



CONFIDENTIAL

OCON
— HEALTHCARE —

Board of Directors
Dec. 15, 2021

Dear OCON shareholders,

As traditionally done every quarter post OCON's Board meeting – I'm happy to share with you all our summary demonstrating our continued progress and work towards bringing our assets to fruition.

2021 was an extremely challenging year but we have prevailed with financing, platform progress and additional KOLs and incredible team members that make our company so resilient!

To remind you all, we are in a CLA (convertible) round (pre-Series B financing round). Since we have already gained momentum on this CLA we will be decreasing the discount shortly, If any of you wish to take part in this round you are welcome to contact me and/or Amir our CFO to discuss details and conditions, we would also be happy for any introductions or thoughts you have for supporting this effort.

My personal regards to each and every one of you and best wishes for a happy, healthy and **FEMstastic** 2022!

<https://www.linkedin.com/feed/update/urn:li:activity:6879481917029281794>

Best Wishes,
Keren Leshem and the OCON Team

AGENDA

1 Corporate Updates

- IP Update

2 IUB™ Ballerine®

- Distribution Status
- FDA/IND Submission progress
- Marketing Update

3 The SEAD™

- R&D update
- Scientific Oral Presentations
- Clinical (PH2a & PH2b) update

4 Therapeutic IUB™

- R&D Status

5 Finances

- 2021 workplan and financial summary
- 2022 workplan

ANNEX

- Updated Corporate Deck slides (non Confidential)

IP UPDATE

OCON's ROBUST PRODUCT FRANCHISE PROTECTED BY **STRONG IP**

FILING of SEAD PCT

PATENT FAMILY #1

INTRAUTERINE DEVICE PLATFORM



Granted

in USA, EU, Canada, China and Israel

PATENT FAMILY #2

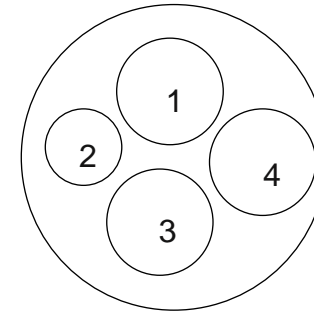
FOCUS ON BEADS (ANY SHAPE)



Granted

in USA, Dec.2020
other territories pending

PATENT FAMILY #3



FOCUS ON SPECIFIC COMPOSITION (OF BEADS)



Patent Pending

DEVICE POSITIONABLE IN THE UTERINE CAVITY AND METHOD OF TREATMENT THEREOF

PCT Appl. No. PCT/IB2021/058603 based on U.S. Provisional No. 63/081,028

Filing Date: September 21, 2021

Discloses a delivery vehicle for a silver ion source, such as silver nitrate and the like, suitable for use in the treatment of menorrhagia, which comprises a plurality of beads bearing a tissue cauterizing amount of a silver ion source.

Independent claims:

1. An intrauterine device comprising:

- a wire having a portion capable of forming an elastically deformable three-dimensional structure; wherein the three-dimensional structure:
 - a) is elastically deformable to a partially collapsed configuration;
 - b) has a crush force of at least 15 grams/cm²; and
 - c) is configured to elastically contract and expand in response to contraction and expansion of the uterine cavity,
- a plurality of beads, comprising:
 - 80% to 98% by weight of formulated active materials, wherein the formulated active materials comprise 75% to 100% by weight of silver nitrate and 0% to 25% by weight of potassium nitrate, wherein the ratio of potassium nitrate to silver nitrate is from 1:19 to 1:3,
 - 2% to 20% by weight of a hydroxy propyl cellulose binder; and
- two fixing beads, each positioned at opposite ends of the wire

15. A method of treating uterine-related disorders, comprising the steps of:

- administering a plurality of beads to a uterine cavity of a human patient in need comprising:
 - i. from 75% to 100% by weight of silver nitrate and 0% to 25% by weight of potassium nitrate; and
 - ii. from 2% to 20% by weight of a hydroxy propyl cellulose binder; and
- maintaining the plurality of beads in contact with an endometrial lining of the uterus for a time period sufficient to necrose endometrial tissue.

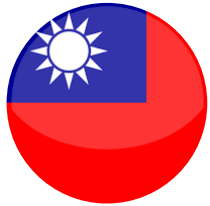


Ballerine[®] users

DISTRIBUTION STATUS



Ballerine® DISTRIBUTION UPDATE



TAIWAN

Approval (2YR indicated)
Launch Q1 2022



SOUTH AMERICA

Order Placed
Launch Q1 2022



CANADA

Order Placed
Launch Planned Q2 2022



JAPAN

Regulatory Submission
~24 months




משרד הבריאות
חטיבת טכנולוגיות רפואיות, מידע ומחקר
אגף ציוד רפואי
מדינת ישראל

אישור רישום בפנקס הציוד הרפואי

ניתן בזאת אישור, כי בהתאם לבקשת רישום מס : 27670002
הציוד הרפואי (אביזרים / מכשירים רפואיים (אמ"ר)) הבא :

שם הציוד הרפואי	התקן תוך רחמי בלרין
דגמים	
יעוד הציוד הרפואי	מניעת הריון הפיכה ארוך טווח
התויה	. גניקולוגיה - התקן תוך רחמי משולב נחושת למניעת הריון לנשים החל מגיל
שם בעל הרישום וכתובתו	: . השדרה המרכזית ת.ד. , מודיעין :
שם היצרן וכתובתו	אוקון מדיקל ; השדרה המרכזית ; ישראל
שם אתר היצור וכתובתו	. אוקון מדיקל - השדרה המרכזית מודיעין -

התניות

הנחיות

- לפי הוראות היצרן שאושרו ע"י גוף המאשר: (אישורי איכות בלבד)
- מאושר לשימוש בהתאם להוראות היצרן, כפי שאושרו ע"י הגוף המאשר.
- השימוש מוגבל לרופא שהודרך והוסמך ע"י היצרן (או ע"י נציג מטעמו שהוסמך על ידו) בבית חולים ובמרפאה בלבד.

התניות לרישום זמני

- על בעל הרישום לעדכן את משרד הבריאות לא יאוחר מה - על החלטתו בתחום הרגולטורי: האם בסוגנת לבקש להעביר את אישור הרישום בישראל כך שיהיה ע"פ אישור / או / אחר

נרשם בפנקס הציוד הרפואי (האמ"ר) במשרד הבריאות.
תוקף האישור לשיווק הציוד הרפואי (האמ"ר) הינו ליעודים ולהתוויות המתוארים לעיל בלבד.
האישור בתוקף עד : 31/08/2022



ד"ר נדב שפר
מנהל אגף ציוד רפואי

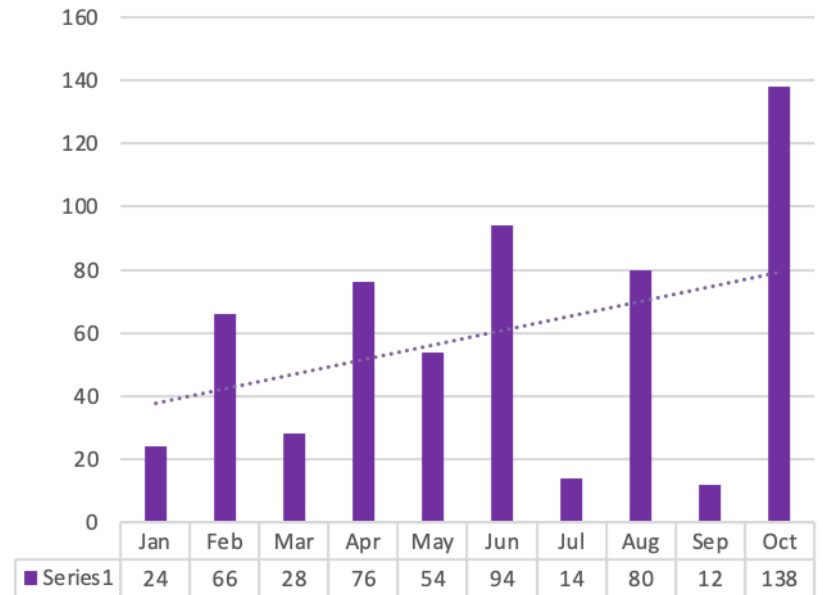
שם ותפקיד המאשר _____
תאריך חתימת האישור _____
חתימה _____


**IL AMAR
APPROVAL
GRANTED
(non-CE)**

1ST HMO Agreement

Meuhedet HMO - premium complementary insurance

2021 sales



Regrowth after summer vacations and holidays



Ballerine® REGULATORY STRATEGY

Remove CE linkage from local country requirements & Sales push non-CE Markets



Austria, Baltics, Belgium, Bulgaria, Czech Republic, Croatia, Cyprus, Denmark, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Netherlands, Norway, Nordics, Poland, Portugal, Romania, Slovakia, Slovenia, Spain



Audit in March 2022

- Australia
- Brazil
- Canada
- Japan
- ~~U.S. (Medical Devices)~~

NO
CE
REQUIRED



Local Registrations

- Israel (AMAR Approval)
- LATAM (5 Approvals)
- Asia (Taiwan Approval)
- Africa (South Africa)
- UK
- ~~Switzerland~~

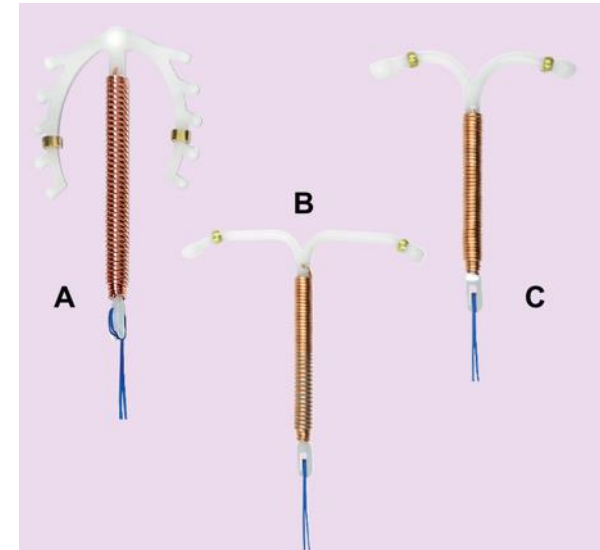


X

Austria, Baltics, Belgium,
Bulgaria, Czech Republic,
Croatia, Cyprus, Denmark,
France, Germany,
Greece, Hungary,
Iceland, Ireland, Italy,
Liechtenstein,
Luxembourg, Malta,
Netherlands, Norway,
Nordics, Poland, Portugal,
Romania, Slovakia,
Slovenia, Spain

Other IUD manufacturers announced they will not file for MDR:

- Goldluna
- PrimiFem IUDs



**Rumors Bayer is selling their European
Women's Health Division**





IUB™

Ballerine®

IND SUBMISSION status



PRE-IND submission activities:



IND Submission: *UPDATED TIMELINE*



U.S. IND KOL ADDITIONS

Jeff Peipert, MD

Clarence E. Ehrlich Professor and Chair of Obstetrics and Gynecology at Indiana University School of Medicine. Principal Investigator of the Contraceptive **CHOICE** Project, which recruited 9,256 women and successfully followed them for 2-3 years for contraceptive effectiveness, satisfaction, and continuation rates among other numerous studies.



Alisa Goldberg, MD

Associate Professor of Obstetrics, Gynecology and Reproductive Biology at Harvard Medical School and Vice President of Research and Clinical Training at Planned Parenthood League Massachusetts. Founded and currently directs the Division of Family Planning and Family Planning Fellowship program at BWH and the Department of Research at Planned Parenthood League of Massachusetts. Currently serves as the Chair on the Family Planning Fellowship Advisory Board. Recently recognized for this work with the 2019 Society of Family Planning Mentor Award.



Andrea Lukes, MD

An experienced principal investigator in industry-sponsored, NIH and CDC clinical trials, overseen more than 80 clinical trials of investigational women's health products, including both drugs and devices, in the last ten years. Published extensively in leading obstetrics and gynecology journals. Served on advisory committees for FDA meetings on the clinical development of a variety of women's health products. Founded the Carolina Women's Research and Wellness Center. Co-founded and served as the Director of Gynecology for the Women's Hemostasis and Thrombosis Clinic at the Duke University Medical Center.



OCON MARKETING UPDATE

Speaking Engagements | Panels | Presentations | Podcasts



Finalist: Women Innovators EU Prize 21 Out of hundreds of applications



Tel-Aviv University Healthcare Innovation Course
Keynote Presentation ~60 participants



Lahav Executive Education
Commemorating Daniel Recanati
Collier School of Management
Tel Aviv University





Spherical Endometrial
Ablation Device



**ABNORMAL
UTERINE BLEEDING**



R&D UPDATE

Clinical batch – ready to go!

44 units – Batch release tests are within specifications



Outer Pack
Carton box



Secondary
Aluminum
pouch under
vacuum
Light & moisture
protected

Primary
Sterile Tyvek
pouch

Feature	Specification	
Tensile force	>12N	✓
EtO residuals	0.163mg/device	✓
LAL	<0.1EU/device	✓
Product weight	1.0046g	✓
Active material weight	0.8082g	✓
Product diameter	16.12mm	✓
Cylinder weight	0.03g	✓
Cylinder diameter	2.70mm	✓
Dissolution kinetics	106% at 30min	✓

(All numbers are averages)



Scientific Oral Presentations & Publications



Certificate of Presentation

This is to certify that
Sergio Haimovich
Presented
A Novel Intra Uterine Ball: Spherical Endometrial Ablation Device
as an Oral Presentation at

XXIII FIGO World Congress of Gynecology and Obstetrics

which took place virtually, 21-28 October 2021

Dr Carlos Fuchner
FIGO and Congress President
XXIII FIGO World Congress of
Gynecology and Obstetrics

Dr André Lalonde
Chair, Congress Organising Committee
XXIII FIGO World Congress of
Gynecology and Obstetrics

Prof. Mary Ann Lumsden
FIGO Chief Executive



FC13.6

SAFETY AND EFFICACY OF THE IUB SEAD™

THEME: AB 3 GENERAL GYNAECOLOGY/SUB-THEME: AB 3.4
BENIGN CONDITIONS IN GYNAECOLOGY

Sergio Haimovich¹; Daniela Schardinger²

¹Gynecology and Obstetrics Department Del Mar University Hospital, Cádiz, Spain, ²Ocon Healthcare, Modiin, Israel

Objectives: The aim of this study is to assess the safety and efficacy of the IUB SEAD™ (Intra Uterine Ball: Spherical Endometrial Ablation Device) introducing silver nitrate to the uterus in women suffering from abnormal uterine bleeding. We present results of 6 months follow up period post treatment.

Methods: The IUB SEAD™ is a novel spherical endometrial ablation device that relies on the ablative action of silver nitrate and was designed to treat HMB, affecting at least 10-35% of women worldwide and adversely impacting quality of life - frequently leading to iron deficiency and related anemia. The study was performed in the outpatient clinics of 2 Bulgarian medical centres between September 2019 and December 2020. 16 women with HMB(PBAC>150) at least 3 months before inclusion were enrolled.

Results: A total of 16 participants aged 37-50 (mean=43) were enrolled with a mean baseline PBAC score of 424; 14 of 16 completed follow up requirements and were evaluable at 6 months. All procedures were completed successfully without device/procedure-related adverse events. At 6 months post-treatment the mean PBAC score was 95 with 55% of the overall cohort ≤ 75 and 72% ≤ 100 and a mean percentage of 83% reduction. The mean procedure related pain score was ≤ 2 (mild).

Conclusions: The IUB SEAD™ device is safe and effective in treating HMB in an outpatient environment. Future studies with larger number of patients are planned.



Volume 155, Issue S2
Special Issue: Abstracts of the XXIII
FIGO World Congress of Gynecology
& Obstetrics

Pages: 1-562
October 2021



ELSEVIER

Journal of Minimally Invasive Gynecology

Volume 28, Issue 11, Supplement, November 2021, Pages S63-S64



Open Communications 12: Research

Iub™ Sead™ - A Novel Intra Uterine Ball: Spherical Endometrial Ablation Device

S Haimovich¹, MG Munro²

Study Objective: The aim of this study is to assess the safety and efficacy of the IUB SEAD™ (Intra Uterine Ball: Spherical Endometrial Ablation Device) introducing silver nitrate to the uterus in women suffering from abnormal uterine bleeding. We present results of 6 months follow up period post treatment. **Design:** Open-label multicenter study to assess the safety and efficacy of the IUB SEAD™ device in premenopausal women with predictable men-strual cycles, who suffer from AUB. Women with HMB were enrolled who had an average pictorial blood loss assessment chart (PBAC) score ≥ 150 over for 3 months. **Setting:** The study was performed in the outpatient clinics of 2 Bulgarian medical centres between September 2019 and December 2020. **Patients or Participants:** 16 women with HMB (PBAC>150) at least 3 months before inclusion were enrolled. **Interventions:** Eligible subjects who met all the inclusion/exclusion criteria were treated during the first 7 days following the cessation of menses. The SEAD™ device was inserted into the uterine cavity via vaginal approach. The device was left in the uterus for 30 (±5) minutes and then removed. **Measurements and Main Results:** A total of 16 participants aged 37-50 (mean = 43) were enrolled with a mean baseline PBAC score of 424; 14 of 16 completed follow up requirements and were evaluable at 6 months. All procedures were completed successfully without device/procedure-related adverse events. At 6 months post-treatment the mean PBAC score was 95 with 55% of the overall cohort ≤ 75 and 72% ≤ 100 and a mean percentage of 83% reduction. The mean procedure related pain score was ≤ 2 (mild).* **Conclusion:** The IUB SEAD™ device is safe and effective in treating HMB in an outpatient environment. Future studies with larger number of patients are planned. *Results may vary until presentation date.



SEAD CLINICAL UPDATE

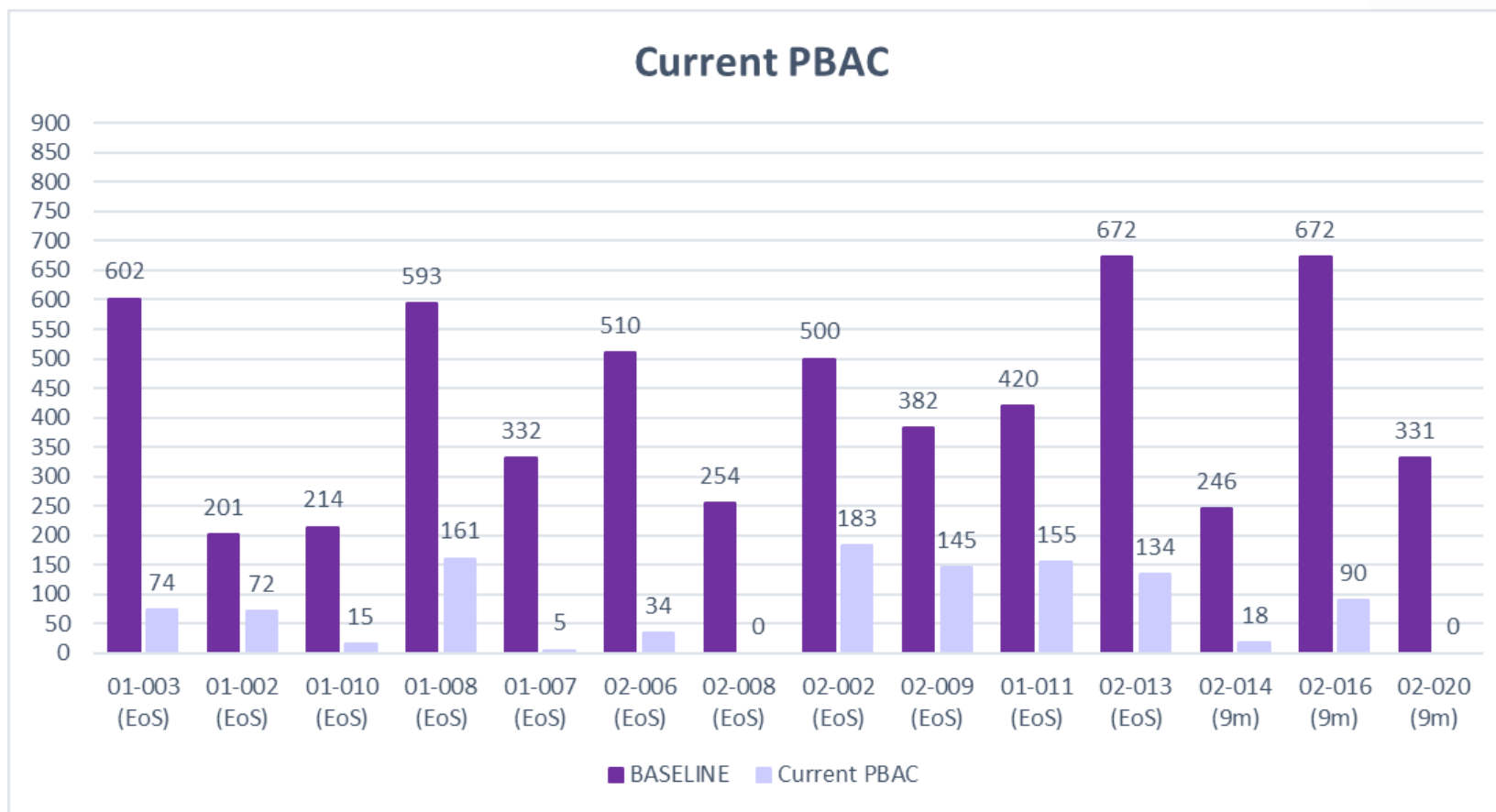




IUB™ SEAD™ PH2a CLINICAL STUDY



Preliminary results: PBAC comparison between Baseline and Current (n=14)



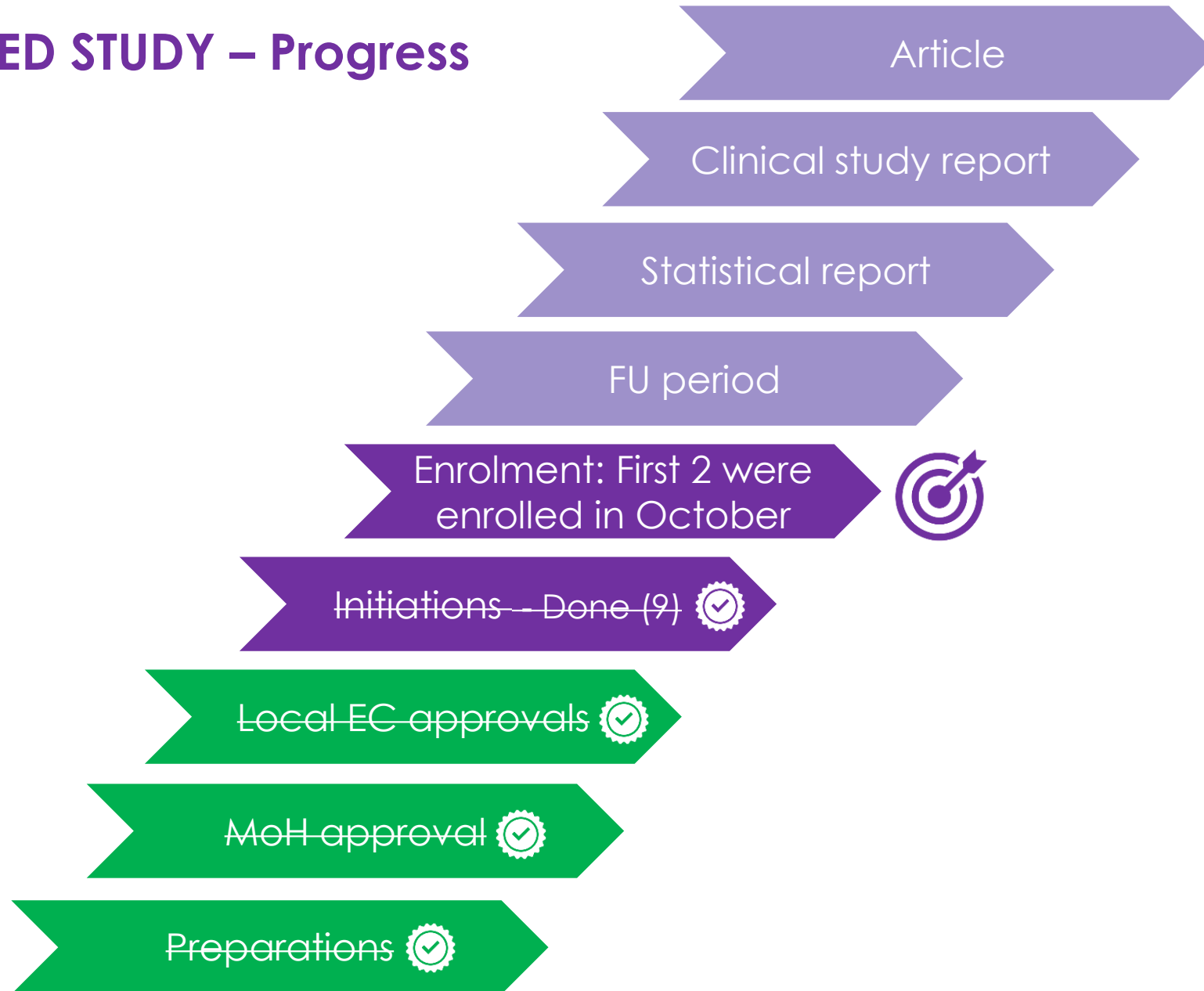
once
and done
treatment

83%
avg. Drop
in PBAC

95%
reported QoL
satisfaction

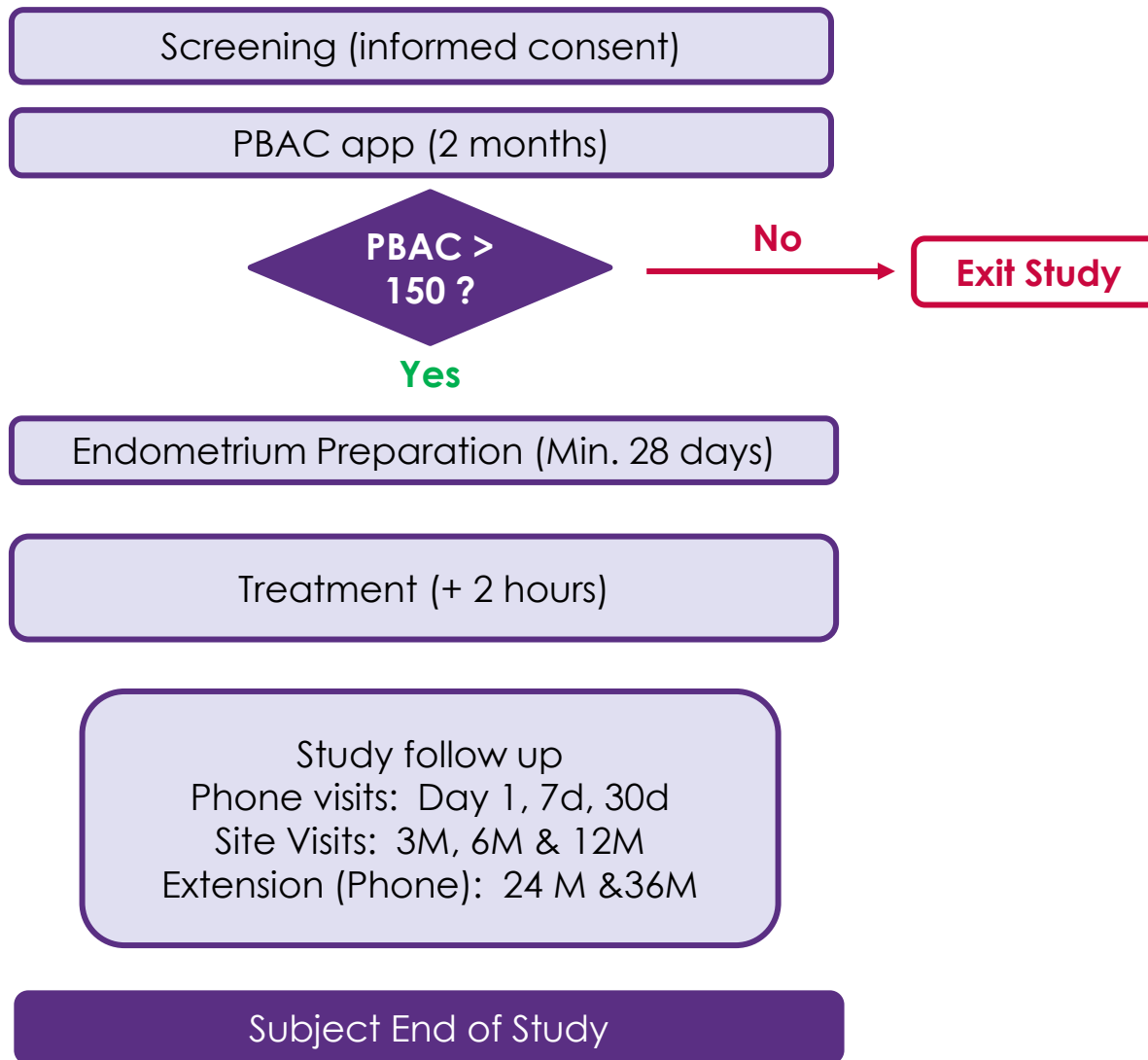
PH2b
initiation in
July 2021

RED STUDY – Progress





RED STUDY – Study Flow (Following FDA Protocol)





RED STUDY (PH2b) – Recruitment status

- **2 patients** have **signed an informed consent** form:
 - started the **2 months PBAC screening phase**
 - expected procedure during **January 2022**
- **Additional 4 patients screened**
- Recruitment efforts* to complete **10-15 patients enrolled by the end of 2021**



RECRUITMENT EFFORTS: COMMUNITY PHYSICIANS CONFERENCE



Lecture held by Prof. Haimovich on October 19th to more than 150 local Israeli community physician in order to raise interest in the RED study and recruitment efforts

תודה רבה על השתתפותכם בהרצאה של פרופסור חיימוביץ בבנס ועל התגובות הלהבות ממוחזשות שלכם

סיכום סופה 2 בתוקן ה" IUB SEAD™:

דיונים רחבי היקף מוגבר משמשים בבנות, משר וסדירות הדיונים הוספו, ונכפה אצל כ 10-25 אחוז מהנשים ויכול למנוע בעזרה משמעותית בפעילות היומיומית, כמו כן יכול להוביל לאנטייה בתגובה מסחרר בבחול ובמקרים חמורים למנוע חיובים רחמי.

התקן ה" IUB SEAD™ הוא התקן חדשני לטיפול לא הורמונלי, בעל צורה חזרת השוקל 1 גרם ומשחרר לחלל הרחם חומצת הבסר, חומר המובר ברפואה אשר גורב כסית את רירית הרחם העשירה בגל דם. פעולה החומר מובלת בזמן האחר 30 דקות מסגרת הרחם נשלמת. הטיפול המונע צמיח לריות משום יותר מהאפשרות הניתוחית הקיימת בזמן, להביא לשיפור חלקי משמעותי בזמן קצר ובכך לחסור את הנוסף בהצטרפות המורכבת יותר או בברירת הרחם.

התחילת כיום מועמדות:

לניסוי יזימו עד 30 נשים בני החלום 40-50 המבלת מדיננים רחמי מוגבר ללא סיבה אורגנית מוגדרת ובעבר נזרבה של רירית הרחם במשך 30 דקות באומנות התקן ה" IUB SEAD™

משר חסון המפני להשתתפות בכיסוי הוא: מערב של 12 חודשים לאחר הפרוצדורה ומעכב טרפויי חד שפני לאחר 24 חודשים 36 חודשים מהפרוצדורה. נשים המשתתפות במחקר צריכות להיות בעלת חומרה תקינה של היסטוריקופיה ובניסיה של רירית הרחם על מנת לשלח ממצאות.

משמח לשיתוף הפעולה שלכם בקהילה לאיתור מועמדות פוטנציאליות לניסוי!

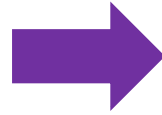
מרכז בניסוי	שם	טלפון	מסמל/מיקום	מיקום/אזור	כתובת/דוא"ר
אסיר הרומא	מרצ'ה סמיר	08-9542012	הילה נגוס	הרומא	shira@asir.gov.il
ירוש	ד"ר עגנון גר	054-8912935	נעם נד	ירוש	egnon@yotv.co.il
ברכה	ד"ר אריאלה שרון	054-8111174	רובי עגנון	ברכה	ariele@barak.co.il
אשדוד	ד"ר אריאלה נדל	072-3398279	נויר אריאלה	אשדוד	ariele@ashdod.co.il
הדר עזריאל	ד"ר ענת חסון	04-6652760	מיכל טנקוילה	הדר עזריאל	enat@hadar.co.il
רמת	מרצ'ה אסתר	04-7771822	מרצ'ה סלומנסקי	רמת	marca@rmat.co.il
תלמי	מרצ'ה רחל שוב	054-9775575	רני רומנסקי	תלמי	marca@telmei.co.il
מנשה	ד"ר רחל שוב	052-8362311	אסתר רומנסקי	מנשה	marca@manasseh.co.il
סוחרה	מרצ'ה רחל הימנוביץ	08-9400774	אסתר רחל	סוחרה	marca@sochara.co.il

למידע כללי: SEAD@occonmed.com
 זמינות מרצ'ה: 072-8281881

OCCON IUB SEAD™

E-mail with a link to the presentation was sent following the lecture, to all mail list received by the Israeli association together with information on Study and relevant sites

RED STUDY MARKETING



www.oconmed.com/red



1 in 3 women experience pain, heavy bleeding, fatigue & depression associated with Heavy Menstrual Bleeding

ACOG

Heavy / Abnormal Menstrual Bleeding

70% of all OBGYN consults in the peri-menopausal & post-menopausal years

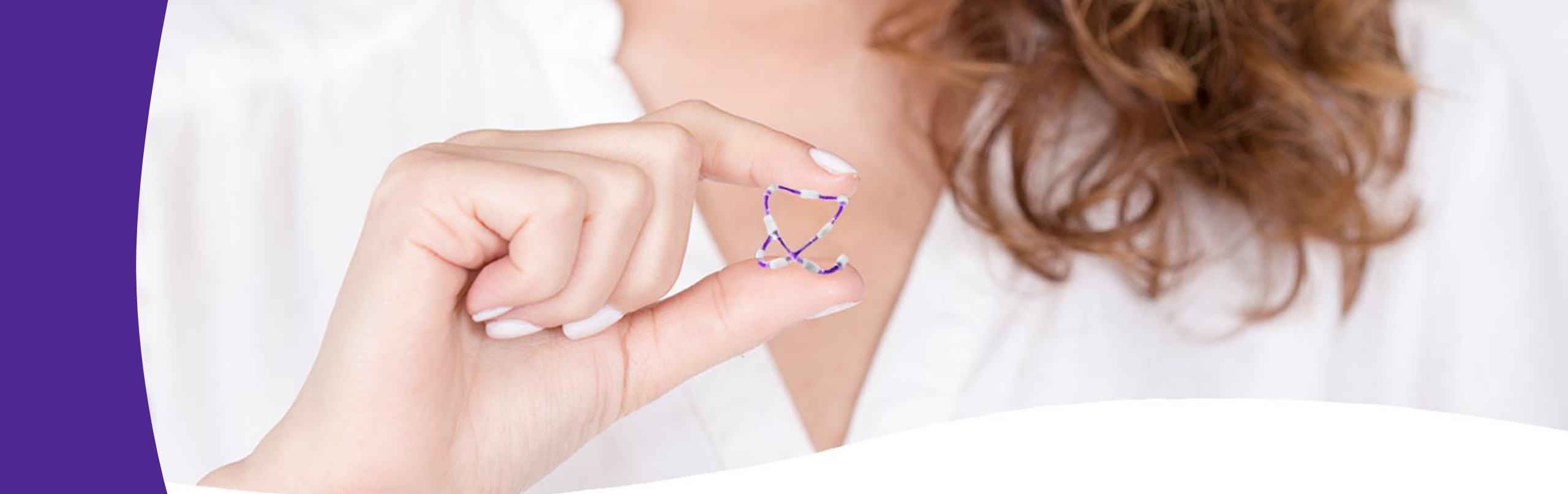
Minerva Surgical

79% of women want treatments that do not involve surgery

Minerva Surgical

28% of women missed work due to symptoms from Heavy Menstrual Bleeding

Borah BJ et al.



THERAPEUTIC IUB™

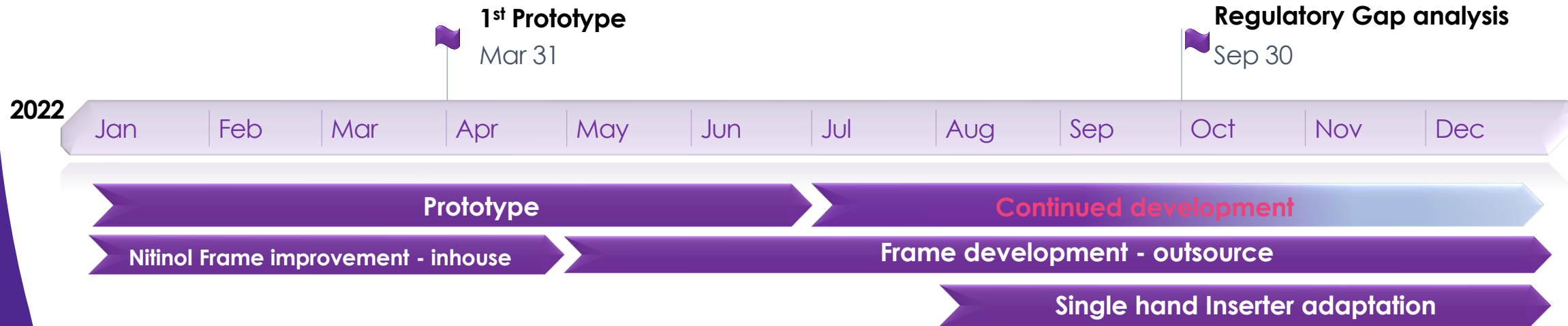


1st
product:
LNG-IUB
(Mirena)

Therapeutic IUB – Q4 R&D Updates:

- ✓ Target Product Profile
- ✓ Selection of Contract Development & Manufacturing Organization (CDMO)
- ✓ Contract signed, kickoff January 2022
- ✗ Grant submission Israeli Innovation Authority: Expected submission Dec. 2021
~\$500K Grant | Total budget: \$1M

LNG-IUB R&D Activities



Due H1/2022

- LNG-IUB 1st prototype (March/April 2022)
- Frame development: design for integral loop (pull-strings)
- Continued Prototype development



CDMO Selection | Out of 4 companies



Experience LNG-IUD

R&D scaleup

Quality system

Cost

**Remote Audit
Performed**

ProMed Minneapolis, MN U.S.



- ✓ Specialized in silicone molding and extrusion of combination products
- ✓ Women's health projects (IVR, IUDs)
- ✓ Experience in LNG-IUDs manufacture+ inhouse analytics
- ✓ R&D to commercial production
- ✓ Packaging & assembly
- ✓ FDA registered, BSI ISO 13485:2003





FINANCES



TERM SHEET* FOR LICENSE AGREEMENT WITH BioGenuine

***Under
negotiations**

- Specialized in women's health
- Up front fees
- Territory: China, HK & Southeast Asia
- China Marketing approval fee
- Sales Royalties payment
- Co-development of IUB therapeutic alternatives (have own formulation (e.g. Fibroids))



2021 WORK PLAN SUMMARY – Planned Vs. Actual

⌘ Investment round Q1/2 – TS signed, not executed.

⌘ Finalization of the SEAD™ phase IIa ✓




⌘ Initiation of the SEAD™ phase IIb ✓

⌘ Ballerine® FDA gap Analysis & Preparation ✓

⌘ Single hand inserter prototype ✓



2022 WORK PLAN PILLARS

- \$ CLA Round Closure
Open Series B investment round
-  IUB Ballerine®
FDA/IND approval
Continued push in Non-CE markets
-  SEAD™ Phase IIb Continued (IIa Finalized)
-  IUB Therapeutic - Working prototype





OCON
— HEALTHCARE —

ANNEX

VALIDATED

IUB™ - INTRAUTERINE BALL PLATFORM TECHNOLOGY



Pillars	Indication	Product	R&D	Pre-Clinical	1st Woman	1st Approval	Market POC	Addressable Market
	IUB™ PLATFORM TECHNOLOGY	IUB™ (INTRAUTERINE BALL) 3D Intrauterine Drug-Delivery Platform					MARKET ACCEPTANCE PILOT STUDY 100K WOMEN	\$35B
Birth Control	Non-Hormonal Contraception	Ballerine® 3D Copper IUD						\$2B
	Hormonal Contraception	Ballerine® 3D Hormonal IUD						\$2.5B
Therapies	Heavy Menstrual Bleeding							
	Abnormal Uterine Bleeding	SEAD™ Spherical Endometrial Ablation Device						\$1B
	Uterine Fibroids	OH-80						\$5B
	Endometriosis	OH-77						\$2B
	Menopause HRT	OH-32						\$16B
Diagnostics	Dx & Detection AI Internal Wearable	OH-94						\$6.5B

RECENT ACQUISITIONS

\$1.1B
 CooperSurgical
Paragard

\$310M
 Daré

\$240M
 ORGANON
Alydia Health

\$954M
 ORGANON
Forendo Pharma

~\$1B
 KaNdy

\$795M
 HOLOGIC
The Science of Safe
Mobidiag

RECENT WOMEN'S HEALTH ACQUISITIONS

2021
2020
2017

ORGANON
+ Alydia Health

\$240M



Abnormal (PP)
Uterine Bleeding

ORGANON
+ Forendo Pharma

\$954M



Endometriosis

@operSurgical
+ Generate Life Sciences

\$1.6B



Reproductive
Health

BAYER
+ KaNDy
Therapeutics

~\$1B



Menopause

BAYER
+ Daré
Bioscience

\$310M



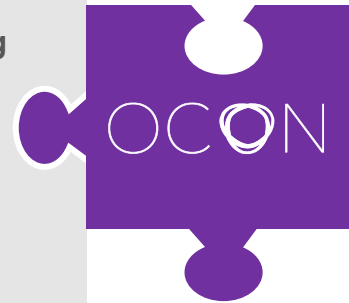
Non-hormonal
Contraception

@operSurgical
+ Teva Paragard (Cu IUD)

\$1.1B



Non-hormonal
Contraception



Reproductive Health
Contraception



Heavy & Abnormal
Uterine bleeding



Uterine Fibroids
Cancers & Endometriosis



Hormonal Therapies
& Menopause





OCON

REVOLUTIONISING
WOMEN'S HEALTH