UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 14, 2019

Myovant Sciences Ltd.
(Exact name of registrant as specified in its charter)

Bermuda	**001-37929**	**98-1343578**
(State or other jurisdiction of incorporation)	**(Commission File No.)**	**(I.R.S. Employer Identification No.)**

Suite 1, 3rd Floor **11-12 St. James's Square** **London SW1Y 4LB** **United Kingdom** **(Address of principal executive office)**	**Not Applicable** **(Zip Code)**

Registrant's telephone number, including area code: +(441) 295-5950

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Shares, par value $0.000017727 per share	**MYOV**	**New York Stock Exchange**

Item 8.01. Other Events.

On May 14, 2019, Myovant Sciences Ltd. made available a slide presentation regarding the top-line results for its LIBERTY 1 Phase 3 clinical trial evaluating once daily relugolix combination therapy in women with uterine fibroids. The slide presentation is attached hereto as Exhibit 99.1 and is incorporated by reference here.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Slide Presentation

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: May 14, 2019

Myovant Sciences Ltd.

By: /s/ Frank Karbe
Name: Frank Karbe
Title: *Principal Financial and Accounting Officer*

Exhibit 99.1

MYOVANT SCIENCES

LIBERTY 1 PHASE 3 UTERINE FIBROID STUDY RESULTS

May 14, 2019

LIBERTY 1

FORWARD-LOOKING STATEMENTS

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include all statements that are not historical statements of fact and statements regarding the Company's intent, belief, or expectations and can be identified by words such as "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "intend," "likely," "may," "might," "objective," "ongoing," "plan," "potential," "predict," "project," "should," "to be," "will," "would," or the negative or plural of these words or other similar expressions or variations. In this presentation, forward-looking statements include, but are not limited to, statements regarding our plans to file for approval of relugolix with the FDA, the timing of such filing and the likelihood of approval, our ability to successfully develop relugolix in the United States and other major markets, including meeting clinical endpoints and adequacy of clinical trial results, the commercial potential for relugolix, including market size and reimbursement status and the potential product differentiation relative to competitors.

The Company's forward-looking statements are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties, assumptions and other factors known and unknown that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by the forward-looking statements. Myovant cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur and actual results could differ materially from those expressed or implied by these forward-looking statements. Factors that could materially affect the Company's operations and future prospects or which could cause actual results to differ materially from expectations include, but are not limited to the risks and uncertainties listed in the Company's filings with the United States Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in the Company's Quarterly Report on Form 10-Q filed with the SEC on February 7, 2019, as such risk factors may be amended, supplemented or superseded from time to time by other reports the Company files with the SEC. These risks are not exhaustive. New risk factors emerge from time to time and it is not possible for its management to predict all risk factors, nor can Myovant assess the impact of all factors on its business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. You should not place undue reliance on the forward-looking statements in this presentation, which speak only as of the date hereof, and, except as required by law, the Company undertakes no obligation to update these forward-looking statements to reflect events or circumstances after the date of such statements.

This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. Projections, assumptions and estimates of the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

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LIBERTY 1 PHASE 3 UTERINE FIBROID STUDY RESULTS

May 14, 2019

LIBERTY 1: POSITIVE EFFICACY & SAFETY RESULTS

- **Primary endpoint achieved ($p < 0.0001$)**
  - Relugolix combination therapy: 73.4%
  - Placebo: 18.9%
- **Six key secondary endpoints achieved with statistical significance**
- **Bone density comparable to placebo**
- **Generally well tolerated with adverse event rates comparable to placebo**

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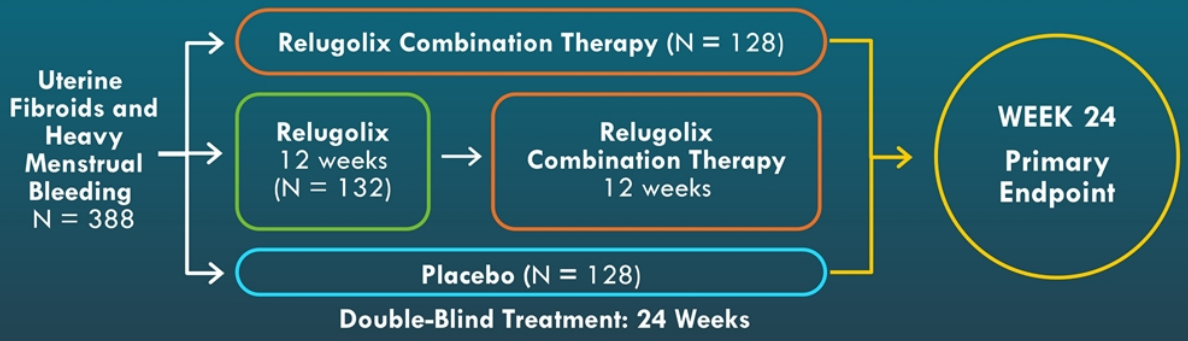
LIBERTY 1: PHASE 3 STUDY DESIGN

INCLUSION CRITERIA

Uterine fibroids and heavy menstrual bleeding: At least 160 mL during one cycle or at least 80 mL during each of two consecutive cycles

PRIMARY ENDPOINT

Proportion of women with < 80 mL menstrual blood loss/cycle and ≥ 50% reduction in menstrual blood loss by alkaline hematin method



Relugolix combination therapy = relugolix 40 mg + estradiol 1.0 mg and norethindrone acetate 0.5 mg

BASELINE CHARACTERISTICS AND DEMOGRAPHICS WERE WELL-BALANCED ACROSS GROUPS

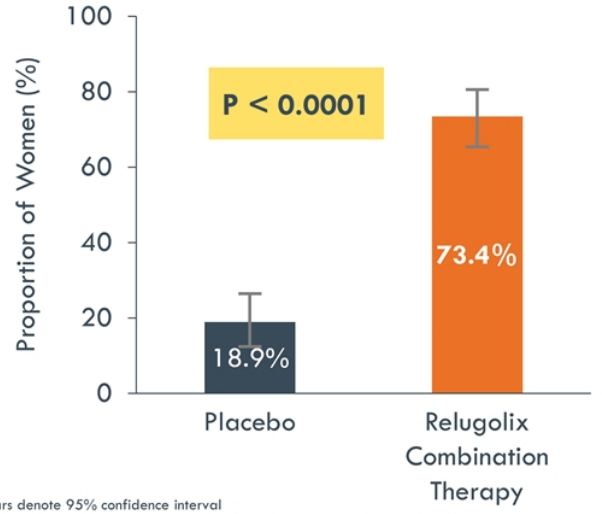
LIBERTY 1 Demographics and Baseline Characteristics	Relugolix Combination Therapy (N = 128)	Relugolix → Relugolix Combination Therapy (N = 132)	Placebo (N = 127)
Age (mean, SD in years)	42.5 (5.0)	41.3 (5.4)	42.2 (5.4)
Geographic Region (number, %)			
North America	98 (77%)	101 (76%)	98 (77%)
Rest of World	30 (23%)	31 (24%)	29 (23%)
Race (number, %)			
White	64 (50%)	53 (40%)	56 (44%)
Black	59 (46%)	67 (51%)	65 (51%)
Other	5 (4%)	12 (9%)	6 (5%)
Body Mass Index (mean, SD in kg/m^2)	31.4 (7.6)	31.4 (7.3)	32.3 (7.5)
Menstrual Blood Loss (mean, SD in mL)	239 (180)	229 (160)	219 (125)

Note: Patient numbers represent safety population (i.e., number of patients dosed)
SD = standard deviation

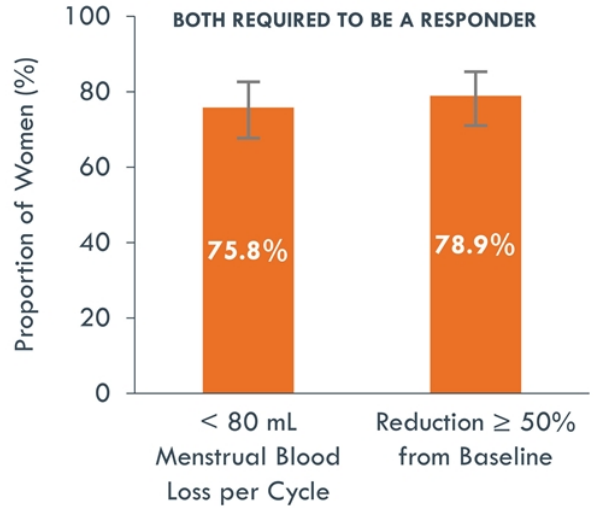
LIBERTY 1 ACHIEVED PRIMARY ENDPOINT

RESPONDER ANALYSIS

PRIMARY ENDPOINT



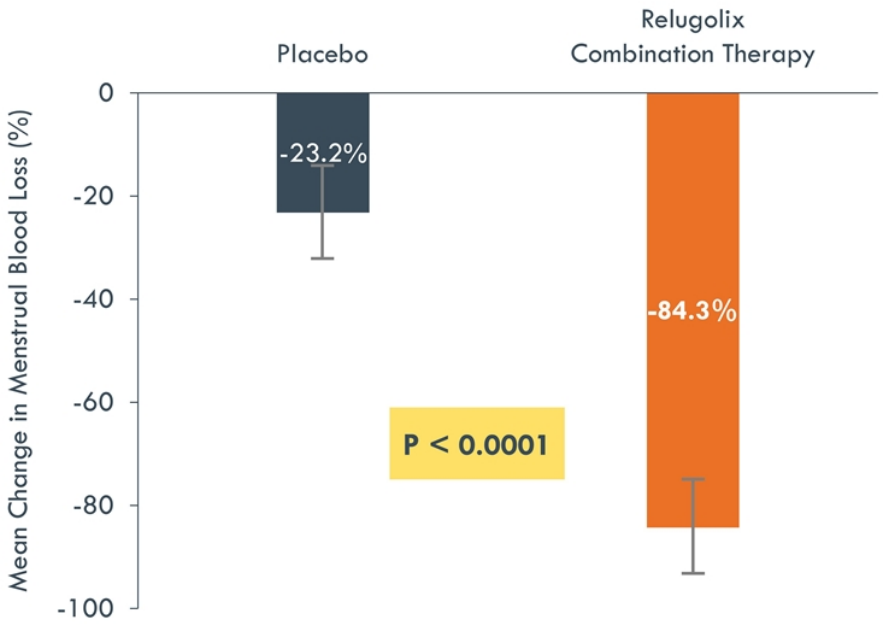
COMPONENTS OF PRIMARY ENDPOINT



Error bars denote 95% confidence interval
Relugolix combination therapy = relugolix 40 mg + estradiol 1.0 mg and norethindrone acetate 0.5 mg

SIGNIFICANT IMPROVEMENT IN SYMPTOM MOST RELEVANT TO WOMEN

ON AVERAGE, 84.3% REDUCTION IN MENSTRUAL BLOOD LOSS AT WEEK 24



Error bars denote 95% confidence interval
Relugolix combination therapy = relugolix 40 mg + estradiol 1.0 mg and norethindrone acetate 0.5 mg

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LIBERTY 1

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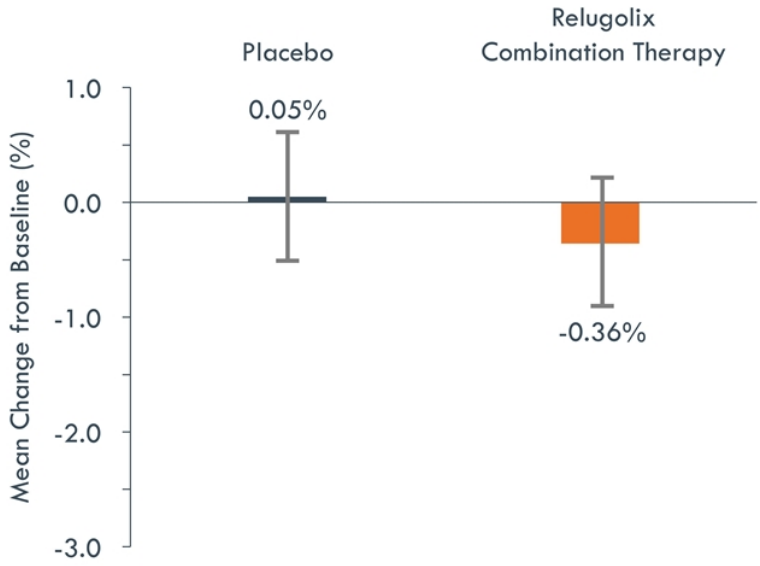
SIX KEY SECONDARY ENDPOINTS ACHIEVED BY RELUGOLIX COMBINATION

KEY SECONDARY ENDPOINTS		p-value
REDUCTION IN MENSTRUAL BLOOD LOSS	Percent mean change in menstrual blood loss from baseline to Week 24	$p < 0.0001$
AMENORRHEA	Proportion of women who achieve amenorrhea	$p < 0.0001$
REDUCTION IN PAIN	Proportion of women with a reduction in pain defined using the Numerical Rating Scale score (at least 4 at baseline; no more than 1 during the last 35 days of the study)	$p < 0.0001$
IMPROVEMENT IN QUALITY OF LIFE	Change in the UFS-QoL bleeding and pelvic discomfort scale score from baseline to Week 24	$p < 0.0001$
IMPROVEMENT IN ANEMIA	Proportion of women with improvement in anemia defined as a hemoglobin below 10.5 g/dL at study entry who achieve an increase of $\geq$ 2 g/dL from baseline to Week 24	$p < 0.05$
REDUCTION IN VOLUME	Percent change in uterine volume from baseline to Week 24	$p = 0.0002$
	Percent change in uterine fibroid volume from baseline to Week 24	$p = 0.09^*$

* Not statistically significant
UFS-QoL = Uterine Fibroid Symptom Health-Related Quality of Life Questionnaire

CHANGE IN BONE DENSITY COMPARABLE TO PLACEBO

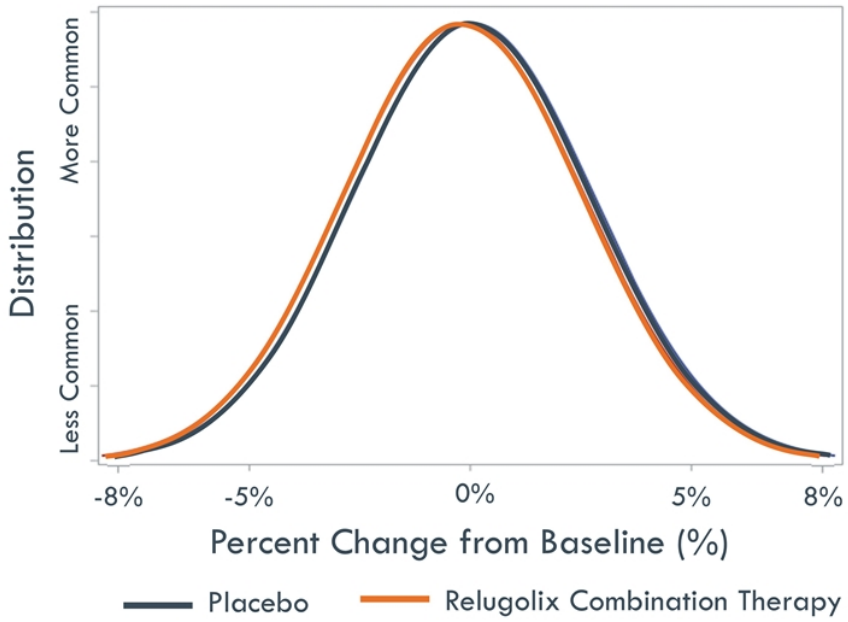
MEAN % CHANGE FROM BASELINE TO WEEK 24 IN BONE MINERAL DENSITY (LUMBAR SPINE)



Error bars denote 95% confidence interval
Relugolix combination therapy = relugolix 40 mg + estradiol 1.0 mg and norethindrone acetate 0.5 mg

DISTRIBUTION OF CHANGE IN BONE DENSITY COMPARABLE TO PLACEBO

DISTRIBUTION OF CHANGE IN BONE MINERAL DENSITY AT WEEK 24 (LUMBAR SPINE)



Relugolix combination therapy = relugolix 40 mg + estradiol 1.0 mg and norethindrone acetate 0.5 mg

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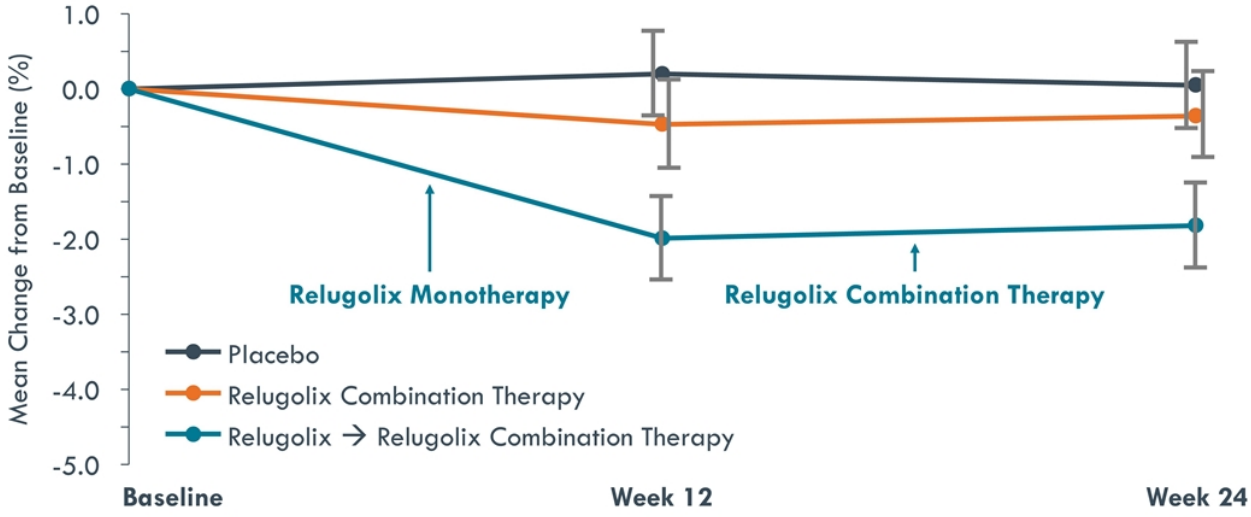
COMBINATION APPROACH MAINTAINED BONE DENSITY THROUGH 24 WEEKS (LUMBAR SPINE)



Error bars denote 95% confidence interval
Relugolix combination therapy = relugolix 40 mg + estradiol 1.0 mg and norethindrone acetate 0.5 mg

SUMMARY OF ADVERSE EVENTS

Number (%) of Women	Relugolix Combination Therapy (N = 128)	Relugolix → Relugolix Combination Therapy (N = 132)	Placebo (N = 127)
At least one adverse event	79 (62%)	96 (73%)	84 (66%)
Adverse event leading to study discontinuation	7 (5%)	16 (12%)	5 (4%)
Serious adverse event related to study drug	2 (2%)*	0	0
Pregnancy	0	0	1 (1%)
Adverse Events Occurring in ≥ 10% of Women in Any Group			
Hot flush	14 (11%)	47 (36%)	10 (8%)
Headache	14 (11%)	14 (11%)	19 (15%)

* 1 fibroid expulsion, 1 pelvic pain
Note: Patient numbers represent safety population (i.e., number of patients dosed)
Relugolix combination therapy = relugolix 40 mg + estradiol 1.0 mg and norethindrone acetate 0.5 mg

RELUGOLIX COMBINATION:

LIBERTY 1 KEY TAKEAWAYS AND NEXT STEPS

- Achieved primary endpoint: 73.4% of women met responder criteria ($P < 0.0001$)
- Key secondary endpoints showed benefits in pain, quality of life, and anemia, in addition to a marked reduction in bleeding
- Bone mineral density comparable to placebo
- Generally well-tolerated; protected women from side effects of monotherapy
- Phase 3 LIBERTY 2 study results expected in Q3 2019
- NDA filing planned for Q4 2019; on track to launch with single pill, once daily regimen for relugolix combination
- Data to be submitted for presentation and publication in 2019

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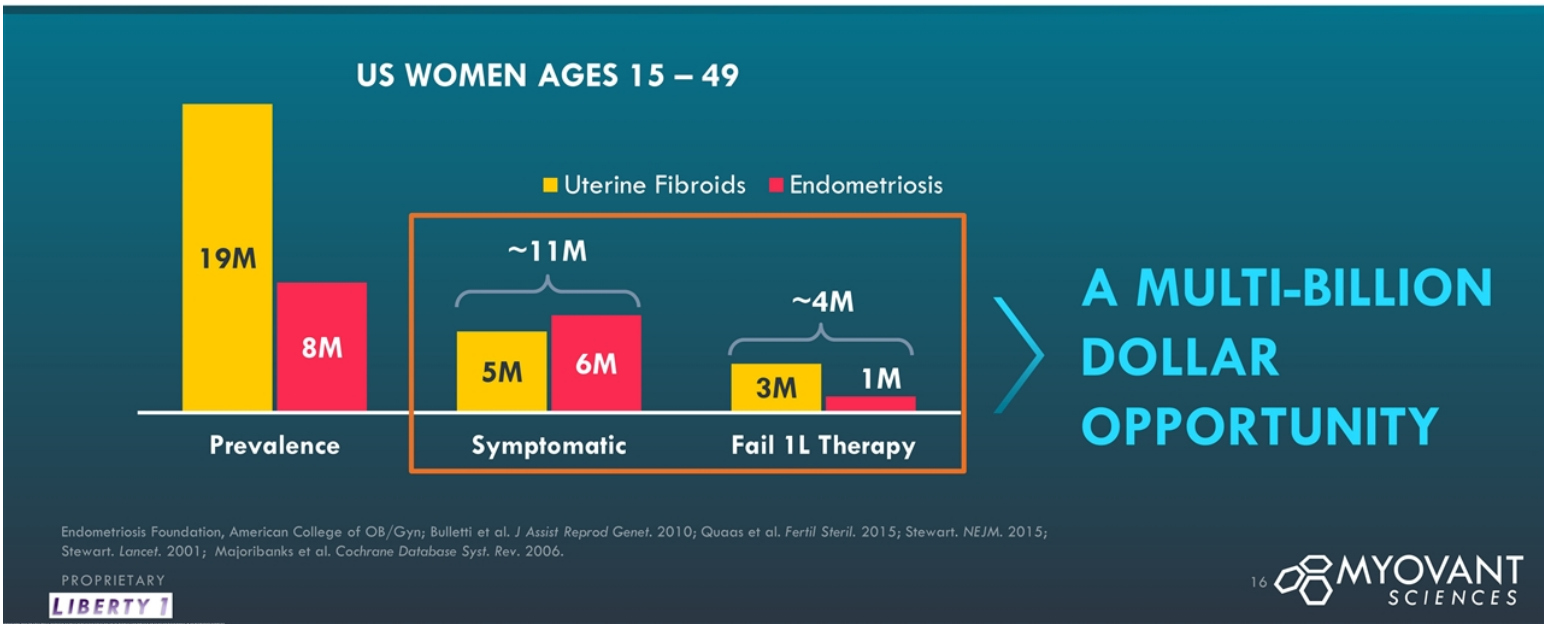
LIBERTY 1

UTERINE FIBROIDS IS A DEBILITATING DISEASE

PREVALENCE	Occurs in up to **70-80%** of women by age 50; more prevalent in black women
SYMPTOMS	**1 in 4** women experience decreased quality of life • Heavy menstrual bleeding and anemia • Pain, urinary frequency, constipation • Pregnancy-related complications
SURGERY	**~250,000** hysterectomies per year (US) Hysterectomies account for ~70% of fibroid procedures
HOSPITALIZATION	Responsible for **30%** of gynecologic hospitalizations among women aged 15-54
COSTS	Annual societal cost is estimated to be up to **$34 BILLION** in the US alone, more than breast and ovarian cancers combined

Baird, Am *J Obstet Gynecol*, 2003, Buletti *J Assist Reprod Genet*. 2010; Bulun *New Engl J Med*, 2013; Cohen, *Obstet Gynec*. 2017; Wright, *Obstet Gynec*. 2013; Barrett, *Agency for Healthcare Research and Quality*, 2016; Stewart, *NEJM*. 2015; Stewart *J Women's Health*, 2013; Cardozo, *Am J Obstet Gynecol* 2012

GREAT NEED IN UTERINE FIBROIDS AND ENDOMETRIOSIS



A MULTI-BILLION DOLLAR OPPORTUNITY

Endometriosis Foundation, American College of OB/Gyn; Bulletti et al. *J Assist Reprod Genet.* 2010; Quaas et al. *Fertil Steril.* 2015; Stewart. *NEJM.* 2015; Stewart. *Lancet.* 2001; Majoribanks et al. *Cochrane Database Syst. Rev.* 2006.

WHAT DO WOMEN AND OBGYNs WANT?

	WOMEN	OBGYNs
Pain & Bleeding	"I want a future where I can do things and **not be controlled by the pain and bleeding**"	"Looking for a **reduction in bleeding** and subsequent **anemia**"
Safe For Chronic Use	"Would love to find a **SAFE treatment**"	"To be able to help my patients and give them the best possible treatment with the **least harmful side effects**"
Non-Surgical Option	"The ideal treatment would be **non-invasive**"	"Patients often **don't want surgery** and available medical options aren't great"
Convenient & Easy to Use	"It would be **easy to take** every day"	"**Convenient** so the patient will follow through with their treatment"

PROPRIETARY LIBERTY 1

Proprietary quantitative market research survey conducted in February 2019;
Sample size of 160 OBGYNs, 140 UF patients

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VISION FOR RELUGOLIX COMBINATION THERAPY

RELUGOLIX 40 MG + ESTRADIOL AND PROGESTIN = **COMBINATION THERAPY DESIGNED TO OPTIMIZE ESTRADIOL LEVELS**

ONE PILL ONCE A DAY DESIGNED FOR WOMEN

- Provide predictable efficacy: bleeding, pain, anemia, quality of life
- Maintain bone health and mitigate hot flashes
- Enable long-term use
- Improve patient adherence and therapeutic effect
- Minimize spotting and breakthrough bleeding
- Prevent ovulation to minimize risk of pregnancy on therapy

Relugolix is an investigational drug that has not been approved for use; these are aspirational statements

RECENT STUDIES INVESTIGATING ORAL GnRH ANTAGONISTS FOR UTERINE FIBROIDS

NOTE: No direct head-to-head data available - Caution advised when comparing information across clinical studies

	LIBERTY 1	ELARIS UF-1	ELARIS UF-2
Dosing	Once Daily	Twice Daily	
	Same dose for Endometriosis	Different doses for Endometriosis	
Responder Rate: Heavy Menstrual Bleeding	73.4%	68.5%	76.2%
Bone Mineral Density Loss at 24 Weeks (Lumbar Spine)	-0.36%	-0.75%	-0.61%
Key Secondary Endpoints Achieved	✓ Pain ✓ Uterine volume ✓ Menstrual blood loss ✓ Amenorrhea ✓ Anemia ✓ Quality of life	✗ Not reported ✗ Not reported ✓ Menstrual blood loss ✓ Amenorrhea ✓ Anemia ✓ Quality of life	

GnRH = gonadotropin-releasing hormone
Source: Carr et al, AAGL 2018

MYOVANT'S LATE-STAGE PIPELINE

	INDICATION	PHASE 1	PHASE 2	PHASE 3	Anticipated Milestones 2019 – Q1 2020
RELUGOLIX COMBINATION THERAPY	Uterine Fibroids *Heavy Menstrual Bleeding*		LIBERTY 1 & 2		Phase 3 Data (Q2/Q3 2019) NDA Filling (Q4 2019)
	Endometriosis *Pain*		SPIRIT 1 & 2		Phase 3 Data (Q1 2020)
RELUGOLIX	Advanced Prostate Cancer		HERO		Phase 3 Data (Q4 2019) NDA Filing (early 2020)
MVT-602	Female Infertility				Phase 2a Data (1H 2019)

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