Repros

THERAPEUTICS INC

***Developing clinical stage small molecule therapeutics to treat hormonal and reproductive system disorders***

# Repros Disclaimer

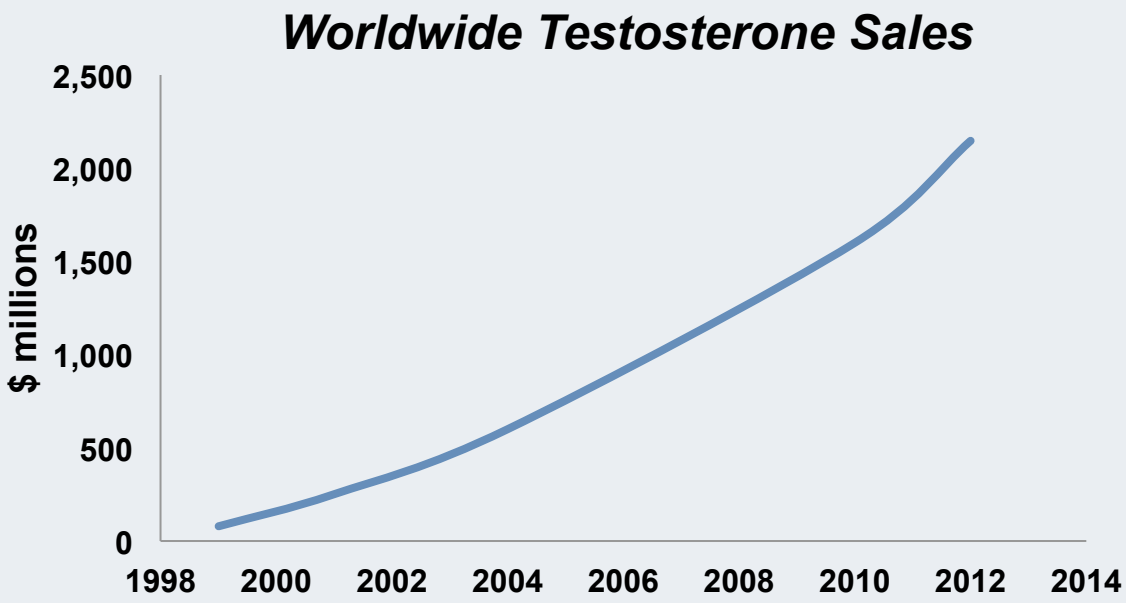
*Any statements made by the Company that are not historical facts contained in this release are forward-looking statements that involve risks and uncertainties, including the ability to raise additional needed capital on a timely basis in order for it to continue to fund development of its Androxal® and Proellex® programs, have success in the clinical development of its technologies, the reliability of interim results to predict final study outcomes, and such other risks which are identified in the Company's most recent Annual Report on Form 10-K and in any subsequent quarterly reports on Form 10-Q. These documents are available on request from Repros Therapeutics or at www.sec.gov. Repros disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.*

# Investment Highlights

- **Focused strategy: small molecule therapeutics for reproductive disorders**
- **Two late stage clinical programs each with +$1B sales potential**
- **Androxal® : PHASE 3 (SPA) oral treatment for Low Testosterone with pending patent/ patent life to the mid 2020's(growing +$2B market)**
  - ***Restoration of testicular function and testosterone levels in treatment of 2º hypogonadism (most common cause of low T)***
- **Proellex: PHASE 2 treatment for uterine fibroids and endometriosis with pending patent/ patent life to the mid 2020's (+ $5B market)**
  - Chronic relief of uterine fibroid symptoms
  - Fibroid de-bulking
  - Chronic relief of the symptoms associated with endometriosis
  - Potential breast cancer intervention
- **Key late stage clinical & regulatory events driven news flow in 2013**

# Testosterone Market Continues to Grow

- *2012 worldwide sales >$2.1B*
- *US accounts for  nearly 75% of global sales*
- *Major pharmaceutical companies have moved to capture 83% of US opportunity*



# Excerpt: FDA SPA Minutes

***1) Proportion of subjects with average serum concentration (Cavg) for T in the normal range (i.e. serum T of 300 ng/dL – 1040 ng/dL).***
***2) Proportion of subjects with a 50% or greater decrease in sperm concentration from baseline to endpoint.***
***To demonstrate efficacy with regards to the first endpoint, at least 75% of subjects in the Androxal group should achieve a Cavg for T in the normal range with the lower bound of the 95% confidence interval not below 67%. At least 100 Androxal subjects would be required to demonstrate a point estimate of 75% or better.***
***For the second endpoint, Androxal should be non-inferior to placebo with respect to the difference in responder rates We have found a 20% non-inferiority margin to be acceptable in prior similar trials.***
***Values for serum T and sperm concentration at baseline and endpoint should be based on at least two assessments. Semen sampling at each time point (baseline and endpoint) should be separated by at least 48 hours.***
***Cmax is an important safety issue. The percentage of patients with Cmax above the following three pre-determined limits (listed below) should be a secondary endpoint:***
***• Cmax>1500 ng/dL***
***• Cmax>1800 ng/dL and <2499 ng/dL***
***• Cmax>2500 ng/dL***

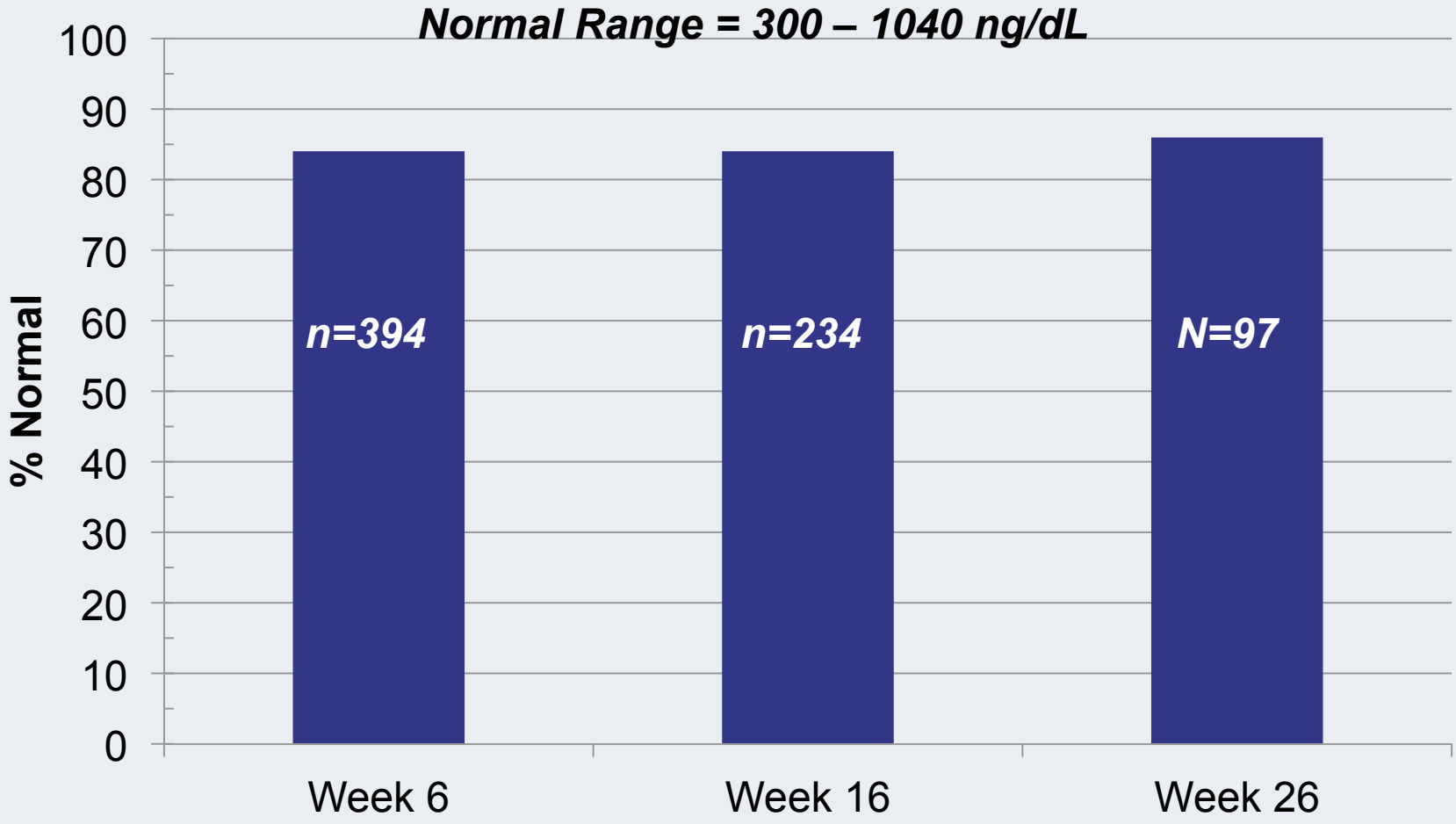
# Testosterone Endpoint Outcome Sensitivity

If the response rate is greater than 75%, then the required sample size to have the lower limit exceed 67% decreases considerably. Here's a table with the minimum number of subjects that would be required to have the lower limit exceed 67% for each responder rate. The last column is what the lower limit of the 95% CI will be with N=113.

| Responder Rate | N | Lower Limit of 95% CI | Lower Limit of 95% CI with N=113 |
|---|---|---|---|
| 75% | 113 | 67.02% | 67.02% |
| 80% | 37 | 67.11% | 72.62% |
| 85% | 16 | 67.50% | 78.42% |
| 90% | 7 | 67.78% | 84.47% |
| 95% | 3 | 70.34% | 90.98% |

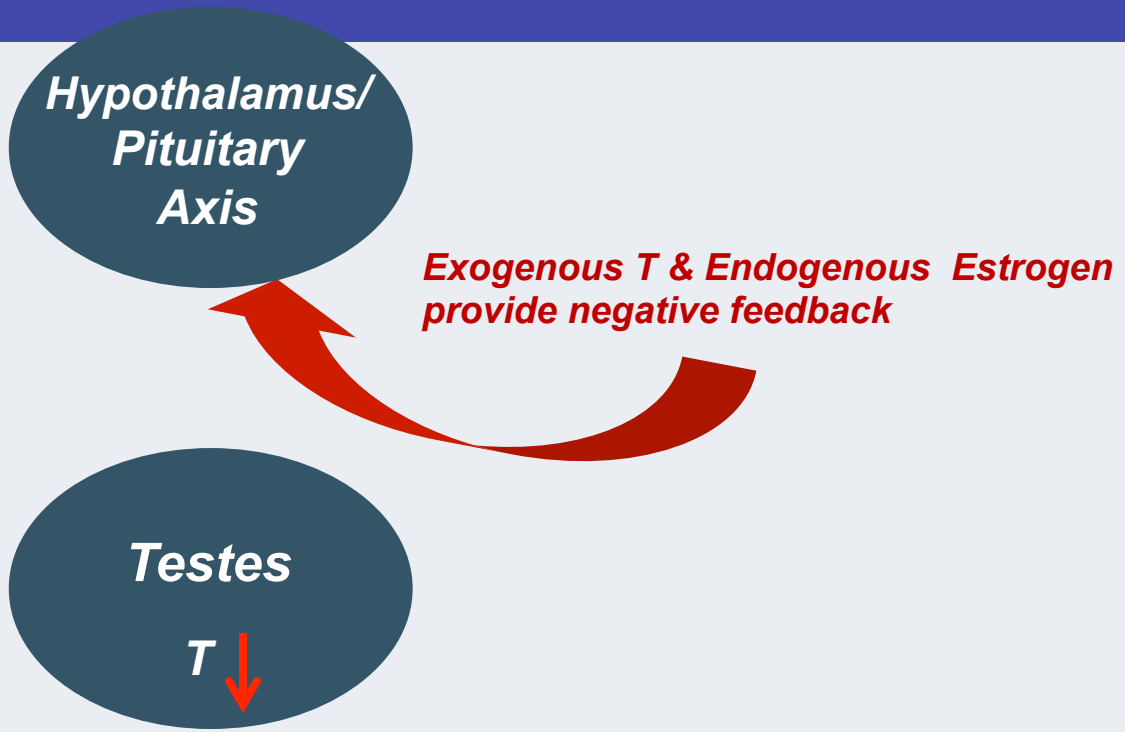
# ZA-300: % of Men with T in the Normal Range

**(26 week open label study, n=500 planned, 499 enrolled as of 2/8/13)**



# Approved T Replacement Products Shutdown Testicular Function

- *Pituitary secretions decrease or shut down*
- *Testicular function decreases or shuts down*
- *30% of men castrated at the level of the pituitary*




***Leydig Cell Activity Suppressed***
***Spermatogenesis Suppressed Leading to Infertility***

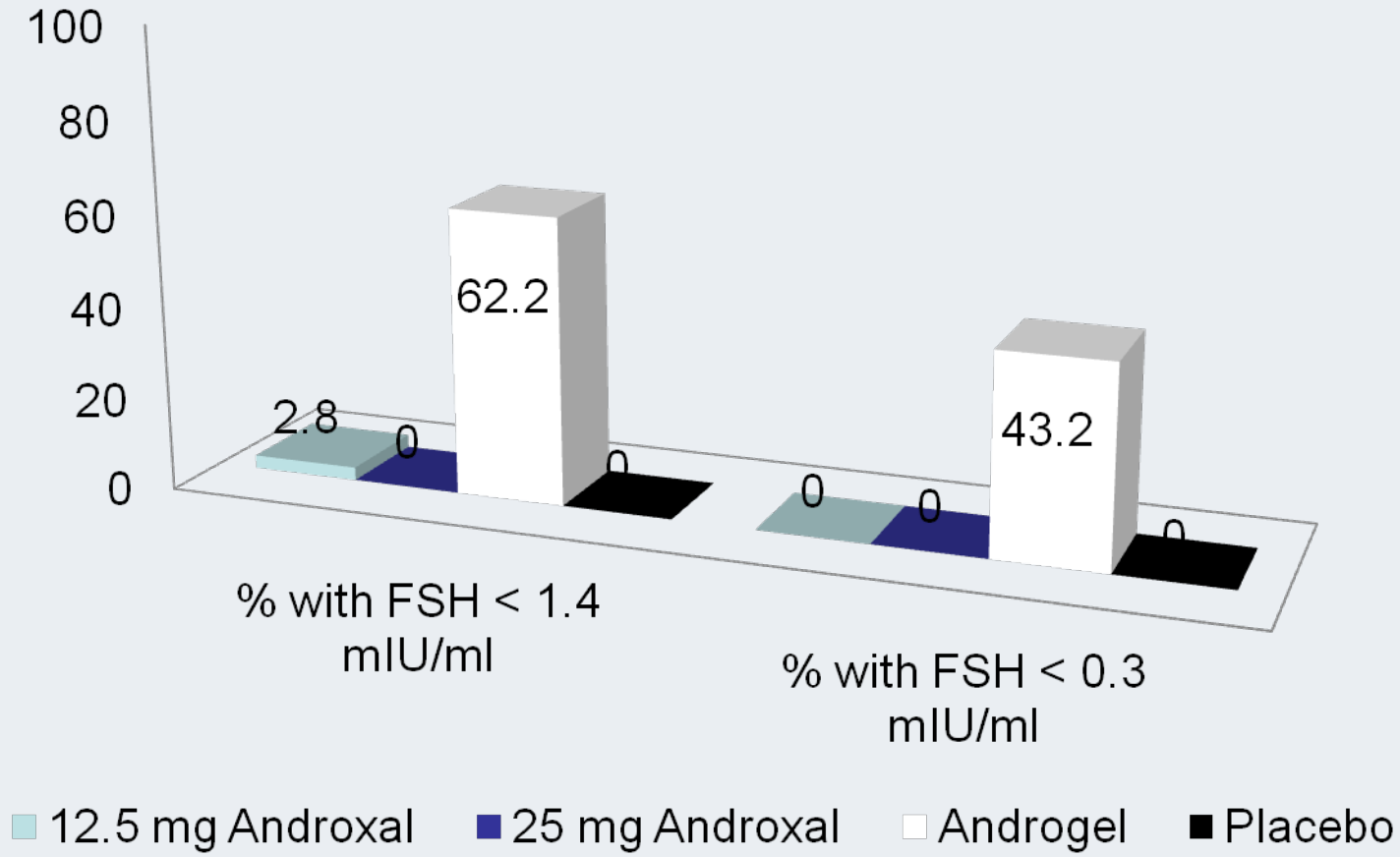
***Over 30% of men with secondary hypogonadism administered an approved topical testosterone have undetectable pituitary and testicular function***
***They are castrated at the level of the pituitary***

# Sperm Endpoint Outcome Sensitivity

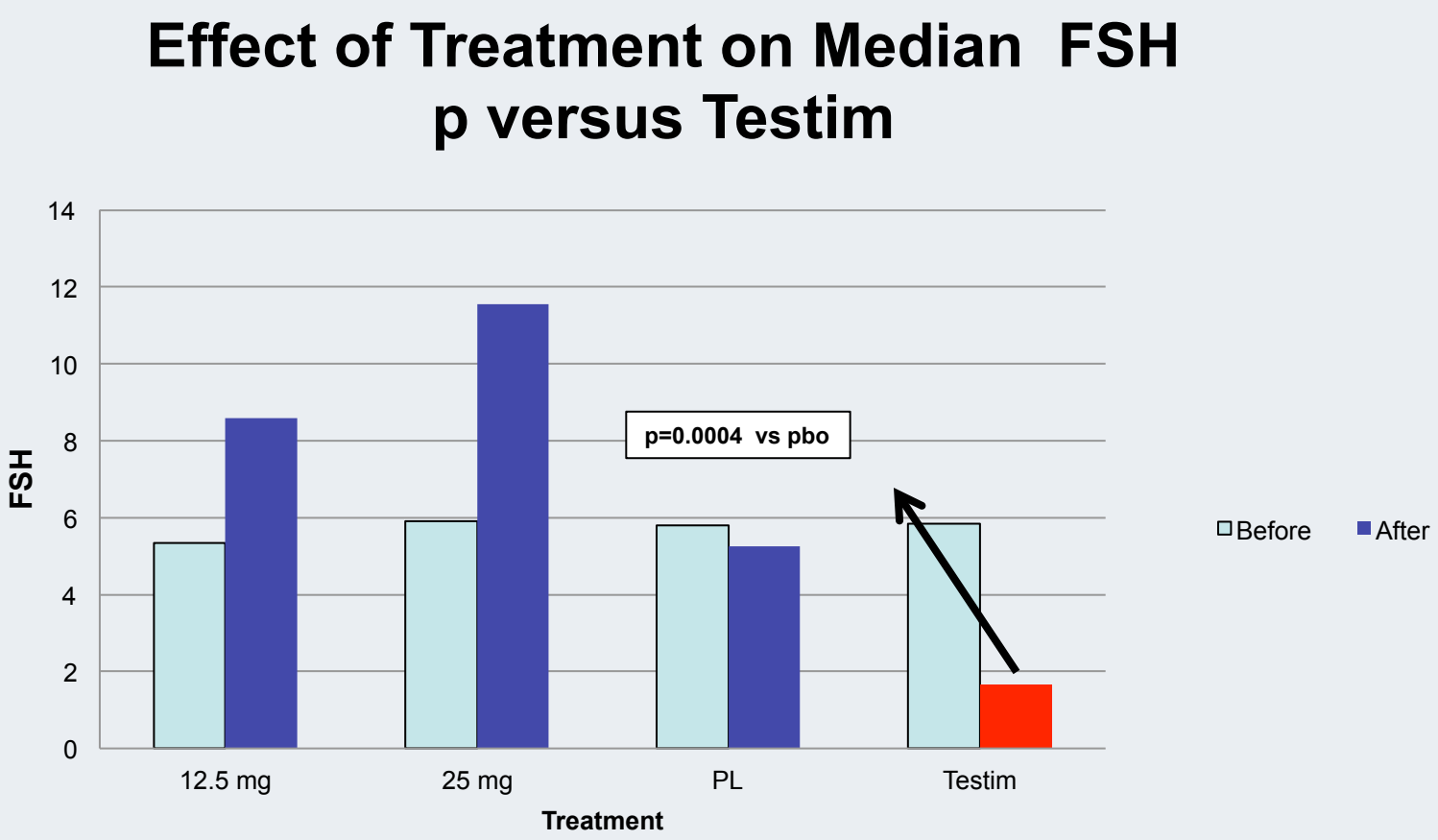
Assuming that 1% of the placebo group and 10% of the Androxal group experience a 50% or greater decrease in sperm concentration with a 3:1 randomization the study requires 114 Androxal/38 placebo/152 total provides for a 0.05 significance level and assuming a non-inferiority limit of 20%.

Translating the statistical jargon into English, if no subjects in the placebo arm drop below 50% of their baseline counts up to 14 subjects in the Androxal arm can drop below 50% and the results meet the non-inferiority outcome.

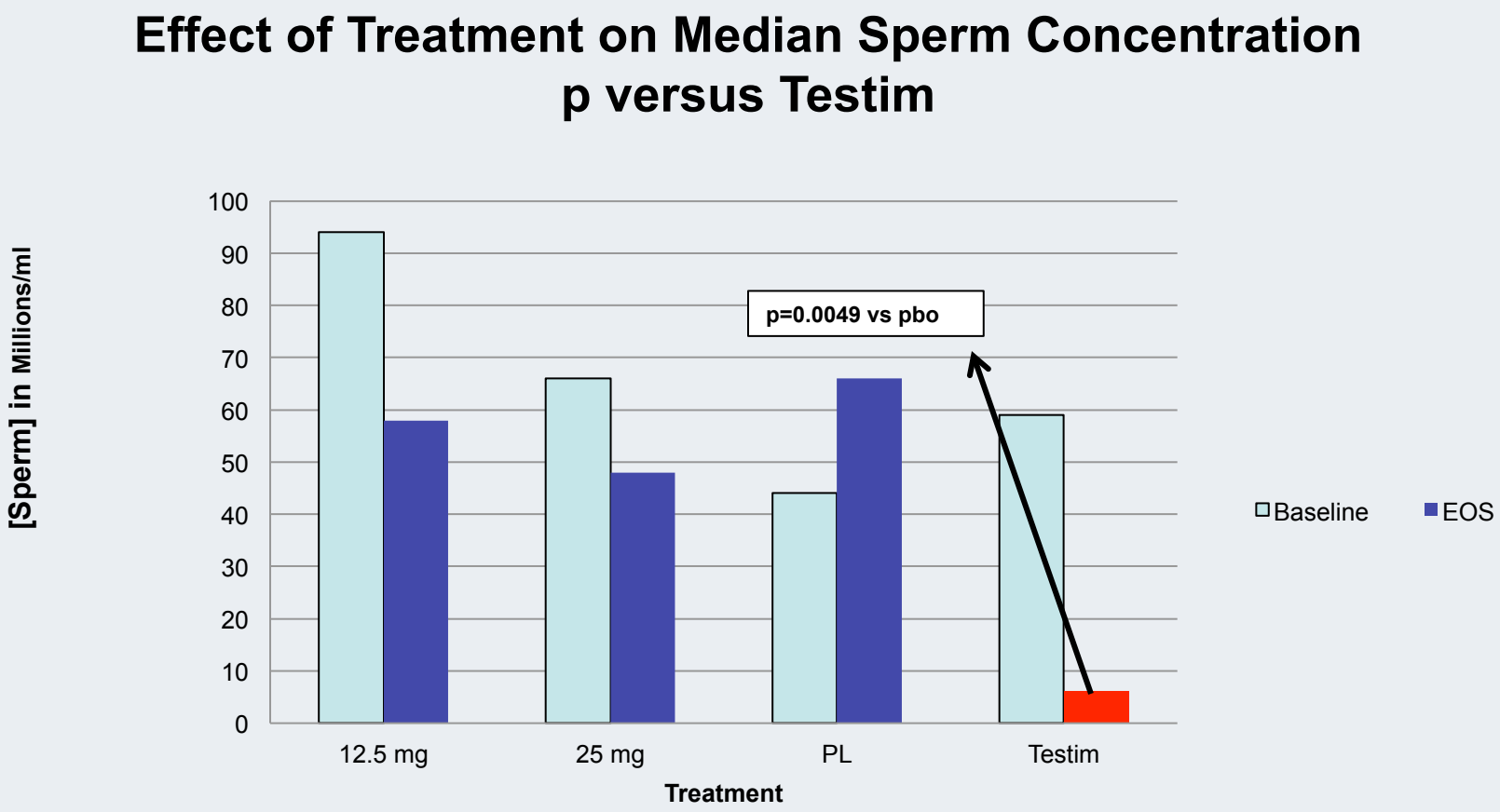
# % of Subjects with FSH Below the Lower Limit of Normal and Below the Lower Limit of Detection (0.3 mIU/ml) after 3 months ZA-003 "Completer" Analysis



# FSH Effects ZA-203 (3 month study)



# Sperm Concentration ZA-203



# Phase III Androxal Program Status:3/12/13
# NDA Target: June 2014

| Study | Target Enrollment | Study Duration | Subjects Screened | Subjects Enrolled | Subjects Pending | Projected Full Enrollment |
|---|---|---|---|---|---|---|
| ZA-300 Safety | 500 | 6 months | 1288 (28 sites) | 500 | | **Fully Enrolled** |
| ZA-301 Pivotal | 152 | 3 months (+ 6 weeks) | 571 (17 sites) | 151 | Enrolled in < 12 weeks | **Fully Enrolled** |
| ZA-302 Pivotal | 180 | 3 months (+ 6 weeks) | 395 (16 sites) | 99 | 29 | May ’13 |
| ZA-303 Safety | 150 | 1 year | 419 (10 sites) | 150 | | Core Study Enrolled |

# Androxal Profile Favorable Compared to Leading T Products

| | T Gels/Creams | Androxal | *Advantage Androxal* |
|---|---|---|---|
| Administration | Applied to Skin | Oral |  |
| Controlled Substance | Yes | No |  |
| Sexual Partner & Risk to Children | Yes | No |  |
| Unpredictable Response | Yes | No |  |
| Super High T Levels | Yes | No |  |
| Prostate Risk | Yes | No |  |
| Shuts Down Testes | Yes | No |  |
| Requires Chronic Treatment | Yes | No |  |

# Third Party Study Suggests Favorable Reimbursement Potential for Androxal

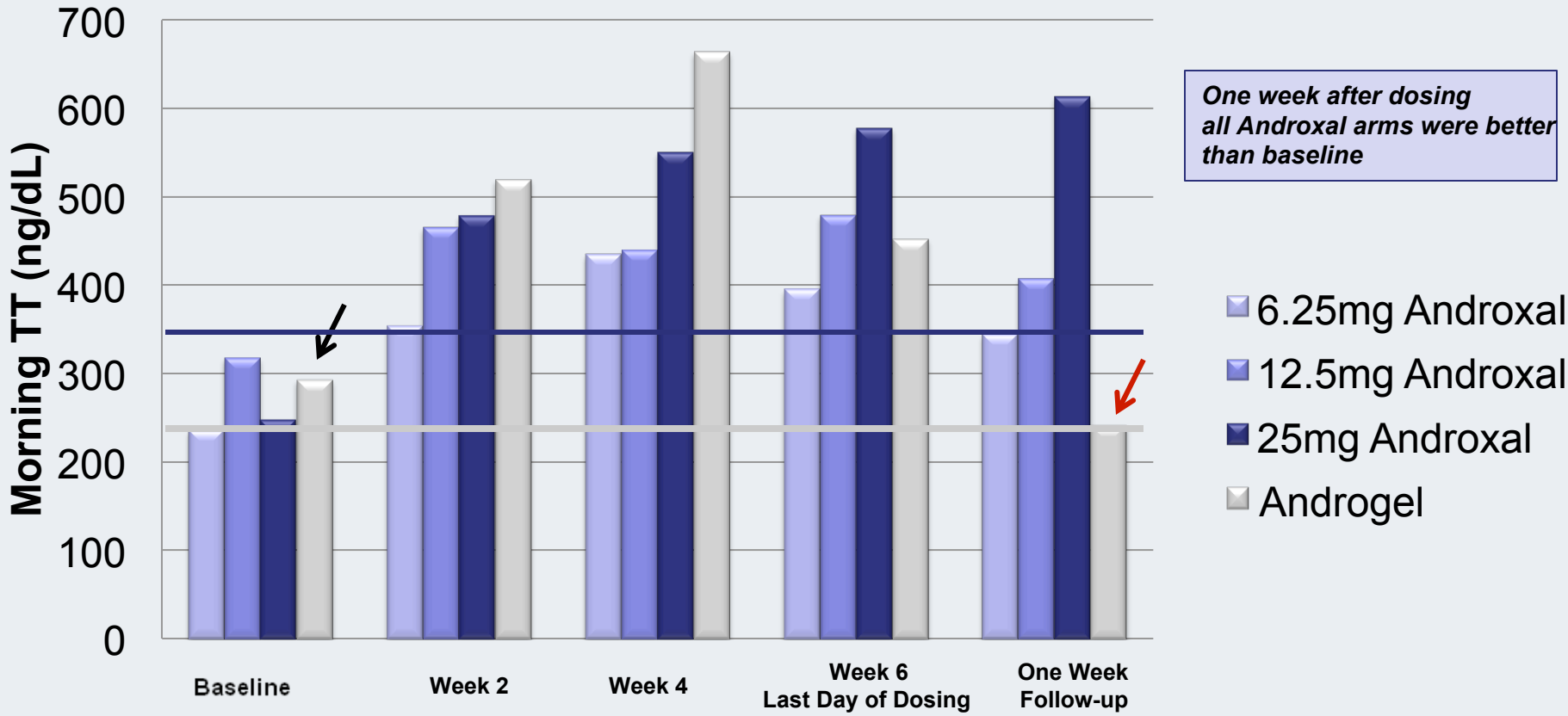
***Majority of payers believe Androxal's oral administration and non-chronic use may offer overall cost savings***

- **Third party assessment of payers indicates vast majority (>90%) would add Androxal to formularies**
  - Cost will be key for tier placement
  - **50% of plans indicated they would require a PA(Prior Authorization) to show proper diagnosis**

- **62% of respondents expect Androxal to be priced at parity to Androgel**
  - Anticipated Androxal pricing of $170-350/month would be competitive with Androgel

# *Men on Androxal exhibit continued improvement in T even after dosing has stopped*

## Fig. 14: Mean Morning TT Over Time (ZA-204)




***One week after dosing all Androxal arms were better than baseline***

***One week after dosing the Androgel arm was worse than baseline***

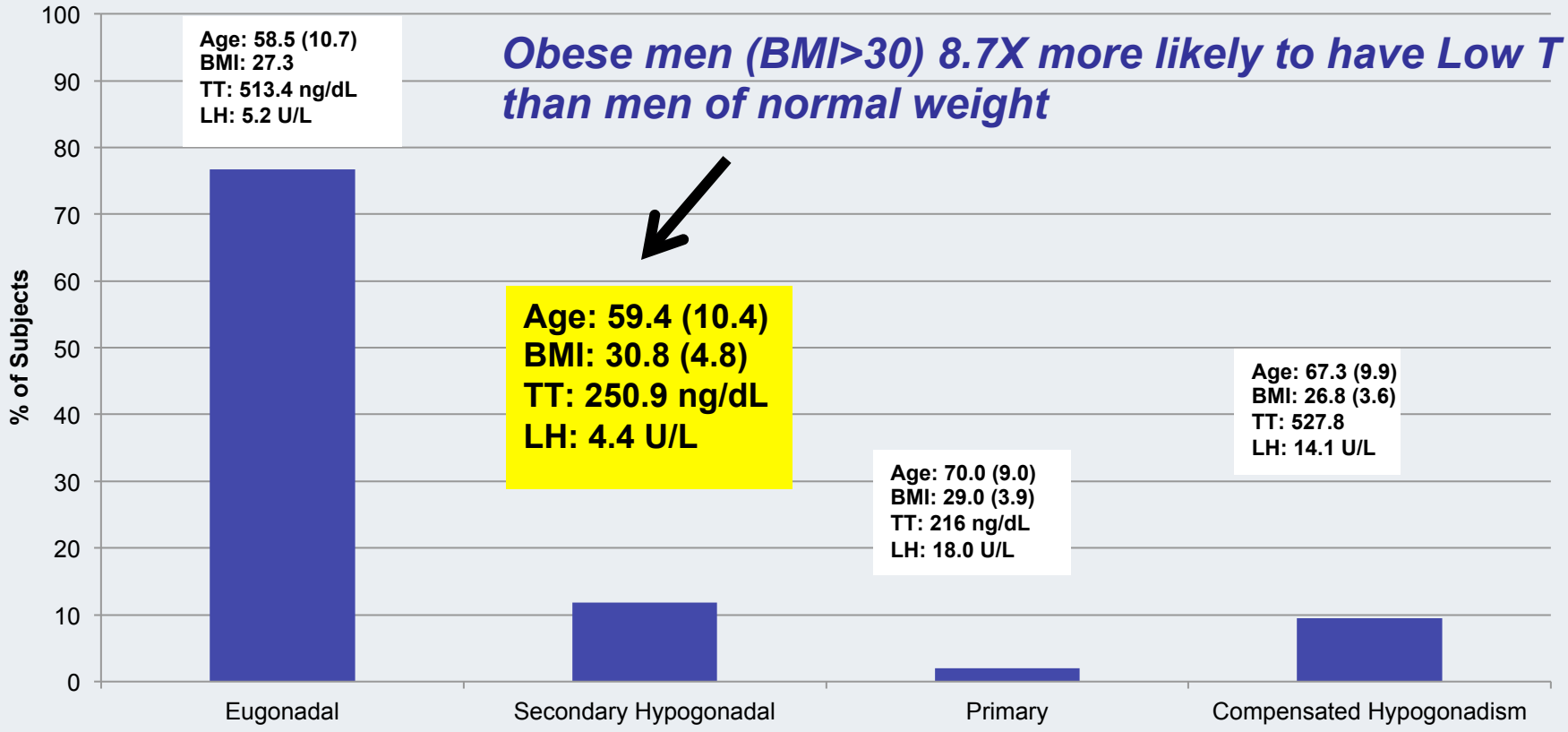
# *Who are the men using testosterone?*

## European Male Aging Study

### *Distribution and Selected Characteristics of Men Ages 40-79 (Tajar et al)*

***Overweight BMI > 25 (6' 190# male BMI=25.8)***
***Obese BMI > 30 (6' 230# male BMI =31.2)***

**Data derived from over 3000 men**




***In 2010 there were ~90 million men in the US between the ages of 20 and 65***

***32% are obese***

# Androxal Take Home Message

- Because of Obesity, 30% of American Males are at Risk of Secondary Hypogonadism
  - Co-morbidities include diabetes and cardiovascular disease
- Approved T Products Worsen the Underlying Condition
- ***We believe only Androxal + Diet + Exercise can reverse this disorder***

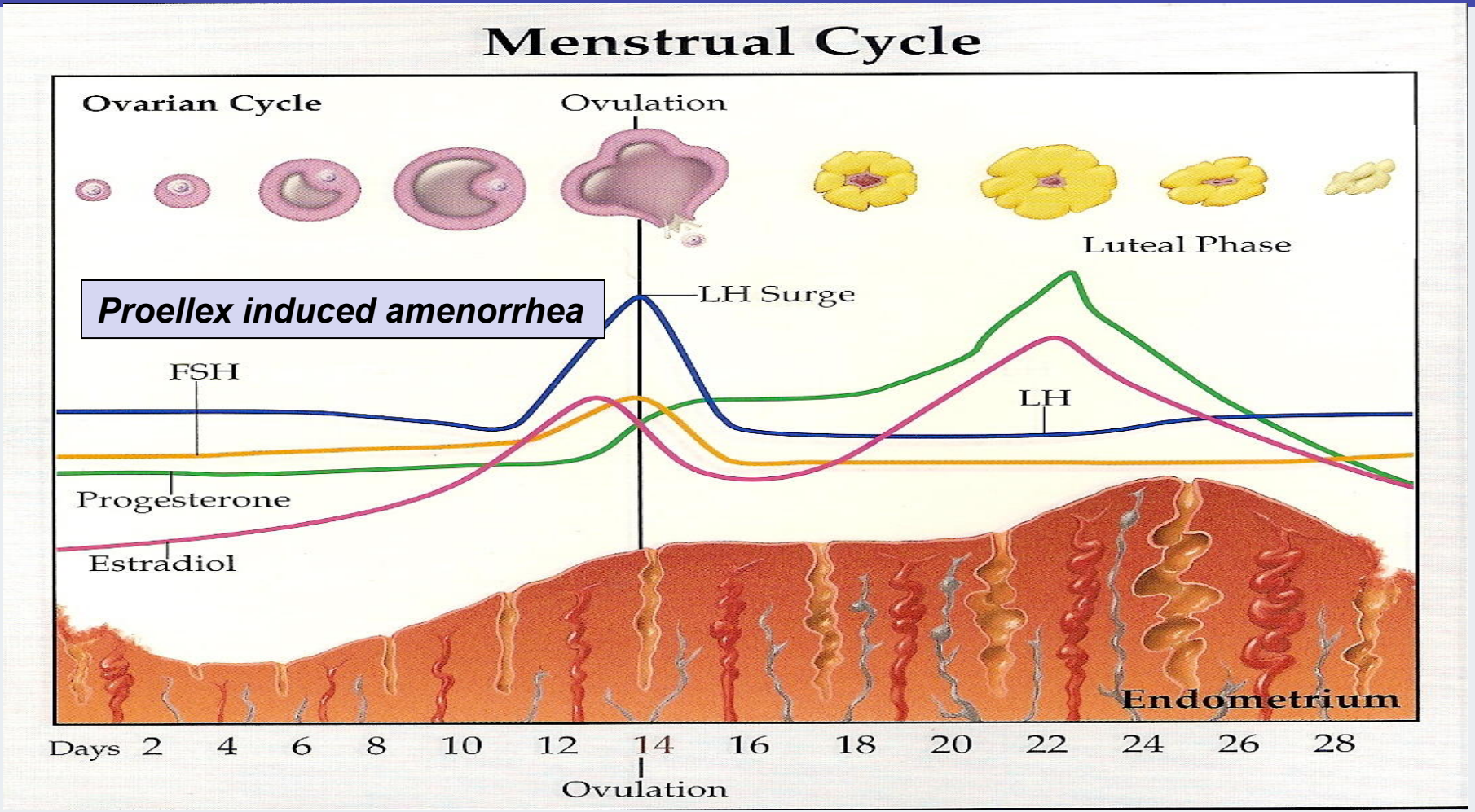
# Proellex for the Treatment of Uterine Fibroids and Endometriosis

***Over 30 million women of reproductive age in the US afflicted with symptomatic uterine fibroids or endometriosis***

***Over 300,000 hysterectomies performed every year in the US to treat these two disorders***

***No acceptable chronic therapeutic options available today***

# An Effective Dose of Proellex Stops Menstruation in Majority of Women

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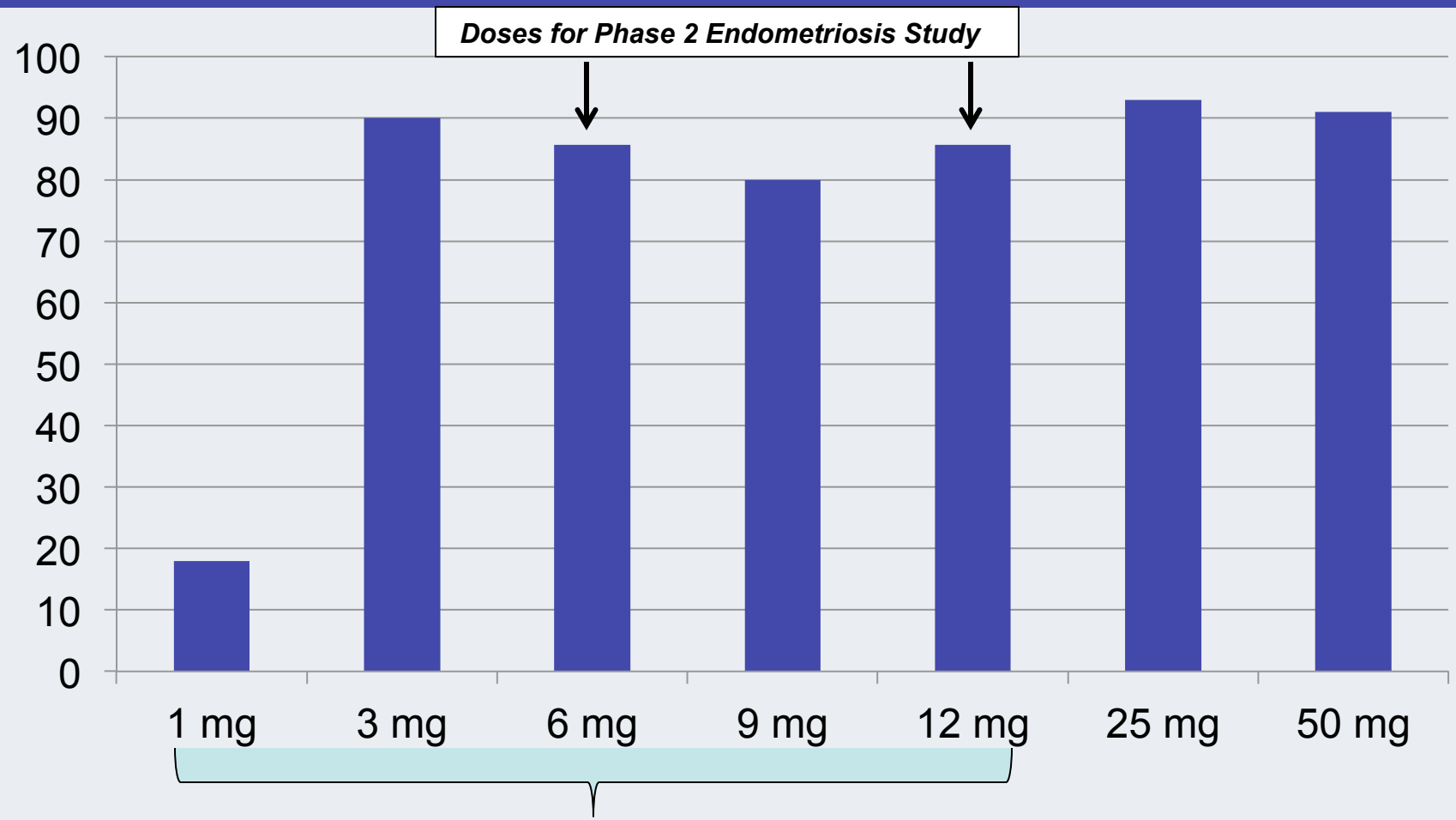
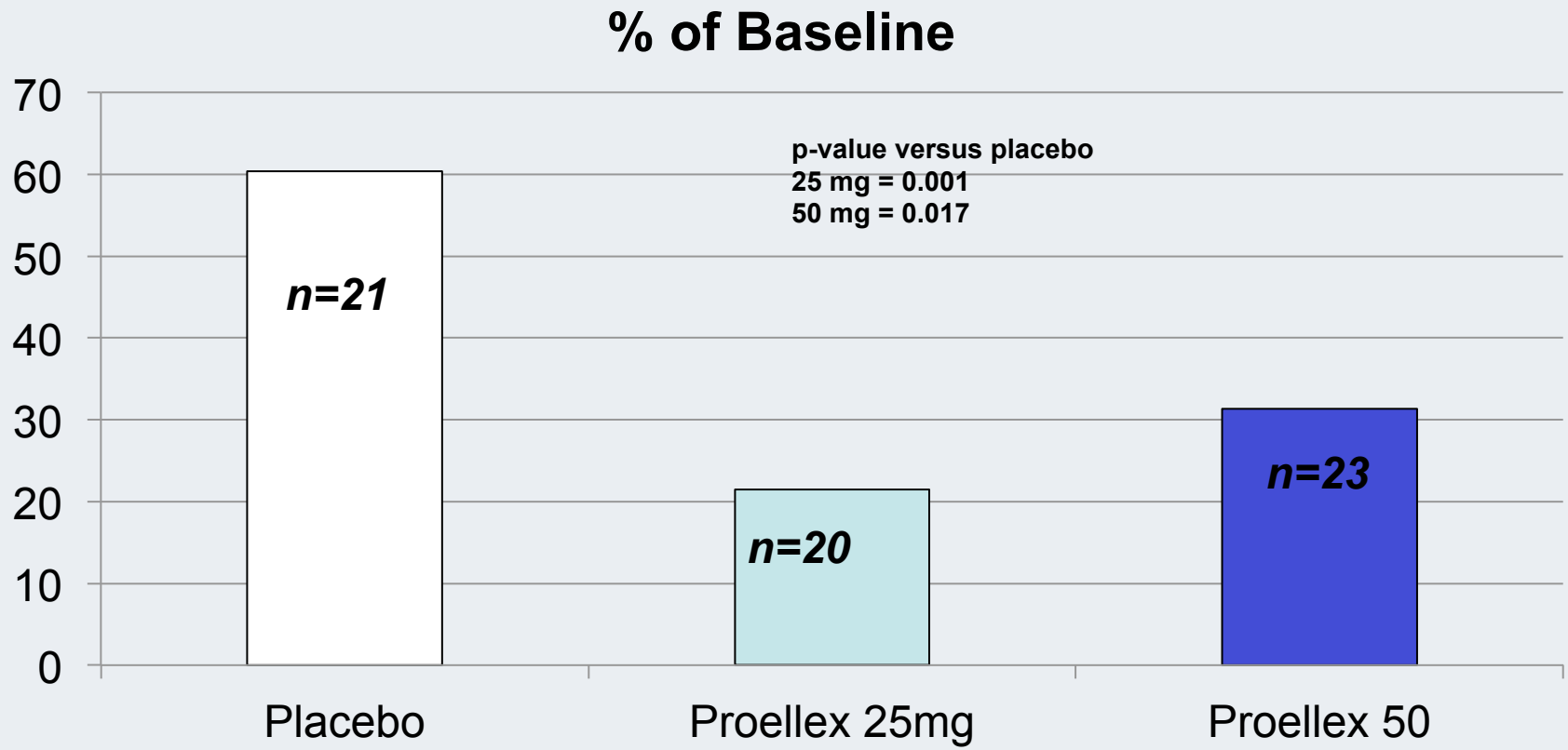
# % of Women Experiencing Proellex Induced Amenorrhea in Low Dose Study



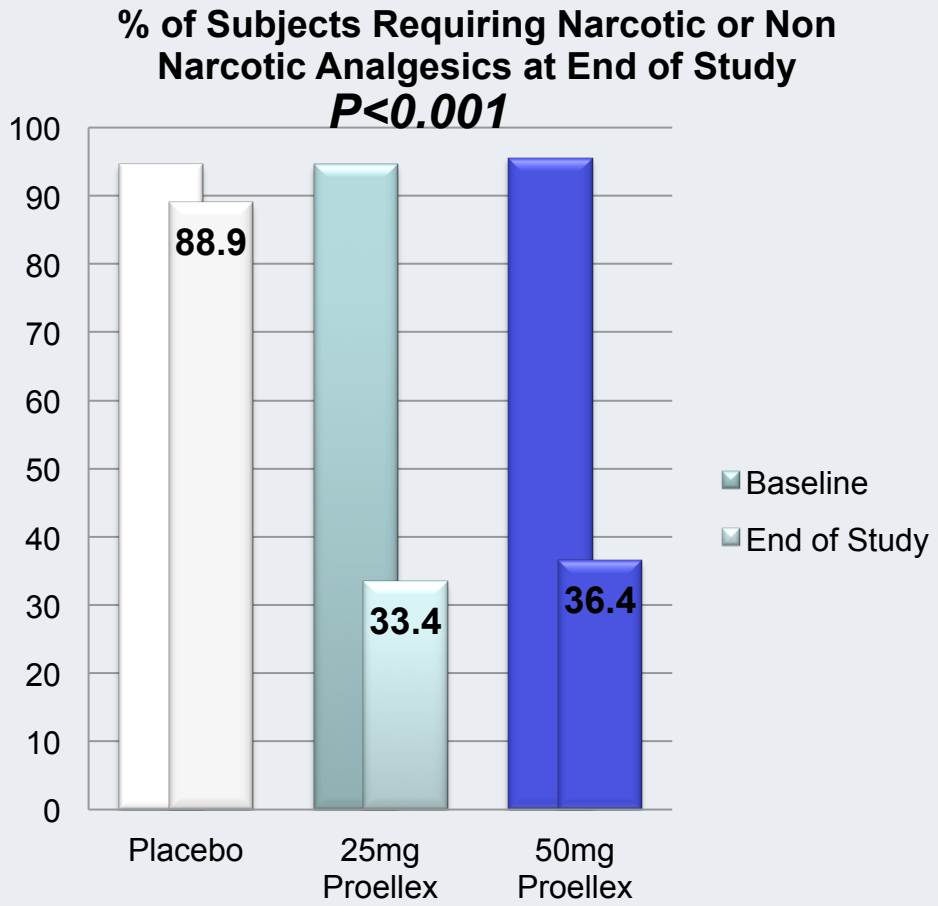

***Doses safely tested in Phase 2 trial***

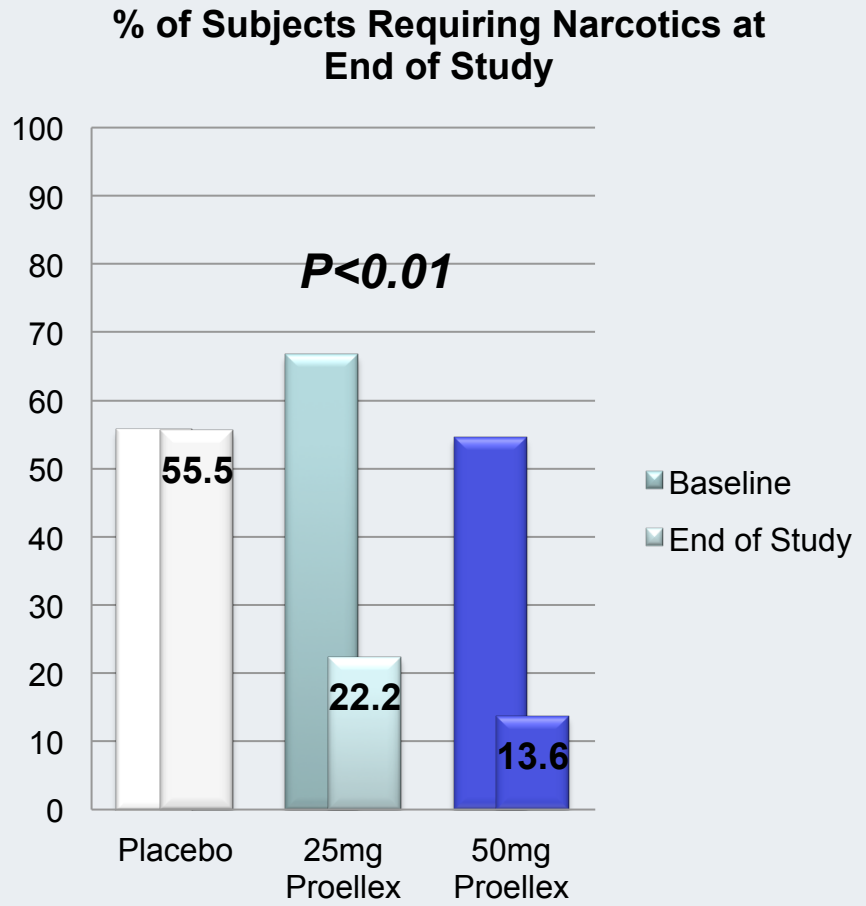
# ZPE- 201 Baseline vs Last 28 Days
# All Patient Reported Endometriosis Pain




***Dysmenorrhea, Dyspareunia and Non Menstrual Pelvic Pain***

# *ZPE-201 Doses That Stop Menses Have Significant Impact on Analgesic Use in the Control of the Pain Symptoms of Endometriosis*




***FDA allows Repros to conduct Phase 2 study in women with severe endometriosis***

# ZPE-202 Phase 2 Endometriosis Study

- 90 subject double blind placebo controlled study balanced between placebo, 6 and 12 mg oral Proellex
  - Subject population (confirmed endometriosis)
    - Severe endometriosis as determined by BBSS score
    - Requiring narcotics or prescription analgesics to control endometriosis related pain
  - Study Duration: 4 months
  - Study endpoints:
    - Reduction in need for analgesics from baseline
    - Change from baseline in BBSS pain scores
  - Status: enrolling sites and subjects

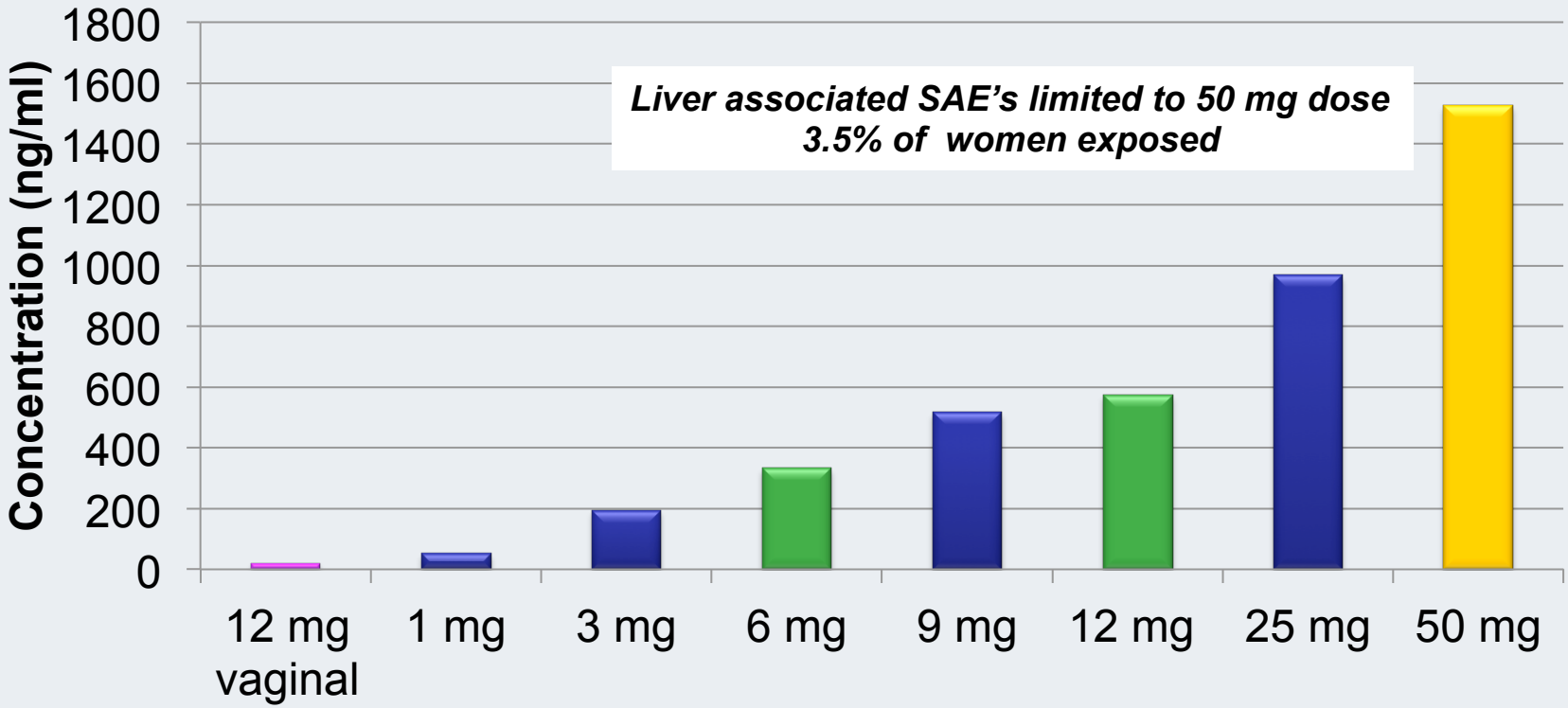
# Vaginal Proellex to Eliminate the Need for Hysterectomy in Most Situations

- Initial Phase 2 study to test four doses of vaginal administration in the treatment of uterine fibroids completed
  - Assess reduction of fibroid size and elimination of symptoms
  - Top line data reported
- End of Phase 2 meeting request with FDA accepted by Agency for end of May 2013
- Propose 90 subject 1st Phase 3 study and…..
  - 2 Phase 3 studies
  - 200 subjects for +1 year
  - 300-600 subjects for +6 months
- Separate IND from low dose oral

# Systemic Exposure to Oral Proellex Varies in a Dose Dependent Manner

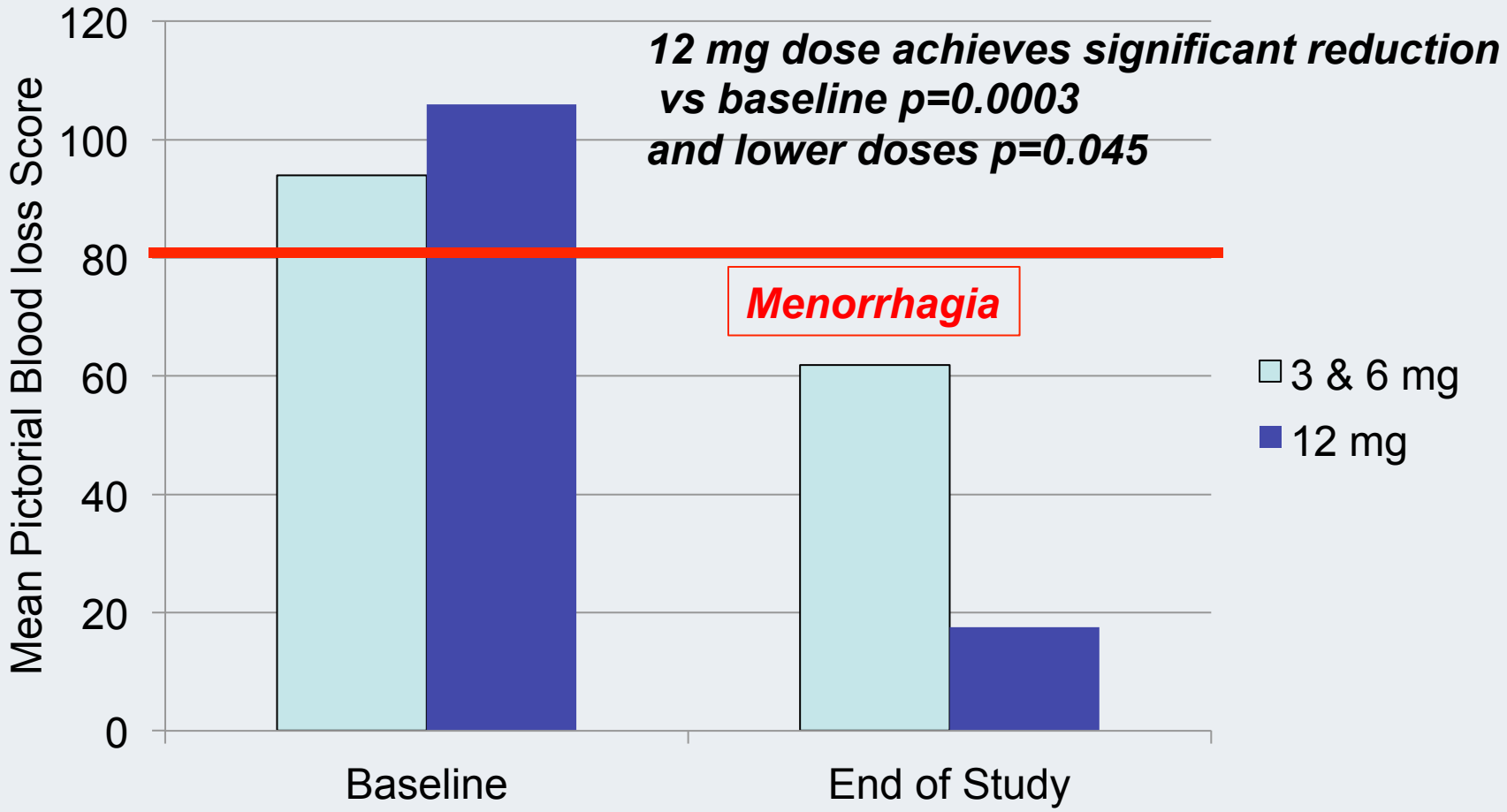
***Significant reduction in exposure via vaginal delivery***

## Combined Cmax for Telapristone and Primary Metabolite



## Vaginal Proellex Update

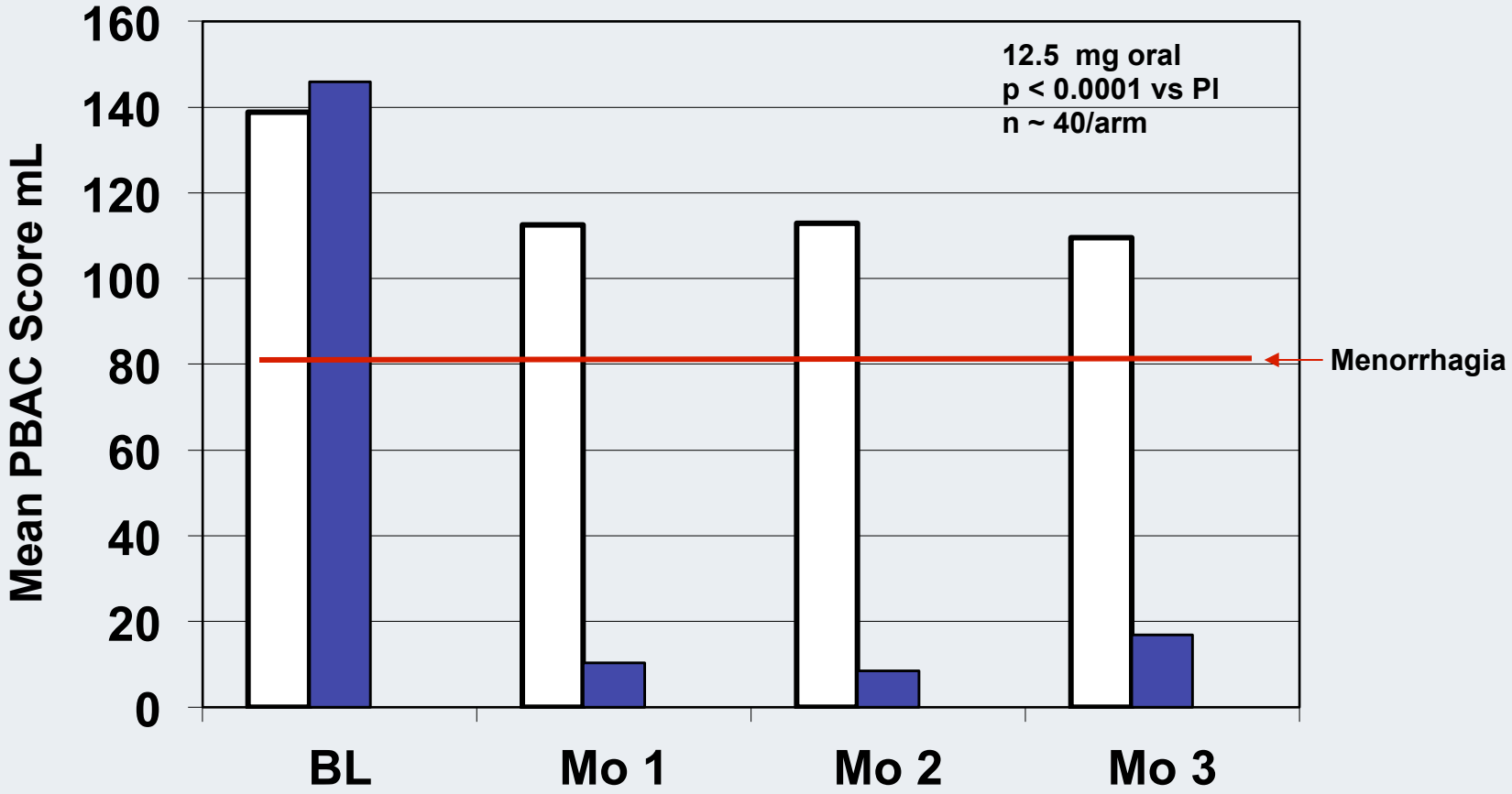
# 12 mg Dose Achieves Significant Improvement in Vaginal Bleeding



ZPU-003

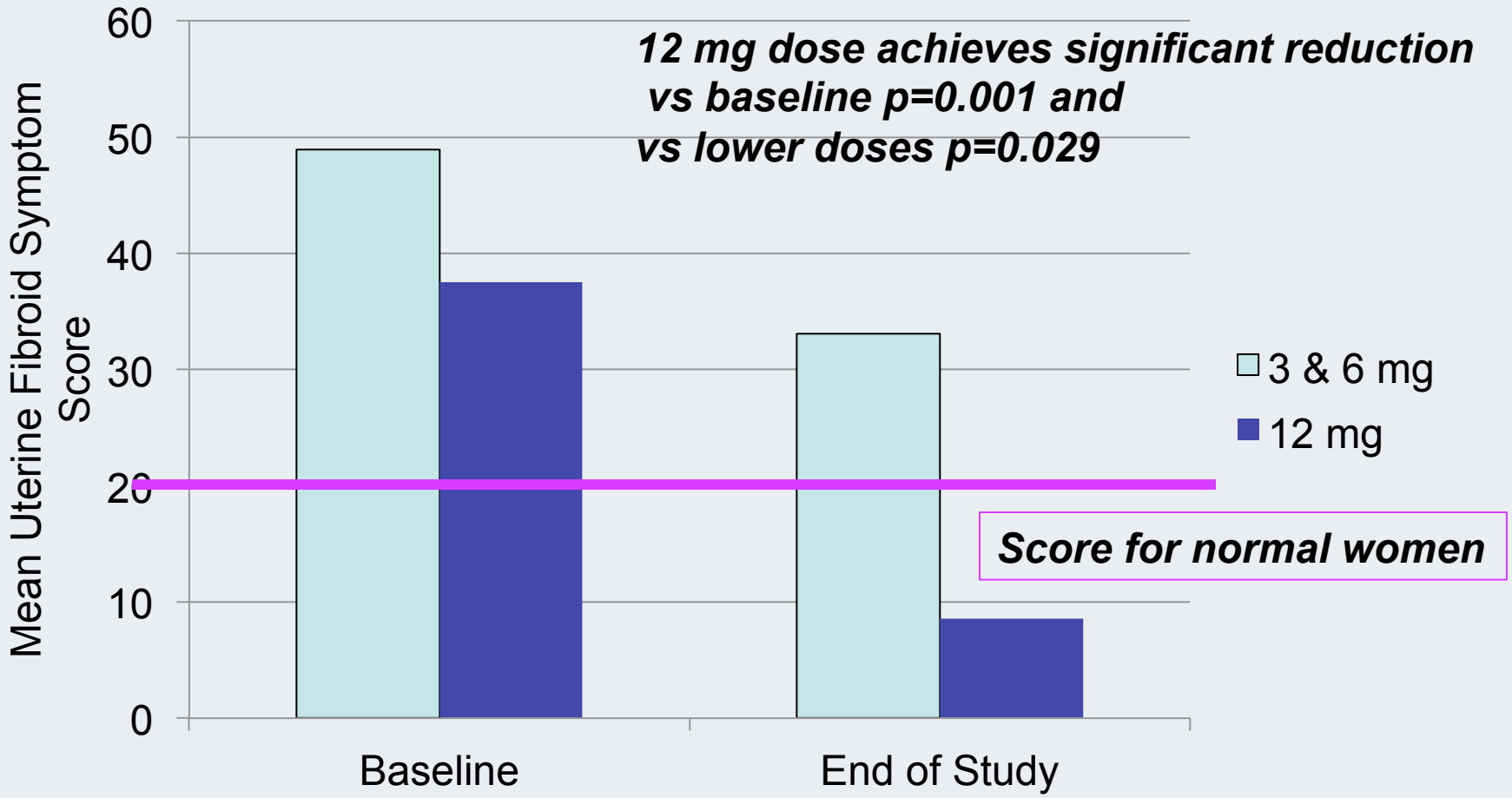
# Phase II Uterine Fibroid Study

## Pictoral Blood Loss

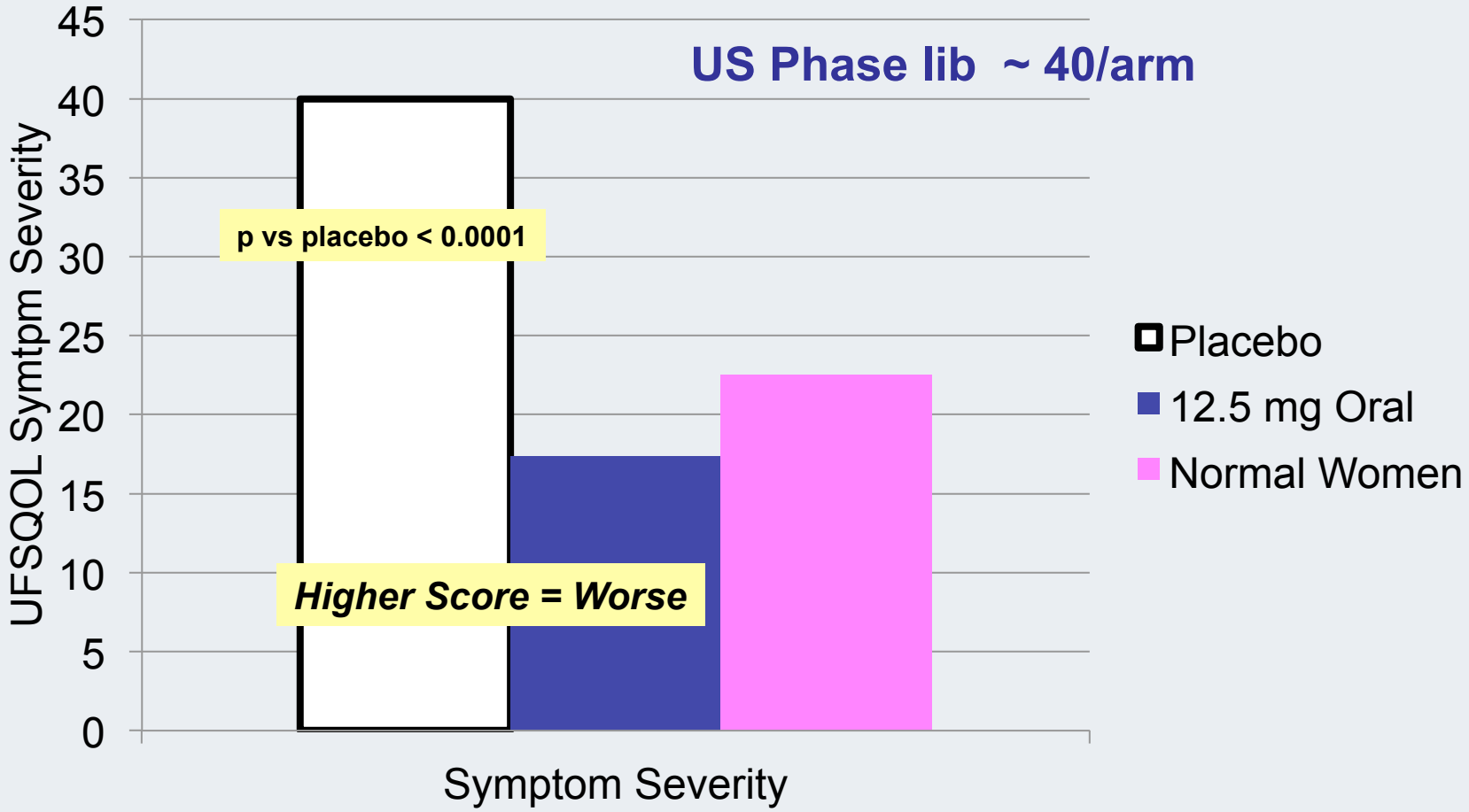


## Vaginal Proellex Update

# 12 mg Dose Achieves Significant Improvement in Symptom Scores

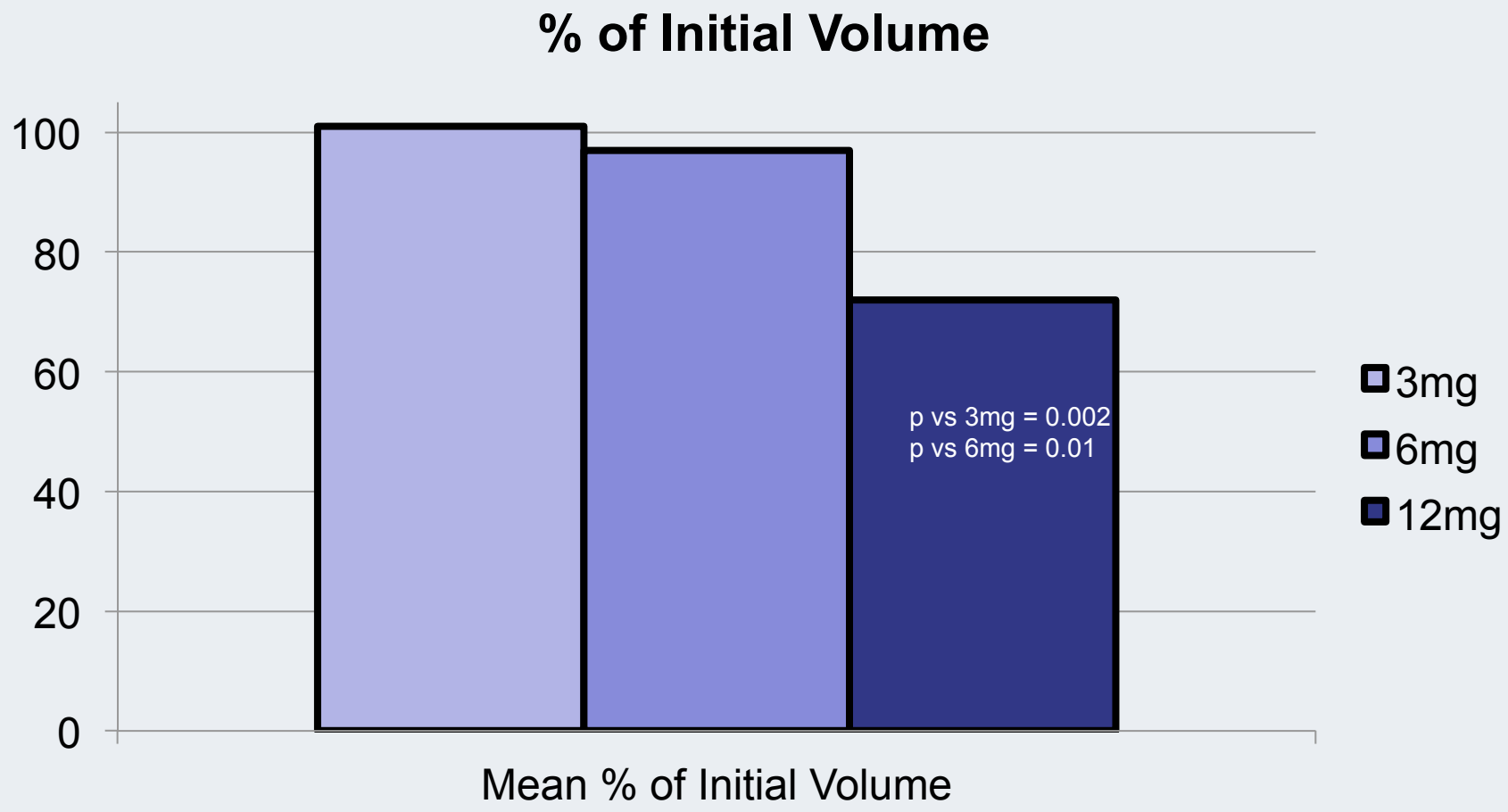


# 12.5 mg Oral Proellex Produces Significant Clinical Benefit Resulting in Substantially Asymptomatic Uterine Fibroids in Phase 2 Study (ZPU-003)

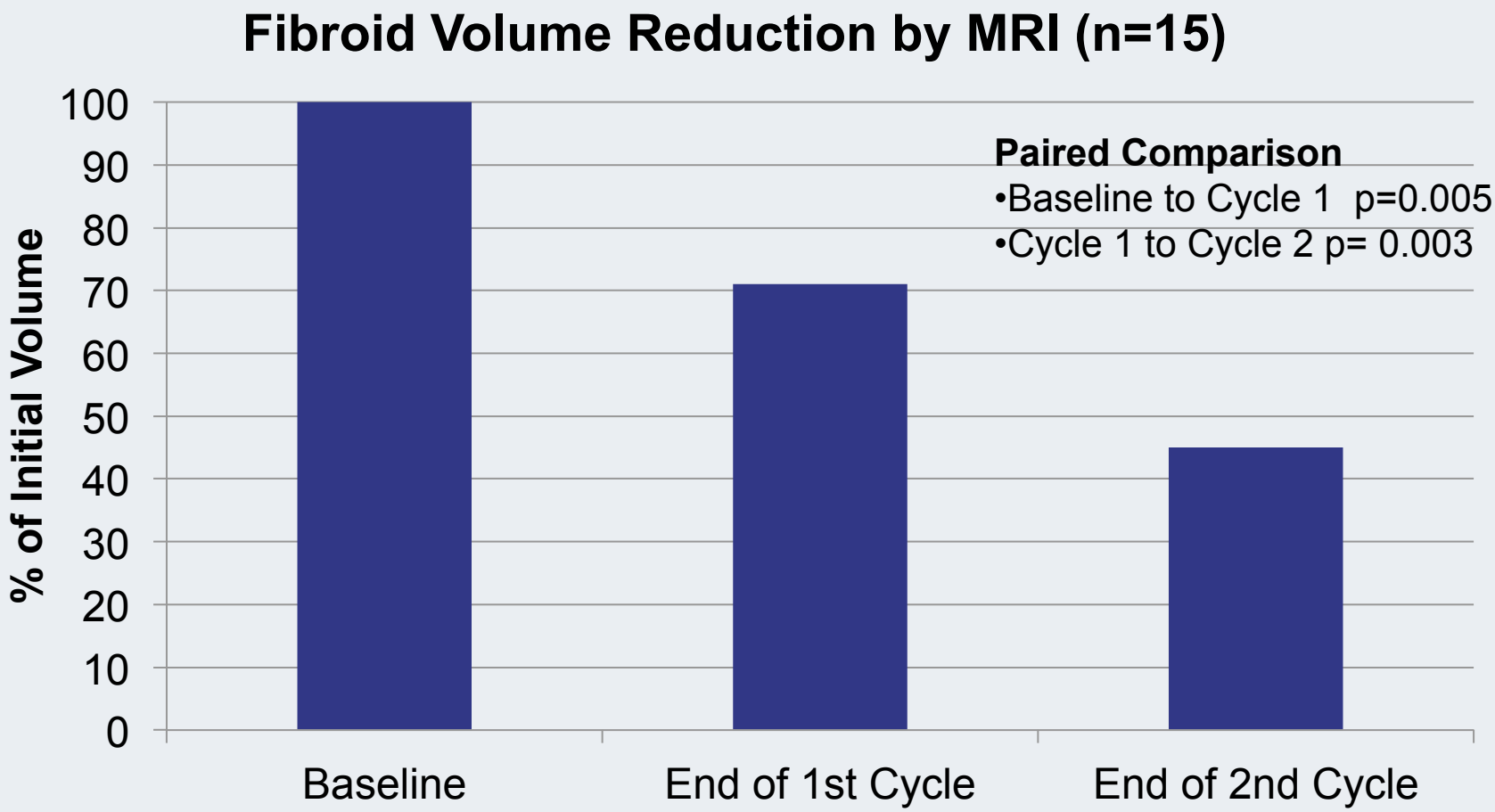



Spies et al, Obstetrics & Gynecology, vol. 99, No. 2, February 2002

# Fibroid Volume Significantly Reduced at end of 4 Month Study @ 12 mg



# ZPV-200 Ext. Proellex Open Label Update (12mg dose)



# Financial Summary

- **Cash and equivalents** (as of 1/2/13, unaudited) ~ $24.2M
- **Cash runway:** Q1 2014
- **Current shares outstanding:** 18.6 M shares
  - This includes approximately 1.5 million shares resulting from the cashless exercise of 872,133 Series A Warrants and 713,741 Series B Warrants on Jan. 29, 2013.
  - Warrants Outstanding – Series A – 877,137 (purchased in unit deal @ $2.45); Series B – 855,680 @ $2.49 exercise price.

# 2013 Milestones

| | |
|---|---|
| • Report results for Phase 2 Vaginal Proellex Study | Q1-13 |
| • Fully Enroll 1 year Dexa Study | Q1-13 |
| • Fully Enroll 500 subject 6 mos. Androxal Study | Q1-13 |
| • Report Results for 1st Pivotal Androxal Study | **Q2-13** |
| • End of Phase 2 Meeting with FDA for Vaginal Proellex | **Q2-13** |
| • Commence Phase 3 Vaginal Proellex Study | Q3-13 |
| • Complete 500 subject 6 mos. Androxal Study | Q3-13 |
| • Report Phase 2 low dose Oral Proellex Study | Q4-13 |
| • Report 2nd Pivotal Androxal Study | Q4-13 |
| • Request Androxal Pre-NDA Meeting with FDA for Q1'14 | Q4-13 |
| • Submit Androxal NDA | Mid-2014 |