OVOCA BIO

June 2020

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Ovoca Bio plc

European-based biopharmaceutical company with a focus on **women's health**

Currently developing BP-101 a novel synthetic peptide for treatment of women with **hypoactive sexual desire disorder** (HSDD)

Affects more than 4 million US women, two marketed treatments with significant side effect profiles

BP-101 is clinically validated, with Phase II and Phase III studies conducted in Russia

Filed for marketing approval of BP-101 in Russia and seeking to develop in major **global** markets

Founded in **1985** and incorporated in Republic of Ireland

AIM and ESM-quoted (AIM/ ESM:OVB/OVXA)

€16.5 million in cash and liquid assets to support drug development activities (June 2019)

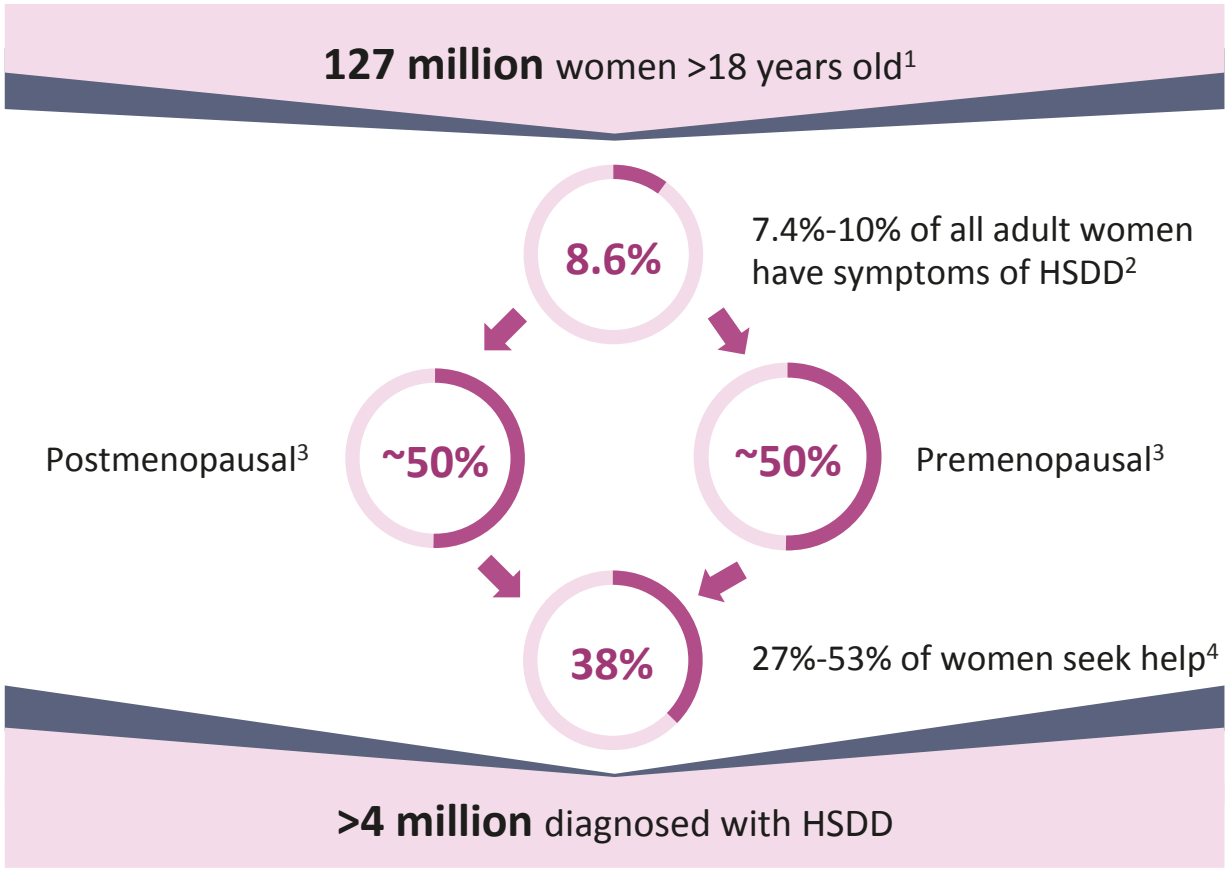
Experienced management team and top technical advisors in place to deliver on corporate goals.

About hypoactive sexual desire disorder (HSDD)

- Estimated one in ten premenopausal women have HSDD, making it one of the most common female sexual problems
- Defined in the Diagnostic and Statistical Manual of Mental Disorders (DSM) as distressing and persistent deficiency of sexual fantasies and desire for sexual activity
- HSDD can have major effects on patients' ability to enjoy a fulfilling sex life and can be driven by a myriad of factors
- Diagnosis via a variety of short screening tools, such as Decreased Sexual Desire Screener, to determine if a woman is affected by HSDD

Scale of the Problem that is HSDD

HSDD prevalence estimates in Europe are similar to those of the U.S.[5]



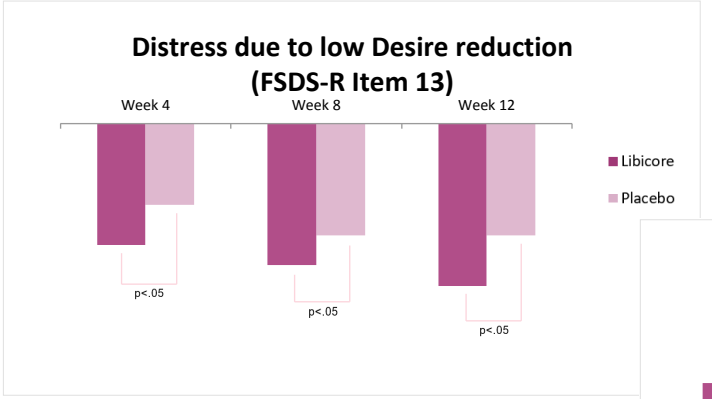
Estimated >4 million US women affected

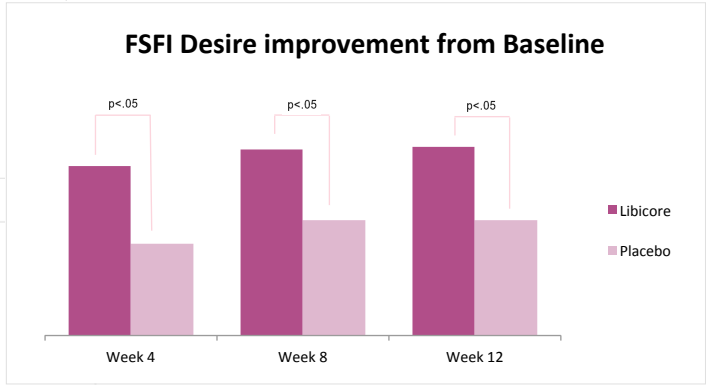
Sources: 1 2015 US Census, 2. Obstet Gynecol 2008 112(5):970-8; Arch Intern Med 2008 168(13):1441-9; J Womens Health (Larchmt) 2012 21(5):505-15, 3. J Womens Health (Larchmt) 2012 21(5):505-15, 4. J Womens Health (Larchmt) 2009 18:461-468; J Womens Health (Larchmt) 2012 21(5):505-15; J Womens Health (Larchmt) 2014 23:817-823, 5. Obstet Gynecol 2008 112(5):970-8

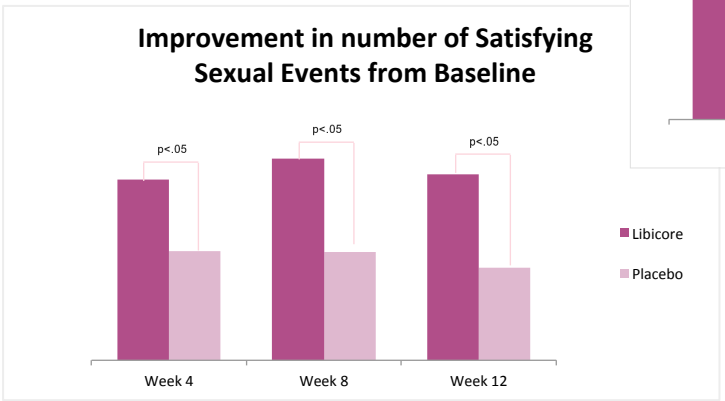
Ovoca's approach - BP-101

- Novel synthetic peptide conveniently administered through a nasal spray.
- Validated in Russian Phase II and Phase III studies
  - Demonstrated statistically significant and clinically meaningful improvement in a number of key efficacy outcomes in HSDD.
- Clinically significant increase in female sexual desire and reduces symptoms of distress associated with HSDD

STRONG EFFFICACY PROFILE – PHASE 3 FINDINGS







Safety profile

Favorable safety profile across all completed studies:

- No drug-related serious or severe adverse events
- 100% patient adherence to treatment (no patient withdrew from the study due to adverse events)

Phase 3
safety findings

Adverse Event	BP-101 (N=95)	Placebo (N=94)
All patients with adverse events	33 (34.7%) / 81	29 (30.9%) / 76
Common adverse events (≥5% irrespective of causality, all Mild-to-Moderate):		
Nasal irritation (several types)	11 (11.6%) / 23	1 (1.1%) / 6
Headache	6 (6.3%) / 12	9 (9.6%) / 17
Menstruation disorders (delays etc.)	5 (5.3%)/ 5	2 (2.1%)/ 3

The table displays numbers and percentages (based on N) of subjects with adverse events (AEs) and numbers of AEs.

Competitive landscape

Treatments for HSDD in premenopausal women

Main competitors comparison

Drug	Administration	Frequency	Safety	Product	Dev. Stage
OVOCA BIO **BP-101**	Intranasal	Daily	No withdrawals due to AE (in >170 treated females)		Pre-MA in Russia Ph. 2 in West
sprout pharmaceuticals **Addyi® (flibanserin)**	Oral	Daily	Black box warning, syncope and hypotension, use with alcohol restricted		Approved US only – August 2015
PALATIN TECHNOLOGIES, INC. amag PHARMACEUTICALS **Vyleesi® (Bremelanotide)**	Subcutaneous injection	On demand before sexual activity	AEs leading to CT withdrawal (rise of blood pressure, nausea)		Approved US only – July 2019

HSDD treatments launched / in development

How BP-101 is differentiated

Drug	MOA	Phase (US)	Delivery	Company
Flibanserin	5-HT agonist/antag. + D4 antag.	Launched	Oral	Sprout
DHEA*	Testosterone agonist	Launched	Suppository	Endoceutics/ AMAG
Bupropion*	Norepi/Dopamine Reuptake Inhib.	Launched	Oral	Multiple
Buspirone*	5HT partial agonist	Launched	Oral	Multiple
Testosterone*	Androgen agonist	Launched/PhII	Patch/Nasal Gel	Multiple/Acerus**
Bremelanotide	MC-4 agonist	Approved	SQ injection	Palatin/AMAG
Testosterone + Sildenafil	Androgen agonist + PDE 5 inhib.	Phase II	Oral	Emotional Brain
Testosterone + buspirone	Androgen agonist + 5HT agonist	Phase II	Oral	Emotional Brain
Bupropion + Trazodone	Norepi/Dopamine Reuptake Inhib, + 5HT antag.	Phase II	Oral	S1 Biopharma***

* Off-label use ** No development reported since 2014 ***No development reported since 2016

- BP-101 specifically targets premenopausal women with HSDD
- Other currently available / development stage approaches include:
  - Hormone agonists (limited to postmenopausal women)
- Repurposed drugs used off-label such as
  - Depression / anxiety medications

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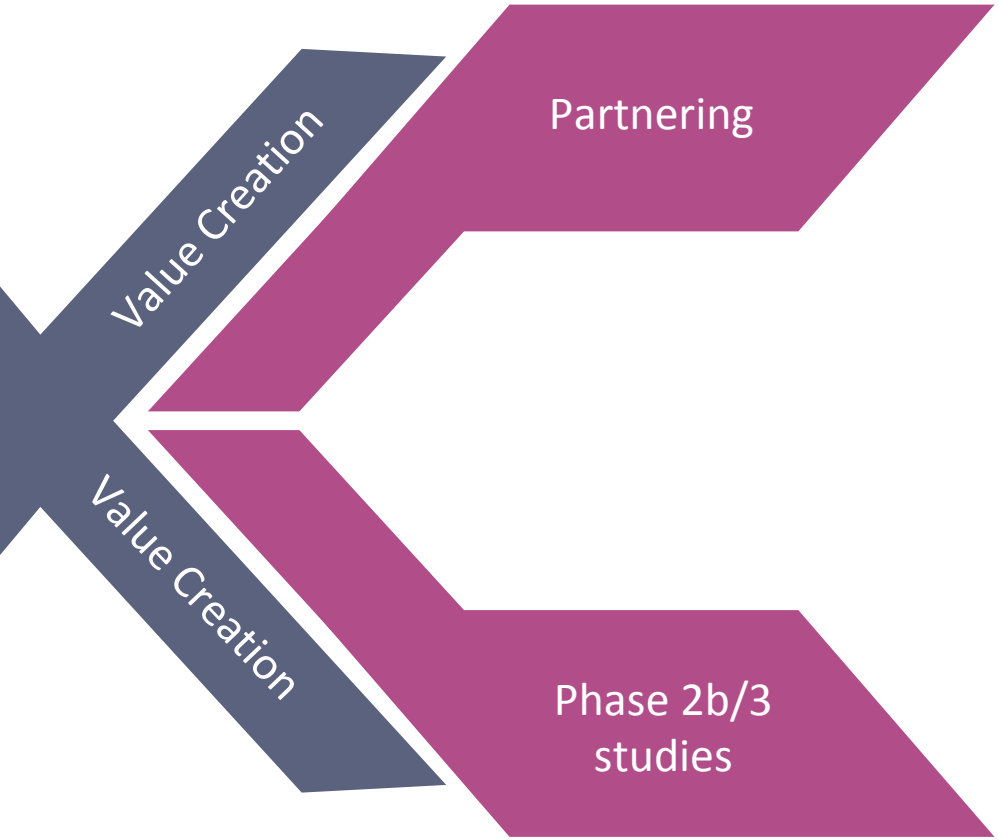
International Development Plans

Building Ovoca's status as an international biotech company

- Validation of Russian clinical trial data in the West
- Confirmation of development plans with BfArM and FDA
- Exploration of different dosing regimen
  - Completion of non-clinical studies enabling long term human dosing
  - Suitability of on demand dosing for long term use
- Access to an international panel of experts in female sexual dysfunction
- Establish commercial drug supply in the West



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First Launch Market - Russian Federation

Market Authorisation filed at Russian Ministry of Health – September 2019

Anticipated license approval H2 2020

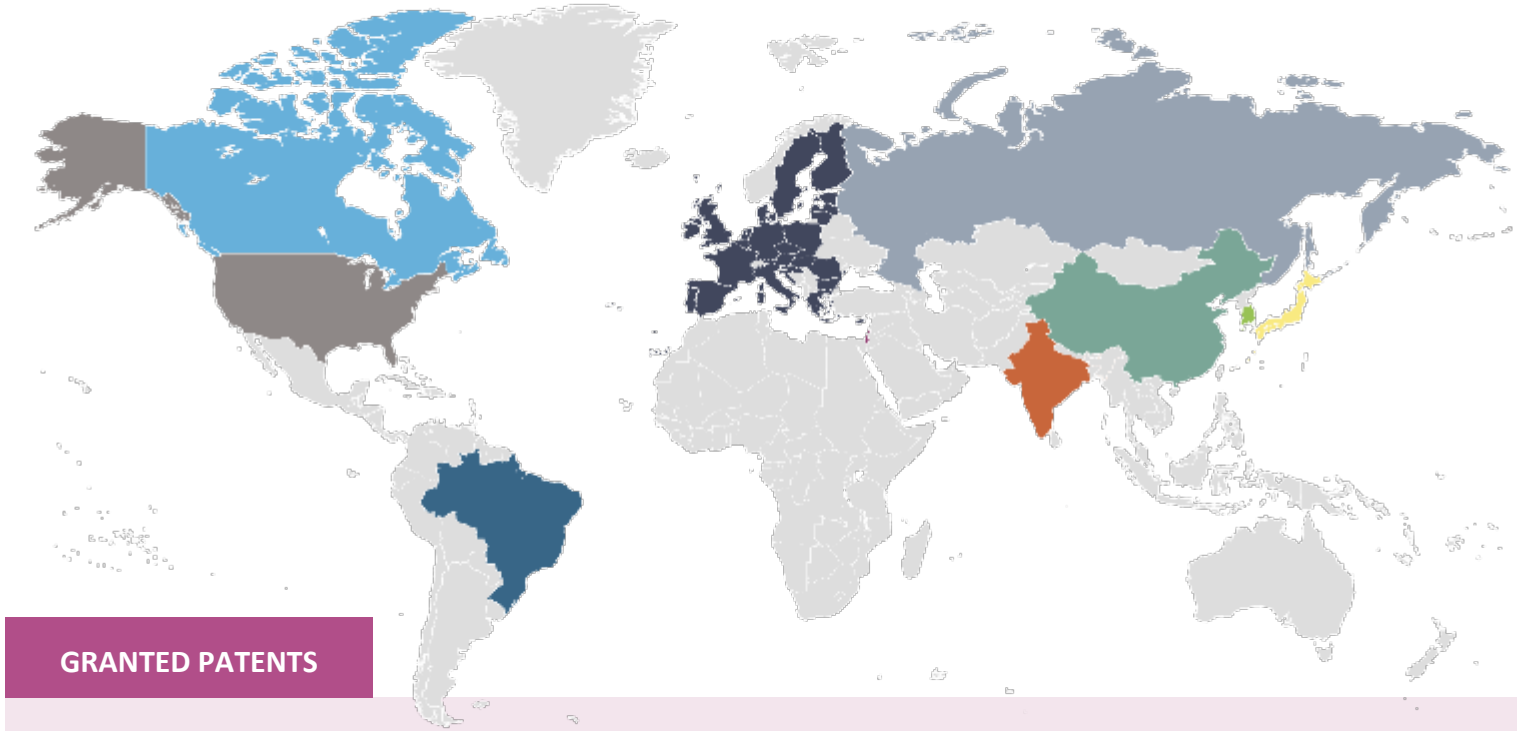
Finished product to be manufactured by established domestic pharmaceutical producer

Russian and international commercial partners considered

- Early experience informing Western development programme

Intellectual Property

Protecting the company's most valuable asset



GRANTED PATENTS

«Method for Producing a Recombinant Peptide and Resultant Peptide», priority year 2012.

- **USA** patent US9409947B2
- **Japan** patent 特第6552960
- **Israel** patent 234753
- **EU** patent 2876113
- **Russia** patent № 2507212, and also
  - New patent № 2626002, priority year 2016, "New group of peptides for treatment of Female Sexual Dysfunction".
  - New patent № 2655763, priority year 2016, "Pharmaceutical composition and method of treatment of Female Sexual Dysfunctions"

PCT APPLICATIONS PROSECUTED IN:

- US
- EU
- BRAZIL
- CANADA
- CHINA
- INDIA
- ISRAEL
- JAPAN
- SOUTH KOREA

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Next steps

USA/EU/Australia

- Regulatory consultations:
  - Scientific Advice in EU with BfArM (Completed 2019)
  - Type C consultation with FDA (Completed Q2 2020)
- Preclinical program: Long term animal toxicity, exposure/MTD study (2020)
- Commence Phase 2 clinical study : submission of IND, CTA and/or local approvals in chosen country(s)

Russia

- Filing for marketing authorization in Russia (Completed 2019)
- Commercial manufacturing
- Partnering for launch

Summary

- HSDD represents **significant area of unmet medical need** with high prevalence in valuable US and European markets
- Ovoca Bio's novel therapeutic approach offers potential **advantages over existing approved treatments**
  - Demonstrated statistically significant and clinically meaningful improvements in a number of key efficacy outcomes in HSDD
  - Shown as safe and well tolerated
  - Convenient dosing form
- Strong cash position and **fully funded** to deliver near term goals
- **Experienced management team** with focus on delivering value

Ovoca Bio Team

Depth in Leadership

Mikhail Mogutov, PhD
Chairman

Business leader in life science, chemicals, natural resources and investing industries

Professor Nikolai F. Miasoedov,
Inventor/Scientific Adviser

Deputy Head of Institute of Molecular Genetics, Moscow – CNS drugs inventor

Kirill Golovanov, JD, MBA
Chief Executive

7 years leading Ovoca, extensive new ventures and banking experience

Chris Wiltshire, MBA
Chief Business Officer (interim), Director

25 years in commercial leadership roles in US/EU biotech, Pfizer and Eli Lilly

Daniil Nemenov, MD
Medical Director and General Director, IVIX Ltd

14 years in clinical development, including at Novartis in Russia

Mikhail Lomonosov, PhD
Head of R&D, IVIX Ltd

15 years of research in molecular biology and genetics, including at Cambridge University


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