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# VIVEVE

**Advancing the Science of Women's Intimate Health**

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# Safe Harbor Statement

*All statements in this presentation that are not based on historical fact are “forward looking statements”. While management has based any forward-looking statements included in this presentation on its current expectations, the information on which such expectations were based may change. These forward-looking statements rely on a number of assumptions concerning future events and are subject to a number of risks, uncertainties and other factors, many of which are outside of our control, which could cause actual results to materially differ from such statements.*

*Such risks, uncertainties, and other factors include, but are not limited to: (i) we currently do not have the ability to market our system in the U.S. for sexual function, vaginal laxity or stress urinary incontinence; (ii) we will need to obtain FDA clearance or approval for other indications, which may not be granted; (iii) our business is not profitable, and we may not be able to achieve profitability; (iv) we depend on distributors to market and sell our products and they may not be successful; (v) we currently have limited sales and marketing resources; (vi) the fluctuation of global economic conditions; (vii) the performance of management and our employees; (viii) our ability to obtain financing; (ix) competition and general economic conditions; and (x) other factors that are to be detailed in our periodic and current reports available for review at [www.sec.gov](http://www.sec.gov). Furthermore, we operate in a highly competitive and rapidly changing environment where new and unanticipated risks may arise. Accordingly, investors should not place any reliance on forward-looking statements as a prediction of actual results. We disclaim any intention to, and undertake no obligation to, update or revise forward-looking statements.*



# VIVEVE

## Leading Women's Intimate Health

- ❖ Track record of commercial success
- ❖ IP protected RF platform technology designed specifically for Women's Intimate Health Indications
- ❖ Most robust clinical evidence in industry focused on vaginal laxity/sexual function & SUI
- ❖ Multi-billion market opportunities forthcoming through near-term clinical readouts and regulatory clearances

# Established & Growing Commercial Business

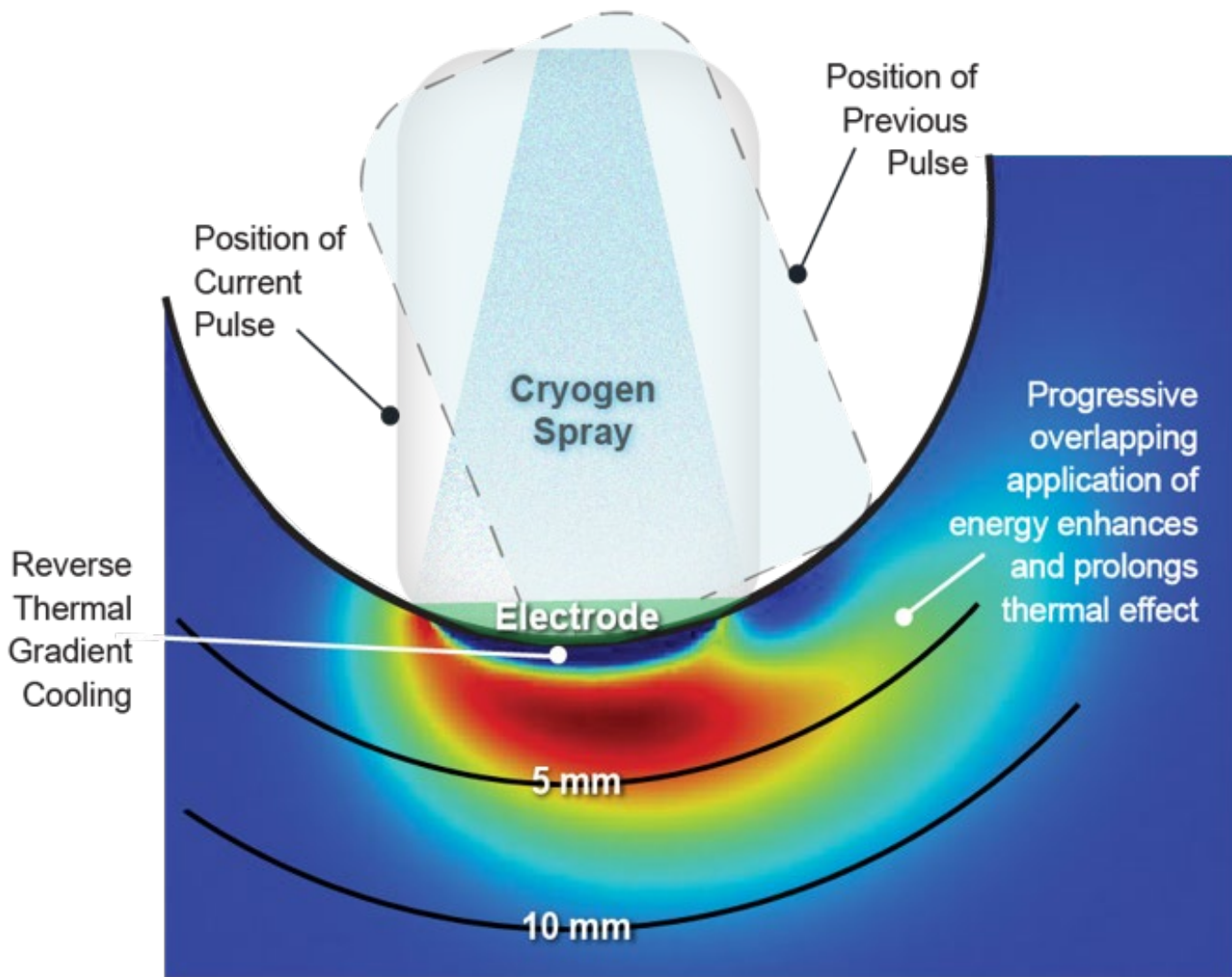
## Continuing Commercial Growth

- ❖ Global installed base – **774 Viveve Systems** worldwide
- ❖ **~38k treatment tips** sold globally since inception
- ❖ Direct sales & distributor network - commercial footprint in **50+ countries** with label for vaginal laxity and/or sexual function

## Significant Label Expansion Opportunities

- ❖ Positive data from 6 clinical studies in Vaginal Laxity/Sexual Function and Stress Urinary Incontinence (SUI)
- ❖ U.S. Sexual Function study – **VIVEVE II** – readout in April 2020
- ❖ Continuing to evaluate results of LIBERATE-INT in SUI
- ❖ International SUI Feasibility Study planned for Q4 – readout expected late Q1 2020
- ❖ U.S. SUI trial pending review of Int. SUI feasibility study – LIBERATE-US

# Proven Solution for Women's Intimate Health Indications



Model represents nominal tissue parameters

## Viveve CMRF

- monopolar radiofrequency with controlled cooling -

- ❖ Allows depth of tissue penetration while maintaining patient comfort and safety
- ❖ Single treatment
- ❖ Consistent patient outcomes
- ❖ Durable results

# Designed for Women's Intimate Health Indications

Evolved to functional treatments through robust scientific and clinical research in women's intimate health conditions

2019

Viveve 2.0 significant reduction in manufacturing costs for entire platform with higher gross margins



# Targeting Large Unmet Medical Needs

## *Sexual Function (Vaginal Laxity)*

Vaginal childbirth overstretches the vaginal introitus (opening)

- ❖ Feeling of “looseness” - diminished sensation during intercourse
- ❖ Reduction in sexual function and quality of life

**12-14 million women worldwide\***

## *Stress Urinary Incontinence (Mild-to-Moderate SUI)*

Pregnancy can damage soft tissues and musculature of pelvic floor

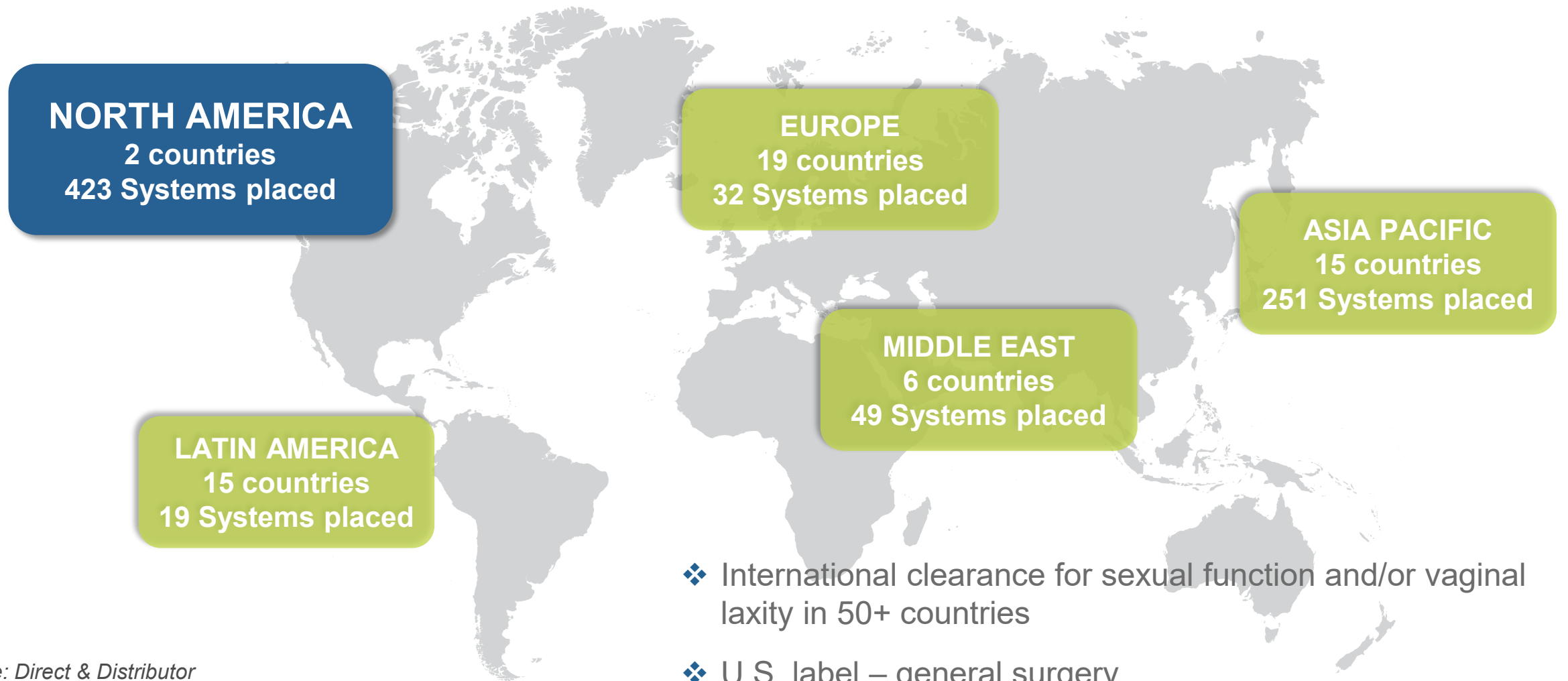
- ❖ Urine leakage associated with Urethral Hypermobility
- ❖ Need to wear pads - reduction in physical activities & quality of life

**25-30 million women worldwide\***

Strong overlap in prevalent populations  
Opportunity to bundle

*\* Estimated based on Company derived research and data analysis.*

# Global Commercial Footprint Spans 50+ Countries

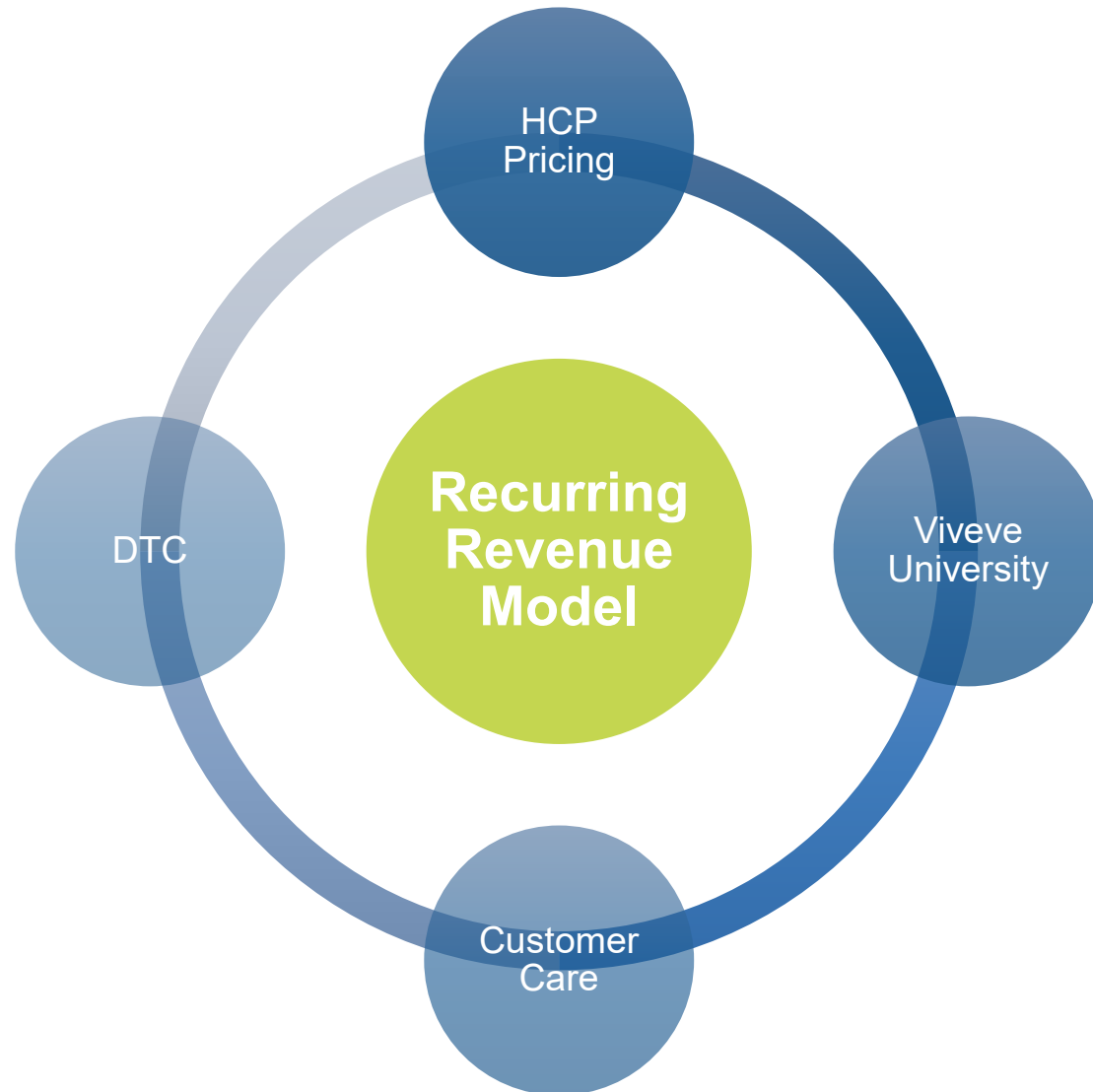


- ❖ International clearance for sexual function and/or vaginal laxity in 50+ countries
- ❖ U.S. label – general surgery

*Blue: Direct & Distributor  
Green: Distribution Only*



# Successful Q2 Launch of New Viveve U.S. Commercial Model



## Recurring Revenue Model

- ❖ **HCP Pricing** – lower upfront pricing to reduce barrier to entry – 2X more placements per rep at significantly decreased sales/acquisition cost
- ❖ **Viveve University** provides comprehensive practice and clinical training
- ❖ **Customer Care Team** provides inside marketing and sales support and practice triage
- ❖ **Targeted Unbranded DTC** aids in driving patients to our customers

# VIVEVE



**April 2020**  
12-month final data readout  
Sexual Function

## Liberate

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INTERNATIONAL

**COMPLETED**  
6-month final data readout  
Stress Urinary Incontinence

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**International SUI Feasibility Study**  
**Q4 2019 Planned Initiation**  
3 arms, 36 patients, 3-month follow-up

## Liberate

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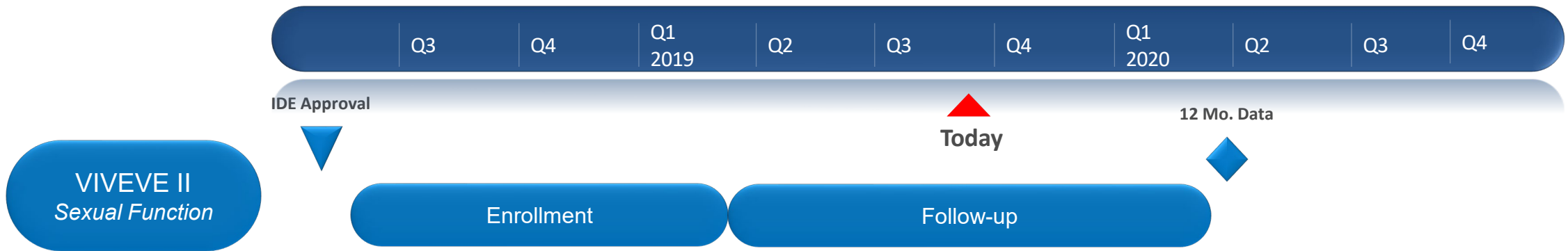
UNITED STATES

**Timing TBD**  
12-month final data readout  
Stress Urinary Incontinence

# Potential for First FDA Female Sexual Function Indication



- ❖ Completed patient enrollment March 2019 – 250 patients at 19 active clinical sites at 1:1 randomization
- ❖ Primary efficacy endpoint: mean change from baseline in total Female Sexual Function Index (FSFI) score at 12 months
- ❖ Study to support FDA clearance - may lead to the first ever overall sexual function claim for women in the U.S.
- ❖ **Expecting end Q1 2020 readout of final 12-month data\***



\* Timelines based on current company estimates.

# LIBERATE-International Final Results



- ❖ Multicenter, randomized, double-blinded, sham-controlled trial – 99 patients at 9 clinical sites at 2:1 randomization
  - Active Tx Tip (cooling and RF) - Sham Tip (cooling only)
- ❖ Final 6-month results:
  - Primary efficacy endpoint not achieved: MCFB 1hr Pad Weight Test at 6-months
  - **Consistent substantial improvements across all 6 endpoints for majority of patients in both active and sham groups**
  - Confounding data from sham control group may indicate effect unlikely due to placebo

# LIBERATE-International Final Results

|  | 1-Hr Pad Weight Test | 24-Hr Pad Weight Test | 3 Day Diary Incon Episodes | UDI-6         | I-QOL        | ICIQ-UI-SF    |
|--|----------------------|-----------------------|----------------------------|---------------|--------------|---------------|
| <b>MEDIAN BASELINE SCORES</b>                              |                      |                       |                            |               |              |               |
| ACTIVE (N=66)  | 12.8g                | 19.8g                 | 8                          | 55.6          | 52.8         | 14            |
| SHAM (N=33)  | 12.9g                | 21.8g                 | 8                          | 55.6          | 56.8         | 13            |
| <b>MEDIAN PERCENTAGE CHANGE FROM BASELINE AT 6 MONTHS*</b> |                      |                       |                            |               |              |               |
| ACTIVE   | <b>-77.2%</b>        | <b>-71.0%</b>         | <b>-83.3%</b>              | <b>-44.4%</b> | <b>35.6%</b> | <b>-46.2%</b> |
| SHAM   | <b>-81.0%</b>        | <b>-61.3%</b>         | <b>-72.7%</b>              | <b>-37.5%</b> | <b>27.1%</b> | <b>-33.3%</b> |

- ❖ No device-related safety issues reported
- ❖ Treatment groups well balanced & early termination from study as expected (~14%)
- ❖ Magnitude, consistency, and duration of effect substantial in both groups – unlikely placebo

\*Percentage change results based upon observed case data; UDI-6: Range of 0 (no problem at all) to 100 (max. problem)  
 IQOL: Range of 0 (max. problem) to 100 (no problem at all); ICIQ-UI-SF: Range of 0 (no problem at all) to 21 (max. problem)

# Strategic Path Forward for SUI Indication

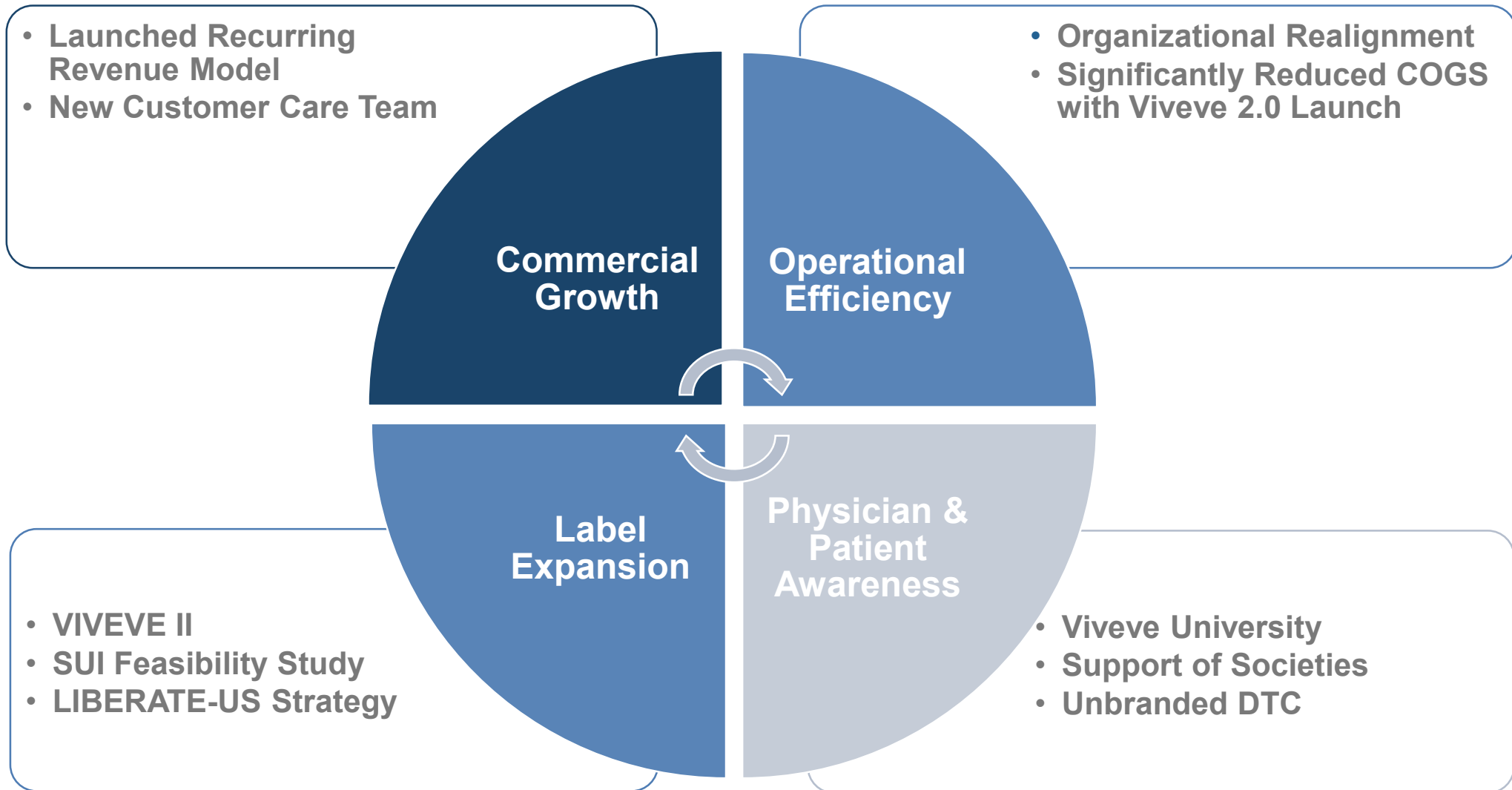
## International SUI Feasibility Study

- ❖ Design: Single blind, three arms, 36 patients, three months follow-up
- ❖ Study Groups: Active Treatment Tip / Cryogen Only Tip / Inert Sham Tip
- ❖ Protocol: Substantially same as LIBERATE-International
- ❖ Target start: Q4 2019
- ❖ Target results readout: late Q1 2020

## LIBERATE – U.S. Trial

- ❖ Resubmission of IDE to FDA pending SUI Feasibility Study results

# Strategic Focus on Core Areas to Drive Value



# VIVEVE

**Advancing the Science of Women's Intimate Health**

NASDAQ: VIVE