

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER

PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

September 9, 2025

Commission File Number: 0-29374

EDAP TMS S.A.
Parc Activite La Poudrette Lamartine
4/6 Rue du Dauphine
69120 Vaulx-en-Velin - France

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F Form 40-F

SIGNATURES

Pursuant to the requirements of the Securities Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: September 9, 2025

EDAP TMS S.A.

/s/ KEN MOBECK
KEN MOBECK
CHIEF FINANCIAL OFFICER

edap | Focal·One®

The **Global Leader** in Therapeutic Ultrasound



EDAP | FOCAL ONE® - September 2025



FORWARD - LOOKING

Statements & Disclaimer

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Company Overview



Strategic Company Focus

Shift from Legacy Technologies and Distributor Model and **Transform** into the Global Market Leader in Robotic HIFU Focal Therapy

Investment Thesis: Strong Growth Opportunity

- ✓ **Large and Growing Market Opportunity:** Urology and Prostate Cancer
- ✓ Solves an Important **Unmet Clinical Need in Cancer**
- ✓ Proven **Compelling Clinical Evidence**
- ✓ **Increasing Patient and Physician Demand**
- ✓ **Strong Hospital and Physician Reimbursement**
- ✓ **Leverages** Current Advancements in **Imaging, AI, and Robotics**
- ✓ **Growing Worldwide Install Base**
- ✓ Ideally Positioned for **Expanded Indications** (BPH, Endometriosis, Other)

EDAP | FOCAL ONE

Strong Growing Global Market Presence

350+ Focal One Robotic HIFU Clinical Sites



- EDAP Offices – United States, France, Germany, Switzerland, South Korea, Japan and Malaysia
- EDAP Customer Sites – Over 350 Clinical Sites

Large and Growing Market Opportunity In Urology and Prostate Cancer



U.S. PROSTATE CANCER MARKET

3.3 Million

American Men Living with Prostate Cancer in the U.S.⁽¹⁾

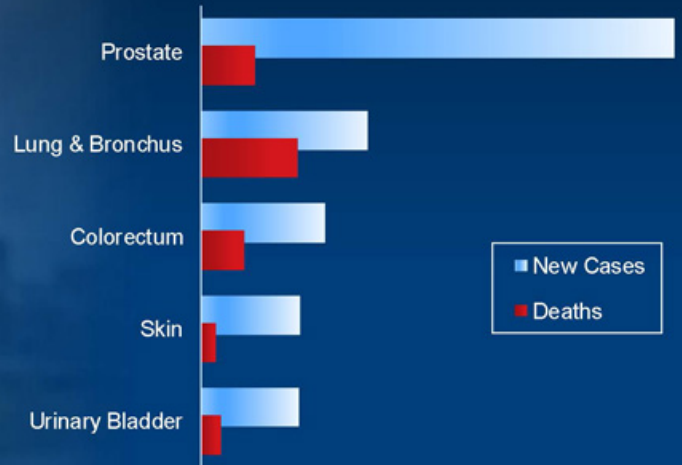
313,780

New Cases Diagnosed in the U.S.⁽¹⁾

35,770

U.S. Deaths from Prostate Cancer⁽¹⁾

Prostate Cancer is the Most Common Cancer Amongst Men In the U.S.



⁽¹⁾ 2025 estimates from the American Cancer Society (www.cancer.org)

LARGE GLOBAL MARKET

Prostate Cancer Market Opportunity

1.5 Million
New Prostate
Cancer Cases
Per Year

| Region | Number of New Prostate Cancer Cases |
|---------------|--|
| Europe | 473,011 |
| Asia | 386,424 |
| North America | 255,782 |
| Latin America | 225,985 |
| Africa | 103,050 |
| Oceania | 23,602 |
| Total | 1,467,854 |

Data Source: Cases refers to Diagnosed Cases per year From World Health Organization- Globocan 2022

Focal One Answers an Unmet Need for a Large Underserved Patient Population



FOCAL ONE ROBOTIC HIFU
Global Addressable Market

470,000

Focal One HIFU Prostate Cancer
Annual Procedure Opportunity



165,000
Europe

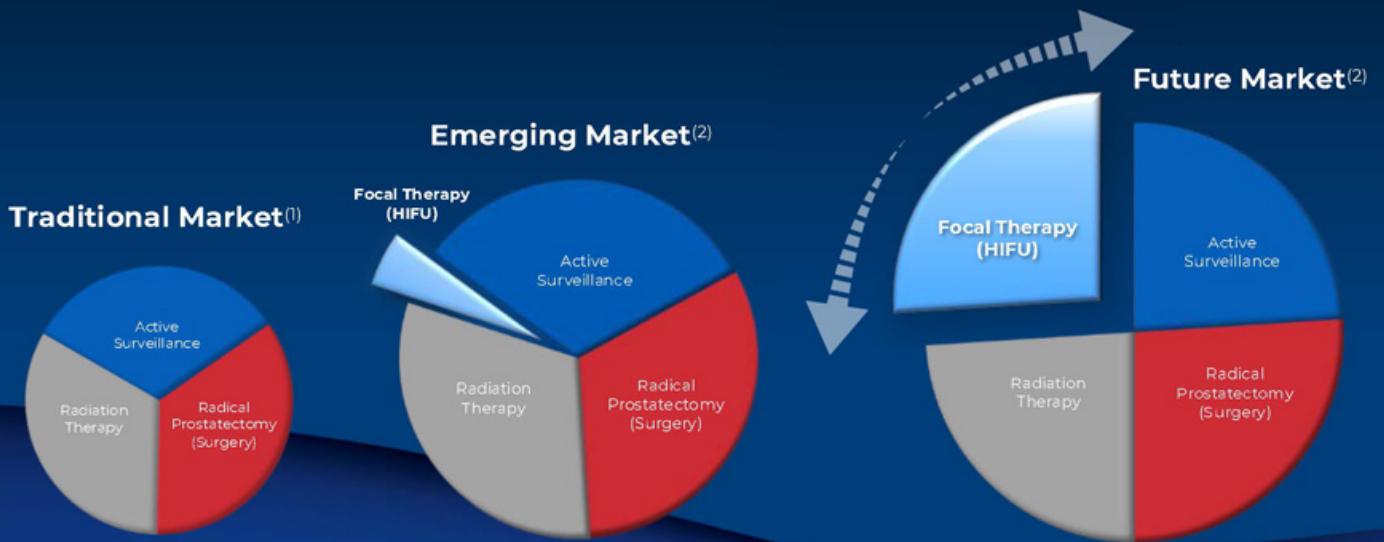
130,000
Asia

100,000
North America

75,000
South America

DRIVING A PARADIGM SHIFT IN PROSTATE CANCER

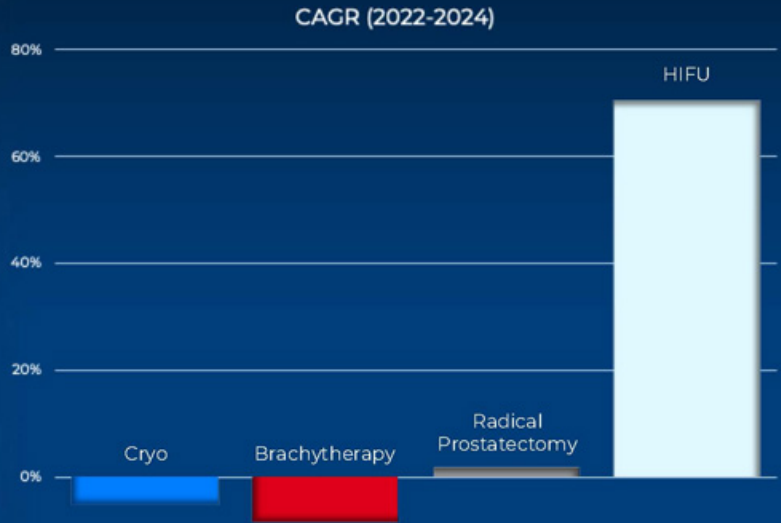
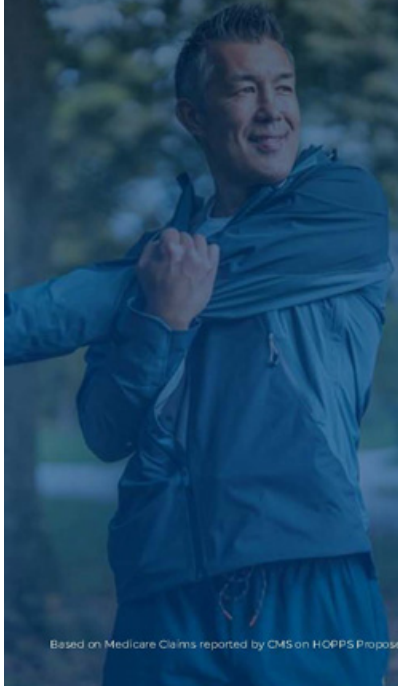
Focal Therapy | The New Emerging Market



(1) As of 2013. Chen et al. National trends in the management of localized prostate cancer: A population-based analysis 2004-2013. Prostate.
(2) Internal market estimate.

DRIVING A PARADIGM SHIFT IN PROSTATE CANCER

HIFU | The Fastest Growing Treatment Option



Based on Medicare Claims reported by CMS on HOPPS Proposed Rule for FY24, FY25 and FY26

Strong Supporting Clinical Evidence



Proven Clinical Evidence Supporting Focal One Robotic HIFU

1000+ Peer-Reviewed Publications Supporting HIFU in the Treatment of Prostate Cancer ⁽¹⁾



Optimizing **Trifecta Outcomes** for Prostate Cancer

1. Cancer Control

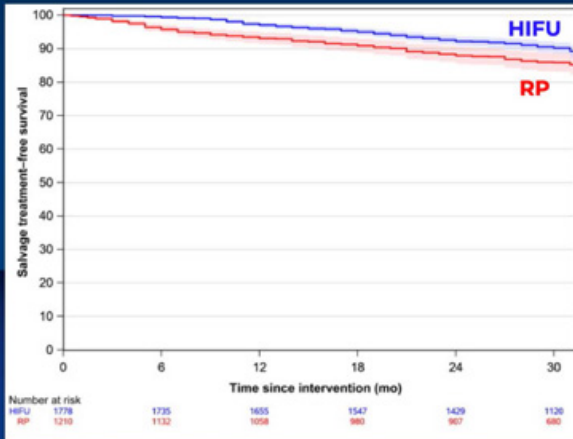
2. Maintain Urinary Control

3. Preserve Sexual Function

Functional Outcomes

HIFI - Prospective Multicentric Comparative Study Focal One HIFU vs Radical Prostatectomy

Published in *European Urology* – December 2024



Prospective, Comparative, Multicentric, non-inferiority clinical trial comparing HIFU to Radical Prostatectomy (RP)

3,328 patients treated (1,967 HIFU - 1,361 RP) across **46 centers**

90% of HIFU patients treated with Focal One

Comparable Cancer Control (Primary Endpoint):
90% STFS for HIFU vs **86%** for RP; $p = 0.008$

Superior functional outcomes for HIFU (Secondary Endpoint):

- Urinary Continence significantly better after HIFU
- Significantly lower stress incontinence after HIFU
- Erectile Function less impaired

Poussard et al. "Whole-gland or Subtotal High-intensity Focused Ultrasound Versus Radical Prostatectomy: The Prospective, Noninferiority, Nonrandomized HIFI Trial." *European urology* vol. 87.5 (2025): 526-533. doi:10.1016/j.eururo.2024.11.006

edap | Focal One

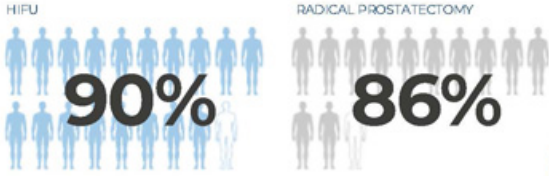
16

HIFI Study Demonstrates Optimal Trifecta Outcomes

1. Cancer Control

Comparable Oncologic Outcomes

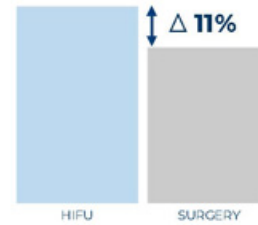
Patients Free from Salvage Treatment at 30 months



2. Maintain Urinary Control

Urinary Continence

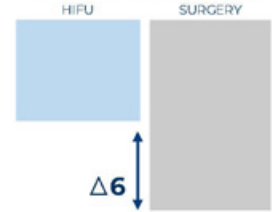
Pad-Free Continence at 12 months



3. Preserve Sexual Function

Erectile Function

Decrease from baseline at 12 months

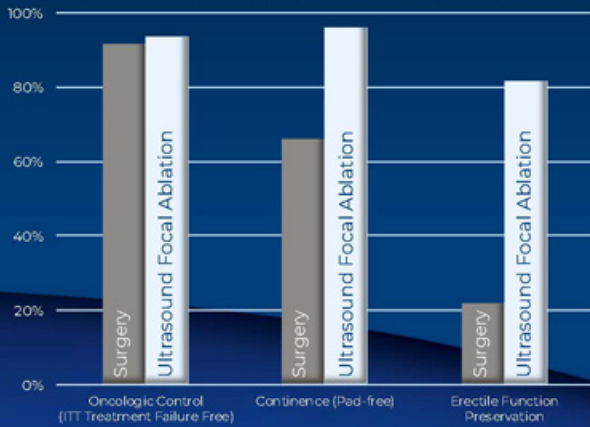


HIFU Provides Superior Functional Outcomes

FARP - Randomized Controlled Trial Focal Ablation vs Radical Prostatectomy

Final Results Presented at AUA 2025

OPTIMAL TRIFECTA OUTCOMES



Randomized Controlled, Non-inferiority Clinical Trial comparing Focal Ablation (FA) to Robot-Assisted Radical Prostatectomy (RP)

Equivalent Oncologic Control at 3 years (93.5% TFF vs 91.5%)

Superior Functional Outcomes after Focal Ablation

213 Patients included in the Clinical Trial

25% of Patients refused radical surgery after randomized to RP and opted for FA

80+% of Focal Ablation patients treated with Focal One®

Baco et al. Final, three-year oncological results of a randomized clinical trial FARP comparing Focal Ablation and Radical Prostatectomy in patients with unilateral clinically-significant prostate cancer. *Journal of Urology* [Internet]. 2025 May 1;213(5S):e714.

Baco et al. Focal Ablation Versus Radical Prostatectomy for Intermediate-Risk Prostate Cancer: Interim Analysis of a Randomized Controlled Trial. *The Journal of Urology*. Vol. 206, No. 3S, Supplement, Sunday, September 12, 2021

Strong Hospital and Physician Reimbursement



STRONG REIMBURSEMENT
**Creates Favorable
Environment
for Growth**



1. **APC Level 6** Under CMS for CY23 and CY24 ^(1,3)
2. **90% Increase** in Reimbursement in 2023 ^(1,2)
3. **APC Level 6** Maintained by CMS in 2025 ⁽³⁾

(1) CMS Hospital Outpatient Prospective Payment System - 2023 Final rule
(2) CMS Hospital Outpatient Prospective Payment System - 2022 Final rule
(3) CMS Hospital Outpatient Prospective Payment System - 2025 Final rule

Hospital Outpatient Medicare Payment

| Procedure | CPT® Code | Site of Service | 2025 | |
|---------------------------------------|---------------|-----------------------|------------------------------|--------------|
| Prostate Brachytherapy | 55875 | Standard OR | \$5,084 ⁽¹⁾ | |
| Cryo Ablation | 55873 | Standard OR | \$9,247 ⁽¹⁾ | |
| MRI Transurethral Ultrasound Ablation | C9734 / 55882 | Specialized MRI Suite | \$12,992 ⁽¹⁾ | |
| HIFU | 55880 | Standard OR | \$9,247⁽¹⁾ | +5.4% |
| Laparoscopic Prostatectomy | 55866 | Standard OR | \$10,411 ⁽¹⁾ | |

(Laparoscopic Prostatectomy with or without Robotic Assistance and/or nerve-sparing)

Favorable Physician Payment

| Procedure | CPT® Code | Work RVU (2025) ⁽²⁾ | Physician Payment (Medicare - 2025) |
|---------------------------------------|--------------|-----------------------------------|--|
| Prostate Brachytherapy | 55875 | 13.46 | \$763 |
| Cryo | 55873 | 13.60 | \$744 |
| MRI Transurethral Ultrasound Ablation | 55882 | 11.50 | \$579 |
| HIFU | 55880 | 17.73 | \$951 |
| Laparoscopic Prostatectomy | 55866 | 22.46 | \$1,157 |

(Laparoscopic Prostatectomy with or without Robotic Assistance and/or nerve-sparing)

(1) CMS Physician Fee Schedule - CY2024 Final rule
 (2) CMS Physician Fee Schedule - CY2025 Final rule

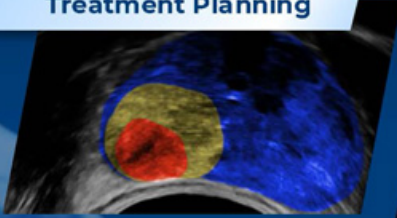
Focal One® Best-in-Class Technology



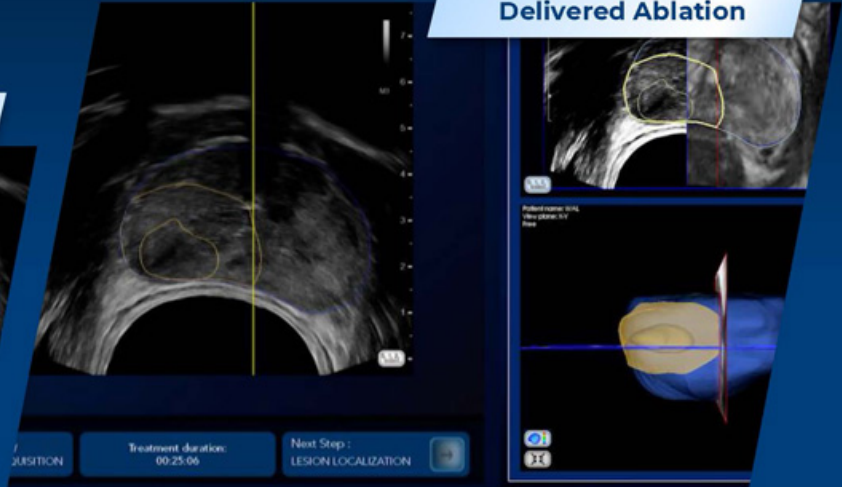
THE LEADING FOCAL THERAPY TECHNOLOGY

Targeting and Imaging

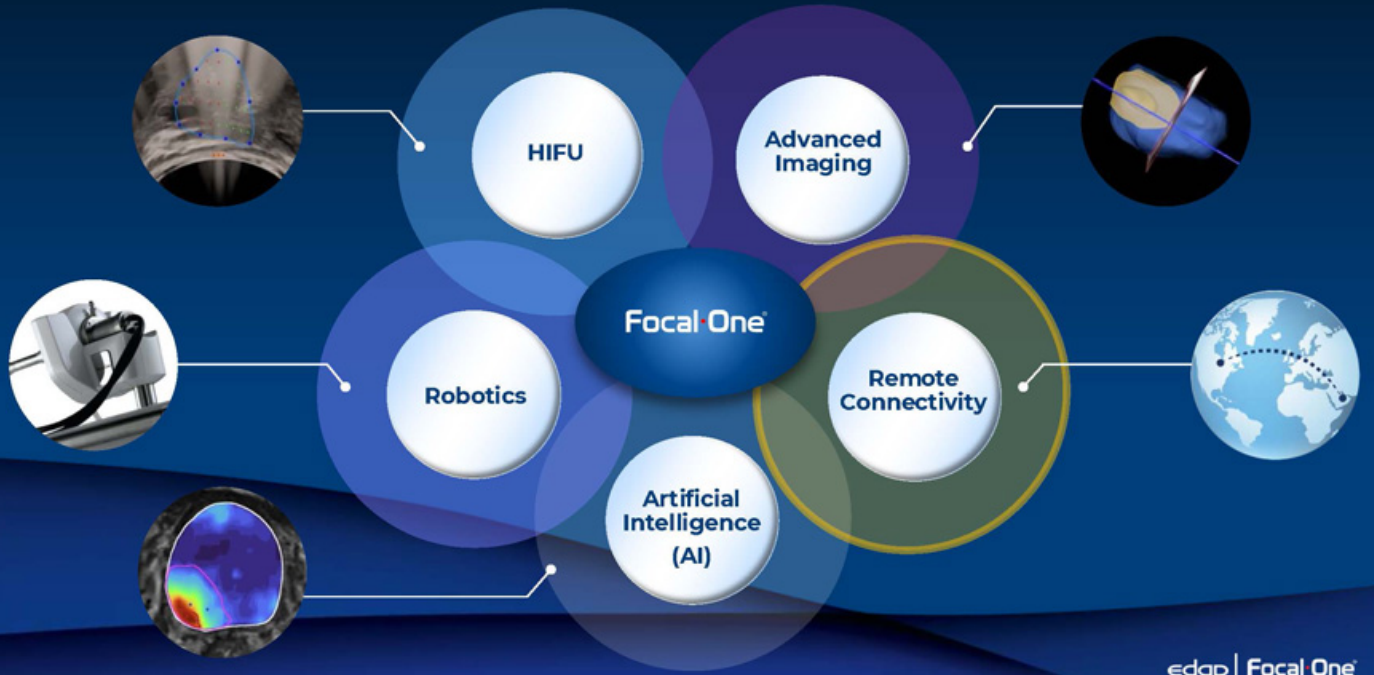
Image Guided
Treatment Planning



Precise Robotic
Delivered Ablation



Focal One® Core Technologies



The **Most Advanced Robotic HIFU**
Platform Controlled by Urologists

Focal One[®] *i*

- Expanded HIFusion[®] Capabilities
- Streamlined Treatment Workflows
- Embedded Video Content Library
- Treatment Streaming and Recording*
- Remote Proctoring & Telecollaboration*
- Endometriosis Treatment Ready*

HIFusion[®] Image-Guided Treatment Planning

MRI, PSMA PET
Unfold AI*, OnQ Prostate*
Koelis* and DynaCAD* 3D Biopsy

Precise Robotic Positioning

Multi-Axis Sub-millimeter Robotic Movements

Dynamic Focusing Probe

Auto-Adjusting Pinpoint Delivery
of HIFU Energy

Integrated Workstation

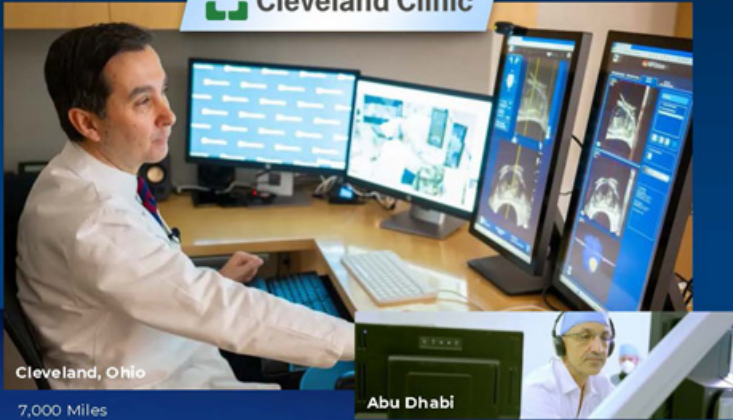
Compatible With
Standard OR Beds



Focal One® *i*

World's First **Focal One** Robotic HIFU
Transcontinental Telecollaboration

 Cleveland Clinic



Cleveland Clinic
Cleveland, Ohio

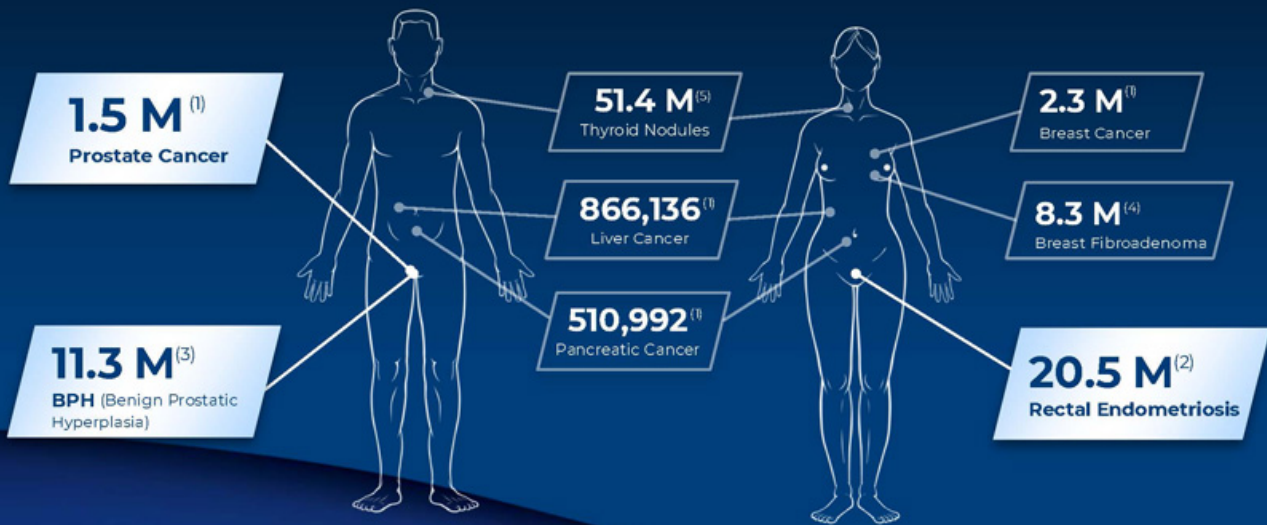
Cleveland Clinic
Abu Dhabi

BPH & Endometriosis

Large Market Opportunities For Expansion



HIFU Unlocks a Large Market Opportunity



⁽¹⁾ Newly Diagnosed Cases per year From World Health Organization - Globocan 2022

⁽²⁾ From WHO and Habib N et al. Bowel Endometriosis: Current Perspectives on Diagnosis and Treatment. Int J Womens Health. 2020

⁽³⁾ Xu et al. Global, Regional, and National Incidence and Year Lived with Disability for Benign Prostatic Hyperplasia from 1990 to 2019. Am J Mens Health. 2021

⁽⁴⁾ Based on UN Population Division and Goehring et al. Epidemiology of benign breast disease, with special attention to histologic types. Epidemiol Rev. 1997

⁽⁵⁾ Based on UN Population Division and Bomelli et al. Evaluation of a thyroid nodule. Otolaryngol Clin North Am. 2010

BENIGN PROSTATIC HYPERPLASIA
(BPH) MARKET

94 Million

Global cases of BPH in 2019 ⁽¹⁾

15 Million

U.S. men are affected by BPH/LUTS ⁽²⁾

600,000

U.S. men aged 65+ newly diagnosed annually ⁽³⁾

Leveraging Expertise in **Robotic HIFU**
and Prostate for **BPH**

12.2 Million men actively managed for BPH/LUTS:

- 55% under Drug Management ⁽⁴⁾
- 35% under Watchful Waiting ⁽⁴⁾
- 300,000+ Active Surgical Treatments ⁽⁵⁾

Focal One Robotic HIFU technology has the potential to provide a **non-invasive** option that can safely treat BPH-related symptoms while avoiding the side effects of standard surgical treatments.

10,000s PCa treatments constitute a robust foundation to build upon for a BPH strategy

(1) Fontahun et al. The Lancet Healthy Longevity. 2022
(2) Egan K.B. Urologic Clinics of North America. 2016
(3) Urologic Diseases in America. 2024. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases. 2024
(4) Vuichoud et al. Can J Urol. 2015
(5) Internal market estimate

Building High-Level Evidence in the Treatment of Benign Prostate Hyperplasia

Feasibility Study

Completed



- Monocentric Feasibility Study (9 patients)
- Confirmed Safety and potential for improvement of BPH-related symptoms

Phase I-II Study

Recruiting



- First Patients Treated
- Phase I: Three-center study HIFU dose escalation
- Phase II: Multi-center Study Safety and Efficacy of Final HIFU Parameters as defined in Phase 1

U.S. Study

Under IRB Review



- Protocol based on previous study findings

6.5 Million

US Women Have Endometriosis ⁽¹⁾

1.3 Million

20% of Cases are Deep Infiltrating Endometriosis (DIE) in the U.S.⁽²⁾

11% of U.S. Women

are Affected by Endometriosis ⁽²⁾

Common symptoms of Rectal Endometriosis may include various conditions (acute pelvic pain, constipation, diarrhea, rectal bleeding), all of which negatively impact quality of life and ability to become pregnant.

Current treatment options are lacking and limited to hormonal and/or surgical management

Focal One has the potential of offering a non-invasive option with the ability of **Reducing Symptoms** and **Improving Quality of Life**

Building High-Level Evidence in the Treatment of Deep Infiltrating Rectal Endometriosis

Phase I Study *Completed*



- Feasibility (20 patients)
- Published in the Journal of Ultrasound in Obstetrics and Gynecology in 2020

Phase II Study *Completed*



- Multicenter Safety and Efficacy Study (60 patients)
- Completed in March 2022
- Published in Journal of Human Reproduction in 2024

Phase III Study *Completed Enrollment*



- Multicenter Double-Blind Randomized Controlled Trial (RCT)
- Enrollment completed (60 patients)
- Follow-up of all patients in progress
- 85% of Sham Group patients elected and received HIFU Treatment

CE Mark March 25, 2025



- Focal One received **CE mark certification** for the treatment of posterior deep endometriosis infiltrating the rectum

Growing Global Install Base



FOCAL ONE IS THE LEADING FOCAL THERAPY TECHNOLOGY

Strong Adoption by the Highest Ranked Prostate Cancer Hospitals in the US



70%

7 Out of 10
Best Hospitals for Urology



54%

19 Out of 35
SUO Approved Programs



National
Comprehensive
Cancer
Network®

48%

16 Out of 33
NCCN Member Institutions

Key Financial Data



Financial Highlights as of June 30, 2025

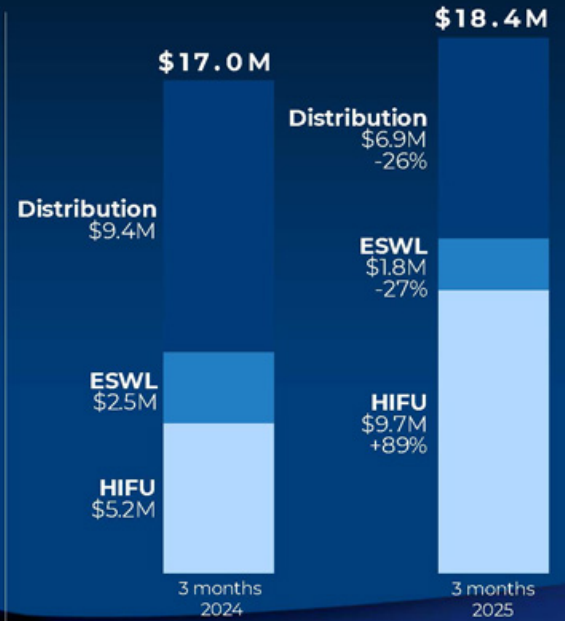
THREE MONTHS ENDED JUNE 30TH

(in \$Million USD except per share data)

| | 2024 | 2025 |
|---------------------------|--------|--------|
| Revenue | 17.0 | 18.4 |
| Gross Profit | 6.4 | 7.8 |
| Gross Margin | 37.5% | 42.5% |
| Operating Profit (Loss) | (6.6) | (6.6) |
| Net Income (Loss) | (6.6) | (6.4) |
| Earnings (Loss) Per Share | (0.18) | (0.17) |

1st Half 2022-2025 HIFU Business Key Metrics

- +29% HIFU Revenue CAGR**
- +50% Focal One US Install Base CAGR**
- +52% US Focal One Procedure CAGR**



NOTE: Translated for convenience of the reader to U.S. dollars at the 2025 average three months' exchange rate of 1 Euro = 1.1489 USD, and 2024 average three months' exchange rate of 1 Euro = 1.0747 USD

Balance Sheet Highlights as of June 30, 2025

| | Balance Sheet As Of: | |
|------------------------------------|----------------------|---------------|
| (in \$Million USD) | June 30, 2025 | June 30, 2024 |
| Cash and Cash Equivalents | 19.1 | 32.4 |
| Other Current Assets | 41.4 | 39.8 |
| Fixed and Other Non-Current Assets | 19.8 | 15.9 |
| | 80.4 | 88.0 |
| Current Liabilities | 40.2 | 29.4 |
| Non-Current Liabilities | 7.5 | 7.6 |
| Shareholders' Equity | 32.7 | 51.0 |
| | 80.4 | 88.0 |

Note: Translated for convenience of the reader to U.S. dollars at the exchange rate of 1 Euro = 1.1770 USD, on June 30, 2025 and at the exchange rate of 1 Euro = 1.0711 USD, on June 30, 2024.

SUMMARY

Positioned for Growth

- Large Addressable Markets in Men's and Women's Health
- Growing Install base of Leading Tier 1 Academic and Community Hospitals
- Differentiated Non-Invasive Robotic HIFU Technology Solving Unmet Needs for Prostate Cancer, BPH and Endometriosis
- Strong Clinical Evidence with Favorable Reimbursement in Place
- Proven Management Team from Industry-Leading MedTech Companies

INTUITIVE

Johnson & Johnson

stryker

Medtronic

Boston
Scientific

 GE HealthCare

edap | Focal·One®

The **Global Leader** in Therapeutic Ultrasound



EDAP | FOCAL ONE® - September 2025