Libicore – medication for treating female sexual dysfunction

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Key team members

Experienced and Reputable Leadership Team

Kirill Golovanov, MBA
Chief Executive
- *7 years leading Ovoca, extensive new ventures and banking experience*

Daniil Nemenov, MD
Medical Director
- *12 years in clinical studies set up and management, including experience managing Novartis clinical studies in Russia*

Mikhail Lomonosov, PhD
Chief Scientific Officer
- *15 years of research in molecular biology and genetics, experience in managing clinical research projects*

Chris Wiltshire, MBA
Non-Exec. Director, Ovoca Bio and Chief Business Adviser
- *25 years in commercial leadership roles in US/EU biotech and big pharma*

Inventor : Professor Nikolay Myasoyedov,
Non-Exec. Director of Ovoca Bio

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

Executive summary

Founded : 2012 by experienced pharma executives and inventors of several CNS drugs; 10 employees

Molecule: BP-101, a novel, first-in-class synthetic peptide administered by intranasal spray

Manufacture: Outsourced to FDA approved GMP CDMO's

IP: Pharmaceutical composition patent granted in USA (2016), COM granted in Russia (2015), PCT national phases started in 2014 in Europe and Canada, Brazil, China, India, Japan, Israel, S Korea

Indication(s): Distressing lack or loss of sexual desire - Hypoactive Sexual Desire Disorder (HSDD)

Development Stage: 2xPh1, 1xPh2 and 1x Ph3 successful clinical trials completed in Russia

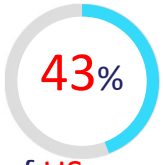
Competitive advantage: Expected in efficacy, safety and ease of administration.

Next Steps (2019):

- File for MA in Russia
- EU vs US market assessment
- Scientific Advice with BfArM and Type C meeting with FDA
- Complete clinical trial-enabling pre-clinical studies
- Apply for and conduct Ph2 in the West

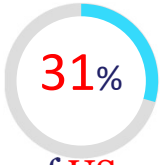
Scale of the problem

Women suffer MORE than men from problems with sexual desire/satisfaction:



of US women

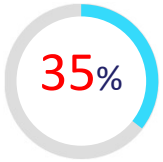
VS



of US men

Reported short or long term problems related to sexual function

(established in a study of 3159 people by Laumann et al. in 1999)



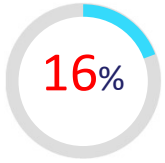
of married women

VS

of married men

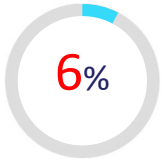
Complained about absence of sexual desire

(established by Masters & Johnson, 1966)



of UK women

VS



of UK men

Sexual problems in last 12 months persisting for at least 6 months

(established in a study by Mercerer et al. in 2003)

Estimated US market size for HSDD

127 million women >18 years old[1]

8.6% — 7.4%-10% of all adult women have symptoms of HSDD[2],

~50% Post-menopausal[3]

~50% Pre-menopausal[3]

38% — 27%-53% of women seek help[4]

4.2 million diagnosed with HSDD → ~2.5 million treated with Rx[5]

US$2.25Bn

$0.9K p.a. net price per patient[6]

Note: HSDD prevalence estimates in Europe are similar to those of the U.S.[7]

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. Michael Higgins et al, of Ladenburg Thalmann & Co. report on Palatin Technologies, jue 27, 2018 , p 19-24 6. Addyi pricing of $99/month (uninsured) with 25% trade discount, 7. Obstet Gynecol 2008 112(5):970-8

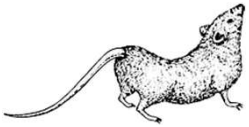
Preclinical efficacy

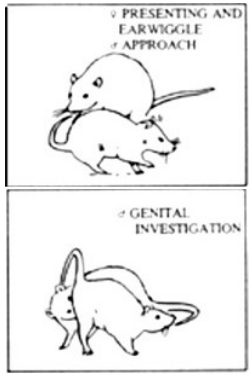
IVIX tested a list of peptides with possible neural activity

Peptide BP-101 identified with efficacy surpassing natural sex hormones, estradiol and progesterone

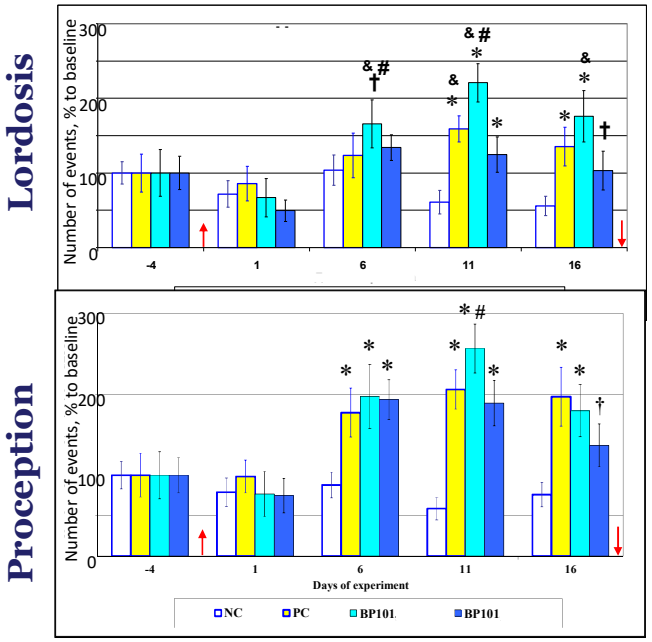
Model:

- Female rats, with surgically removed ovaries.
- Hormone replacement therapy to reproduce normal estrous cycle.
- To measure sexual behavior females put together with active males





NC - negative control, low hormone levels
PC - positive control, high hormone level
dose1 - low hormone levels + BP101 at dose 1
dose 2 - low hormone levels + BP101 at dose 2



Preclinical toxicity

Candidate substance tested for toxicity. Multiple tests performed to evaluate any possible toxic effects.

Test	Result
Study of 30-day toxicity (in rats, dogs and monkeys), including local irritation assessment	>50 times therapeutic dose equivalent checked, no toxicity observed.
Mutagenicity in the Ames test (bacteria)	No mutagenicity
Effect on chromosomal aberrations in mouse bone marrow cells	No chromosomal aberrations
Evaluation of potential carcinogenicity	No potential carcinogenicity
Immunogenicity, immunotoxicity and allergenicity	No adverse effect on immune system
Reproductive toxicity	No effect on pregnancy or on fetus

BP-101 appears safe and quickly degrades in the bloodstream to natural amino acids.

Ivix's novel therapeutic : Libicore

Description: a novel synthetic peptide, BP101, that regulates female sexual function

Discovery: Confirmed observations of increased sexual activity of female rats in unrelated research into anxiolytic properties of BP101

- MOA studies ongoing

Delivery method: nasal spray

- Simple, convenient and safe way of using the medicine

Manufacture: Outsourced to FDA-approved GMP CDMO's

- API substance – Switzerland
- Final drug product – UK
- Vials – France (1st GL class)
- Nasal pump – Germany

Clinical/Regulatory program

4 clinical trials completed in Russia:

- First-in-human Phase I Study (15 female healthy volunteers)
- Phase 1 Study to assess pharmacokinetics and safety at higher doses (18 female healthy volunteers)
- Proof-of-concept Phase II Study (110 HSDD patients)
- Phase 3 Study (189 HSDD patients): to confirm drug safety and efficacy for Marketing Authorization application in Russia

1 clinical trial being planned in the West:

- Phase 2 dosing study in US/EU/Australia
- FDA pre-IND meeting held in 2016; follow-up Type C meeting planned in 2H 2019
- Preparations in hand for Scientific Advice meeting with BfArM (Germany) in 1H 2019

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)

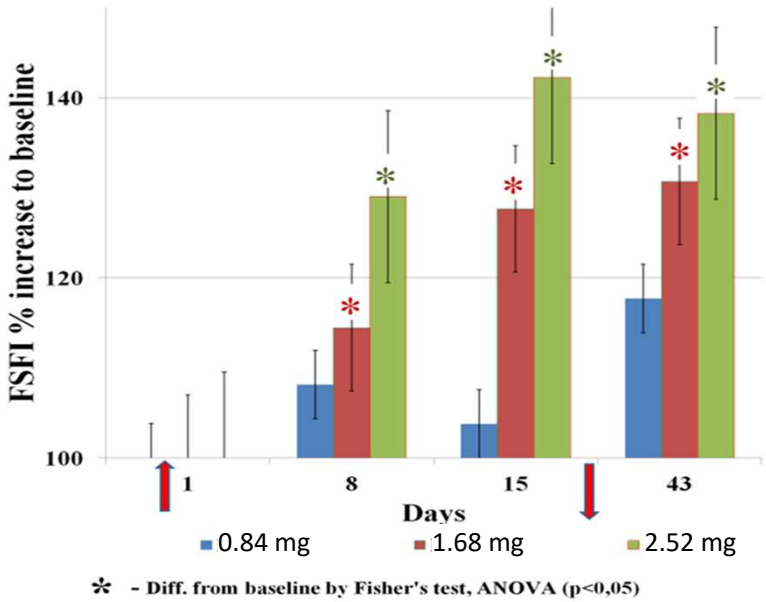
Phase II safety findings:

Adverse Event	BP101 (N=55)	Placebo (N=55)
All patients with adverse events	31 (56.4%)	22 (40.0%)
Common adverse events (≥5% irrespective to causality):		
Irritability	4 (7.3%)/ 4	1 (1.8%)/ 1
Mild-to-moderate Headache	10 (18.2%)/ 10	6 (10.9%)/ 6
Nasal dryness	5 (9.1%)/ 5	3 (5.5%)/ 3

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

First in Human Study (Ph I)

Beneficial safety profile, and dose-dependent sexual improvement



Overall 15 adult healthy women were treated in 3 dose cohorts

Dose-dependent sexuality improvement

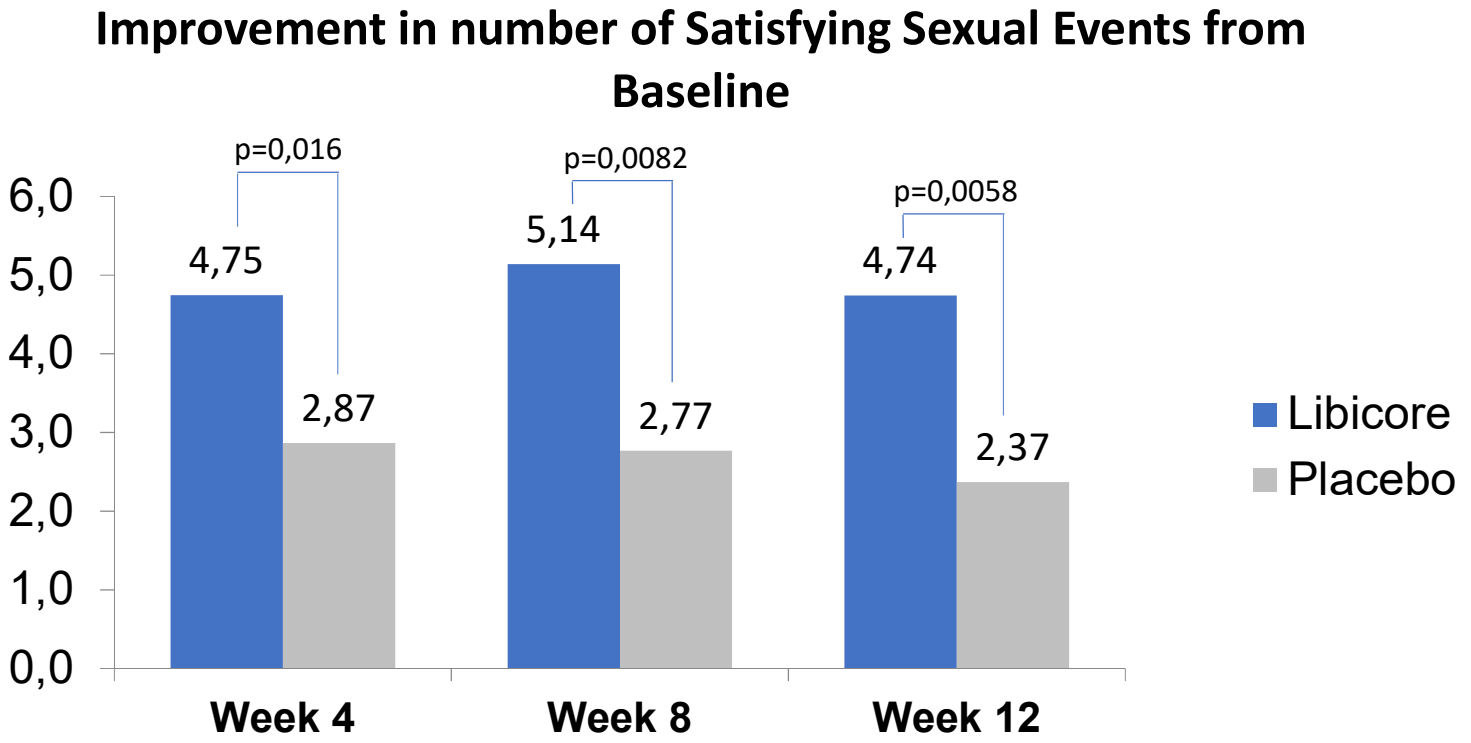
- starting from the first week of Libicore treatment

Long-lasting effect:

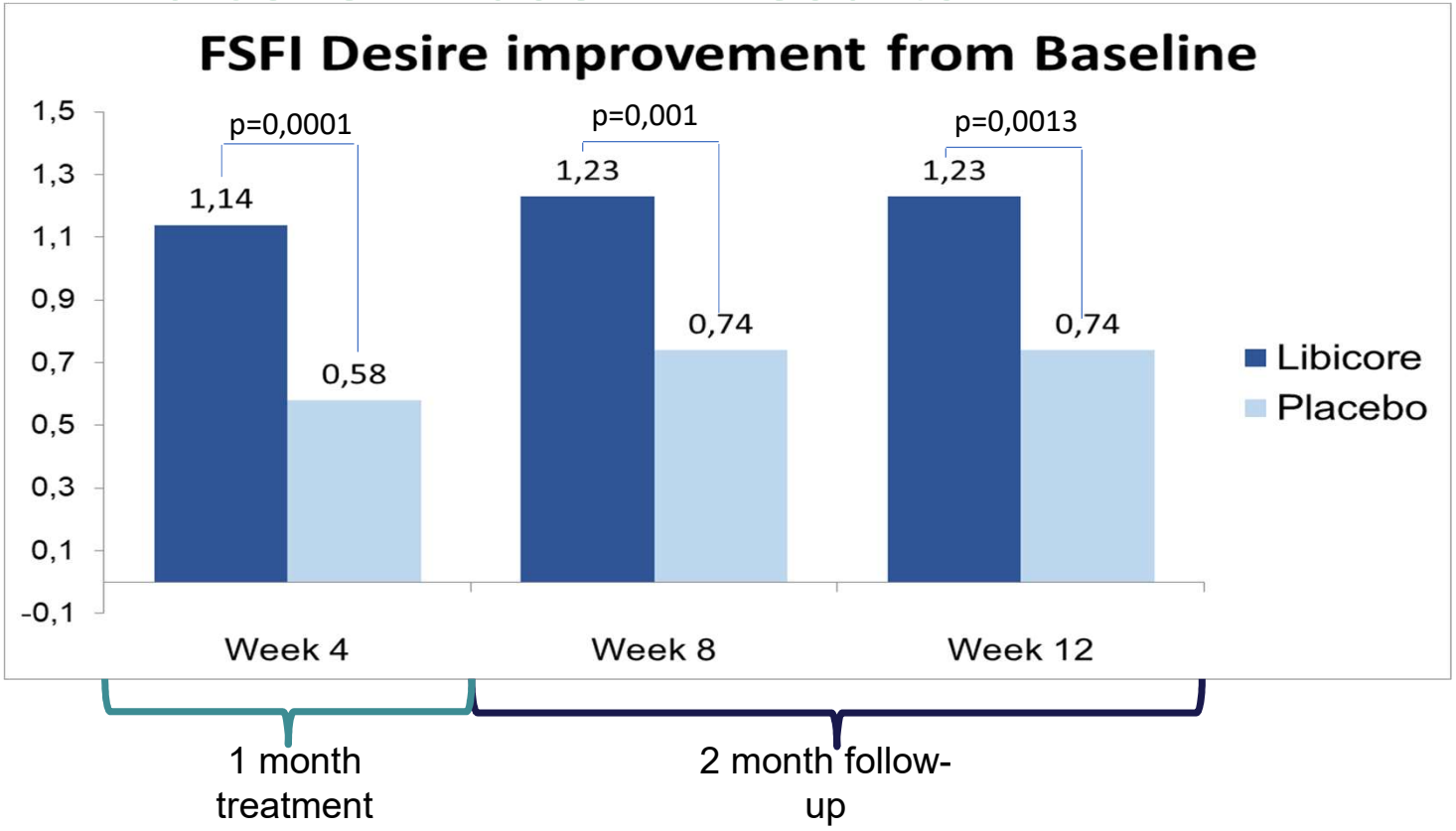
- elevated sexual behavior sustained at least 4 weeks after end of treatment

Favorable safety profile with only mild and short-term AEs

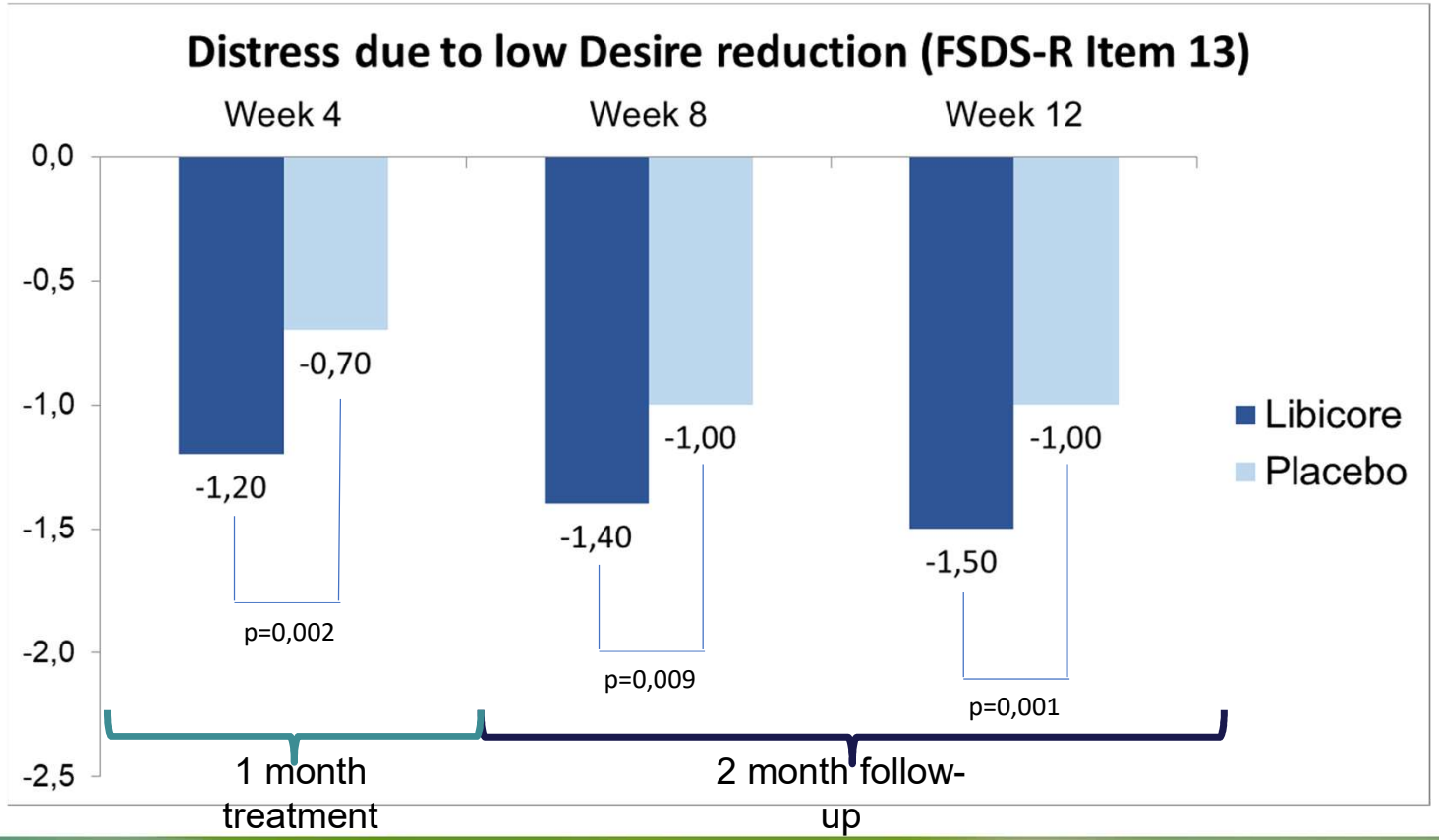
Libicore Phase III Results



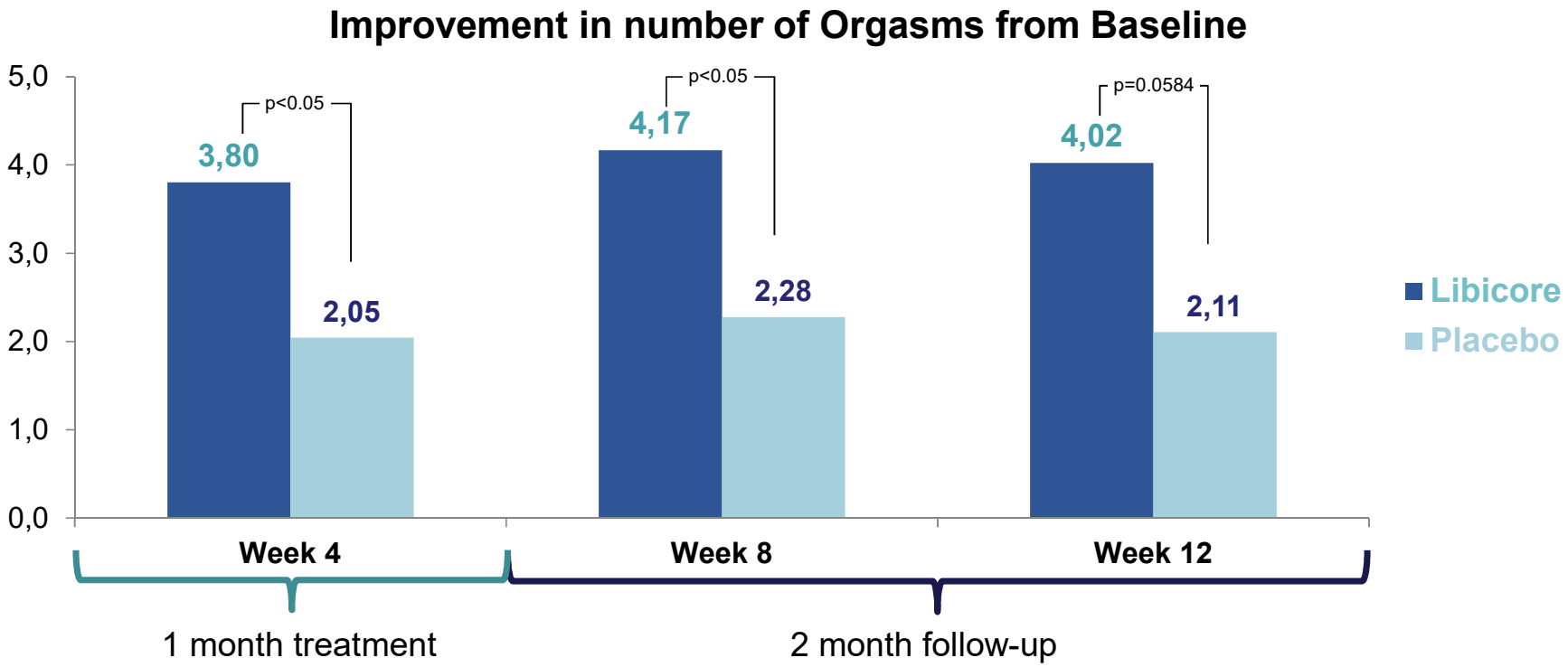
Libicore Phase III Results



Libicore Phase III Results



Libicore Phase IIa Results



Phase III clinical trial design

Multicenter randomized double-blind placebo controlled study to confirm efficacy and safety of Libicore (BP-101)

- 189 female patients with lack or loss of sexual desire (hypoactive sexual desire disorder) in 21 active clinical sites in Russia
- Adaptive design with pre-defined interim analysis: early completion as primary endpoint reached
- Primary endpoint – change in mean number of Satisfying Sexual Events
- Secondary endpoints – change in FSFI total and domains scores, sex-related distress via FSDS-R total and Item 13 score, number of orgasms and number of responders (PGI-I).

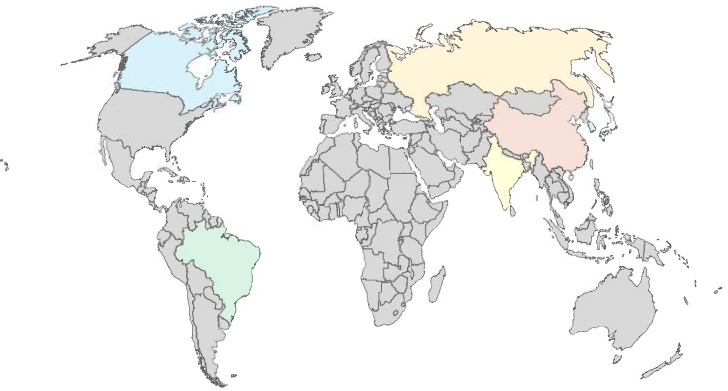
Competitive landscape

Main competitors comparison

Drug	Administration	Frequency	Safety	Product
Libicore (BP-101)	Intranasal	Daily, efficacy seen from **1 week**	No withdrawals due to AE (in >170 treated females)	
Addyi® (flibanserin)	Oral	Daily, at least **8 weeks** to establish efficacy	Black box Syncope and hypotension, incompatible with alcohol	
Vyleesi® (Bremelanotide)	Subcutaneous injection	On demand before sexual intercourse	AEs leading to CT withdrawal (rise of blood pressure, nausea)	

Intellectual Property

Protecting the company's most valuable asset



Patent Attorney: Troutman Sanders LLP, New York, USA

Obtained patents:

USA

- «Method for Producing a Recombinant Peptide and Resultant Peptide», US9409947B2, priority year 2012.

Russia

- Patent № 2507212 «Method for Producing a Recombinant Peptide and Resultant Peptide», 2012.
- 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"

Applications are prosecuted:

CHINA	№201380028491.4
EU	№13772776.4
JAPAN	№2015-503152
INDIA	№8984/DELNP/2014
CANADA	№2,868,820
ISRAEL	№234753
SOUTH KOREA	№10-2014-7030301
BRAZIL	№BR 11 2014 023888 0

Applications of PCT «Method for Producing a Recombinant Peptide and Resultant Peptide», PCT/RU2013/000433

Next steps

Clinical Development in the West & Marketing Authorization in Russia

USA/EU/Australia

- Scientific Advice in EU with BfArM (2019)
- Type C meeting with FDA (2019)
- Complete preclinical program: LT animal tox, HERG and spay droplet size (2019)
- Conduct Phase 2 clinical study : submission of IND, CTA and/or local approvals in chosen country(s)

Russia

- Complete analysis of Phase 3 clinical study
- Filing for marketing authorization in Russia (2019)

Market deals

Demand for comparable drugs

VALEANT Pharmaceuticals North America LLC & addyi (flibanserin) 100mg tablets for $1bn.

sprout

Valeant acquired Flibanserin (Addyi™) (Sprout Pharmaceuticals) in August 2015.
Flibanserin (Addyi) is the first and only FDA approved treatment of female sexual dysfunction

amag PHARMACEUTICALS &  PALATIN TECHNOLOGIES, INC. for $0.44bn.

In 2016, AMAG Pharma acquired US rights to Bremelanotide (Vyleesi™), currently in registration (PDUFA date June 2019) (originator Palatin Tech)

***https://www.smarteranalyst.com/2017/02/24/3-reasons-buy-palatin-technologies-inc-ptn/*

Thank you for your attention!

Contact Information:
info@ovocabio.com ; ir@ovocabio.com
Kirill Golovanov, CEO, Ovoca Bio
Daniil Nemenov, General director, IVIX
Chris Wiltshire, Director/CBA, Ovoca Bio

www.ovocabio.com