



*Transforming Strong
Medicines into
First-Line Therapies*

ARSTAT Inc. – Medicated Tampon (Duafem™) Entirely New and Different Way to Treat Heavy Menstrual Bleeding

***Medicated Sanitary Product Delivers
Antifibrinolytic Directly to Uterine Cavity***

- ***Duafem™ could be developed by either ARSTAT or a dedicated start-up.***
- ***We may also pursue early out-licensing opportunities.***
- ***The R&D costs and milestones, funding and exit details are disclosed below***

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Introduction

- *The company has developed and patented a novel, proprietary medicated menstrual tampon (Duafem™) to control heavy menstrual bleeding. Duafem™ delivers well-studied drug by a novel route.*
- *It could be a breakthrough therapy for a highly prevalent condition.*
- *Data from a study of intravaginally delivered antifibrinolytic proves the concept and significantly increases the odds of successful development. Feasibility of medicated menstrual tampons is also proven.*
- *Rx and OTC formulations could capture a decent share of the global market.*
- *The patent applications are developed by the ARSTAT's principal - Arkady Rubin, PhD., a researcher with 20+ years of pharma industry experience.*
- *Dr. Rubin is expertly knowledgeable in the treatment of dysfunctional uterine bleeding; he has analyzed extensive clinical databases and co-authored related publications. He was also recognized as one of the inventors of Ortho Tri-Cyclen Lo®, the best-selling oral contraceptive in the US (>\$450M in 2013).*
- *To advance Duafem™, the principal seeks business partner(s). We will also consider out-licensing of the intellectual property or other arrangements, including joint development. The last three slides present related details.*

Medicated Menstrual Tampon for Heavy Menstrual Bleeding

Clinical and Commercial Highlights

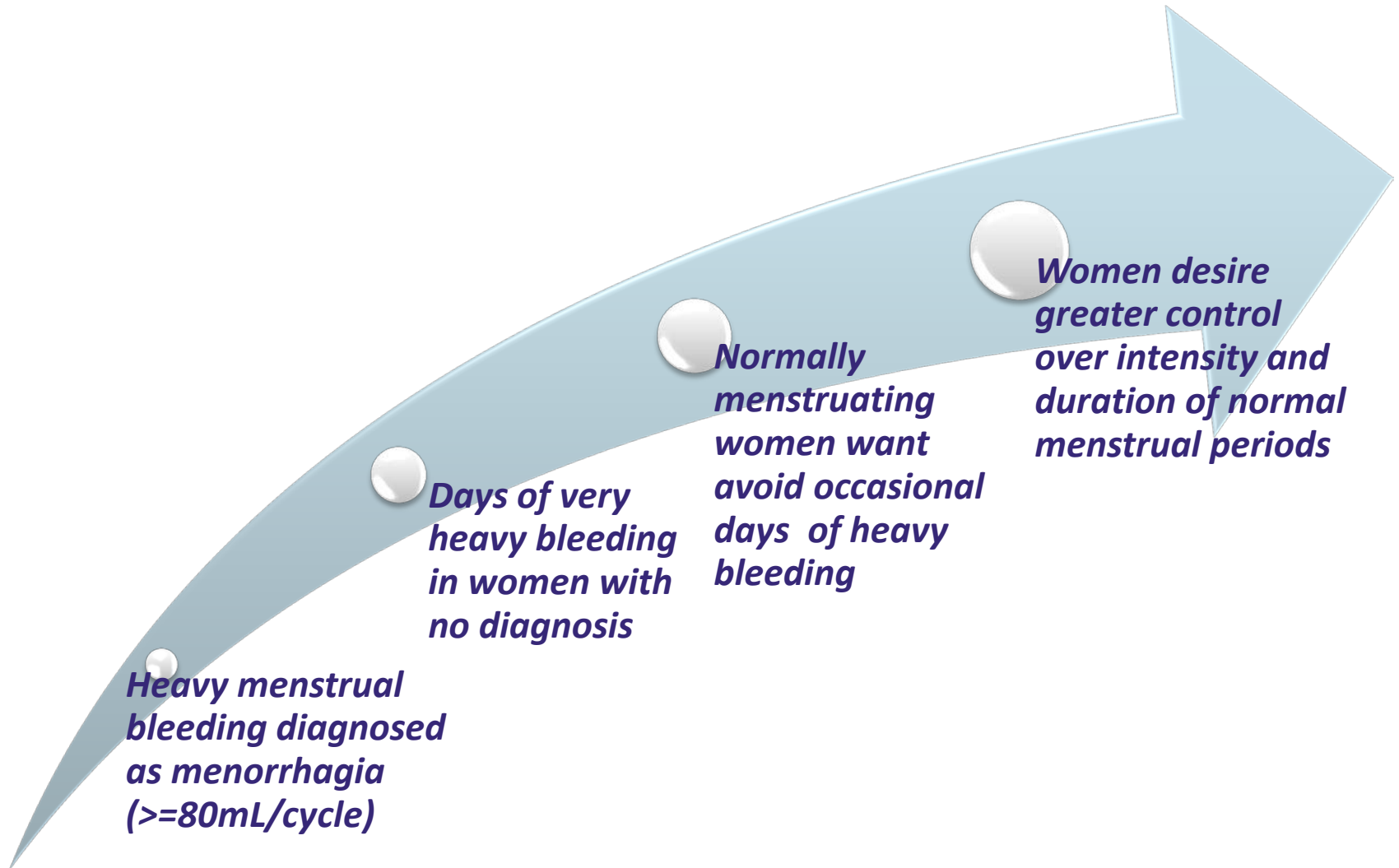
- *Menstrual tampon delivers antifibrinolytic, while absorbing menstrual fluids*
- *Fits into typical use of feminine sanitary products – most convenient option*
- *Creates new, very large market segment with no competition*
- *Unlike hormonal medications (e.g. Mirena®), Duaferm™ does not alter menstrual cycles; women may conceive if pregnancy is desired.*
- *Unlike with oral antifibrinolytics (Lysteda®), menstrual bleeding could be reduced to normal levels in most of women using a fraction of the oral dose.*
- ***US precedent: another medicated tampon approved with no clinical data***
- *If efficacy data required, testing starts with Phase IIb; <5 years to market*
- *Rx and OTC versions could capture hundreds of millions in potential sales*
- *Great exit opportunities for VC (earliest exit in ≤ 2 years, after Phase IIb study)*

Strong Proprietary Position

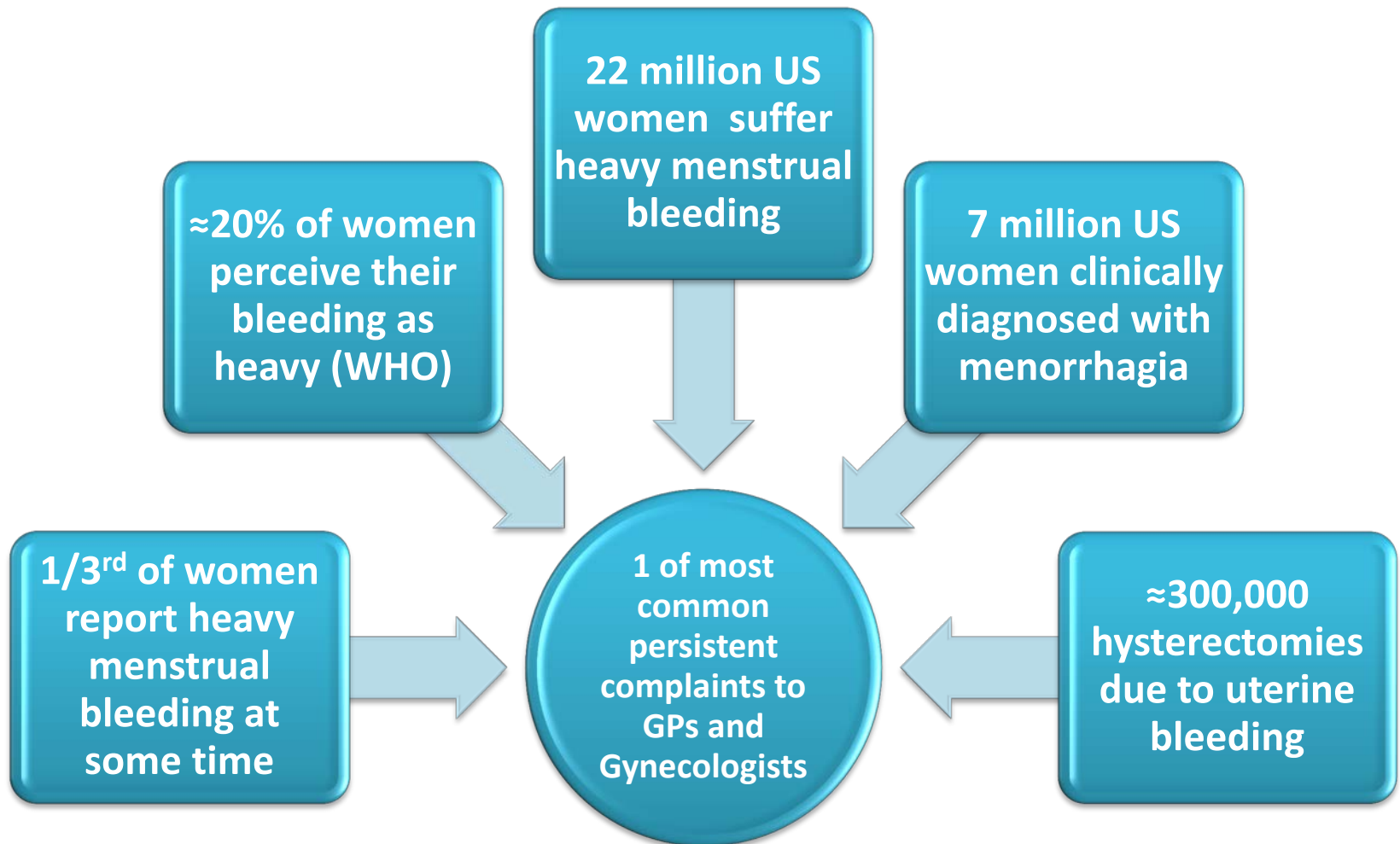
- **Our innovation:** Local delivery of antifibrinolytic was never used to treat heavy menstrual bleeding. Scientific and clinical data supports this option as highly efficacious, safe and most convenient therapy.
- **Three patent applications*:** (US provisional, non-provisional (PCT), and German utility model), developed with a top IP firm (Fish & Richardson)
 - The PCT patent application is currently pursued in the US.
 - A 10-year protection of all compositions is already secured in Germany.
- **Novel, proprietary** medicated sanitary products (e.g., menstrual tampons) releasing ultra-low dose of antifibrinolytic, while absorbing menstrual fluids
- **Novel:** delivery of antifibrinolytic directly to uterine cavity for significant reduction of menstrual bleeding
- **Novel:** antifibrinolytic doses much lower than those given orally for the treatment of menorrhagia

* Other patent applications: (1) vaginal ring with antifibrinolytic for excessive menstrual bleeding; (2) vaginal ring with antifibrinolytic and NSAID for painful & heavy menstrual periods. Two PCT applications are pursued in the US; all related compositions are already protected in Germany.

Heavy Menstrual Bleeding Adversely Affect Women's Quality of Life



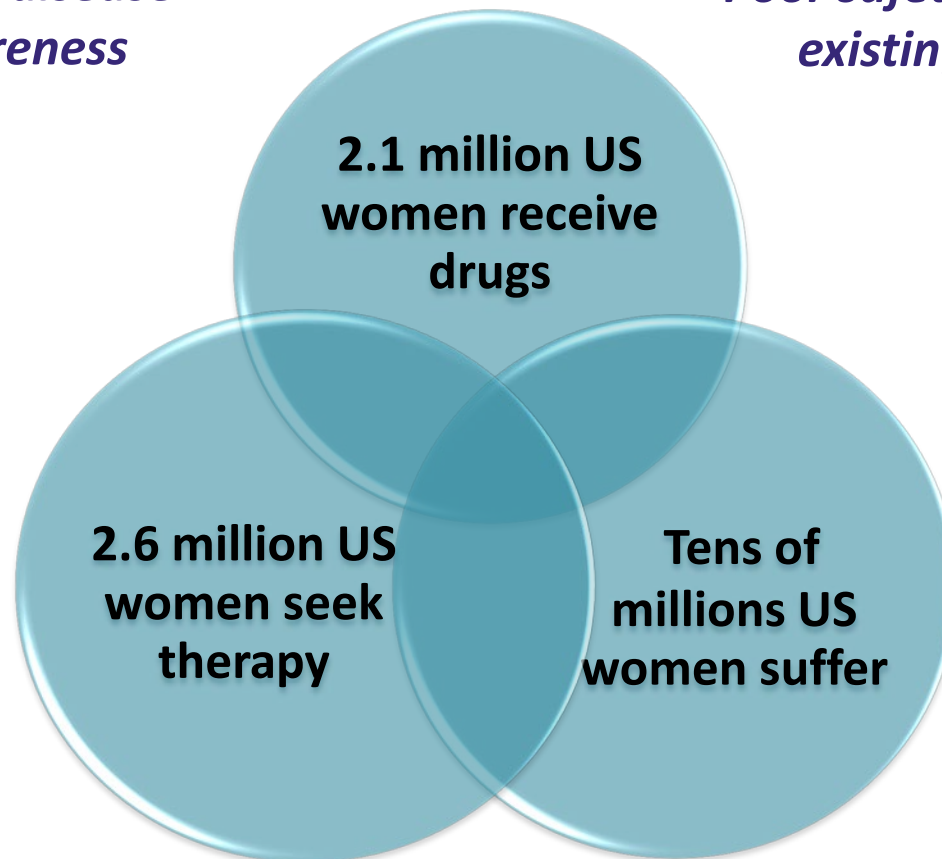
Heavy Menstrual Periods Extremely Prevalent



Huge Market - Underdiagnosed and Undertreated

Lack of disease awareness

Poor safety & efficacy of existing therapies



Competitors Far from Optimal

Lysteda®

- First-line among non-hormonal medications
- Inadequate efficacy, bleeding still heavier than normal in most cases

Hormonal Contraceptives

- Progestin-only: altered menstrual pattern, amenorrhea
- Combined: inferior reduction of heavy bleeding, hormonal side effects

NSAIDs

- Particularly when the menstrual periods painful
- Poor efficacy, gastrointestinal and other adverse events

Androgens

- e.g., Danazol®
- Serious safety and tolerability issues

Surgeries

- Hysterectomy: permanent loss of fertility, morbidity and high cost
- Ablation of endometrial tissue : inferior efficacy, possible injuries

Targeted Delivery of Antifibrinolytics could be Beneficial for Heavy Menstrual Bleeding

Efficacious Drugs

- Drugs with proven efficacy in heavy menstrual bleeding
- Strong local hemostatic effects in various clinical settings

Delivered on Target

- Uterine fibrinolytic activity elevated during menstrual periods
- Much higher in menstrual blood than in peripheral blood
- Especially in women with heavy menstrual bleeding

For Fast and Strong Effects

- Rapid and significant bleeding reduction
- Improvement in quality-of-life metrics
- Exceeding clinical targets for heavy menstrual bleeding

With Very Low, Safe Doses

- Efficacious with hardly detectable circulating drug levels
- Doses much lower than those administered orally
- Excellent safety

Duafem™: Menstrual Tampon (or Specially Designed Pad) Medicated with Antifibrinolytic

Medicated Tampon or Pad

- Delivers ultra-low dose of antifibrinolytic
- While absorbs menstrual fluids

Extremely Convenient

- Fits into typical use of menstrual tampons, pads
- Tampon replacement = treatment compliance

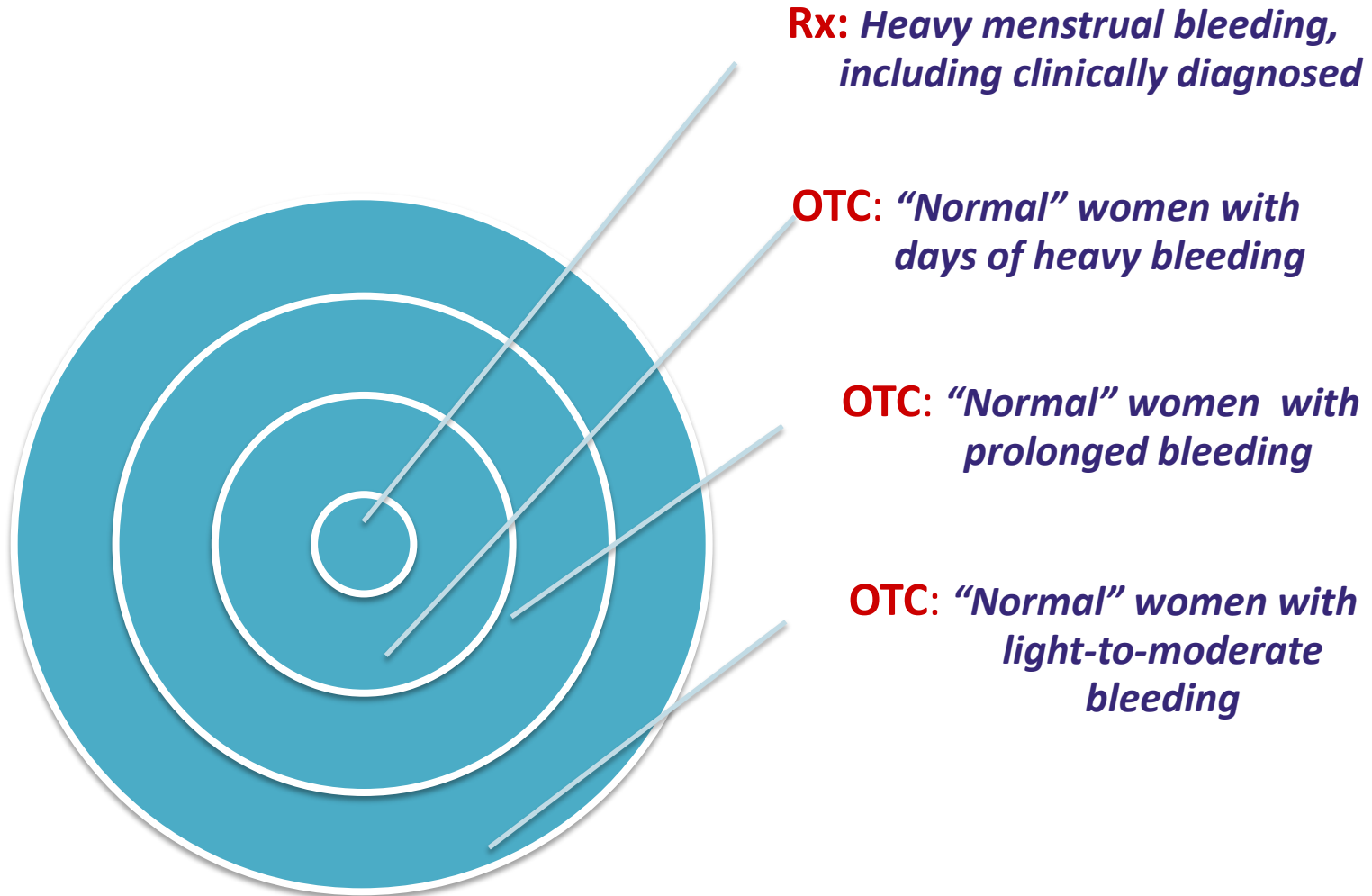
Can be Rx and OTC

- Good for heavy bleeding (Rx)
- Better control of normal menstrual periods (OTC)
- Creates huge new market segment

Proven

- **Concept confirmed in clinical studies**
- **Proven feasibility of medicated sanitary product**
- **Known regulatory precedents**

Duafem™: Rx and OTC Target Populations



Duafem™: Superior Efficacy, Fewer Side Effects



Efficacy better than competitors (Lysteda®, NSAIDs, contraceptives, etc.)

- *Much greater bleeding reduction*
- *In majority of women menorrhagia will be treated—menstrual bleeding returns to normal*
- *Faster formation of blood clots - shorter menstrual periods*



Much safer than competitors (NSAIDs, contraceptives, surgery, etc.)

- *No serious side effects reported for NSAIDs*
- *No hormonal side effects, such as amenorrhea*
- *Women can conceive if desired*
- *No morbidity of surgery*

Duafem™: Hundreds of Millions in Sales for Rx and OTC – Conservative Assumptions

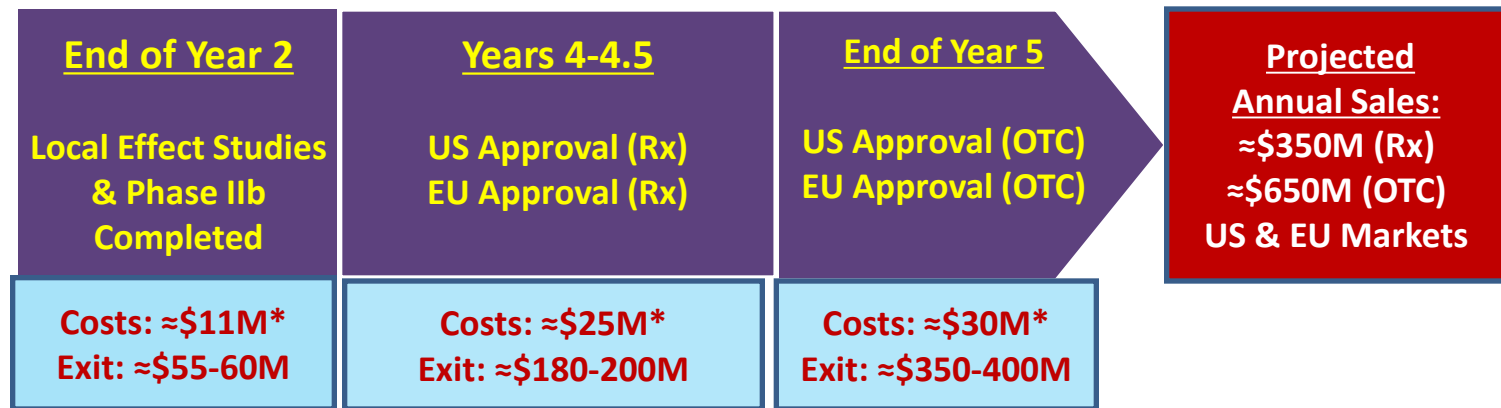
**Rx:
\$350M/year
(US)**

- **Assuming 20-25% of current US market for heavy menstrual bleeding (\$1.5B)**

**OTC:
\$650M/year
(US and ex-US)**

- **70M menstruating women in US**
- **Global feminine hygiene market - \$14B**
- **Assuming 4-5% of global market**

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



Costs = **Cumulative** development costs (i.e., \$30M at Year 5 are the total R&D costs);

Exit = **Upfront payments** to all shareholders (royalties are also expected)

Notes: * (1) The R&D costs are for both Rx and OTC if efficacy studies required. The R&D costs for Rx only – \$20M.

(2) Much lower costs if Rx and/or OTC could be approved with no new data.

Business Model

- ❖ *Our business plan is to advance Duafem™ up to completion of the first clinical efficacy study and to commercialize it in 2.5-3 years. We may also pursue an early out-licensing agreement.*
- ❖ *DuafeM™ could be developed by a dedicated start-up. As a breakthrough solution for a prevalent condition, DuafeM™ R&D could be suitable for an equity crowdfunding model.*
- ❖ *We may also pursue an early out-licensing agreement.*

Seeking Business Partner

- ❖ *The principal seeks one or two co-founders for the specialty start-up dedicated to development of this candidate*
- ❖ *Ideally, it will be an angel investor experienced in pharmaceutical start-ups. Please take a look at the last slide for details*
- ❖ *It could also be an industry veteran in search of a new venture.*
- ❖ *The co-founder's expertise in women's health and/or connections to VC entities would be an asset*
- ❖ *If interested, the partner may assume an executive position (possibly, CEO) within the new company*

Business Plan Details

- ❖ ***Over the next 12-15 months, the following milestones will be achieved:***
- ✓ ***A meeting with the FDA will confirm the US regulatory pathway.***
- ✓ ***A prototype medicated tampon will be manufactured; in-vitro testing will be performed.***
- ✓ ***Meetings with Health Authorities to confirm the clinical program for major EU markets***
- ✓ ***Following the meetings with regulators, a US IND and, possibly, EU CTA will be filed.***
- ✓ ***Ready to start a local effects study, if such a study is required by the FDA***
- ❖ ***Accomplishment of these tasks is expected to secure a licensing agreement or a Series B round of financing which would be applied toward the completion of the Phase IIb study***

The Value Proposition

- ❖ ***To support Duafem's R&D, the company seeks to raise \$500-600K from angel investor(s) in exchange for the company's equity.***
- ❖ ***In 12-15 months, Duafem's valuation will increase at least 5-fold, bringing it up to \$10M.***
- ❖ ***In 3-4 years, we will offer the investors an opportunity for exit or to continue with their support. The anticipated return could be 10-12x.***