OVOCA bio

LIFE SCIENCE INVESTMENTS

Libicore – medication for treatment of female sexual dysfunction

ivix

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Your attention is drawn to the 'Risk Factors' set out in Part 2 of the Admission Document published by the Company on 4 July 2018.

Key team members

Experienced and Reputable team

Dmitry Golikov, MD, MBA
Chief Executive Officer
- *12 years managing biomedical and pharmaceutical projects*

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

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

Professor Nikolai F. Miasoedov,
Non-executive Director of Ovoca Bio

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

Executive Summary

Company: founded in 2012 by experienced pharma executives and inventors of several CNS drugs

Molecule: BP101, a novel synthetic peptide

IP: composition of matter patent granted in the USA (2016), Russia (2015), PCT national phases started in 2014 in Europe and 7 other countries – Canada, Brazil, China, India, Japan, Israel, S Korea

Mechanism of action: restoration of activity of brain centers involved in female sexual function regulation

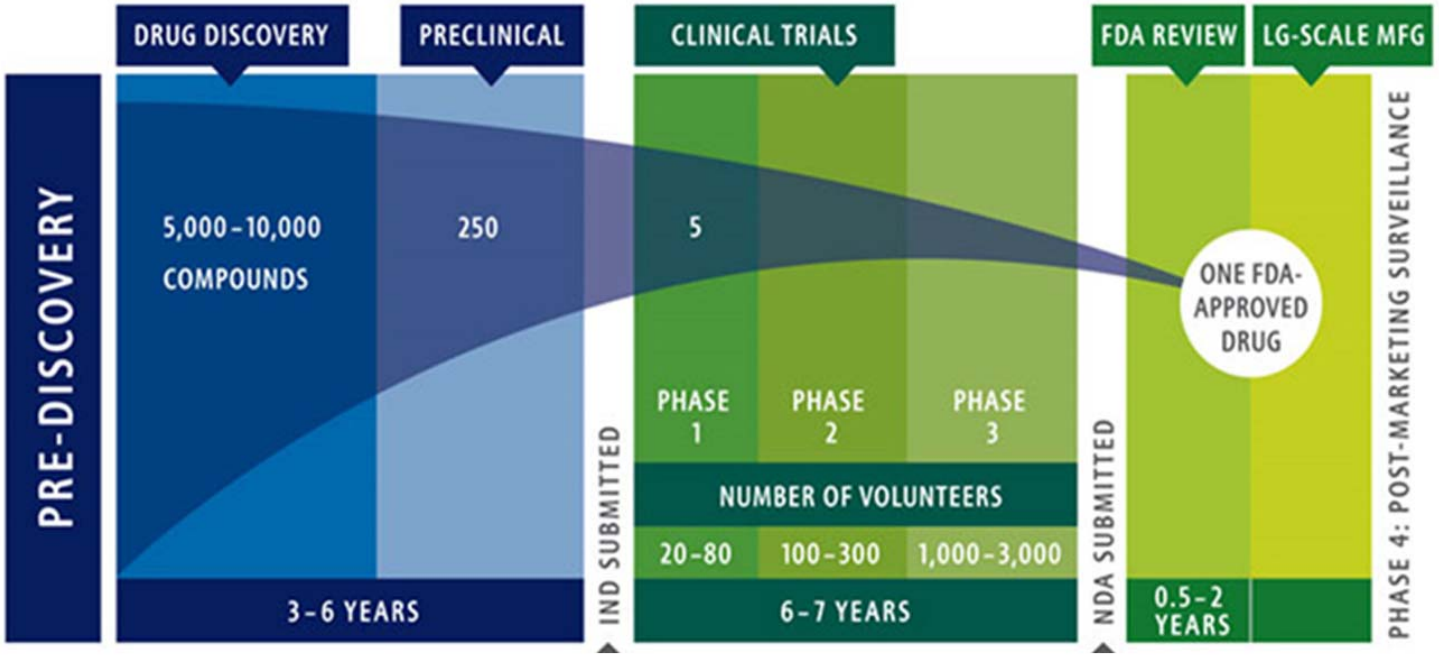
Indication: Female Sexual Dysfunction (FSD), Hypoactive Sexual Desire Disorder (HSDD)

Development stage: Ph3 is ongoing in Russia

Administration: intranasal spray

R&D process in Pharma

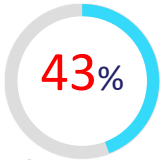
Drug Discovery and Development



Source: Pharmaceutical Research and Manufacturers of America

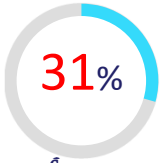
Scale of the problem

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



of women

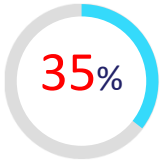
VS



of men

in USA reported short or long term problems related to sexual function

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



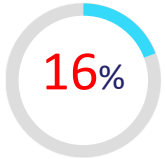
of married women

VS

of married men

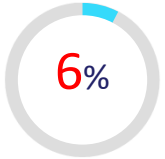
complain about absence of sexual desire

(established by Masters & Johnson)



of women

VS



of men

in Great Britain have had sexual problems in a last 12 months persisting for at least 6 months

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

Market size

Potential to lead in the $6bn worldwide market segment

POTENTIAL SUFFERERS (US)

17 m

POTENTIAL MARKET (US)

$4,1 B*

POTENTIAL SUFFERERS (RU)

5 m

POTENTIAL MARKET (RU)

$300 m

* https://www.researchgate.net/publication/7977139

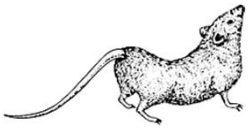
Preclinical efficacy

IVIX tested a list of peptides with possible neural activity

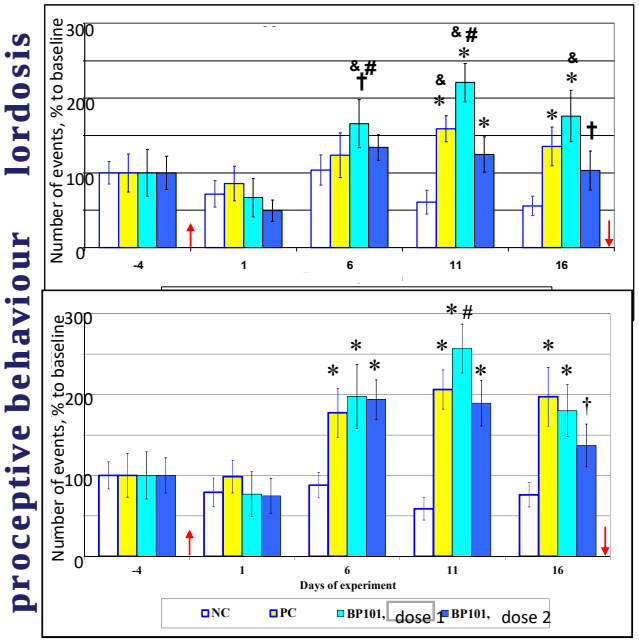
Identified peptide BP101 with efficacy surpassing fully saturated natural hormone

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

Study of 30-day toxicity (in rats, dogs and monkeys), including local irritation assessment	up to x50 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

Conclusion: BP101 appears to be very safe. It quickly degrades in bloodstream to natural amino acids.

Ivix' solution - Libicore

BACHEM

juniper PHARMA SERVICES

SD PHARMA

Aptar pharma

Ivix' solution: a novel synthetic peptide

Activating brain centers regulating female sexual function

Delivering method: a nasal spray

Simple, convenient and safe way of using the medicine.

Manufacturers:

Pharmaceutical substance - Bachem AG (Switzerland)

Final product - Juniper Pharma Services (UK)

Vials - SGD (France) 1st GL class

Nasal pump - Aptar (Germany)

Existing Clinical Program overview

3 clinical trials completed:

- First-in-human Phase I Study (15 female healthy volunteers)
- Proof-of-concept Phase II Study (110 female sexual dysfunction patients)
- Additional Phase I Study to assess pharmacokinetics and safety at high doses (18 female healthy volunteers)

FDA Pre-IND meeting held in 2016

1 clinical trial is ongoing:

- Phase III Study to confirm drug safety and efficacy for Marketing Authorization application in Russia: up to 256 female patients

Safety profile

Favorable safety profile across all completed studies**:**

- No drug-related serious or severe adverse (unfavorable) events
- 100% patient adherence to treatment (no single patient had withdrawn the study due to adverse events)

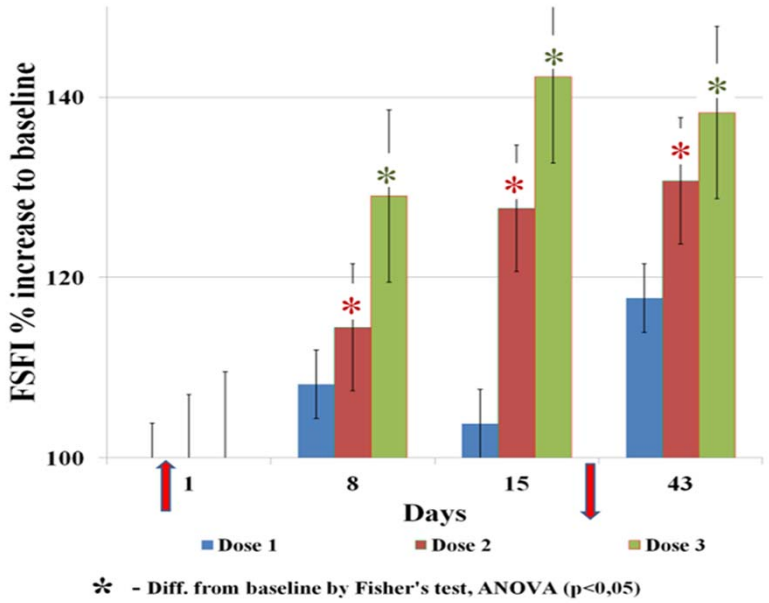
Phase II safety findings:

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 (n) and percentages (based on N) of subjects with adverse events (AEs) and numbers of AEs (E).

First in Human Study (Ph I)

Beneficial safety profile, and dose-dependent sexual improvement



Overall 15 adult women we treated in 3 dose cohorts

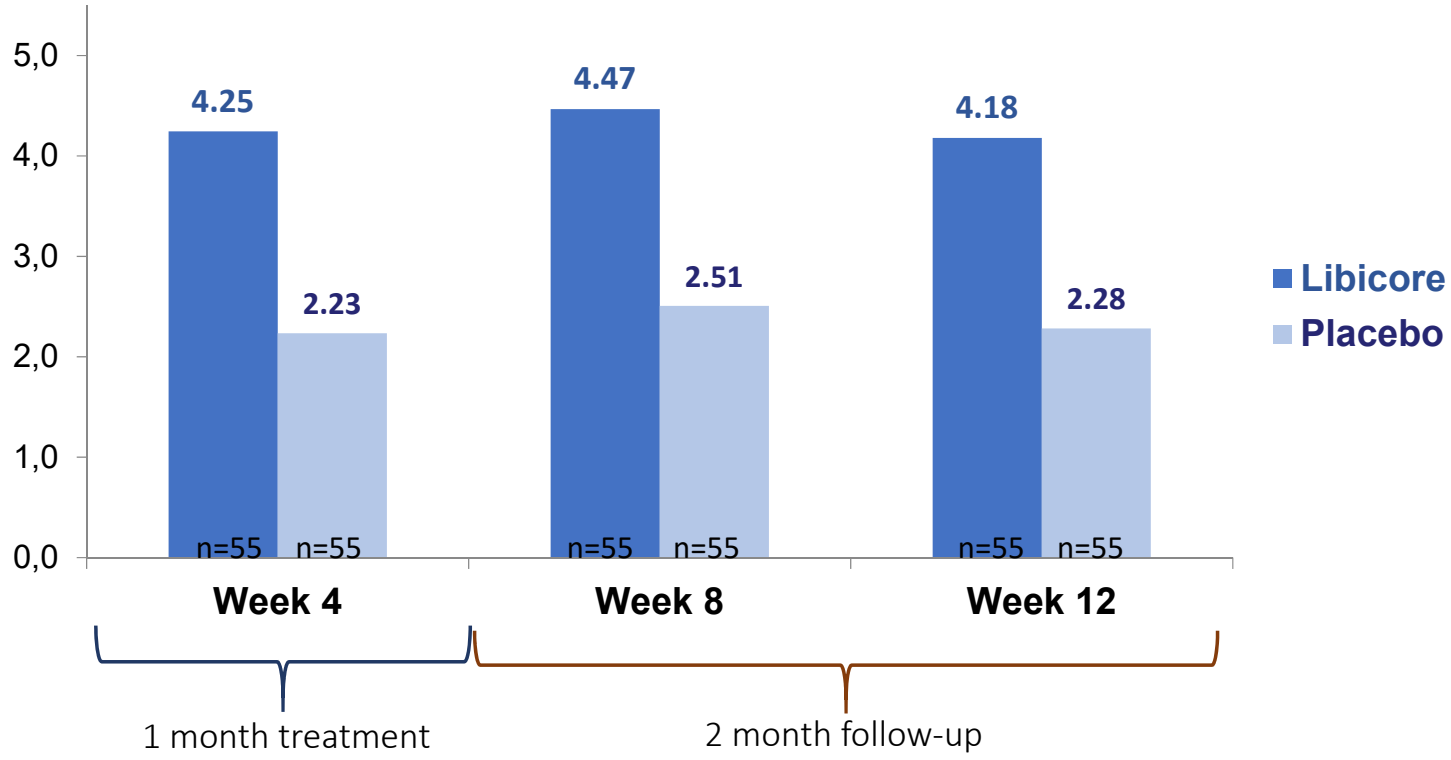
Dose-dependent sexuality improvement was seen starting from the first week of Libicore treatment

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

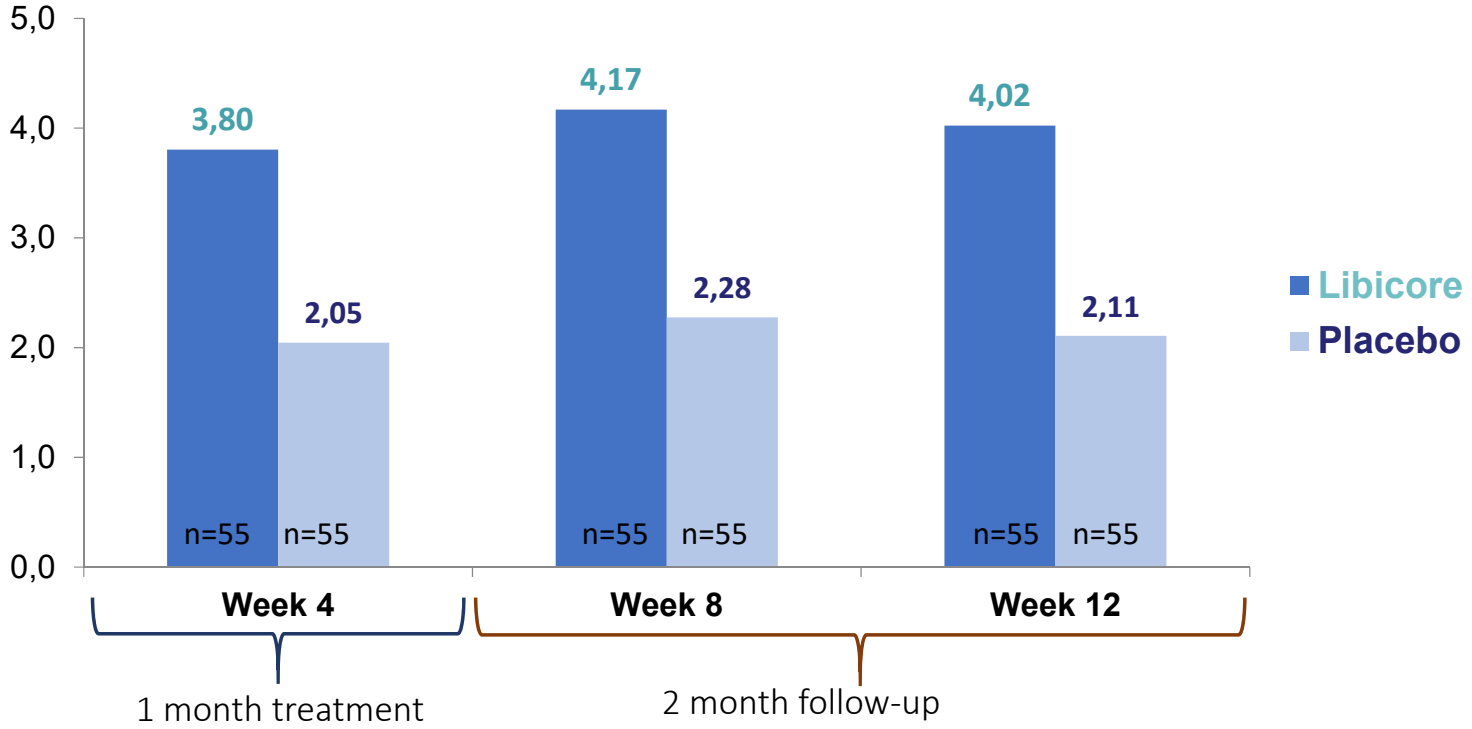
Libicore Phase IIa Results

Improvement in number of Satisfying Sexual Events



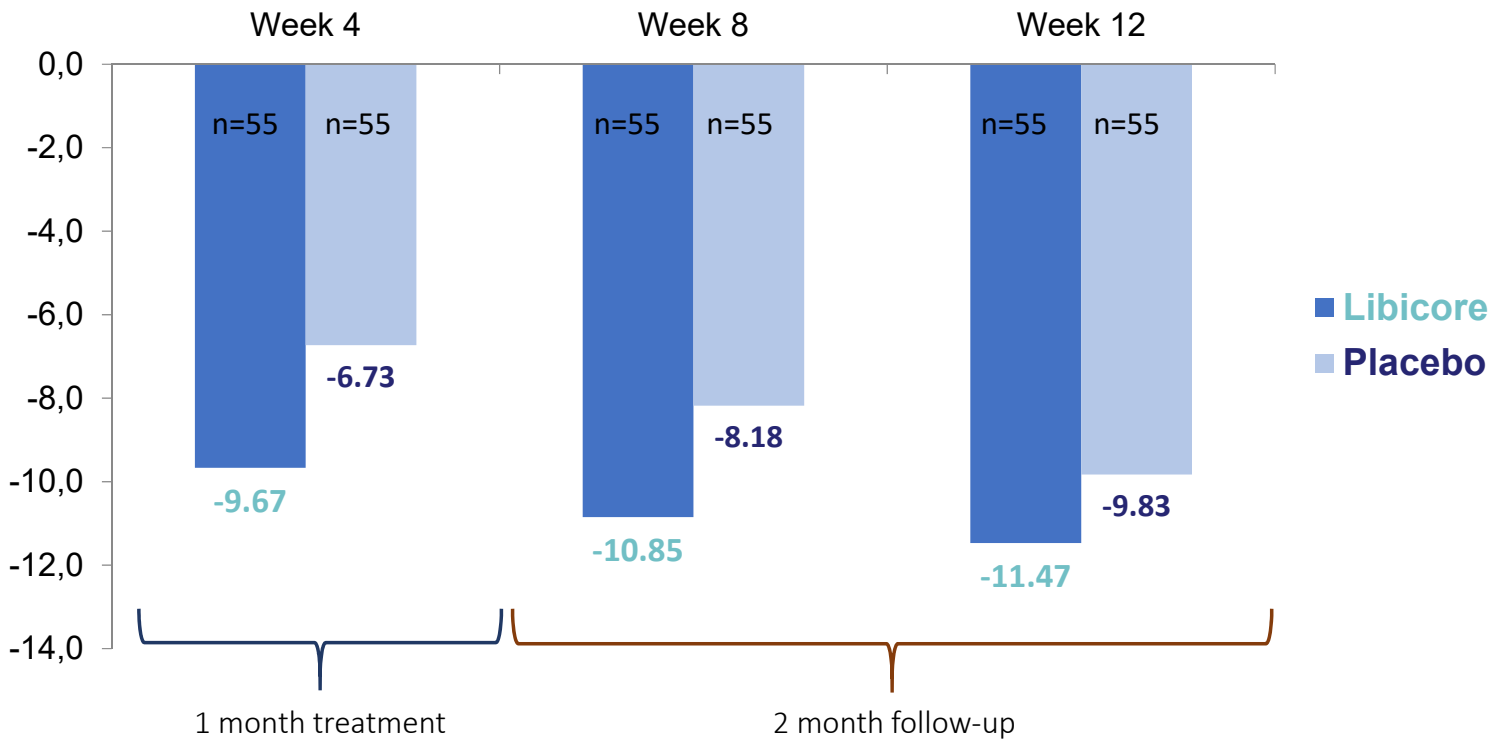
Libicore Phase IIa Results

Improvement in number of Orgasms from Baseline



Libicore Phase IIa Results

Female Sexual Distress reduction (via FSDS-R total score)



Phase III clinical trial in Russia

Multicenter randomized double-blind placebo controlled study to confirm efficacy and safety of Libicore (BP101)

- Anticipated end of Study – Q3 2019
- Up to 256 female patients with lack or loss of sexual desire (hypoactive sexual desire disorder) in 21 active clinical sites
- Adaptive design with interim analysis at 160 enrolled patients will reach primary endpoint (expected in Q1 2019)
- Primary endpoint – change in mean number of Satisfying Sexual Events
- 181 patients screened so far, 145 of them enrolled

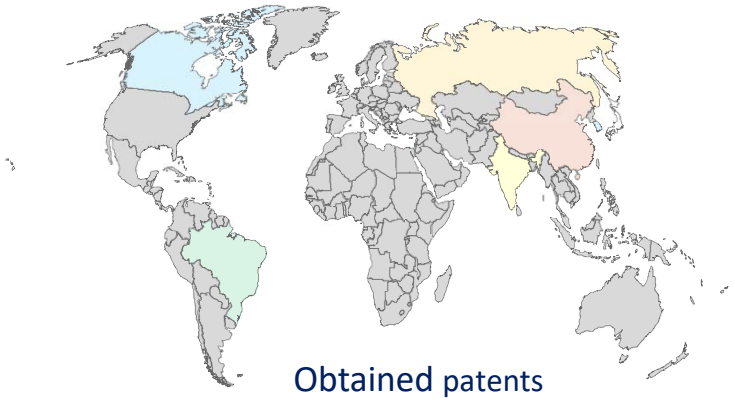
Competitive landscape

Main competitors comparison

Drug	Administration	Course	Safety	Product
Libicore (BP101)	Intranasal	From 1 week	NO withdrawals due to AE (in >100 treated females)	
Addyi® (flibanserin)	Oral	At least 8 weeks to establish efficacy	Black box Side effects, incompatible with Alcohol	
Rekynda® (Bremelanotide)	Subcutaneous injection	On request before sexual intercourse	AEs leading to withdrawal (rise of blood pressure, nausea)	

Intellectual Property

The main value of biotech company, its actual asset, is company's IP



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"

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

PCT «Method for Producing a Recombinant Peptide and Resultant Peptide», PCT/RU2013/000433 is prosecuted in following countries:

Patent Attorney: Troutman Sanders LLP, New York, USA

Next steps

Application to FDA & marketing authorization in Russia

USA (or Europe)

- Submission of IND application to FDA (2019)
- Scientific advice in EU (2019)
- Production of a new drug product batch for Phase 2B in USA/EU (2019)
- Phase 2b clinical studies

Russia

- Completion Phase 3 clinical study
- Receiving marketing authorization in Russia

Market deals

Demand for comparable drugs

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

sprout

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

amag PHARMACEUTICALS &  PALATIN TECHNOLOGIES, INC. for $0,44bn.

AMAG Pharma acquired Bremelanotide (Rekynda) in Ph3 (by Palatin Tech) in 2016.

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

Thank you for your attention!

Dublin

July, 2018

www.ovocabio.com www.libicore.info