

# Novel Pharmaceutical Products for Women's Health Executive Summary

## **Strong Proprietary Position:**

- 5 provisional and 5 non-provisional (PCT) patent applications
- Developed with a top IP firm
- All are currently pursued in the US
- All have already received a 10-year protection in Germany
- No similar products were ever considered before; this is confirmed by International Search Reports.

## **The Company:** [www.arstatinc.com](http://www.arstatinc.com)

ARSTAT Inc. provides clinical, regulatory and biometric consulting services to pharma companies. In addition, we are engaged in proprietary R&D activities. The principal - Arkady Rubin, PhD. - has 20+ years of industry experience, mostly in women's health. In the area of patent applications, he has designed multiple studies, contributed to successful NDAs, and co-authored numerous publications. Dr. Rubin was a co-inventor (US Patent 6214815, EU Patent 1140109) of Ortho Tri-Cyclen Lo®, the best-selling oral contraceptive in the US (>\$450M, 2013).

## **Seeking Executive Partner**

- Potentially an industry veteran. The partner may assume a CEO position.
- Expertise in and/or passion for women's health would be an asset.

**Exceptional R&D Portfolio.** Potential breakthrough opportunities for uterine fibroids & endometriosis (Premring™) and for dysfunctional menstrual bleeding (Duafem™); a first-in-class therapy for painful, heavy menstrual periods (Enhanta™); an oral contraceptive brand (Nuvocept™)

**Fast, Low-Risk Programs.** All candidates offer substantially improved medical use of drugs, which have already been proven to work. The R&D risk, time and costs are markedly reduced. Clinical testing begins with Phase IIb or Phase III. Rapid (505)(b)(2) NDAs; 3-5 years to launch.

**Sales potential in hundreds of millions** due to large markets and serious limitations of current treatments. At least one likely blockbuster.

## **Business Model:**

- Our business plan is to advance the candidates up to the completion of the first efficacy study and to commercialize each of them within the next 2-3 years
- We will seek strategic R&D partners with existing women's health portfolios
- For some candidates, we may pursue early out-licensing agreements.
- Our oral formulations (Enhanta™ and Nuvocept™) will be ready for Phase III in 1 year or less. They could be developed by either ARSTAT or a dedicated start-up with very rapid, low-cost, low-risk R&D and exciting exit opportunities.
- Within the next 1.5 years, we will complete development of our drug/device combinations (Premring™ and Duafem™) and be ready for a Phase IIb study
- As potential breakthrough solutions for highly prevalent, serious disorders, the last two candidates could be suitable for an equity crowdfunding model.

## **Value Proposition:**

- ARSTAT seeks to raise up to \$2 Million from angel investors. Interested parties may invest in the entire package or in the individual candidates.
- Within the next 12 months, we expect to accomplish some key R&D and IP development tasks and to secure one or more partnership agreements.
- It will increase the company's evaluation at least 5-fold, bringing it to ≈\$30M.
- In 2.5-3 years, we will offer the investors an opportunity for exit or to continue with their support. The anticipated return could be >10x.

**The Candidates** (with links to individual summaries; to download presentations, please visit [www.arstatinc.com](http://www.arstatinc.com)):

### **Optimal Use of SPRMs for Uterine Fibroids and Endometriosis (Premring™)**

Vaginal Ring Delivers Ultra-Low Doses  
Directly to Affected Tissues

[www.arstatinc.com/ARSTAT\\_Ring.pdf](http://www.arstatinc.com/ARSTAT_Ring.pdf)

- ← A fast and strong therapeutic action at a fraction of an oral dose
- ← Safe long-term therapy (not an option for other hormonal meds)
- ← Each indication could generate > \$1B/year in global markets

### **Entirely New and Different Treatment for Heavy Menstrual Bleeding (Duafem™)**

Tampon Delivers Antifibrinolytic, while  
Absorbing Menstrual Fluids

[www.arstatinc.com/ARSTAT\\_Tampon.pdf](http://www.arstatinc.com/ARSTAT_Tampon.pdf)

- ← Fits into typical use of sanitary products – most convenient
- ← Creates new, very large market segment with no competition
- ← Hundreds of millions in potential sales for both Rx and OTC

### **A First-in-Class Therapy for Painful and Heavy Menstrual Periods (Enhanta™)**

Oral Combination of an NSAID and  
Low Dose Tranexamic Acid

[www.arstatinc.com/ARSTAT\\_Combination.pdf](http://www.arstatinc.com/ARSTAT_Combination.pdf)

- ← Unlike NSAID alone (current first choice), the candidate will effectively treat heavy menstrual bleeding in most women.
- ← Rx and OTC could capture significant sales in a very large market

### **A Novel Multiphasic Contraceptive – the Safest Product of its Class (Nuvocept™)**

Multiphasic Oral Contraceptive with  
Robust Hormonal Balance

[www.arstatinc.com/ARSTAT\\_Contraceptive.pdf](http://www.arstatinc.com/ARSTAT_Contraceptive.pdf)

- ← An improved European "Gold Standard" in oral contraception
- ← A better label vs. most available pills, including top US brands
- ← In some countries, it could be approved with no new clinical data.

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# Novel Pharmaceutical Products for Women's Health

## Executive Summary

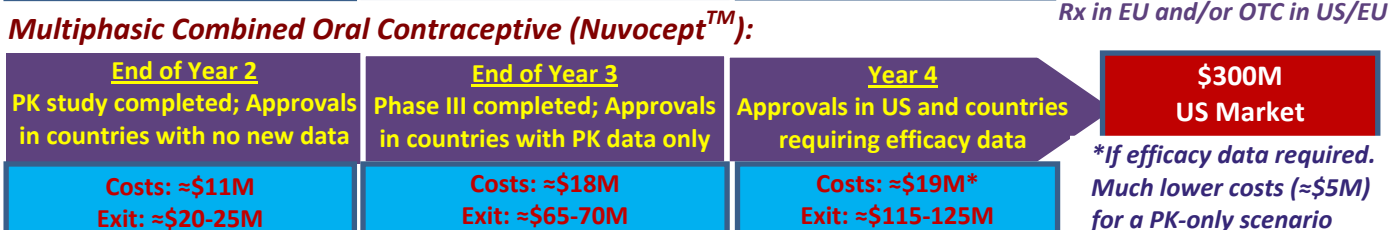
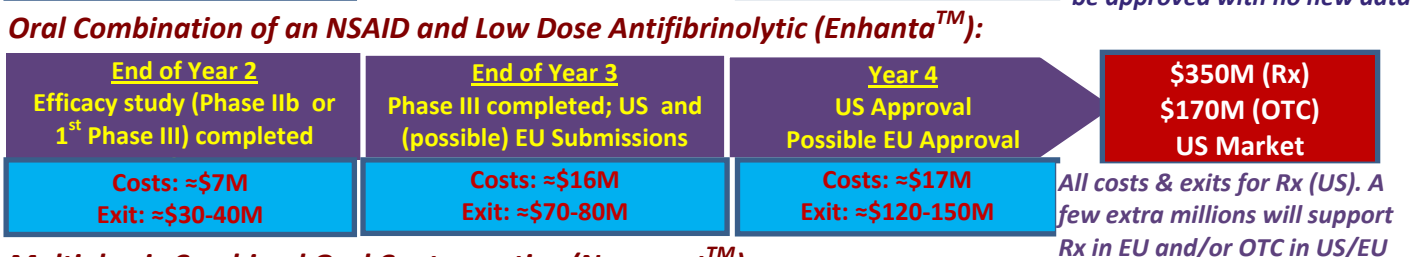
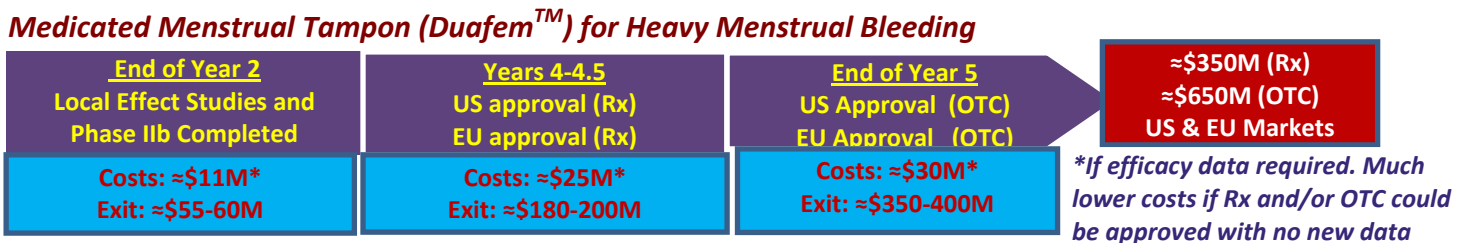
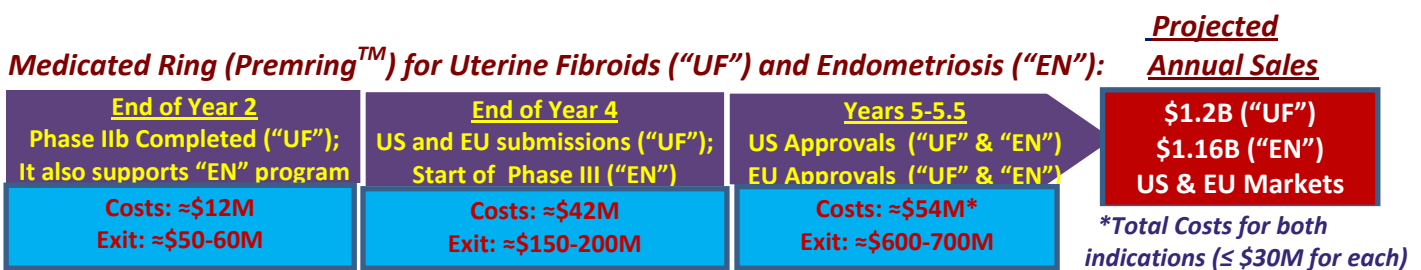
### Business Plan Details:

Over the next 12 months, the following milestones (in the order of priority) will be achieved:

- **All Candidates:** (1) continued prosecution of the patent applications in the US; (2) formal agreements with key vendors and consultants are finalized; (3) be poised to close partnership agreements for 1-2 candidates.
- **Enhanta™:** (1) confirmation of the clinical program in the US and the regulatory path in major EU markets; (2) filing of an IND; and (3) be ready to initiate the first clinical study (Phase IIb or the first Phase III study);
- **Nuvocept™:** (1) confirmation of the regulatory path in the US and other targeted territories, while submitting Marketing Authorization Applications (MAAs) in European countries where no additional clinical studies are required for approval; (2) filing of an IND; and (3) be poised to initiate PK study (for countries where approval may be achievable with the sole addition of a pharmacokinetic trial);
- **Premring™:** (1) confirmation of the clinical programs in the US and major EU markets; (2) development and in-vitro testing of the prototype vaginal ring which can support IND and CTA filings.
- **Duafem™:** (1) confirmation of the regulatory path in the US and global markets; (2) development of the prototype medicated menstrual tampon which can support IND and CTA filings.

If a Series B round of financing is needed in 12 months, it would be applied toward the following major milestones: (1) completion of the 1<sup>st</sup> clinical study on Enhanta™; (2) completion of the PK study on Nuvocept™; (3) filings of INDs and CTAs on Premring™ and Duafem™.

### R&D Costs, Major Milestones, Projected VC Exits and Sales: Overview



Costs = Cumulative R&D costs (e.g., \$19M at Year 4 are the total R&D costs of the program for Nuvocept™);  
Exit = Upfront payments to all shareholders, including VC (royalties are also expected).

All estimates are based on some conservative assumptions that may be discussed.

**NOTE:** A parallel development of 3-4 candidates could be an optimal scenario. Early exit revenues from Enhanta™ and/or Nuvocept™ will adequately support all remaining R&D activities.