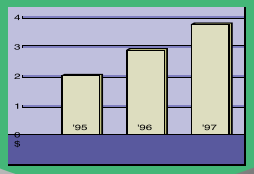
Transforming Strong Medicines into First-Line Therapies

ARSTAT Inc.– Novel Oral Contraceptive (Nuvocept™)

An Optimal Multiphasic Regimen – the Safest Product of its Class

A Novel Multiphasic Regimen, an Improved European "Gold Standard" in Oral Contraception

Could be Approved in EU with No New Data; Hundreds of Millions in Potential Annual Sales



- ***Nuvocept™ 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

- *We have patented Nuvocept™ (a novel multiphasic oral contraceptive).*
- *While the oral contraceptive market is mature, it still offers great opportunities for top brands with hundreds of millions in annual sales. The companies are attracted by new products with incremental improvements, low-cost R&D, and a short time to market. Nuvocept™ meets all of these criteria.*
- *Most importantly, this is also an optimal multiphasic regimen with the safest progestin and a predictably better label vs. US market leaders.*
- *Due to its unique dosing pattern, Nuvocept™ relies heavily on publicly available databases. In some EU countries, it could be approved with no new data; in the US, it is ready for a predictably small Phase III study.*
- *The patent applications are developed by the ARSTAT's principal - Arkady Rubin, PhD., a researcher with 20+ years of pharma industry experience, mostly in women's health.*
- *In the area of contraception, Dr. Rubin contributed to several successful NDAs and co-authored multiple publications. He designed a unique Phase III trial for Ortho Tri-Cyclen Lo® and was one of the original inventors of this best-selling oral contraceptive in the US (>$450M in 2013).*
- *To advance Nuvocept™, the principal seeks partner(s) experienced in pharmaceutical start-ups. The last three slides present related details.*

Novel, Proprietary, Multiphasic Combined Oral Contraceptive

Clinical and Commercial Highlights

- ***An optimal multiphasic oral contraceptive with a robust hormonal balance (constant progestin-to-estrogen ratio) during any phase of the dosing period – the safest product of its class with no similar predecessors***
- ***An improved European "Gold Standard" in combined oral contraception***
- ***New medical use of the safest progestin (levonorgestrel) - a lower risk of venous thromboembolism and a better label vs. current market leaders***
- ***Strong supporting data; a rapid 505(b)(2) NDA pathway, low-risk program***
- ***In some countries, Nuvocept™ could be approved with no new trials (<$2M; ≤2years to market) or may need 1-2 PK studies (<$5M, 2.5 years)***
- ***The scenarios above offer excellent early exit opportunities for VC.***
- ***If efficacy data required, ready for a small Phase III (<$20M, 3-4 years)***
- ***Maximum value if two recommended dosing regimens are developed concurrently, at a typical cost of one. Most preferred candidate alone could capture ≈$300M/year (US)***

Strong Proprietary Position

- ***Our innovation:*** *A multiphasic contraceptive with a constant progestin-to-estrogen ratio throughout entire dosing period was never considered before. It is a predictably optimal regimen, the safest in its class.*
- ***Three patent applications:*** *(US provisional, non-provisional (PCT), and German utility model), developed with Fish & Richardson*
  -Applications support variety of new contraceptives with any progestin/ estrogen combination; a number of phases and dosing days also flexible
- *The PCT application is currently pursued in the US and EU*
- *A 10-year protection of all compositions is already secured in Germany.*
- ***Novel, proprietary:*** *multiphasic contraceptive dosing regimens*
- ***Novel:*** *Gradual increase in both progestin and estrogen doses*
- ***Novel:*** *Constant progestin-to-estrogen ratio during any treatment phase*
- ***Novel:*** *A multiphasic contraceptive with a shortened drug-free interval*
- ***Novel:*** *The combination of the features above*

US Oral Contraceptive Market: Open for New Entrants

- *Combination hormonal contraceptive market is large: $4.2B (US, 2013); ≈ 50% of it is contributed by 8 brands with sales in hundreds of millions*

- *The market is open for new, commercially & clinically appealing entrants. Several pills have recently been approved; some are in late development.*

- *The companies (including big pharma) focus on incremental advances with well-known compounds, low R&D costs, and a short time to market*

- *There are also important clinical reasons to develop new pills:*
  - The FDA-mandated labeling changes regarding the risk of venous thromboembolism (VTE) for pills with modern progestins majorly impacting top brands (e.g., Yaz®)
  *- Inferior contraceptive efficacy & cycle control among contraceptives with low doses of estrogen (ethinyl estradiol, EE)**
  - Search for a dosing regimen that mimics a woman's natural cycle

** Despite an aggressive promotion of the low EE (<20 mcg/day) doses, 67% of US women prefer pills with ≥30 mcg EE (Trussell, 2012)*

Nuvocept™: New and Different Multiphasic Oral Contraceptive

- ***A novel, proprietary multiphasic contraceptive with no similar predecessors***
- ***Some existing multiphasics (e.g., Estrostep®) increase amount of estrogen with the same progestin dose; other multiphasics increase amount of progestin with the same (e.g., Ortho-Novum 7/7/7®, Ortho Tri-Cyclen Lo®) or fluctuating (Triphasil®) estrogen dose***
- ***An increase in progestin and/or estrogen amounts matches a woman's natural cycle and improves contraceptive efficacy and menstrual bleeding pattern***
- ***However, varying progestin-to-estrogen ratios are more likely to cause hormonal side effects when compared to monophasic regimens with the same doses during the entire treatment period.***
- ***A constant ratio will greatly reduce unopposed progestin or estrogen effects.***
- ***When combined with a robust hormonal balance, a gradual increase in both progestin and estrogen doses creates an optimal multiphasic regimen from both efficacy and safety perspectives.***

An Improved European "Gold Standard"

- ***Nuvocept™ may utilize any progestin/estrogen combination***
- ***Two recommended dosing regimens combine levonorgestrel (LNG) & ethinyl estradiol (EE): (a) triphasic (1st choice) and (b) biphasic regimen. Both are predictably safe and efficacious – potential market leaders***
- ***The regimens' dosing schedule and the LNG-to-EE ratio are supported by large clinical databases of monophasic LNG/EE formulations: low-dose (Alesse®, Levlite®) and high-dose (Nordette®, Levlen®) pills***
- ***A gradual increase in both LNG and EE will greatly improve efficacy and menstrual bleeding pattern vs. a low-dose LNG/EE formulation***
- ***A reduced total drug exposure will improve safety vs. a high-dose LNG/EE formulation (European "Gold Standard" in oral contraception)***
- ***Since LNG is one of the safest progestins, Nuvocept™ will also have a lower risk of VTE and more favorable label vs. most other contraceptive pills, including current leading brands***

In some countries, could be marketed in 1.5-2 years Ready for Phase III (if efficacy data required)

❖ *Due to their unique dosing patterns, preferred Nuvocept™ dosing regimens could be approved in some countries based entirely on publicly available clinical data for marketed LNG/EE pills*

May be approved with no new data

- *In some European countries, may be approved with no additional clinical data*
- *A hybrid application (based on an expert report): may support two regimens*
- *Could be <$2M and 1.5 years to market*

OR Only needs 1-2 pharmacokinetic trials

- *40-80 subjects*
- *<$5M to market: one or two regimens may be developed*
- *Could be 2.5 years to market*

OR Enters Phase III for efficacy

- *400-500 subjects*
- *<$20M to market: one or two regimens may be developed*
- *Predictable efficacy, very high probability of success, 3-4 years to market*

❖ *Per known US regulatory precedents, the NDA filing may require an abbreviated Phase III study*

Sales Potential in Hundreds of Millions

- ***The global contraceptive market is growing fast; could reach $19.2B by 2017***

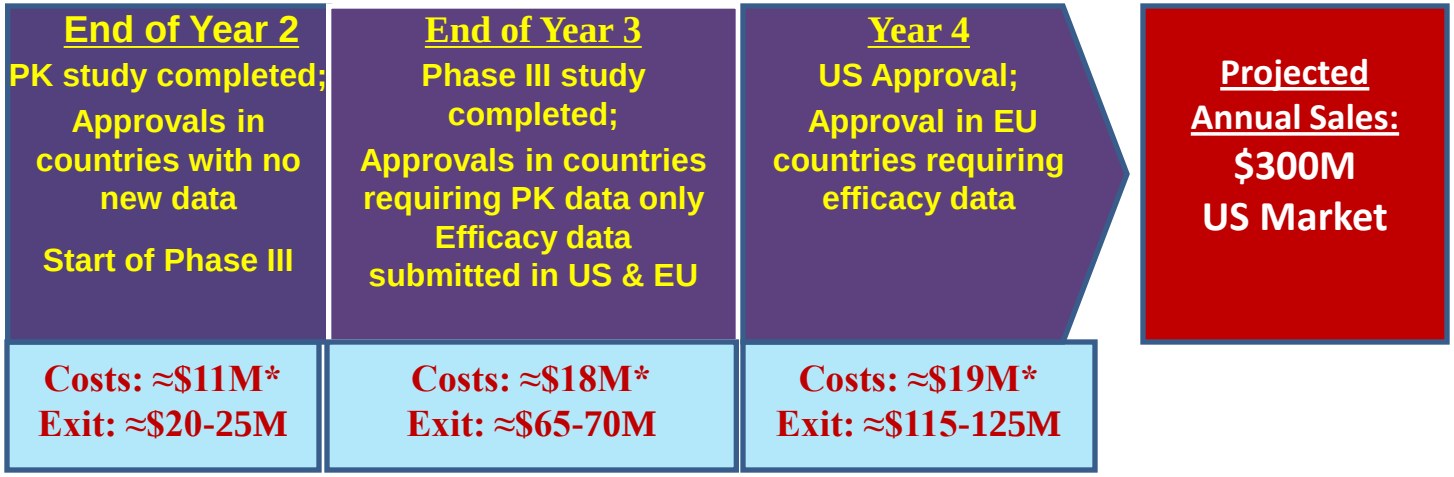
- ***The US oral contraceptive market is increasingly appealing. Two reasons:***
  - ***A sharp (≈80%) spike in monthly price of leading branded contraceptives: from $50 (2008) to $90 (2013)***
  - ***Significant sales volume (>$100M) for each percent of the US market share***

- ***With some conservative assumptions, our preferred triphasic regimen is expected to capture up to 3% of the US market ($300M/year). This is less than two-thirds of the market share reported for another, predictably inferior, triphasic oral contraceptive, Ortho Tri-Cyclen Lo®.***

- ***Modest R&D costs and a fast path to market contribute to the commercial appeal of the candidate. Possible EU approval with little or no new data further increases the value of this opportunity.***

- ***We also recommend concurrent development of both triphasic and biphasic regimens at a typical cost of one. We are currently evaluating commercial aspects of possible oral contraceptive franchise in both the US and EU.***

R&D Costs, Major Milestones and Exit Opportunities: Overview



***Costs** = **Cumulative** R&D costs (i.e., $19M at Year 4 are the **total R&D costs**);*
***Exit** = **Upfront payments** to all shareholders (royalties are also expected).*

*Notes: * (1) R&D costs if efficacy data required. Much lower costs (≈$5M) for a PK-only scenario;*
(2) Projected annual sales are for one candidate (triphasic regimen)
(3) Exit assessments will be increased if two dosing regimens are offered to potential partners. The projected costs must accommodate development of both recommended regimens.

Business Model

- ***Our business plan is to advance Nuvocept™ and to commercialize it in 2.5 years or less.***
- ***Nuvocept™ could be developed by either ARSTAT or a new start-up with well-defined development targets and great exit opportunities.***
- ***We will pursue a strategic R&D partnership or a 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 months, the following milestones will be achieved:***
- ***A meeting with the FDA will confirm the clinical program and a 505(b)(2) NDA path (a sole pharmacodynamic study could suffice; alternatively, a truncated Phase III efficacy study may be needed)***
- ✓ ***Following the meeting, an Investigational New Drug application (IND) will be filed.***
- ✓ ***Meetings with EU Health Authorities to confirm the filing requirements for other targeted territories, while submitting Marketing Authorization Applications (MAAs) in European countries where no additional clinical studies are required for approval***
- ✓ ***Ready to start a PK study to support filings in EU countries requiring PK data only***
- ***Completion of these tasks is expected to secure a licensing agreement or a Series B round of financing which would be applied toward the funding of the Nuvocept™ PK trial, an optional Phase III study as well as regulatory submissions in the US and EU countries.***

The Value Proposition

- ***To support Nuvocept's R&D, the company seeks to raise $300-400K from angel investor(s) in exchange for the company's equity***
- ***A year from now, the product's valuation will increase at least 4-5-fold, bringing it to $8-10M.***
- ***In 2-2.5 years, we will offer the investors an opportunity for exit or to continue with their support. The anticipated return could be 10-12x.***