Transforming Strong Medicines into First-Line Therapies

ARSTAT Inc. - Combination Pill (Enhanta™)

A First-in-Class Therapy for Painful, Heavy Menstrual Periods

Oral Combination of NSAID and Low Dose Tranexamic Acid

- *Unlike NSAID alone (current first-line), the candidate will effectively treat excessive menstrual bleeding in a majority of women.*
- *Two valuable options - Rx and OTC formulations*
- *≈4 years and ≈$17M to the US market (≈$20M for both US and EU)*

Introduction:

- *Painful and heavy menstrual periods are a highly prevalent condition which currently lacks a single, specific non-hormonal therapy. Our candidate addresses this large unmet medical need*
- *We have developed and patented a pill combining an NSAID (first-line for menstrual pain) and a small fraction of an approved dose of tranexamic acid (first-line for excessive bleeding)*

Our Innovation and Proprietary Position:

- *Novel, proprietary oral drug formulations with no similar predecessors*
- *Novel: a tranexamic acid dose is dictated by the NSAID's ability to reduce menstrual bleeding*
- *Novel: the tranexamic acid doses are much lower than those currently marketed or ever tested*
- *A PCT patent application (developed with a top IP firm) is currently pursued in the US*
- *A 10-year protection of compositions is already secured in Germany*

Business Model:

- *Our business plan is to advance Enhanta™ up to completion of the first efficacy study (Phase IIb or Phase III) and to commercialize it in 2.5 years or less. Enhanta™ could be developed by either ARSTAT or a dedicated start-up. We may also pursue early out-licensing opportunities.*
- *ARSTAT seeks funding from angel investor(s) to be poised to start the first efficacy study*
- *In 12 months, we will secure a licensing agreement or a Series B round of financing which would support completion of the efficacy study and a profitable early exit.*
- *The R&D costs and milestones, funding, business plan and exit details are disclosed below.*

Clinical Rationale:

- *In a majority of women, NSAIDs (first-line therapy for painful and heavy menstrual periods) cannot adequately control menstrual bleeding. Maximal NSAID doses must often be given.*
- *A first-line medication for heavy bleeding (tranexamic acid, Lysteda®) at the approved, fairly high doses is not recommended for a co-administration with NSAIDs for safety reasons*
- *Solution: a combination pill with an NSAID and a low complementary dose of tranexamic acid*
- *At a small fraction of the Lysteda dose, the pill is predictably safe. Enhanta™ will effectively treat heavy menstrual bleeding while keeping NSAID at a minimal dose for pain.*
- *Clinical data also strongly supports superiority of the combination pill vs. NSAID alone in the reduction of menstrual bleeding (a primary efficacy endpoint in a future Phase III study)*
- *The doses of NSAID and tranexamic acid may be adjusted for various levels of menstrual pain and menstrual bleeding. Two Enhanta™ formulations (Rx and OTC) will be developed.*
- *Rx will be intended for women clinically diagnosed with dysmenorrhea and/or menorrhagia; OTC – for women who perceive their periods as heavy and painful (no clinical diagnosis)*

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Development and Commercial Details:

- *Preferred formulations (specific NSAID and recommended doses) will be disclosed later.*
- *Clinical testing begins with Phase IIb which could be positioned as the 1st Phase III study*
- *Known regulatory precedents and approvability criteria; a rapid 505(b)(2) NDA pathway*
- *≈4 years and ≈$17M to the US Market (≈$20M to both US and EU Markets)*
- *A substantially improved first-line therapy in a large, underdiagnosed, undertreated market*
- *In addition to superior efficacy vs. NSAIDs, Enhanta™ is a safer alternative to hormonal medications (e.g., combined and progestin-only contraceptives) and surgical procedures*
- *Could capture significant annual sales for Rx ($≈350M) and OTC (≈$170M) – US projections*
- *Great exit opportunities for VC; earliest exit in 2-2.5 yeas, after completion of the first study.*

Business Plan Details:

- *Over the next 12 months, the following milestones will be achieved:*
  - *A meeting with the FDA will confirm the clinical program and a 505(b)(2) NDA path (based on US precedents, we expect to run 2-3 relatively small efficacy studies and one PK trial).*
  - *Following the meeting, an Investigational New Drug application (IND) will be filed.*
  - *Meetings with Health Authorities to confirm the filing requirements for major EU markets (based on initial input from European regulatory experts, we do not plan ex-US studies).*
  - *Ready to start the first clinical study (Phase IIb or Phase III) in the US*
  - *Continued prosecution of the patent application; the US patent could be issued.*
- *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 1st clinical efficacy study.*

Value Proposition:

- *To support Enhanta's R&D, the company seeks to raise $400-500K from angel investor(s).*
- *The investor's expertise in women's health or connections to VC entities would be an asset.*
- *A year from now, Enhanta's valuation will increase at least 5-6-fold, bringing it to $10-12M.*
- *In 2.5 years, we will offer the investors an opportunity for exit or to continue with their support. The anticipated return could be 10-12x.*
- *We also seek an executive partner, potentially an industry veteran in search of a new venture*

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

End of Year 2	End of Year 3	Year 4	Projected Annual Sales:
Efficacy study (Phase IIb or 1st Phase III) completed	Phase III completed; US and (possible) EU Submissions	US Approval ; Possible EU Approval	$350M (Rx); $170M (OTC) US Market
Costs: ≈$7M Exit: ≈$30-40M	Costs: ≈$16M Exit: ≈$70-80M	Costs: ≈$17M Exit: ≈$120-150M	

Note: Costs & exits are for Rx (US). A few extra millions will support Rx in EU and/or OTC in US/EU

Costs = Cumulative R&D costs (i.e., $17M at Year 4 are the total R&D costs);
Exit = Upfront payments to all shareholders (royalties are also expected).

The Company's Background: The ARSTAT's principal - Arkady Rubin, PhD. - is a researcher with 20+ years of pharma industry experience. In the area of dysfunctional uterine bleeding, Dr. Rubin has analyzed extensive clinical databases and co-authored related publications. He was also a co-inventor of Ortho Tri-Cyclen Lo®, the best-selling oral contraceptive in the US (>$450M, 2013)