An Innovative User Controlled Long-Acting Contraceptive Reversible Implant

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Daré Bioscience, Inc.

February 6, 2020

To become the coordinating presence in women's health. We achieve this by identifying, unlocking and advancing innovation that improves health outcomes and promotes a better quality of life for women.

DARÉ

IN ITALIAN, IT MEANS " **TO GIVE.**"
IN ENGLISH, IT MEANS " **TO BE BOLD.**"

To us, Daré means to give women novel treatment options by **boldly addressing existing therapeutic gaps**. And that's exactly our mission.

February 6, 2020

Forward Looking Statements

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ADVANCING PRODUCTS **WOMEN WANT**

	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	REGULATORY FILING

DARE-BV1^
Bacterial Vaginosis

Phase 3 Commence - 2020

Potential First-line Option for Bacterial Vaginosis (BV)
Bio-adhesive gel, clindamycin 2%

Ovaprene®
Hormone-Free, Monthly Contraception

Pivotal Study Start - 2H 2020

First-in-category Hormone-Free, Monthly Contraception
Barrier IVR, ferrous gluconate for multiple weeks of contraceptive protection. Self-administered.

Sildenafil Cream, 3.6%^
Female Sexual Arousal Disorder

Phase 2b Commence - 2020

First-in-category for Treatment of Female Sexual Arousal Disorder
Topical Cream, same active ingredient as Viagra®

DARE-HRT1^‡
Hormone Replacement Therapy

Phase 1 Commence - 2020

First-in-category Sustained-Release Hormone Replacement Therapy
IVR, combination bio-identical estradiol + bio-identical progesterone

DARE-VVA1^
Vulvar and Vaginal Atrophy (HR+ Breast Cancer Population)

Phase 1 Preparations - 2020

First-in-category Treatment for VVA for ER/PR+ Breast Cancer Patients
Proprietary formulation of tamoxifen for vaginal administration in patients with hormone-receptor positive (HR+) breast cancer.

DARE-FRT1^
Pregnancy Maintenance (PTB & ART)

Phase 1 Preparations - 2020

First-in-category Sustained Release Progesterone for Pregnancy Maintenance
IVR, bio-identical progesterone for the prevention of preterm birth and for fertility support as part of an IVF treatment plan.

Microchips
User-Controlled, Long-Acting Reversible Contraception

Pre-clinical

First-in-category, User-Controlled, Long-Acting, Reversible Contraceptive (UC-LARC)
A novel integrated drug/device technological approach to long-acting, reversible contraception.

ORB 204/214^
6 & 12 Month Injectable Contraception

Pre-clinical

First-in-category 6 & 12 Month Injectable Contraception
A potential new injectable contraceptive that is designed to provide discreet, noninvasive, longer-acting reversible protection.

DARE-RH1
Non-Hormonal Male and Female Contraceptive Target

Pre-clinical

First-in-category Male or Female Contraceptive Target
A novel approach to male and female contraception.

Timeline reflects management's current estimates and constitutes a forward-looking statement subject to qualifications noted elsewhere in this presentation. Actual development timelines may be substantially longer, and Daré is under no obligation to update or review these estimates.
"First-in-category" statements are forward-looking statements relating to market potential of Daré's product candidates based on currently available, FDA-approved therapies.
^505(b)(2) regulatory pathway anticipated
‡DARE-HRT1 Phase 1 study to be conducted in Australia by Daré subsidiary

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Microchips Program

User-Controlled Long Acting Reversible Contraception

(UC-LARC)

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WE ARE **ACCELERATING INNOVATION** IN WOMEN'S HEALTH

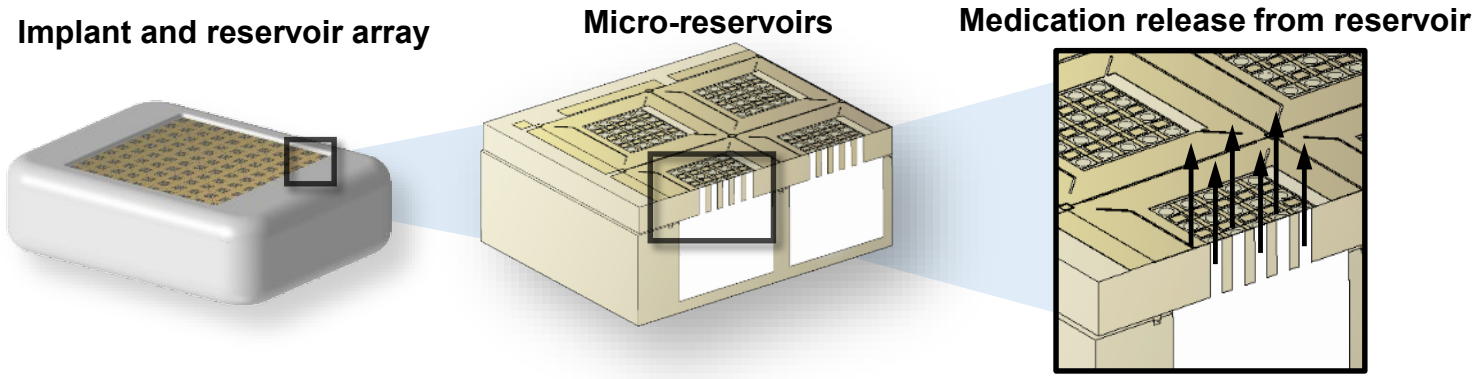
How the Microchips Technology is Designed to Work

Drug Storage

- Individual drug doses are stored in micro-reservoir arrays
- Reservoirs are hermetically sealed at room temperature
- Thin metallic membranes over each reservoir protect drug post-sealing

Drug Release

- Drug doses are initiated automatically on schedule or wirelessly on-demand by patient or clinician
- Reservoirs are opened via electrothermal ablation of membranes
- Upon opening, interstitial fluid diffuses in and drug diffuses out



The Microchips technology has successfully progressed an implantable, drug delivery combination product from concept through clinical validation with the current focus on product development.

Concept Validation (1999)

- Foundational MIT patents
- Nature publication
- Microchips, Inc. formed in 1999 by Drs. Robert Langer and Michael Cima

Technical Validation (2008)

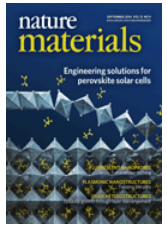
- Electronic activation
- Hermetic sealing
- Drug formulation strategies
- Animal tests
- Nature Materials
- Nature Biotechnology

Clinical Validation (2012)

- Human Clinical Trial (Parathyroid hormone)
- Science Translational Medicine publication

Product Development (2013 – ongoing)

- Grant-funded contraceptive program with the Bill & Melinda Gates Foundation (~$20.5M)
- Optimized platform design and smaller size
- Acquired by Dare Bioscience Nov. 2019



We continue to develop a robust IP portfolio that includes over 98+ patents and 19+ applications.

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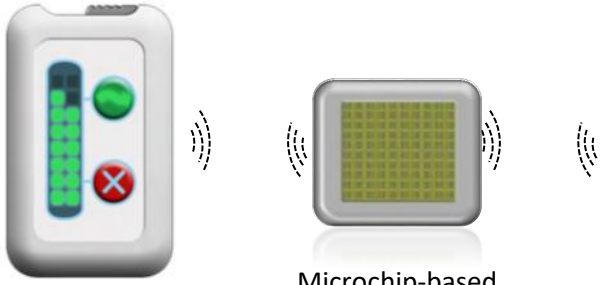
The Microchips technology system facilitates smart implant programming, medication delivery or cessation, and wireless communication/reporting of patient-specific adherence data.

In addition to the microchip-based implant the system also includes:

- A clinician programmer to program implants at the clinic
- Control software on a PC to issue instructions to the clinician programmer
- A user programmer for patient monitoring and/or control (if applicable)

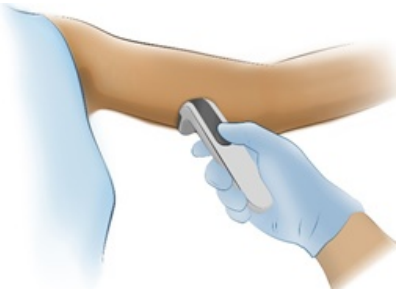


User Programmer

Microchip-based Implant

Clinician Programmer

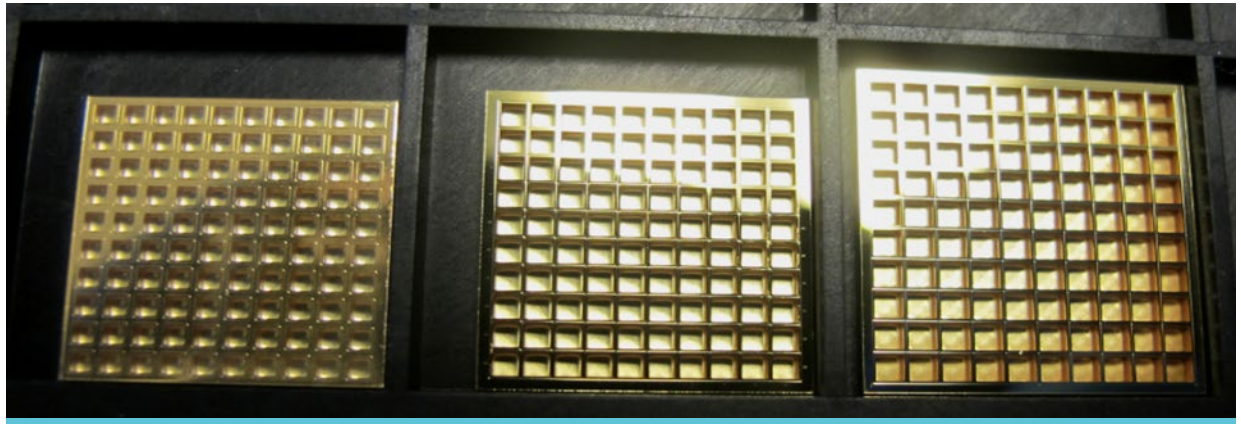
PC Software/Database



The Microchip technology is highly scalable and can accommodate diverse designs

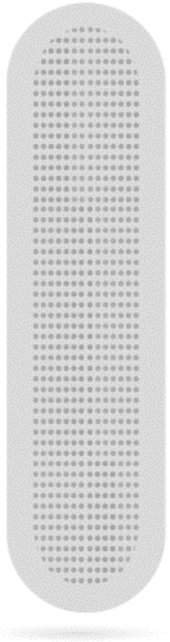
- Platform is suitable for multiple indications and drugs: small molecules, proteins, antibodies, peptides, enzymes
- Liquid or solid formulations are feasible
- Reservoir number and size can vary
- Implant form can be optimized for the indication and anatomical location

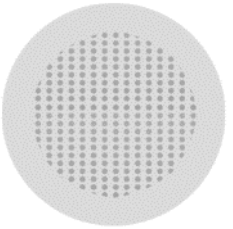
Baseline Design: 200 reservoirs



Increasing Reservoir Size (1 µL, 1.5 µL, 2 µL)

Design Concepts





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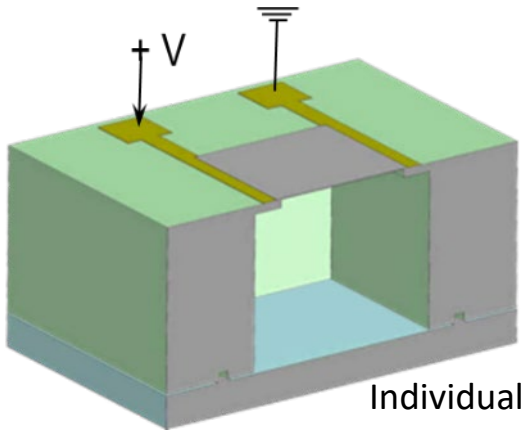
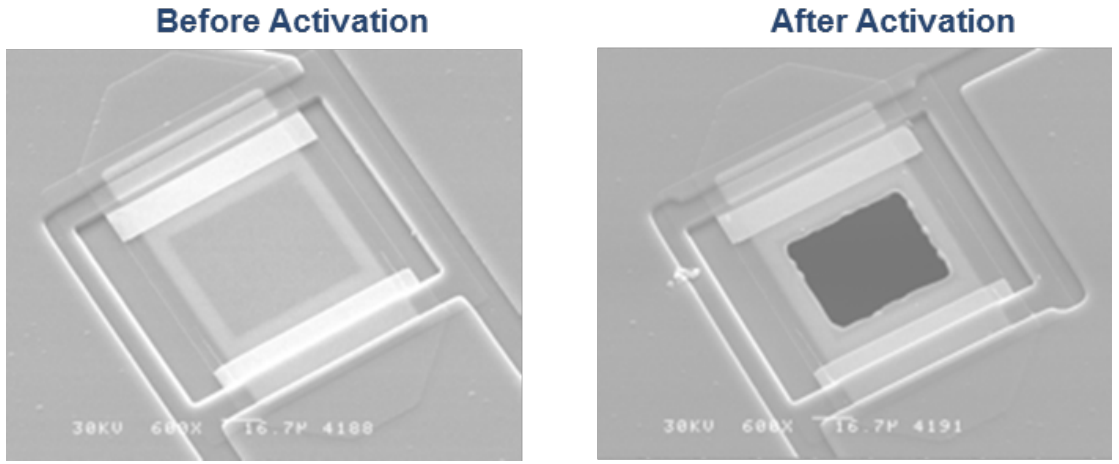
The mechanism of drug exposure occurs via electrothermal ablation of metal membranes and provides precision in drug delivery unique to this microchip platform

- The drug filled reservoirs have multiple openings called apertures, each covered by a composite membrane of titanium and platinum
- Circuit traces on the microchip connect the metal membranes to the internal electronics and provide a path for a current pulse to electrothermally open the membranes
- Upon opening, the interstitial fluid can diffuse into the reservoir, interacting with the drug and initiating the release event



Individual reservoir

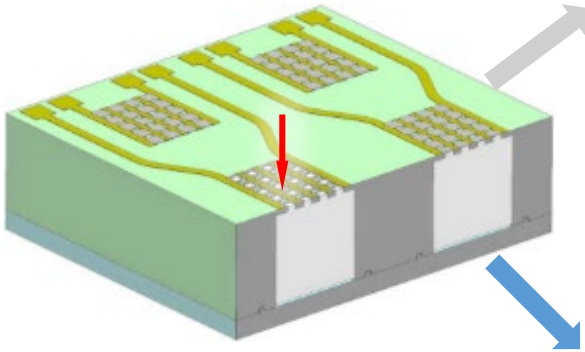


Electron photomicrographs of aperture membrane (600x)

Microchip platform is versatile to enable either pulsatile or continuous release

- Approach depends on required dose and release profile for efficacy

When reservoir is opened, interstitial fluid diffuses into reservoir.



Release Mechanism

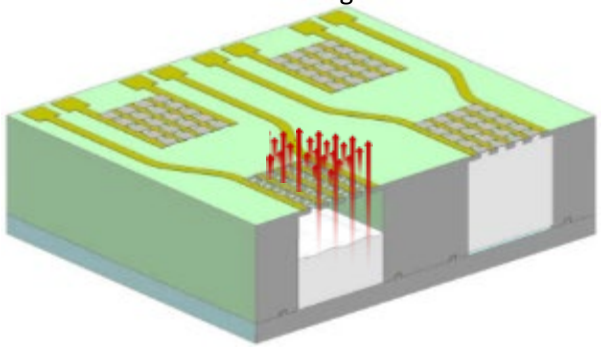
Diffusion

Dependent on drug properties, formulation composition, and microchip geometry

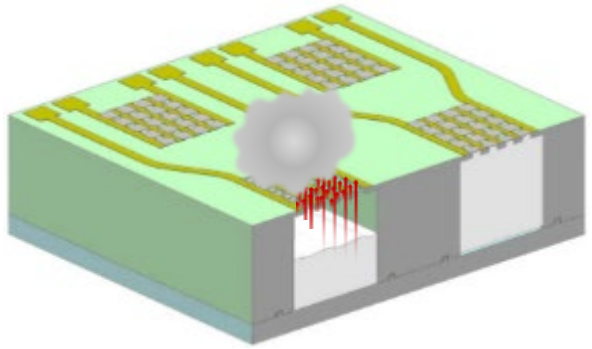
Extrusion

Dependent on drug properties, formulation composition, and matrix properties (if used)

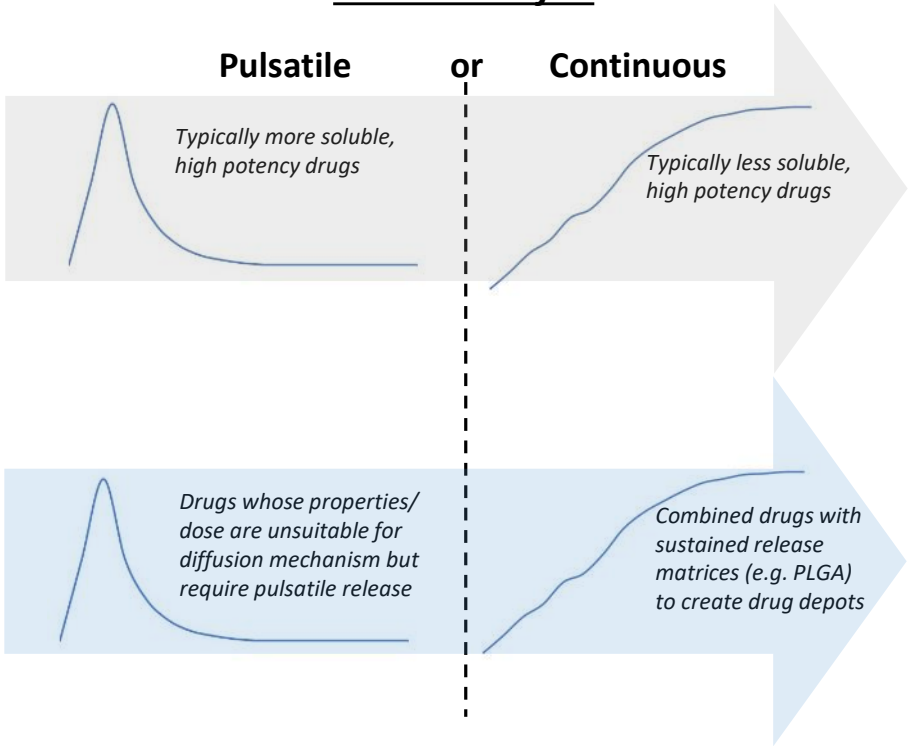
Dissolved drug diffuses out of reservoir while undissolved drug remains



Excipient swells when hydrated and solid drug/excipient is extruded through apertures.



Release Profile



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Clinical Opportunities in Women's Health

- Platform is ideally suited for hormone and peptide delivery with eight plus years of development in women's health applications
- Key indications include:
  - ***Contraception (current grant funded by Bill & Melinda Gates Foundation)***
  - Fertility
  - Hormone replacement therapy
  - ***Osteoporosis (proof of concept, first-in-human clinical trial)***
  - Multiple sclerosis

	Contraception	Fertility	Hormone Replacement Therapy	Osteoporosis	Multiple Sclerosis
Patient Segment	Reproductive Health		Menopausal Health		MS
Current Approaches	Orals, implants, IUDs	Sub-cutaneous injections	Orals, cream, patches, IUDs	Subcutaneous injections, orals	Subcutaneous injections, orals
Microchips Delivered Drug	levonorgestrel (progesterone)	Gonadotropin, FSH	estrogen / progesterone	parathyroid hormone	interferon beta

First-In-Human trial conducted delivering human parathyroid hormone (1-34) (PTH) to demonstrate technology proof-of-concept and to answer key questions

- How will the pharmacokinetics of microchip delivery compare to that of a subcutaneous injection, particularly after the formation of a fibrous tissue capsule?
- How will patients accept the device?

Trial Design

- Eight post-menopausal women between the ages of 65 – 70 in Denmark
- Implanted sub dermally in abdomen area through a small incision
- Eight week healing period after implant to allow fibrous capsule to fully form
- Four week microchip dosing period with 4 pharmacokinetic (PK) assessments (days 60, 65, 70, 84 post-implantation)
- Four PK procedures with FORSTEO injections as controls

Trial Endpoints

Primary

- Assess pharmacokinetics of hPTH(1-34) delivery via the microchips implant

Secondary

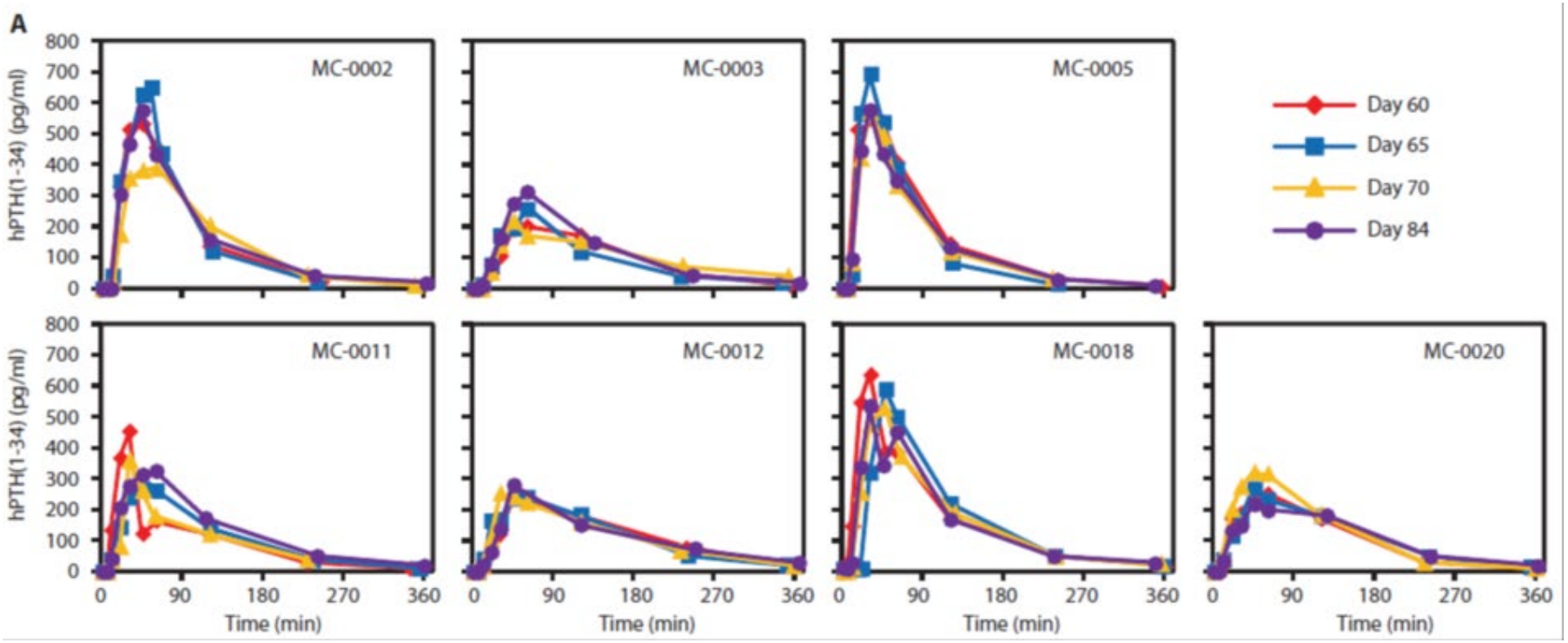
- Drug bioavailability compared to SC injections
- Presence of P1NP bone marker
- Device functionality as defined by wireless communication and reservoir opening

Device safety

- Biological response (wound healing, histology)
- Drug toxicity (serum calcium levels, kidney and liver function)

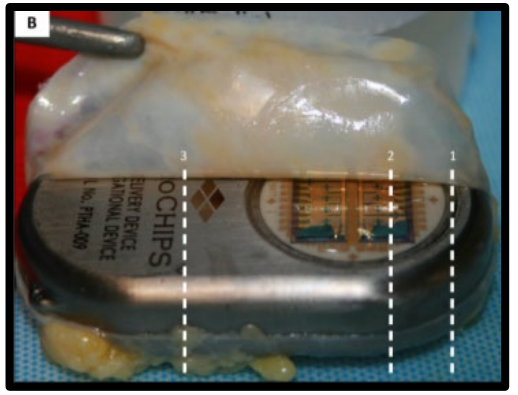
PTH was delivered rapidly and reproducibly by the microchip implant

- PK was consistent, within patient, throughout the dosing period
- PTH dose is not weight adjusted



Early prototype device design

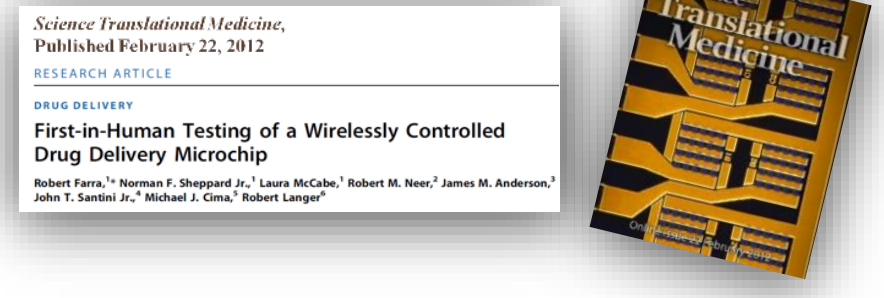
Explanted device in tissue capsule



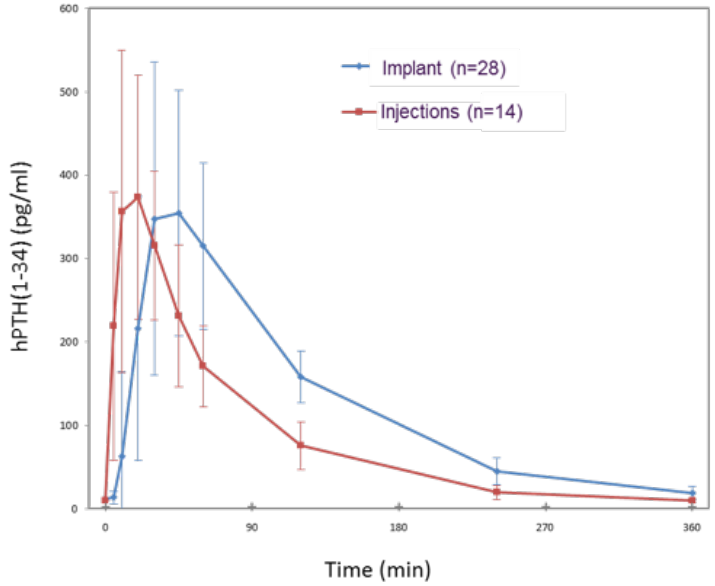
(dashed lines indicate location of histology sections)

Clinical trial objectives of the study were successfully met.

- *Primary*
  - PK from microchip was pulsatile and consistent with delivery from a subcutaneous injection
- *Secondary*
  - Drug releases were comparable to injections of Forsteo
  - P1NP bone marker progressively increased by 143%
  - Device functionality was confirmed via wireless communications
- *Safety*
  - Biocompatible device with no remarkable histology
  - Blood chemistry showed calcium levels remain within normal range
- *Excellent patient acceptance*
  - Patients could not feel device unless palpated



Average hPTH(1-34) Concentration in Plasma (all patients)



Study / Delivery	Dose	N	C_{max} (pg/ml)	T_{max} (min)	AUC (ng min/ml)	$T_{1/2}$ (min)
MicroCHIPS Implant	40 µg	28	405 (203 to 696)	45 (30 to 60)	44 (31 to 59)	70 (38 to 130)
MicroCHIPS SC Inj.	2 x 20 µg	15	380 (140 to 801)	20 (5 to 46)	31 (18 to 43)	62 (31 to 87)
Eli Lilly (CDER) SC Inj.	40 µg	34	460 (146 to 875)	58 (40 to 91)	46 (17 to 69)	Not reported

The Bill & Melinda Gates Foundation has strong interest in family planning in the developing world.

- An estimated 215 million women in developing countries do not have access to contraception
- Even women with access may not find products that meet family planning needs or result in undesirable side effects
- High rates of infant/child and maternal mortality
  - 1 in 9 children dies before the age of 5 years[1]
  - Causes range from issues during delivery to illness in young children to poor growth rate due to lack of proper nutrition[1]
  - The lifetime risk of maternal death is 1 in 36 for women in SSA[2]
- Cultural, social, geographic and economic factors can make it difficult for women to plan their families, creating burdens in caring and providing for their children
  - Women in Africa have 5 children on average[3]

Microchip-based product has the potential to addresses a vast unmet need for women in Sub-Saharan Africa.

Resources:
[1]Committing to Child Survival: A Promise Renewed Progress Report 2012: http://apromiserenewed.org
[2]Unicef Data: Monitoring the Situation of Children and Women 2015: https://data.unicef.org
[3]UN World Fertility Patterns 2015: www.un.org/en/development/desa/population/publications/pdf/fertility/world-fertility-patterns-2015

Microchips Contraceptive System Concept

The MCS concept will consist of the following components:

A small implantable electronic device to deliver levonorgestrel (LNG)

A programmer device to be used by women or healthcare workers to program and perform diagnostics on the implant post insertion

A procedural kit including custom instruments to facilitate insertion and removal of the implant in addition to all other ancillary supplies

Key features of the system:

Small overall device footprint to provide discretion when place inside the upper arm

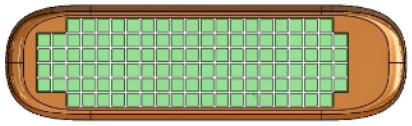
A narrow implant to facilitate simple surgical insertion

10 years of LNG stored in the implant

30 days of drug per reservoir to allow hormone clearance at/around 1 month

Wireless protocol designed for low power and high security communication

Implant



Not to scale

Programmer

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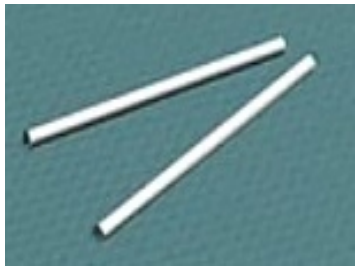
Constant drug release at a rate of 30 micrograms per day is required to provide contraception

- Current implantable products are in the form of cylindrical rods which deliver the drug levonorgestrel over a period of 5 years, but at a variable rate, initially starting higher and eventually trailing off to the target
  - If a woman wants to have a child she would have to return to a clinic to have the rods removed

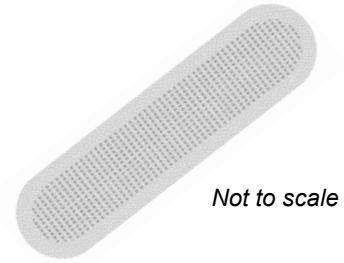
- Our goal is to provide a more precise, constant release rate and combine that with the ability to turn the device on and off, without removal, when a woman wants to have her children

Simulated Drug Release Profiles

Jadelle® rods



Microchips' Concept



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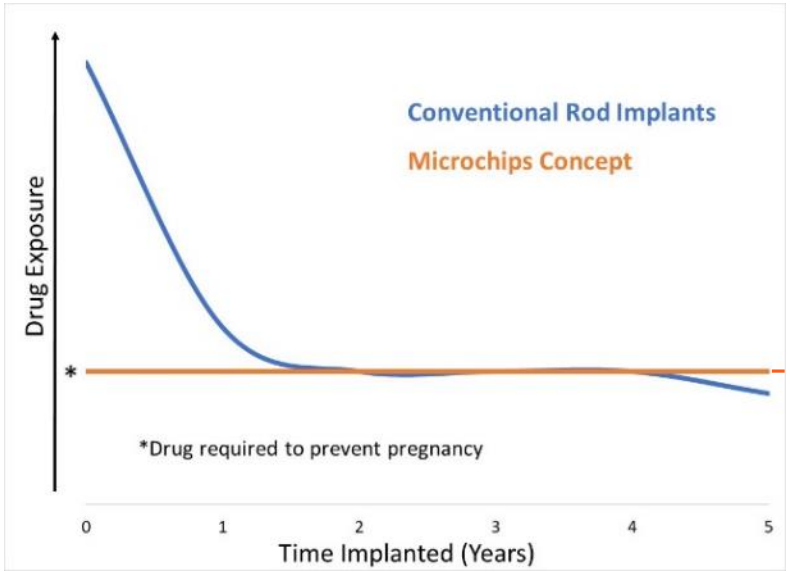
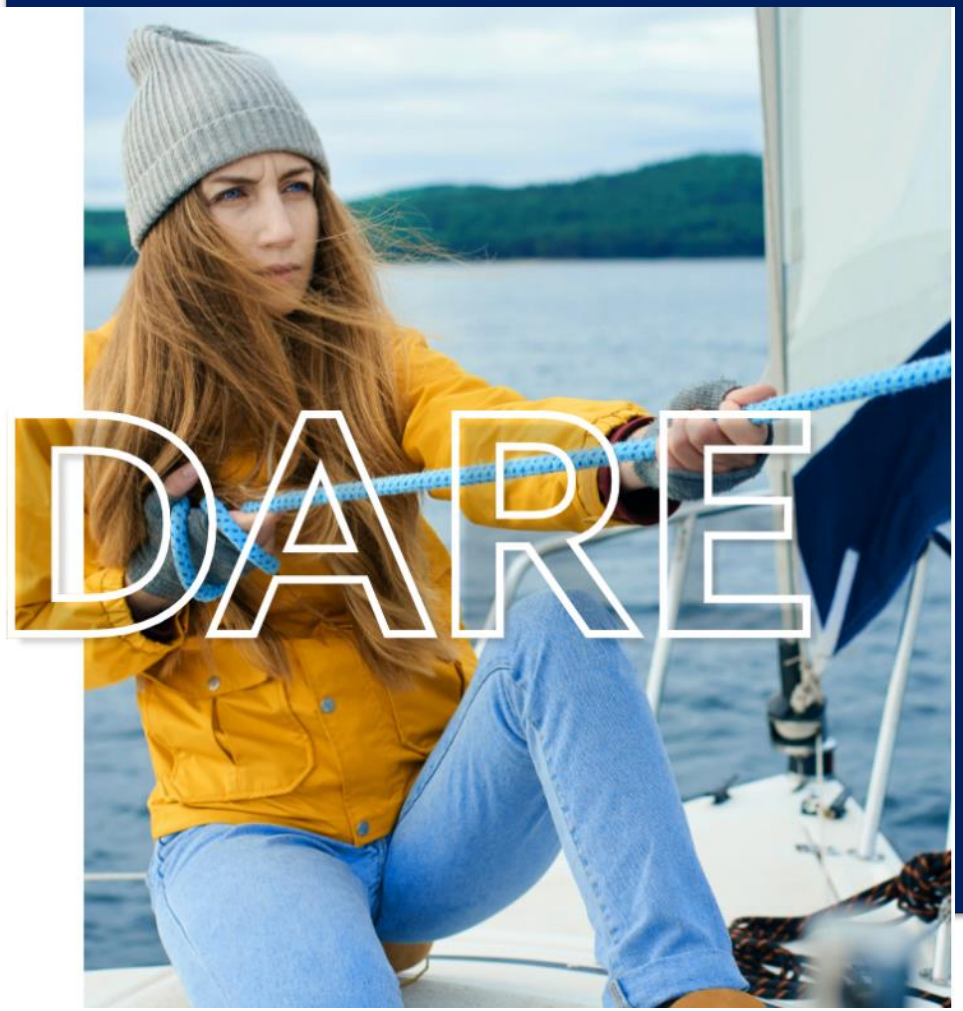


Significant progress in the areas of drug delivery, product design, and market research, resulting in a clearly defined product profile.

Current Status

- The contraceptive product is currently in preclinical development
- Based on market feedback, advanced device concepts have been developed that are both technically feasible, meet market needs and capture desirable features from both women and health care workers perspectives
- Current work is focused on further refinement of the drug delivery mechanism, research to develop a robust insertion procedure and technical de-risking activities leading to a plan for clinical development



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