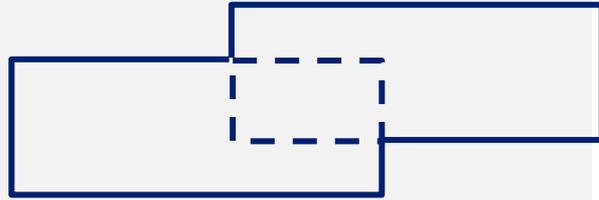
- **A potential breakthrough solution for uterine fibroids and endometriosis.** Vaginal ring delivers ultra-low doses of a well-studied SPRM directly to affected tissues
- **Greater efficacy:** Targeted drug delivery results in strong therapeutic action at a small fraction of oral dose – superior to other therapies.
- **Better safety:** Unlike other hormonal therapies, PREMRING will NOT be associated with severe menopausal symptoms (hot flashes and bone loss)
- **Low-risk program:**
 - efficacy testing starts with Phase IIb
 - < \$8M to reach Phase III;
 - it will be sold in 3-3.5 years

ENHANTA™

- **A novel, proprietary oral drug formulation for painful and heavy menstrual periods.** Likely first-line for a highly prevalent disorder
- **Two popular medications:** A specific NSAID** and low-dose tranexamic acid are combined in the safest and most efficacious way.
- **Two valuable formulations:** Prescription-strength (Rx) and Over-the-counter (OTC) for tens of millions of US women
- **Rapid Development:**
 - Phase IIb ready; could be a Phase III asset (FDA confirmation needed)
 - \$17M & 4 years to the US market

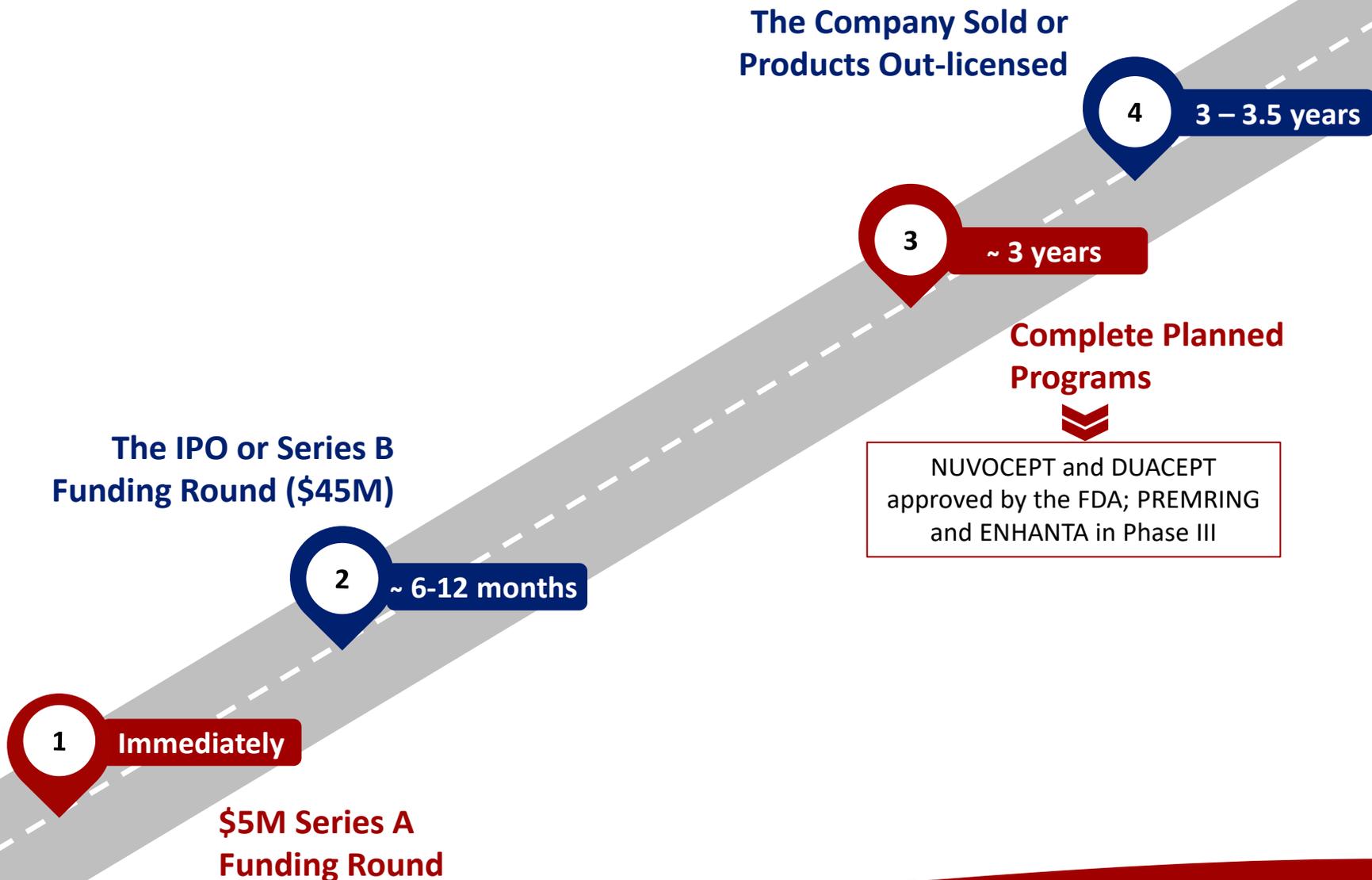
DUACEPT™

- **An improved version of the best-selling European oral contraceptive brand** that is particularly suitable for normal-weight women, adolescents and perimenopausal pill users.
- **Phase III-ready:** It may be developed in parallel with Nuvocept for ≈\$5M and submitted under the same NDA - < 3.5 years to the US market
- **In some countries, it may be approved with no new clinical data**



SPRM = Selective Progesterone Receptor Modulator;
** NSAID = Nonsteroidal anti-inflammatory drug

Business Model: Strategic Roadmap and Objectives

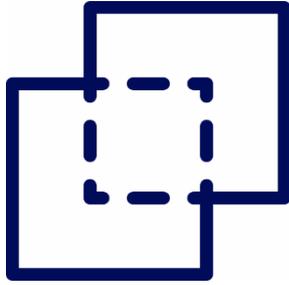


Sound Valuation Targets and Exit Opportunities

 **~ 1 year**

IPO
(subject to market conditions)

Valuation Target: 4-5x increase in the current company's valuation*



 **3 - 3.5 years**

EXIT

Valuation Target: at least \$850M**

 **Acquisition**

OR

Trading on a Major Stock Exchange

 High valuations will be supported by rapid, low-cost R&D and strong sales projections

***Conservative estimate:** well below the average valuation of pharmaceutical IPOs at the same R&D stage. See slide 17.

****Conservative estimate:** <50% of the portfolio value (Net Present Value, NPV) at exit. See slide 19.

Going Public via IPO: Strategic Considerations

Why IPO?

- 1 Investment bankers and analysts consider ARSTAT a potentially great public company — advanced products, rapid, low-risk R&D, huge markets, clear and achievable strategic goals
- 2 The overruling of Roe v. Wade makes Nuvocept a precious opportunity for IPO investors
- 3 The IPO will provide an early exit option to investors of the current funding round
- 4 **Appealing IPO benchmarks:** \$457M is the median IPO valuation (with a lead asset in Phase III)* — NUVOCEPT is likely superior to the majority of noted Phase III assets
- 5 **Prudent IPO funding goal:** \$45M, which is less than any women’s health IPO (see table below)
- 6 **Solid IPOs have been recently reported by other women’s health pharma companies** — with comparable (if not inferior) pipelines

Company	IPO Year	Amount Raised	Company Valuation
Agile Therapeutics	2014	\$55M	≈ \$180M
ObsEva SA	2017	\$96M	\$450M
Myovant Sciences	2016	\$218M	≈ \$880M

* www.mtspartners.com/wp-content/uploads/sites/2/2016/08/Early-Stage-IPOs-2012-2018-August-2018.pdf

IPO: Key Details



- ✓ **ARSTAT is aware of current IPO market dynamics**
 - the company's IPO metrics could be well below historical precedents
- ✓ **Under favorable market conditions, ARSTAT will pursue a “comprehensive” IPO**
 - R&D activities will support the entire portfolio with an IPO funding goal of \$45M
 - the IPO could be completed ≈ 12 months after the closing of the current round
- ✓ **Under challenging market conditions, ARSTAT may elect a “fast-track” IPO**
 - R&D activities will focus on Nuvocept with a reduced funding goal of \$20-25M
 - the IPO could be completed ≈6-8 months after the closing of the current round
- ✓ **Under any scenario, the company expects a potentially solid near-term ROI**
 - the current financing round is deeply discounted relative to the projected IPO valuation

➤ **While the IPO is preferred, a reverse merger with a public company or a SPAC could be considered. ARSTAT may also explore a Series B financing round.**

Impressive Portfolio Value in 3.5 Years



Our valuations and exit targets are realistic*

Product	Net Present Value (NPV) in 3.5 years**	Conservative Exit Targets
NUVOCEPT	\$1,060M	\$540M
DUACEPT	\$170M	\$60M
PREMRING – Uterine Fibroids	\$180M	\$90M
PREMRING – Endometriosis	\$110M	\$70M
ENHANTA (Rx)	\$240M	\$90M
Total	\$1,760M	\$850M (~48% of NPV)

* In collaboration with **Bio-strategy Analytics**, we have determined the value of the portfolio in 3.5 years (after the FDA approval of NUVOCEPT/DUACEPT, completion of the PREMRING IIb study in uterine fibroids, and ENHANTA Phase IIb study)

** **“Most Likely Scenario”** using the Discounted Cash Flow (DCF) and Expected (Risk-Adjusted) Net Present Value (eNPV) methods

ENHANTA US over-the-counter (OTC) sales and worldwide sales across the entire portfolio will further increase the value of the company

Team (Management/Advisors)

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



Arkady Rubin, PhD
Chief Scientific Officer, Acting CEO

Dr. Rubin has designed pivotal trials for leading women's health brands and supported multiple successful NDAs.

Agis Kydonieus, PhD
Drug Delivery Advisor

Co-founder of the Controlled Release Society, holder of 55 U.S. patents, the author of 10 books

Andrea S. Lukes, MD, FACOG
Lead Clinical Advisor

Dr. Lukes has conducted >80 of women's health trials and served on the FDA advisory committees.

Jeffrey Frick, MBA
Commercial Advisor

He contributed to the most successful US contraceptive launches (Yasmin®, YAZ®, Mirena®) with combined sales of \$2B/year

Russell Barrans, MBA
Commercial Strategy Advisor

An award-winning commercial expert who has helped introduce widely known contraceptive brands.

Jason Spitz, MBA
Strategic Marketing Advisor

Executive who was responsible for marketing and commercial operations in a public women's health company

Other Key Advisors:

Alan N. Walter, JD
Legal Affairs Advisor

Karla Loken, DO, OBGYN, FACOG
Medical Affairs Advisor

Mary Kucek, PMP, ITIL
Public Health/Social Media Advisor

Several additional candidates are identified as potential C-level employees and consultants

After the funding is secured, we will recruit a permanent CEO and Board Members

The Ask and Pre-IPO Action Plan

We are raising **\$5M (Series A equity financing)** to continue our R&D and to support at least 15 months of operations, including the IPO

Major Tasks

- ✓ Finalize executive team, hire key consultants
- ✓ Assemble a well-connected board of directors and a scientific advisory board
- ✓ Conduct two more pre-IND meetings with the FDA (PREMRING and ENHANTA)
- ✓ Prepare to start two studies: Phase III (NUVOCEPT/DUACEPT) & Phase IIb (ENHANTA)
- ✓ Complete marketing assessments, including surveys with OB/GYNs and patients
- ✓ Support IPO-related activities (legal, accounting, regulatory filings, marketing)
- ✓ Significantly extend outreach to investors and potential strategic partners





ARSTAT Pharmaceuticals



Contact:

Arkady Rubin, PhD

Chief Scientific Officer and Acting CEO

 +1 347-385-0878

 arubin@arstatinc.com

 www.arstatinfo.com