

Investor Presentation

June 2018

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Management team— Co-founders



François Fornieri Chief Executive Officer Co-founder

- Over 30 years in the Pharma industry
- Founder & CEO of Uteron Pharma (sold to Watson/Actavis)
- Master in Chemical Engineering



Jean-Michel Foidart Scientific Committee & Board member Co-Founder

- Former CSO of Uteron Pharma & Actavis Belgium
- Former Head of the Gynecology and Obstetrics Department of the University of Liège
- MD & PhD in Cell Biology & Biochemistry



Transforming Women's Health through innovation

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Expert in Women's Health, re-energizing the \$22bn Contraceptive and \$8.6bn Hormone Therapy markets

- Markets characterized by a lack of innovation, with recent return of interest from Big Pharma
- Unique portfolio based around (1) E4 natural estrogen with improved benefit / risk profile and (2) Complex Therapeutics

E4: two potential blockbusters in late-stage development for launch as of 2020

- Estelle® 5th generation oral contraceptive in Phase III
- Donesta® next generation HT Phase III ready

Leveraging knowhow in Complex Therapeutics

- Pipeline of complex, polymerbased generics
- International launches of Tibelia® (2017) and with MyringTM potentially as of 2018

Mithra CDMO: fully integrated ecosystem for state-of-the-art R&D and manufacturing

- Develop products from POC to market,
- For own product portfolio and partners

Clear growth strategy: Existing commercial portfolio combined with partnering strategy with leaders in Women's Health at key value inflection points

- Multiple mid- to nearterm catalysts
- Cash flow generative commercial generics portfolio and partnering strategy



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Expert in Women's Health

re-energizing the \$22bn Contraceptive and \$8.6bn Menopause market*

- Women's Health Market characterized by lack of innovation; recent return of interest from Big Pharma
- Unique Women's Health portfolio of E4-based pipeline and Complex Therapeutics
 - Highly innovative new approaches based on E4, a native estrogen with improved benefit/risk profile
 - Complex Therapeutics: leveraging polymer science & formulation expertise to develop complex generics
 - Powered by Mithra CDMO (Contract Development & Manufacturing Organization)



*Based on Datamonitor 2014; Transparency Market Research 2017...



Advanced pipeline offering multiple mid-to near-term catalysts

	Product	Indication	Ph1	Ph2	Ph3	Next milestone
E4*	Estelle [®]	Contraception				PhIII results Q3 2018-Q1 2019
	Donesta [®]	Menopause				Detailed PhII results (CSR) Q2/Q3 2018

^{*}Preclinical: Neuroprotection (ODD in neonatal encephalopathy)

			PK/PD	BioEq	Filing	Market Approval	Next milestone
Complex Therapeutics	Myring™	Contraception					MA EU Q2/Q3; MA US Q4/Q1 2019
	Zoreline®	Cancer					H1 2018: PK results
	Tibelia [®]	Menopause					2018: Additional launches



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E4 (Estetrol) — Answer from Nature with Unique Potential

E4: **native estrogen** produced by **human fetus** around week 9

Fetal plasma levels 12x higher than those of mother

E4's broad potential for use in Women's Health validated in multiple peer-reviewed academic journals¹⁻⁸

E4-based programs protected by **29 patent families**, including synthesis pathway until 2032



¹ Kluft C et al., Contraception 2016; 2 Gerard C et al., Oncotarget 2015;6(19):17621-36; 3 Visser M et al., Horm Mol Biol Clin Invest. 2012;9:95-103.; 4 Visser M et al., Climacteric 2008; 11 Suppl 1:64-8.; 5 Mawet M et al., Eur. J. Contracept. Reprod. Healthcare 2015:1-13.; 6 Apter D. et al., Contraception 2016;94(4):366-73; 7 Abot et al., EMBO 2014; 6 (10); 8 Apter et al., Eur. J. Contracept. Reprod. Healthcare 2017:22(4)

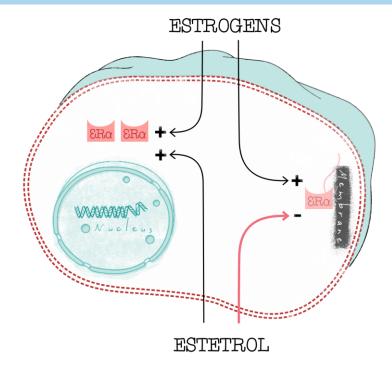
E4 (Estetrol) — Unique Agonist-Antagonist Mode of Action

Cells exhibit 2 types of estrogen receptors (ERa): membrane and nucleus receptors

Depending on the tissue either the membrane or the nucleus receptor is predominantly active

E4 acts differently compared to other estrogens depending on the tissue:

- Agonist on nuclear receptor: E4 acts as an estrogen in bone, vagina, endometrium stability & heart to provide beneficial effects (as other estrogens)
- Antagonist on the membrane receptor: E4 blocks the estrogen receptor in breast and has a neutral effect on the liver (unlike other estrogens)





Safety concerns of estrogens: an unmet clinical need potentially addressed by E4

Estrogen's systemic side effects:

- Heart and liver: increased risk of Myocardial infarction, Thrombophlebitis
- **Brain:** increased risk of Stroke, Alzheimer's and Dementia
- Ovary and uterus: increased risk of Ovarian and Endometrial cancer
- Breast: increased risk of Breast cancer
- Quality of life: bleeding, cycle control

E4 has the potential to address most of these concerns:

- + Favorable VTE risk profile¹
- + Favorable drug-drug interaction profile4
- + Minimal increase of triglycerides⁵
- + Lower **breast** pain⁶ and lower **carcinogenic** potential in the presence of E2*,2,3
- + Good **user acceptability**, body weight control, excellent cycle control, improved spotting and general well-being^{6,7,8}

¹ Kluft C et al., Contraception 2016.; 2 Gerard C et al., Oncotarget 2015;6(19):17621-36.; 3 Visser M et al., Horm Mol Biol Clin Invest. 2012;9:95-103.; 4 Visser M et al., Climacteric 2008; 11 Suppl 1:64-8.; 5 Mawet M et al., Eur. J. Contracept. Reprod. Healthcare 2015:1-13.; 6 Apter D. et al., Contraception 2016;94(4):366-73; 7 Abot et al., EMBO 2014: 6 (10); 8 Apter et al., Eur. J. Contracept. Reprod. Healthcare 2015:1-13.; 6 Apter D. et al., Contraception 2016;94(4):366-73; 7 Abot et al., EMBO 2014: 6 (10); 8 Apter et al., Eur. J. Contracept. Reprod. Healthcare 2015:1-13.; 6 Apter D. et al., Contracept. Healthcare 2015:1-13.; 6 Apter D. et al., Contracept. Reprod. Healthcare 2015:1-13.; 6 Apter D. et al., Contracept. Reprod. Healthcare 2015:1-13.; 6 Apter D. et al., Contracept. Reprod. Health



^{*}E2: Estradiol

E4 – Promising clinical study results in over 800 women

Program	Trial	# Subjects	Characteristics	Objectives	Results
Estelle®	Phase IIa	109	Healthy premenopausal	Ovulation inhibition	No ovulation
			women of childbearing potential	Effect on liver function (surrogate markers of VTE)	Only slight increase vs EE of SHBG ¹ plasmatic concentration (surrogate marker of VTE risk)
Estelle®	Phase IIb	389	Healthy premenopausal	Vaginal bleeding profile	Well controlled bleeding pattern
			women of childbearing potential	Cycle control	Indications of reduced VTE risks
Donesta [®]	Phase la	32	Healthy postmenopausal	Safety and tolerability	Fast oral absorption
			women		Half life +/- 28 hours
Donesta [®]	Phase Ib	49	Healthy postmenopausal	Safety and tolerability	Decrease in number of hot
			women: Hysterectomized & non-hysterectomized	Number of hot flushes &	flushes
			sweating E4 as eff		E4 as efficient as 2 mg E2V in decreasing hot flushes
Donesta [®]	Phase IIb	260	Healthy postmenopausal women: Hysterectomized & non-hysterectomized	Dose-finding study Frequency & severity of hot flushes	15 mg minimally effective dose Significant reduction in VMS & VVA



Excellent safety and efficacy results for Estelle® (15 mg E4/3mg DRSP) & Donesta® (E4 alone)

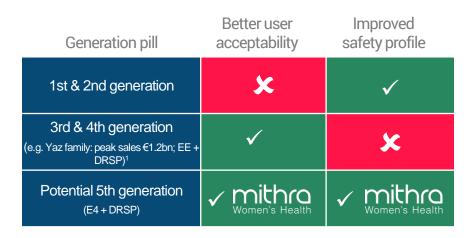
¹Sex hormone-binding globulin

Estelle®

Estelle® for Contraception, a \$22bn blockbuster market¹

Regulators are encouraging new approaches through

non-reimbursement, market withdrawal and warnings for existing products









27%
use no
contraceptive
at all²



30% of US women not taking pill mainly due to safety or convenience⁴

⁴ K. Daniels et al., National Health Statistics report n° 62, 2013



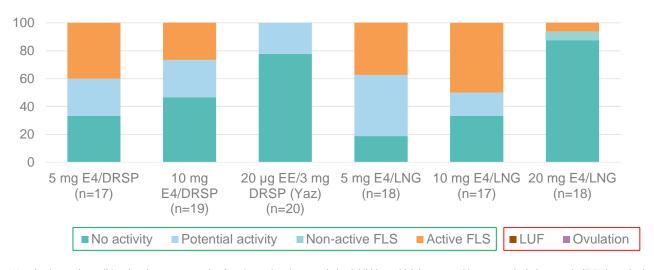
¹ Transparency market research 2017. \$22bn is total hormonal contraceptive market. The oral contraceptive market stands at \$9.6bn.

² IMS Health Data

^{* 3} In the 8 biggest markets: US, France, Germany, UK, Spain, Italy, Belgium & Netherlands. United Nations, Department of Economic and Social Affairs, World Bank

Estelle® Phase IIa: Not a single ovulation

Evaluation of ovulation inhibition: % of patients scored according to Hoogland score (treatment cycle 3; n= 109 healthy premenopausal women of child bearing age)¹



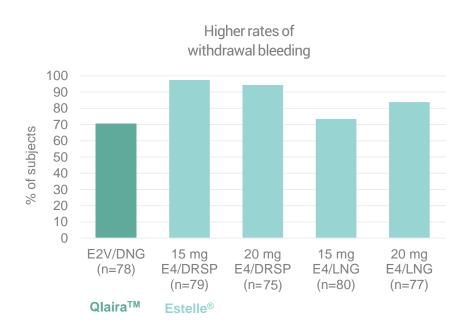
E4 inhibits ovulation in association with a progestin and allows rapid & complete return to fertility

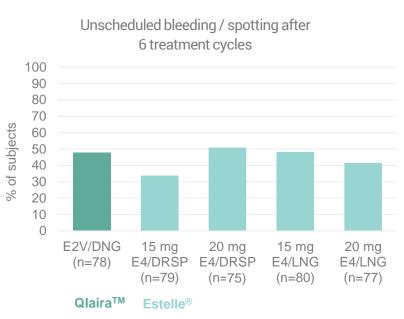
Note: Hoogland score is a validated tool to assess ovarian function and evaluate ovulation inhibition, which is assessed by transvaginal ultrasounds (TVUS) monitoring of follicle size and analysis of serum E2 and progesterone levels, and consequently classified according to a 6-point scoring (1 = no ovarian activity; 2 = potential activity; 3 = non-active follicle-like structure (FLS); 4 = active FLS; 5 = luteinised unruptured follicle (LUF); 6 = ovulation).

1 Duijkers et al. 2015, Eur. J. Contracept. Reprod. Healthcare



Estelle® Phase IIb: Dose-finding study shows well-controlled bleeding pattern¹



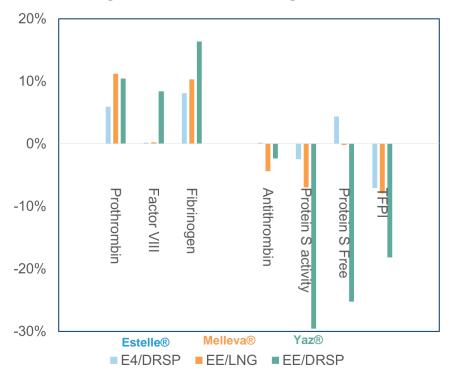


¹ Apter D. et al., Contraception. 2016;94(4):366-73



Estelle® Phase II substudy: Reduced VTE risk profile

Coagulation Factors/Anticoagulant Proteins

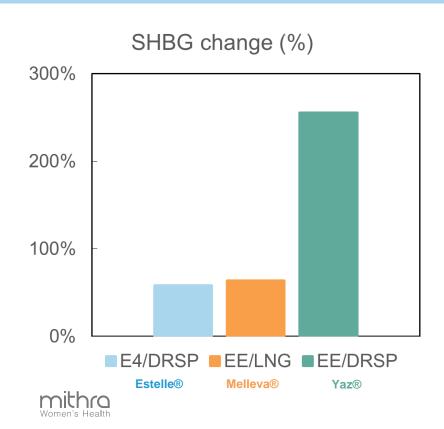


Effect of COCs on VTE Risk Factors

Cycle 6 – Baseline (Mean % change)

- Limited hemostatic impact for Estelle® (E4/DRSP)
- Comparable to EE/LNG (Melleva®), the 'safest' 2nd generation pill
- Much lower than 4th generation benchmark EE/DRSP (Yaz®)

Estelle® Phase II substudy: Reduced VTE risk profile



Change of SHBG (Sex-hormone binding globulin) plasma levels as marker of VTE risk¹

Cycle 6 – Baseline (Mean change)

- Limited impact on SHBG levels for Estelle® (E4/DRSP)
- In line with EE/LNG (Melleva®), the 'safest' 2nd generation pill
- Much lower than 4th generation benchmark EE/DRSP (Yaz®)

¹Change of APC resistance (Thrombin generation). Preliminary data; full CSR to follow H1 2018

Estelle® - Phase III program — Results expected Q3 2018 - Q1 2019

Two multicenter, open-label, single arm studies, 13 cycles

EU / Russia: June 2016 (Results expected: Q3 2018)

Contraceptive Efficacy Study	1,577 subjects, 18-50 years	✓
Lineacy Stady	1,350 subjects, 18-35 years	√
Endometrial Safety Substudy	175 subjects, 18-50 years	✓

US / Canada : Sept 2016 (Results expected: Q1 2019)

Contraceptive	2,148 subjects, 16-50 years			
Efficacy Study	1,940 subjects, 16-35 years	✓		
PK Substudy (body weight, race, smoking)	500 subjects, 16-50 years	✓		

Study objectives

Primary objective:

Contraceptive **efficacy** based on the **Pearl Index (PI)**

Secondary Endpoints:

Cycle control – bleeding pattern; Safety – S(AE) reporting; Subject's well being; Population PK substudy (US/CA); Endometrial safety (EU)

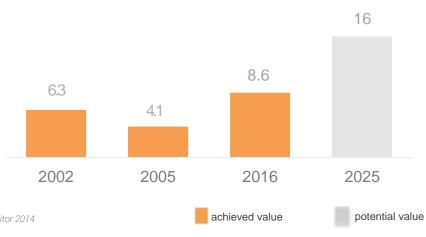


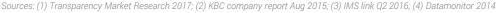
Donesta®

Donesta® for Menopause and HT, a \$8.6bn blockbuster market¹

- 78%¹ of menopausal women suffer VMS (hot flushes) only 7.8% receive HT²
- Increased safety issues:
 VTE, stroke, breast cancer risks
- No new estrogen-based products for more than 10 years, but renewed interest & developments (hormonal & nonhormonal)
- \$16bn billion potential HT Market in 2025 – VMS potential with safer alternative

Menopause market (in \$bn)^{3,4}







Donesta® Phase IIb: Positive Topline Results Q2 2018

A Multicenter Dose-Finding, Randomized, Double-Blind, Placebo-Controlled Study to Select the Daily Oral Dose of E4 for the Treatment of Vasomotor Symptoms (VMS) in Postmenopausal Women

Study Design:

- > Apprx. 250 subjects
- Non-hysterectomized and hysterectomized women
- > Aged 40 to 65 years
- Presenting at least 7 moderate to severe hot flushes / day or at least 50 moderate to severe hot flushes / week
- 4 dose levels of E4 or Placebo up to 13 weeks
 (2.5 5 10 15 mg)
- In non-hysterectomized women, E4 therapy is followed by a Progestin therapy (Dydrogesterone 10 mg) for 2 weeks

Primary objective:

Minimum effective dose of E4 for vasomotor symptoms (VMS) or hot flushes

Secondary Endpoints:

- > Genitourinary syndrome of menopause (GSM) or vulvovaginal atrophy (VVA)
- > Vaginal maturation index (MI)
- > Vaginal pH
- Change in the Menopause Rating Scale (MRS)
- > Lipid and glucose metabolism
- Hemostatic and bone laboratory variables
- > E4 concentrations at baseline and steady state

Key safety objectives:

- Transvaginal ultrasonography (TVUS) change of endometrial thickness at each study visit during the E4/placebo treatment period
- > Serious adverse event (SAE) monitoring
- > Electrocardiogram (ECG)
- > Bleeding control

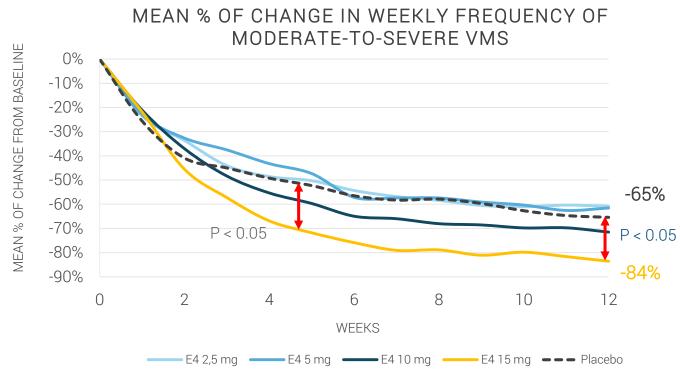
Donesta® Phase IIb: Positive Top-line Results — Optimal minimal dose & Significant effect on VMS

- Primary study objective reached: optimal minimal effective dose defined at 15 mg
- Frequency and severity endpoints met, despite not being powered for statistical significance:
 - Significant reduction of frequency of VMS at Week 12 (p < 0.05)
 - Reduction of over 80% vs baseline, vs. apprx. 60% for placebo
 - Near-significant effect at Week 4 (p = 0.056)
 - Significant reduction of severity of VMS at Week 4 and Week 12 (p < 0.05)
 - Reduction of over 40% vs baseline for moderate to severe VMS, vs. apprx. 25% for placebo

*Note: High placebo effect well-documented in VMS studies (see e.g. Maclennan et al. 2009)

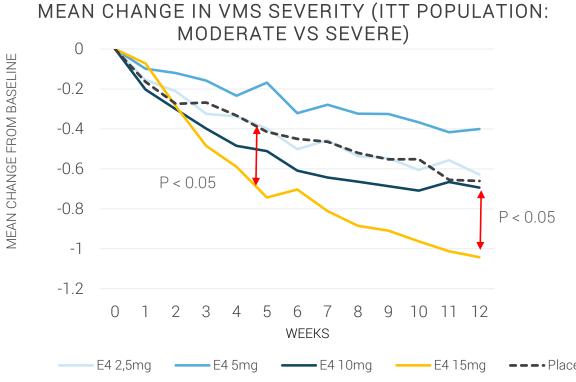


Donesta®Phase IIb: Positive Top-line Results: Significant effect on frequency of hot flushes





Donesta® Phase IIb: Positive Top-line Results: Significant effect on severity of hot flushes





Donesta® Phase IIb: Efficacy on Secondary endpoints & promising safety profile (1/2)

- Highlights secondary efficacy endpoints:
 - Statistically significant result for vaginal maturation index (VVA/vulvo-vaginal atrophy; p < 0.001)
 - Strong improvement in Menopause Rating Scale (Quality of life)
 - 15 mg dose shows lower bone turnover vs placebo at Week 12
 Near-significant decrease for CTX-1 & significant decrease for osteocalcin marker (p < 0.05) vs placebo
- At 15 mg, need to add progestin for non-hysterectomized women to curb endometrial proliferation (separately or combined)
 - However, no endometrial hyperplasia detected in any of the study subjects



Donesta® Phase IIb: Efficacy on Secondary endpoints & promising safety profile (2/2)

- Safety parameters confirming published results on hemostatic profile of E4:
 - Limited impact on pro- and anti-coagulant factors
 - Encouraging limited increase in SHBG levels (Sex-hormone binding globulin), as marker of hepatic estrogenicity
- Significant improvement in metabolic factors, especially for 15 mg dose, pointing to promising cardiovascular safety profile:
 - Glucose levels significantly improve, as measured by hemoglobin A1C (p < 0.001 vs placebo)
 - Metabolism of lipids also significantly improved (p < 0.05 for increase in cholesterol-HDL levels vs placebo for 10 & 15 mg)
 - Only very slight increase in **triglyceride** levels



Donesta® Phase IIb: Summary and Next steps

- 15mg E4 highly efficacious for relieving most bothersome symptoms of menopause; with promising safety profile
- Detailed results to follow, incl. at IMS International Menopause Society conference (June 6-9)
- European KOL Board very supportive to progress Donesta; US KOL Board planned in Q2 2018
- Phase III development plan:
 - o Launch of both an E4 alone and a combination trial (E4 + progestin) in order to maximize market potential of Donesta
 - Preparatory/bridging studies to commence as early as Q3 2018 (e.g. food effect study; combitox), followed by initiation of recruitment for Phase III trials
 - Detailed Phase III design to be discussed with KOLs and agencies

Positive top line Phase IIb data strongly support further Donesta® development, as a unique next-generation hormone therapy



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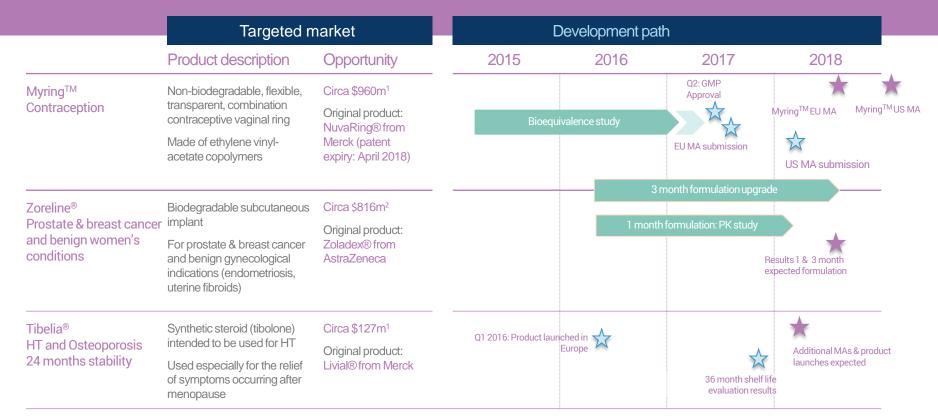


Leveraging know-how of Complex Therapeutics

- Expertise in developing complex and innovative polymer products
- Targeting safer, long-lasting delivery and controlled release of trusted, established approaches to contraception, menopause and hormonedependent cancers
- Duration ranging from 1 month to 5 years
- One of handful of companies that can deliver **multiple drug delivery strategies** including vaginal rings, implants and intra-uterine systems (IUS)
- To be developed and manufactured in-house at Mithra's dedicated
 CDMO research, development and specialist manufacturing center









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Mithra CDMO: Integrated development & production platform

Specialized pharmaceutical ecosystem, to take products from POC to market



Rationale for CDMO:

- > Keep quality control, IP & expertise in-house
- > Operate independently from 3rd parties using its own proprietary production technology
- > Additional source of revenue via production of (partnered) programs
- > Leverage development expertise through 3rd party production contracts

2-Phase construction process:

- H2 2016: R&D facility and polymeric forms, implants and sterile injectables production line facilities
- ➤ Received European GMP approval for MyringTM (May 2017); FDA visit in Q2 2018
- > H1 2019: Production line for tablets to be completed



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Partnering with leaders in Women's Health at key value inflection points

Accelerating business development while strengthening in-house expertise

E4 Partnering Strategy'

Estelle® intended partnering after Phase III Partnering for world-wide commercialization

Donesta® intended co-development for Phase III

Fuji Pharma: partnering agreements for Estelle® (2016) and Donesta® (2017) in Japan & ASEAN; Libbs for Estelle® in Brazil (2017); Searchlight for Estelle® in Canada (2018), Hyundai Pharm for South-Korea (2018)

Complex Therapeutics

Develop concepts internally until market commercialization

Selecting specialist, regional partners e.g. Myring™: Mayne Pharma in the US (2017); Gynial in Austria (2017); Adamed in Czech Republic; Alvogen in Russia; GSP and Midas Pharma for injectables

Mithra CDMO

*Preclinical research in neuroprotection (ODD received for neonatal encephalopathy in Q2 2017): Partnering intended for clinical development



Partnering with leaders in Women's Health at key value inflection points

	EU		US	RoW			
Estelle®	Partnering intended for commercialization			Libbs It's how we treat life Brazil	Partnering o Fuji Pharma Co., Ltd. Japan & ASEAN		HYUNDAI PHARM South Korea
Donesta®	Partnering intended for co-development Phase III			Partnering ongoing Fuji Pharma Co., Ltd. Japan & ASEAN			
Myring™	Partnering discussions ongoing ADAMED Austria Czech Republic Russia	Orifarm	mayne pharma		Partnering discuss	sions ongoing	
Other products (incl. Zoreline®; Tibelia®)	Partnering discussions ongoing	ng*	Partnering discussions ongoing	Pharma	Partnering discuss	sions ongoing	



News Flow – Key inflection points in 2018/19





Summary Financial Information



IFRS P&L and cash balance (in m€, FY as of 12/31/2017)**

	FY 2016	FY 2017	
Revenues	22.5	46.3	
R&D Expenses	(34.3)	(48.2)	
G&A	(8.3)	(8.7)	
Selling expenses	(7.6)	(4.7)	
REBITDA	(34.9)	(18.1)	
Cash & Equivalents	45.8	36.2	

- > Revenues doubled thanks to
 - > Stable Benelux business
 - Licensing revenue
 - Fuji Donesta
 - Mayne Myring
 - ➤ Libbs Estelle
- Costs controlled; lower selling expenses
- ➤ Cash: EUR 26.1m private placement in June 2017

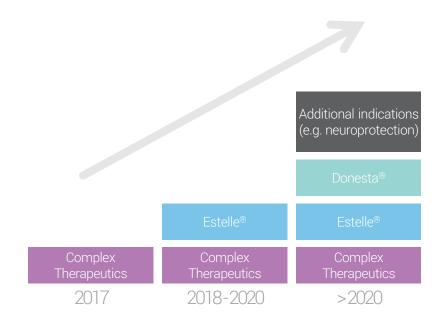
^{**} CEO (François Fornieri) holds warrants for 1,023,000 additional shares of Mithra



^{*} Shareholdership in accordance with transparency declarations received by the company and notified managers' transactions. Market Cap: €1.1bn as of June 2018 (Euronext: MITRA)

Building a transformative Women's Health company

- Multiple prospective near- and mid-term milestones and launches to drive long-term growth
- Estelle® and Donesta® late-stage potential blockbusters built on unique E4 platform
- Acceleration of business development including partnerships for E4-based programs
- Industry partner with specialist research, development and manufacturing capabilities
- Diversified model spreads risk and maximizes product opportunities through collaborations





Contact Us

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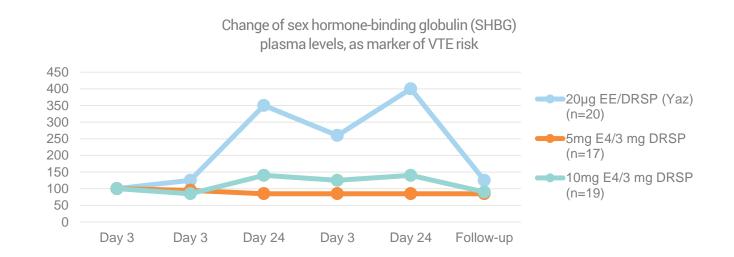
Thank you

investors.mithra.com

Appendices

Estelle® Phase IIa: Reduced VTE risk profile

Low increase in SHBG demonstrating significantly reduced VTE risk as compared to Yaz^{®1}







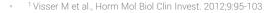
Pre-clinical results: Lower risk of drug-drug interaction

Minimal interference with liver cells and drug degradation process

No unwanted inhibition of cytochrome P450, major family of drug degradation enzyme¹

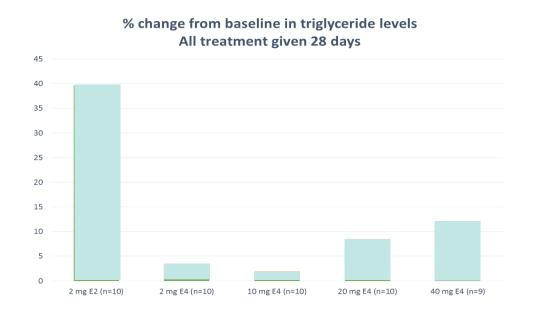
% inhibition of cytochrome P450 enzymes

Compound	CYP 1A2	CYP 2C9	CYP 2C19	CYP 2D6	CYP 3A4
EE	<10	<10	82	<10	45
E2	19	<10	63	<10	<10
E4	<10	<10	<10	<10	<10





Donesta® Phase Ib: Minimal increase of triglycerides, a key marker for coronary heart disease



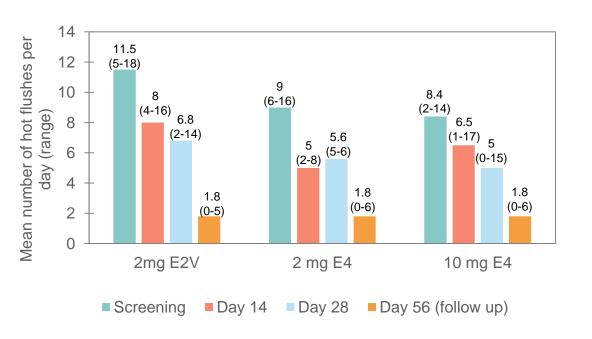
Elevated triglyceride levels are associated with coronary heart disease

Different dose levels of E4 show minimal impact on triglyceride levels¹

¹ Coelingh Bennink et, al. Menopause. 2017.



Donesta® Phase Ib: Dose-dependent effect on number of hot flushes



Consistent decrease in the mean number of hot flushes was observed in all dose groups (49 subjects with 35+ hot flushes per week at screening)



E4: Low carcinogenic potential (preclinical)

3,0

0.0

ve hicle

Lower carcinogenic potential¹

No stimulation of normal or malignant breast cell growth at therapeutic doses Anti-estrogenic effects in the presence of E2²,³

Mammary tumours/animal at autopsy (+SEM)

In the laboratory, E4 was shown to protect against breast cancer development and to decrease size of already existing tumors

> Female rats exposed to DMBA for 8 weeks and receiving E4 in parallel

TAM 3 mg

OVX

11

³ Visser M et al., Horm Mol Biol Clin Invest. 2012;9:95-103.11 Suppl 1:64-8.



E4 0.5 mg

80

17

E4 2.5 mg

¹ Yagi E et al., Carcinogenesis. 2001;22(9):1505-10.

² Gerard C et al., Oncotarget. 2015;6(19):17621-36.;

Hormone Replacement Therapy: Back to the Future

1990-2001: HT widely use for Donesta[™] (E4) 2016: Pharma Industry reinvests in postmenopausal women



Advisory boards and clinical collaborations¹

- EU and US-based advisory boards of key opinion leaders for both Donesta® and Estelle®
- Endorsement of the major potential of E4, providing strategic guidance on clinical programs
- Clinical collaborations with world renowned leaders in women's health























































