



OVOCAL BIO

June 2021

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Ovoca Bio plc



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

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, and
Phase II underway in
Australia/New Zealand

Submitted 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:OVV/OVXA)

>US\$15 million in
cash and liquid assets to
support drug development
activities (June 2020)

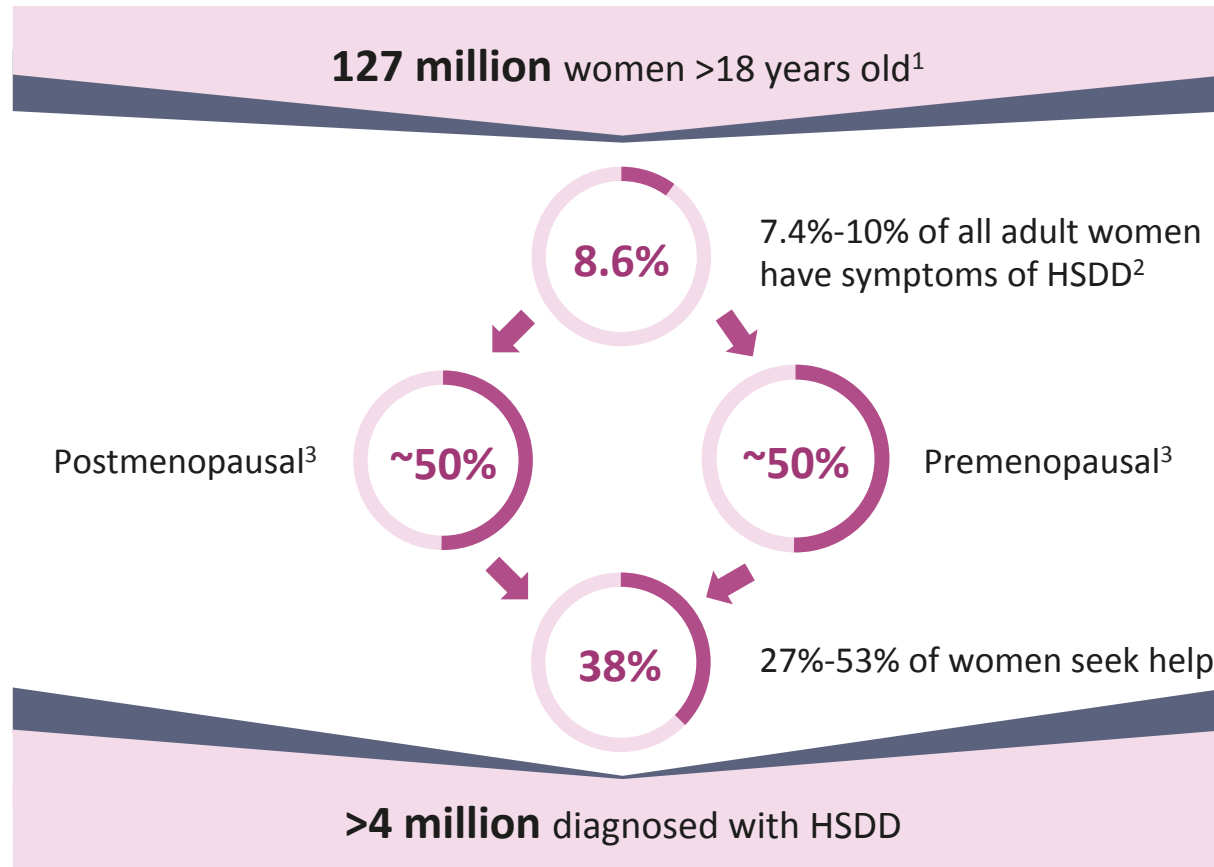
Experienced
management team and
top technical advisors in
place to deliver on
corporate goals.

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 is 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 Women's Health (Larchmt) 2012 21(5):505-15, 3. J Women's Health (Larchmt) 2012 21(5):505-15, 4. J Women's Health (Larchmt) 2009 18:461-468; J Women's Health (Larchmt) 2012 21(5):505-15; J Women's Health (Larchmt) 2014 23:817-823, 5. Obstet Gynecol 2008 112(5):970-8

Novel Treatments for HSDD in Premenopausal Women

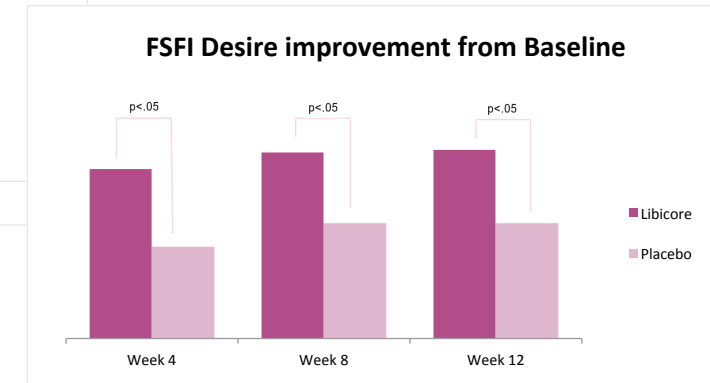
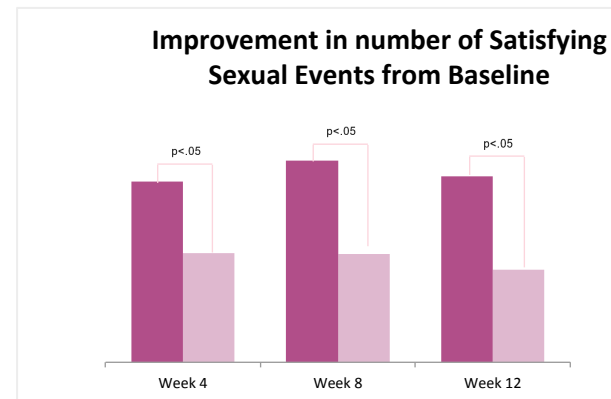
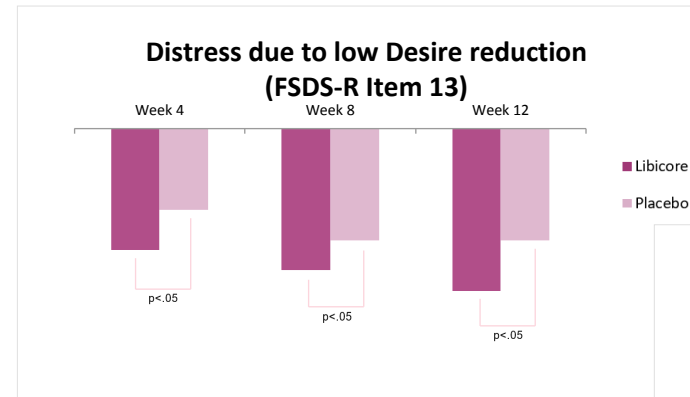
Main competitors comparison

Drug	Administration	Frequency	Safety	Product	Dev. Stage
 "BP-101"	Intranasal	Daily	No withdrawals due to AE (in 177 treated females)		Pre-MA in Russia Ph. 2 in West
 Addyi® (flibanserin)	Oral	Daily (bedtime)	Black box warning, syncope and hypotension, use with alcohol restricted		Approved US only – August 2015
 Vyleesi® (Bremelanotide)	Subcutaneous injection	On demand 45 mins before sexual activity	AEs leading to CT withdrawal (rise of blood pressure, nausea)		Approved US only – July 2019

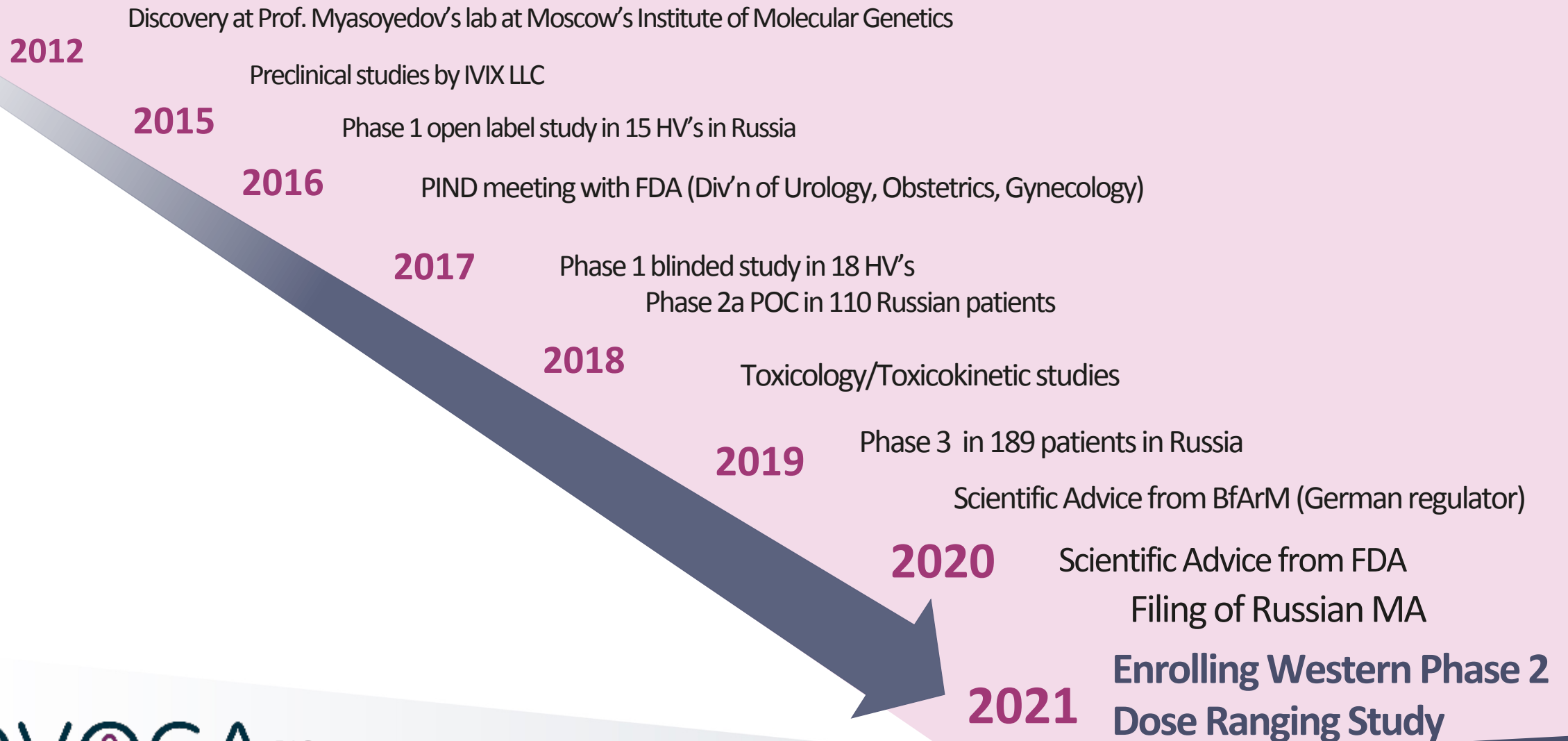
Ovoca's approach - BP-101

- 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 EFFICACY PROFILE – PHASE 3 FINDINGS



BP-101: A history of investment and progress



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.

International Development Program

Building Ovoca's status as an international biotech company

- Validation of Russian clinical trial data in the West
 - Phase II dose ranging study enrolling in AUS/NZ Q1 2021
- BfArM and FDA advisory meetings held
- Commencement in 2021 of non-clinical studies in Europe enabling long term human dosing
- Exploration of a different dosing regimen and application in other sexual disorders
 - Suitability of on demand dosing for long term use
 - Potential use in Female Orgasmic Disorder
- Advice from an international panel of experts in female sexual dysfunction

Value Creation

Partnering

Value Creation

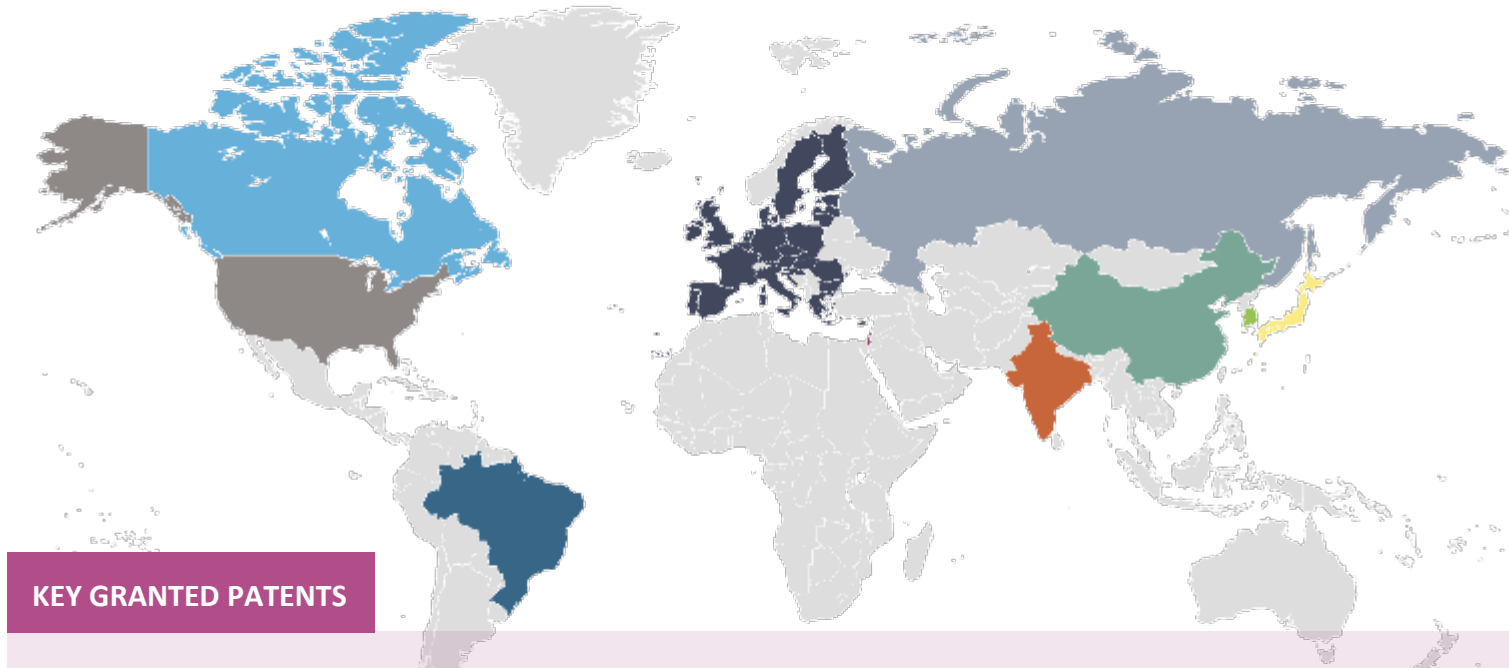
Phase 2b/3 studies

BP-101 - Phase II Dose Ranging Study

- Double-blind placebo-controlled study to enroll >450 patients across 13 sites in Australia and New Zealand – commenced enrolment in Q1 2021
- Drug supplied by experienced, high quality contract manufacturers in Switzerland (Bachem) and the UK (Upperton)
- Aims to further validate the results of the Russian studies and provide evidence of efficacy in a Western culture
- Provides data fully compliant with the standards of the International Conference on Harmonisation supportive of a clinical programme in the US and EU.

Intellectual Property

Protecting the company's most valuable asset



KEY 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
- **India** patent 349465
- **S Korea** 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

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 clinical results in Russia being tested in Australia/New Zealand
- Strong financial position and **fully funded** to deliver near term goals
- **Experienced management team** with focus on delivering value



**Thank you for
your attention!**

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