# VIVEVE

**Corporate Presentation** 

September 2022



#### **Safe Harbor Statement**

All statements in this presentation that are not based on historical fact are "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. 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, the cost, timing, progress and results of our clinical trials, including the initiation, progress of, and results from, our PURSUIT trial and whether the clinical trial will support the intended uses for treatment of stress urinary incontinence ("SUI") in the United States, the fluctuation of global economic conditions, the impact of the novel coronavirus termed COVID-19 on our clinical development and regulatory review and clearances and on the manufacturing, placements and patient utilization of our Viveve Systems, the performance of management and our employees, our ability to obtain financing, our evaluation of strategic alternatives, our ability to obtain approval or clearance for sale of our medical device for all indications sought, including whether we are successful in having our medical device approved or cleared for sale by the U.S. Food and Drug Administration ("FDA") for the SUI indication, competition, general economic conditions and other factors that are detailed in our periodic and current reports available for review at 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 to reflect events or circumstances that subsequently occur or of which we hereafter become aware, unless required by law.

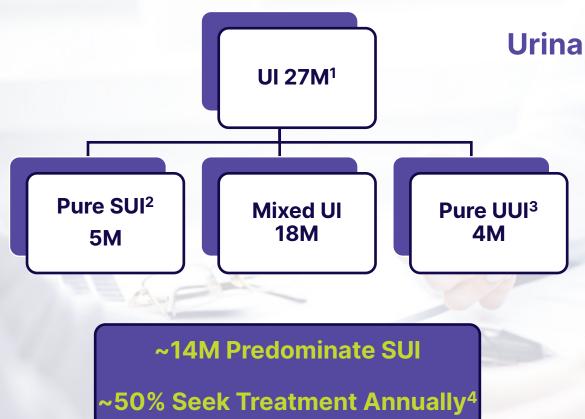


## **UROGYN Company Focused on SUI**

**Vision...THE leading provider of treatments for Female Stress Urinary Incontinence (SUI)** 

- ◆ Proven, IP protected, novel dual-energy technology
- Bifurcated treatment landscape leading to enormous market opportunity
- ◆ Pivotal U.S. PURSUIT trial completion anticipated at the end of 2022
- ◆ Pre-launch existing core installed base
- ◆ Resources and experience to achieve success

## **Urinary Incontinence is an Under Treated Condition**



Urinary Incontinence is typically defined as either Stress, Urge or Mixed

#### **Stress Urinary Incontinence (SUI)**

- ♦ Involuntary loss of urine during physical or strenuous activities - most common form of urinary incontinence
- ♦ Leading cause ~ Urethral hypermobility ~ excessive movement of the female urethra due to weakened pelvic floor connective tissues

Sources: 1) Average prevalence across several published papers including Hannestad 2000, Nygaard 2008, Markland 2011, Thom, 1998, Hampel 1997, Hunskar 2003; 121Mn US Women age 25 – 64; 2) Pure stress urinary incontinence: Rubilotta, BMC Urology 2019; 3) Only 14% of UI is pure UUI; Hannestad 2000; 4) Diokno AC,2004 Feb

### **Novel Dual-Energy Treatment for SUI**

- ◆ Table-top console with disposable single-use treatment tip
- ◆ 45-minute, office-based, single treatment
- ◆ Dual-energy (RF with Cryogen Cooling) results in deep tissue penetration while maintaining patient comfort and safety
- ◆ Consistent patient and clinical outcomes
- ◆ Durable results demonstrated to 12 months
- ◆ Strong IP portfolio Method of use for SUI & vaginal tissue for RF and Cryo in combination and alone

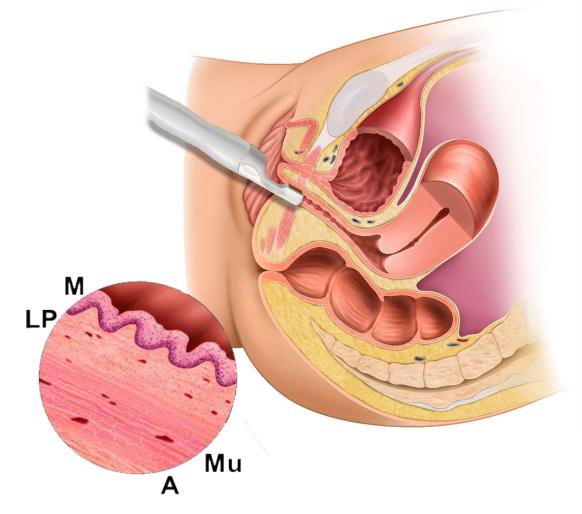


RF: Radio Frequency

### **Viveve Treatment Supports Urethra and Bladder Neck**

#### **Unique Mechanism of Action**

- ◆ Treats the entire depth of the lamina propria to the muscularis
- Energy dispersed without affecting paravaginal tissues or organs
- ◆ Demonstrated fibroblast activation and collagen remodeling ~ 30-90 days ~ strengthens and improves function of the connective tissues
- Improved tissue integrity reduces urethral hypermobility – leading underlying cause of SUI



M=Mucosa; LP=Lamina Propria; Mu= Muscularis; A=Adventitia

## **Enormous Opportunity for a Non-Invasive SUI Treatment Option\***

**CONSERVATIVE** 

**NON-INVASIVE** 

**AGGRESSIVE / INVASIVE** 

Conservative Therapy & Continence Pessaries (40-50% Efficacy)

VIVeve

Injectable Implantable
Bulking Agents Surgical Slings
(60-70% Efficacy) (85-90% Efficacy)

2M Patients Per Year

90K Patients Per Year

- Pelvic Floor Exercises
   Physical Therapy (Kegels)
- Biofeedback Pelvic Floor Stimulation
- ♦ Continence Pessaries

Total Available U.S. Market

14M Women w/ Predominate SUI

6,700 Target Core Physicians

- Urethral Bulking Agents
- ♦ Pelvic Floor Slings
- Colposuspension

<sup>\*</sup> Sources: 1)2016-2020 Patient counts from DRG proprietary study of 300+M patient insurance claims and EHR reports; 2) Average prevalence across several published papers including Hannestad 2000, Nygaard 2008, Markland 2011, Thom, 1998, Hampel 1997, Hunskar 2003; 121Mn US Women age 25 – 64; 3) Pure stress urinary incontinence: Rubilotta, BMC Urology 2019; 4) Only 14% of UI is pure UUI; Hannestad 2000; 5) Diokno AC, Medical and self-care practices reported by women with urinary incontinence 2004 Feb

## **Robust Clinical Development Program in SUI**





Strong body of clinical evidence supporting pivotal PURSUIT trial for potential SUI indication in U.S.



**3-Arm Feasibility and Preclinical Studies:** achieved primary efficacy endpoint of median CFB in 1-hour Pad Weight Test at 5 mos post-treatment between CMRF and Cryo-only Sham to New Inert Sham group; In-vivo preclinical testing validated New Inert Sham tip



LIBERATE International Trial: meaningful improvement in objective 1-hour Pad Weight Test, as well as all secondary endpoints, from baseline in subjects with mild-moderate SUI; CMRF vs Cryo-only groups did not show statistical separation; No serious adverse events



**Single Arm Pilot Trial(s):** safety, efficacy, and durable positive clinical outcomes demonstrated at 6- and 12-months post-treatment for improvement of mild-moderate SUI; No serious adverse events



**Animal Studies:** documented fibroblast activation, collagen remodeling, no cellular or tissue damage

**CMRF Technology:** based on proven aesthetic commercial technology





Final Follow-up Visits Anticipated YE 2022

**Top-line Results Shortly Thereafter** 

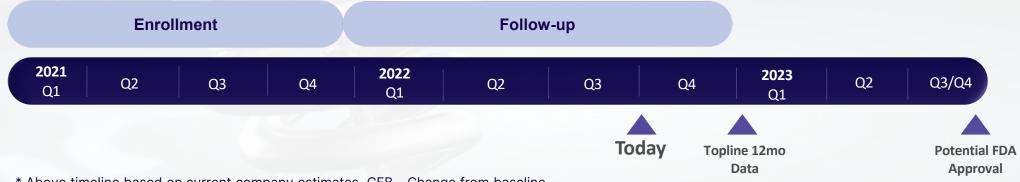
Multicenter, randomized, double-blinded, sham-controlled trial 415 subjects enrolled at ~30 US clinical sites at 2:1 randomization

**Intended Use:** Pre-menopausal women with moderate SUI (10ml-50ml)

**Primary Endpoint:** Proportion of patients with >50% reduction in 1hr Pad Weight Test (PWT) at 12 mos vs Sham treatment

#### **Multiple Secondary Endpoints:**

- ♦ Proportion of pts with >50% reduction in 1hr PWT at 3 and 6 mos
- ♦ CFB in 1hr PWT at 3, 6, and 12 mos
- ♦ CFB in 3-day voiding diary at 3, 6, and 12 mos
- ♦ CFB in MESA, I-QOL, PGI-1, and ICIQ-UI-SF at 3, 6, 9, and 12 mos



\* Above timeline based on current company estimates. CFB - Change from baseline



#### **Pre-launch Existing Core Installed Base**

- US & APAC installed base of 902 systems\*
- Over 66k single-use disposable treatment tips sold globally\*
- ◆ Increase adoption w/core market physicians in urology, urogynecology and gynecology
- Successfully driving increased patient treatments and disposable utilization

#### **Commercial Launch Focus**

- ◆ Established long-term pathway for reimbursement AMA approved Category III CPT® Code
- ◆ Targeting large core physician market ~ 6,700 physicians submit >50% of SUI claims today
- ◆ 14M women in U.S. who could be candidates for the Viveve treatment

\* As of June 30, 2022



## **Resources and Experience to Achieve Success**

- Highly experienced leadership team and board
- Expert KOL advisory board in urinary incontinence
- ♦ Financial:\*
  - ♦ Cash balance of \$9.4M as of June 30, 2022
  - ♦Low cash burn rate ~\$3M/quarter for 2H 2022
  - ♦ Clean capital structure \$5.5M senior secured debt

- Proven, IP protected, novel dualenergy technology
  - ♦ Bifurcated SUI treatment landscape leading to enormous market opportunity
  - Pivotal U.S. PURSUIT trial completion anticipated at the end of 2022
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# VIVEVE

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