



CONFIDENTIAL

OCON
— HEALTHCARE —

Board of Directors
March 2, 2022

AGENDA

1 Corporate Updates

- Company Milestones Review & Update



2 IUB™ Ballerine®

- CE Regulatory Status
- Distribution Status
- FDA/IND Submission activities



3 IUB™ SEAD™

- Clinical status
- R&D Status



3 IUB™ PRIMA

- R&D Status



OCON'S MILESTONES / SERIES B PREPARATION



IUB™ **Ballerine®**



100,000+ women
real-world data
peer-reviewed article



IND
Submission



IUB™ **SEAD™**



5-10 Patients
enrollment
in RED Study (Phase IIb)



IUB™ **PRIMA**

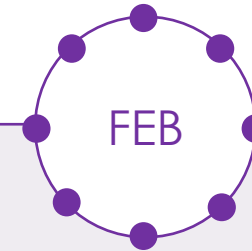
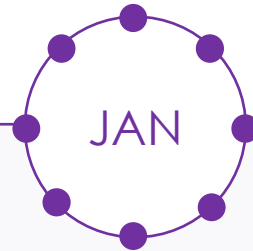


Working
Prototype

ADVANCING WOMEN'S HEALTH

OCON'S Q1 MILESTONES PROGRESS

End of Q1



IUB™ Ballerine®

100K PMS Article

Review / Edits by Prof. Jeff Peipert (PI Choice Study)

Review / Edits by Drs. Goldberg, Peipert & Lukes (Lead Author)

Submission to Contraception Journal for Peer-Review

FDA IND Submission

Data Collection Helena Grinberg, Protocol Review by U.S. Advisory Board

Finalization Protocol, IB, ICF Submission Publishing Solution Signed

IND-Submission FDA



IUB™ SEAD™

5-10 Patients recruited in RED Study

Finalization IFU / PIL Start patient recruitment

4 Patients recruited First Procedure - delayed

Total 8 Patients recruited 2-3 Procedures



IUB™ PRIMA

Working Prototype

Project Initiation – ProMed USA

Polymer Molding successful

On time for 1st prototype



 IUB™
Ballerine® **UPDATE**

- CE Regulatory Status
- Distribution Status
- Milestone UPDATE: FDA/IND Submission activities



Ballerine®

Regulatory Update



Temporarily Suspended

Jan 10, 22

Jan 15, 22

up to Mar 22

Deadline for Document Submission

Review started by GMED

Final Decision
(expected March)



Approval Relocation



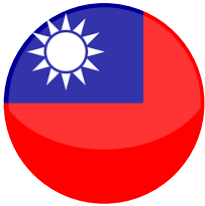
Started Feb 21 (10 day audit)

IUB™
Ballerine® **DISTRIBUTION UPDATE**



CROATIA  **ADEXILIS**

Launched Q1 2022



TAIWAN  **WOH MEDICAL**

Order Placed/Non CE
Launch Q2 2022



LATAM 

Order Placed/Non CE
Launch Q2 2022



CANADA 

Order Placed, *MDSAP Audit End March 3rd*
Launch Planned Q2 2022

TERRITORY EXTENSION



+



Dr. Schittenhelm
PHARMA

German distributor to expand into Austria

PENDING FINAL AGREEMENTS:

MEXICO & Central America



Marketing
Authorization hand
over from Exeltis



CHINA



BioGenuine
TS Signed.
Definitive Agreement Draft

BALLERINE Q1 MILESTONES UPDATE



Andrea Lukes, MD + NURSE

FDA Advisory Committees
>> LEAD AUTHOR ON ARTICLE



Jeffrey F. Peipert, MD, PhD

Choice Study U.S.A
>> SENIOR AUTHOR ON ARTICLE



Alisa Goldberg, MD

Planned Parenthood
>> EDITOR SPECIAL MENTION



**100,000+ women
real-world data
peer-reviewed article**



“I have recently reviewed the extensive dataset of the IUB Ballerine in over 110,000 insertions with up to 5 years of use in a diverse population throughout Europe, the middle east and parts of Africa.

The efficacy, as expected, is in line with traditional copper IUDs while the safety performance of the device demonstrates low rates of perforations, expulsions, ectopic pregnancies and an overall low side effects profile when compared to other IUDs. Satisfaction rates in published peer-reviewed articles are favorable.” Jeffrey F. Peipert.

BALLERINE Q1 MILESTONES UPDATE



IND Submission

STRENGTHEN TEAM FOR U.S. REGULATORY EFFORTS

Susan Alpert, MD, PhD

Dr. Alpert was previously Senior Vice President, Global Regulatory Affairs at Medtronic until her retirement in May, 2011

Prior to joining Medtronic, Susan served C.R. Bard, Inc., as Vice President of Regulatory Sciences.

Dr. Alpert worked at the FDA where she held a variety of positions in the Centers dealing with drugs, devices and radiological health, and foods, including six years as the Director of the Office of Device Evaluation.



FDA
Medtronic

Helena Grinberg, PhD, MBA

Dr. Grinberg is a Life-science executive with over 15 years' experience in leading roles at pharmaceuticals and medical devices companies. Deep knowledge in clinical development, regulatory aspects and more.

Proven track record of achievements at the intersection of science, academia, business, industry and other key healthcare ecosystem parties.

Dr. Grinberg is in charge of the full write up of OCON's IND submission



Dina Coll, Director RA

Ms. Coll is an experienced Senior Regulatory Affairs Director with more than ten years experience in the biopharmaceutical industry, mostly in Regulatory Affairs and in Quality Assurance. Experienced in working with the FDA, EMA, & IMOH.

Dina will oversee all projects and regulatory aspects pertaining to Ballerine, SEAD and PRIMA (mainly focused on USA/FDA)





 IUB™
SEAD™ UPDATE

- Clinical status RED Study (PhIIb)
- Clinical status PhIIa (Bulgaria)
- R&D Status

RED Study (PhIIb) - Recruitment status

- **4 patients** are enrolled and will undergo the procedure between Feb. to April 2022
- **Additional 4 potential patients** invited to give consent in the next couple of weeks
- **Recruitment efforts**
20 patients enrolled by the end of Q2 2022



RED Study (PhIIb) Additional Recruiting Efforts



Open New Sites in Georgia

Opportunity

Limited GEA availability in Georgia



Step 1:
CRO
& site
selection



Step 2:
Regulatory
submissions
Local EC
submission
in process
as of Feb 7, 2022

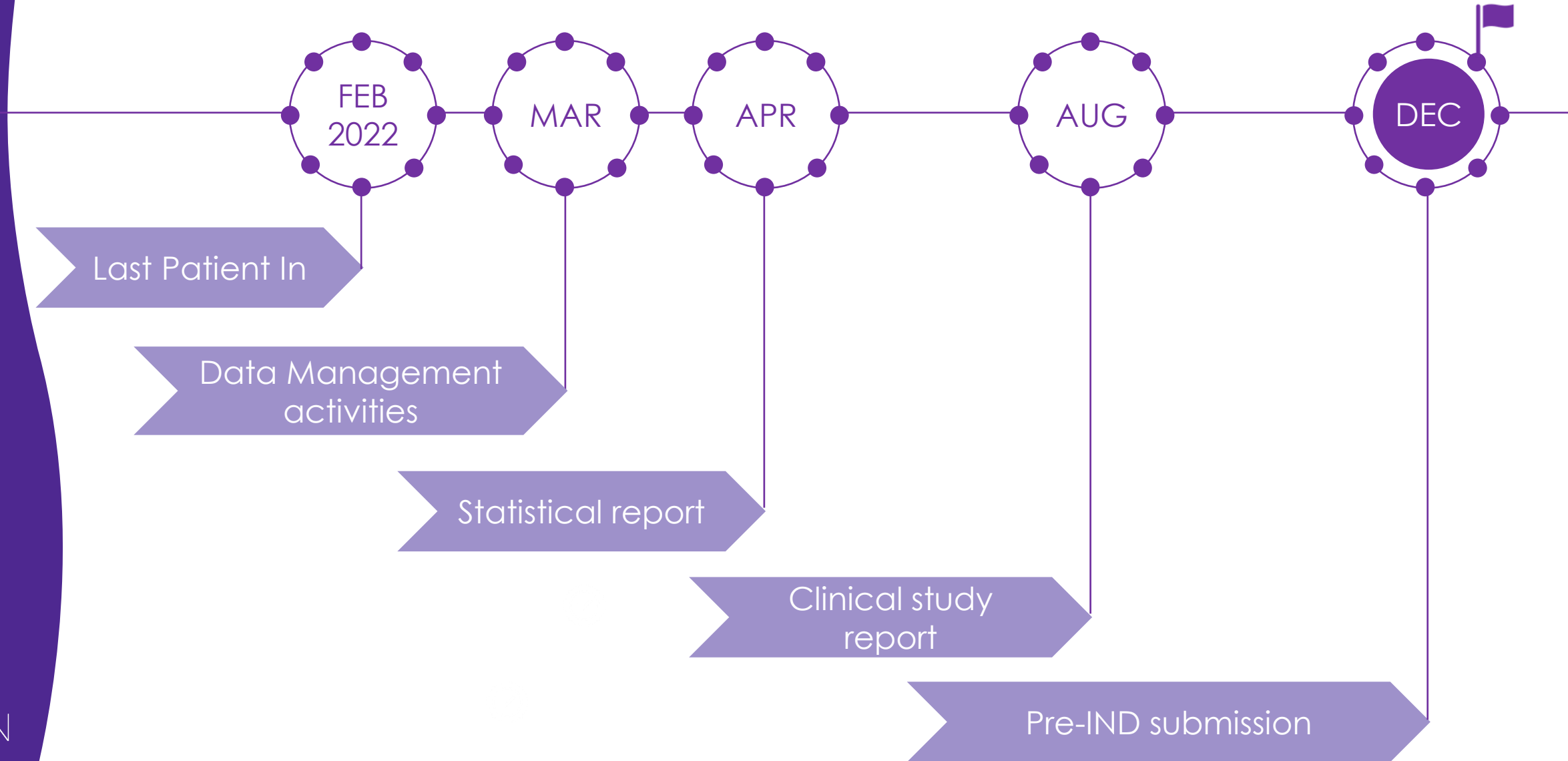


Step 3:
Initiation visits
& recruitment
May 2022

Target:
at least 10 patients
in the first 3 months
of recruitment



PHIIa (Bulgaria) CLINICAL STUDY – Closing Activities



PH1a CLINICAL STUDY – LAST PATIENT IN

PBAC comparison between Baseline and Current | Last-Patient-in Feb. 2022



once
and done
treatment

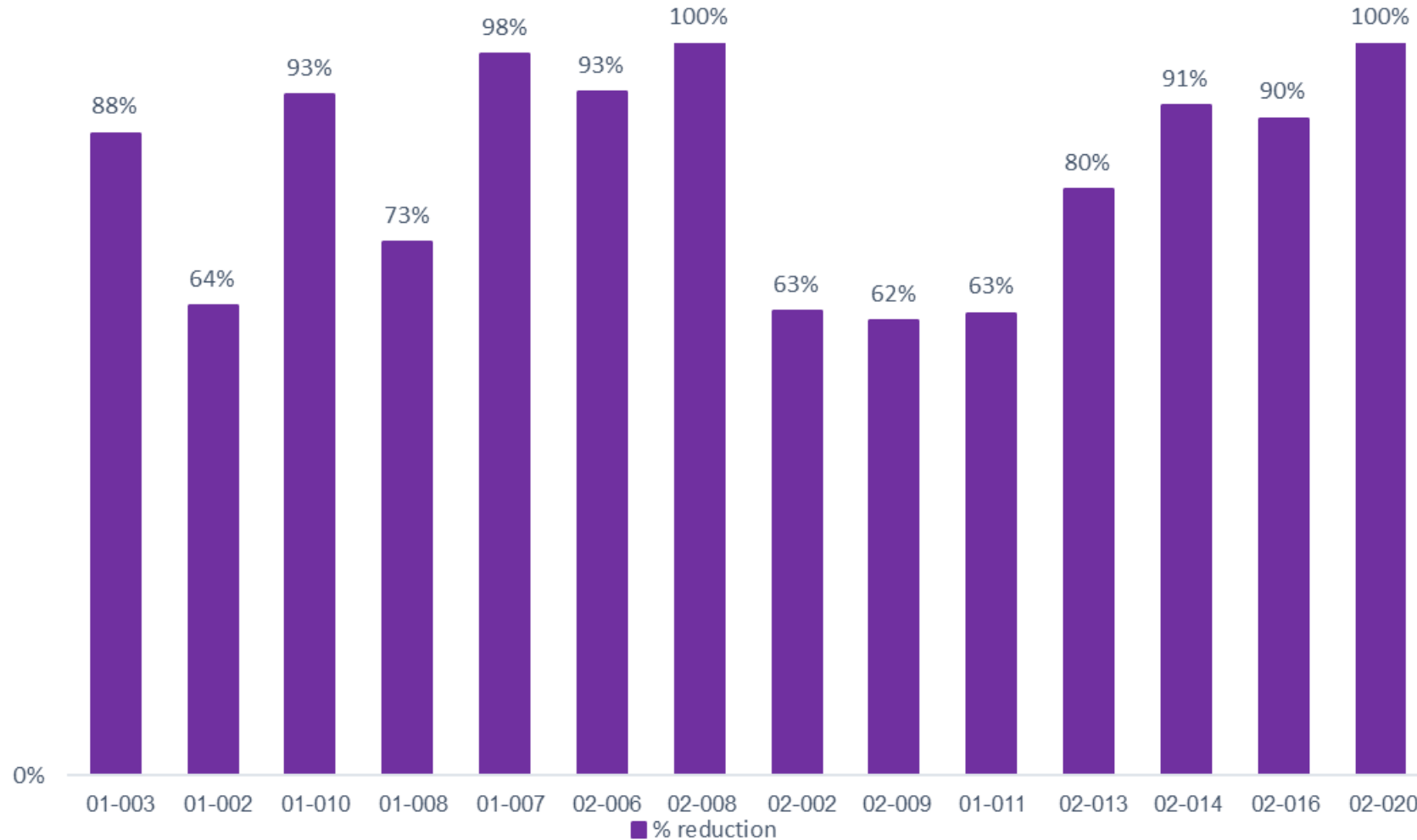
83%
avg. Drop
in PBAC

95%
reported QoL
satisfaction

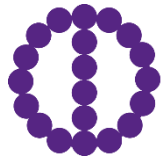
PH2b
initiation in
July 2021

PHIIa CLINICAL STUDY – LAST PATIENT IN

Preliminary results: Average PBAC Reduction in %








83%
avg. Drop
in PBAC



IUB™ SEAD™ R&D STATUS

**Focus on
Clinical
Milestone
(RED Study)**
*R&D Pause
(VP R&D Released)*

Task	Status	Comments
 Beads to cylinders	Complete	Successful bridging
 Initial scale-up (x4 fold)	Complete	From 16 to 60 units/lot
 Analytical tests for QC	Complete	But not validated
 Packaging system	Complete	Primary and secondary = Light & humidity protective
 2Y - Stability shelf life	Complete	on prototype, non-GLP
Scale – up (x10-20)	Paused	1 LOT = 60 units currently
Biocompatibility	Paused	Cytotoxicity only
Characterization tests	Paused	Nickel release, nitinol corrosion
Single hand inserter	Paused	Design input and first drawings





IUB™ PRIMA UPDATE

OCON MARKETING UPDATE

Name Contest | Poll on LinkedIn for IUB™ “Therapeutics”



OCON Healthcare
2,494 followers
1w · 🌐

WOW!!! Thank you LinkedIn community for all the suggestions, support and #FemFun looking for a name to our new IUB™ Family member. We had OVER 10,000 shares, likes, suggestions & engagements. #Femtastic! ...see more

Tell us which of the 4 #FEMtastic names you like the most for OCON's revolutionary 'Therapeutics' Platform IntraUterine Ball (IUB™):

You can see how people vote. [Learn more](#)



CELEBRATING
OUR NEWEST
ADDITION TO
THE IUB™
FAMILY

IUB™ PRIMA

Kick-off call
with ProMed
Jan. 2022

Grant Submitted to IIA
(Israel Innovation Authority)

**Frame Design
Improvement (loop)**

**On
schedule
to reach
milestone
in Q1**



OCON MARKETING UPDATE



Hi Daniela

First and foremost, I hope this email finds you and the team at OCON Healthcare in good health.

Following on from your recent nomination in **Global Health & Pharma's seventh annual Biotechnology Awards**, I am delighted to be reaching out to inform you that OCON Healthcare has been successful in this years' edition, and has been awarded:

Best Uterine Drug Delivery Solutions Provider - Middle East



101 Top Israeli Pharmaceutical Companies and Startups



Re: Congratulations! Your company has been included in the Global FemTech Overview Q4 2021

FA ○ FemTech Analytics <info@femtech.health>
To: Daniela Scharding

Dear Daniela,

Thank you for your email.
The corrections were made, please view OCON updated profile: <https://mindmaps.dka.global/firms/59785>

OCON Healthcare

Company



OCON Healthcare develops innovative and safe medical solutions that are inspired by women's bodies and anatomy, to better the lives of women everywhere.

OCON Healthcare's novel platform technology, namely IUB™ (IntraUterine Ball) is made from a super-elastic spherical high-tech frame that can retain its shape and is an ideal drug-delivery platform to the uterus to treat various health conditions such as heavy and abnormal uterine bleeding, endometriosis, fibroids, contraception, menopause and more.



Prof. Sergio Haimovich
CMO

Keren Leshem
CEO



We could not be more proud of OCON's Chief Medical Officer having been elected **Vice-Chair of the AAGL HYSTEROSCOPY SIG.** Congratulations!



CONGRATULATIONS TO OUR CMO PROF. HAIMOVICH



OCON
— HEALTHCARE —

THANK YOU