UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 11, 2026

EDAP TMS S.A.

(Exact name of Registrant as specified in its charter)

France	**000-29374**	**98-1644844**
(State or other jurisdiction of incorporation)	**(Commission File No.)**	**(I.R.S. Employer Identification No.)**

Parc d'Activites la Poudrette-Lamartine
4/6, rue du Dauphiné
Vaulx-en-Velin, France 69120
(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: (+33) 47-215-3150

Not Applicable
(Former name or former address if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Trading Symbol(s)**	**Name of Each Exchange on Which Registered**
American Depositary Shares, each representing one Ordinary Share (Ordinary Shares, nominal value €0.13 per share)	FOCL	NASDAQ Global Market

Indicated by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging Growth Company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On August 11, 2026, EDAP TMS S.A. (the "Company") announced certain preliminary unaudited estimated financial results as of and for the six months ended June 30, 2026. This announcement was contained in a press release (the "Press Release"), a copy of which is attached as Exhibit 99.1 hereto. Such exhibit and the information set forth therein shall not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise be subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act.

The information set forth under Item 8.01 of this Current Report on Form 8-K is incorporated by reference in this Item 2.02.

Item 7.01 Regulation FD Disclosure.

The information set forth in Item 2.02 of this Current Report on Form 8-K pertaining to the Press Release is incorporated herein by reference.

Item 8.01 Other Events.

On August 11, 2026, the Company made a presentation (the "Investor Presentation") available on the "Investors" section of its website at www.focalone.com. The Investor Presentation is filed as Exhibit 99.2 hereto and is incorporated herein by reference.

Expansion into New Indications

Expansion into Benign Prostatic Hyperplasia (BPH)

The Company is advancing the evaluation of its Focal One Robotic HIFU platform for the potential treatment of benign prostatic hyperplasia ("BPH"). Based on published third-party estimates, more than 100 million men worldwide are living with BPH, with more than 13 million new cases diagnosed annually including over 600,000 in the United States. The Company believes its experience in robotic HIFU for prostate cancer may provide a foundation for developing a non-invasive treatment option for patients with BPH. The Company's BPH development program is currently focused on feasibility studies inside and outside the United States. In the United States, the feasibility study has received Institutional Review Board approval. Outside the United States, a multicenter feasibility study is underway.

Focal One has not been cleared or approved by the U.S. Food and Drug Administration (the "FDA") or any other regulatory authority for the treatment of BPH, and its use for that indication is investigational. There can be no assurance that the Company's BPH development program will be successful or that Focal One will receive regulatory clearance or approval for this indication.

Expansion into Endometriosis

The Company is also advancing development of the Focal One Robotic HIFU platform for the potential treatment of deep infiltrating endometriosis, a severe form of endometriosis for which treatment options are currently limited primarily to hormonal therapy and surgery. Based on published third-party estimates, approximately 38 million women worldwide are affected by deep infiltrating endometriosis, with more than 783,000 patients diagnosed annually including over 225,000 in the United States. The Company believes its robotic HIFU technology may provide a non-invasive treatment alternative, as opposed to current treatment options that are limited to hormone therapy and/or invasive surgery, designed to reduce symptoms and improve quality of life. Outside the United States, the Company's endometriosis program is progressing through ongoing clinical development, including a randomized controlled pivotal study, and the Company has initiated a limited commercial launch in Europe under its CE mark for this indication. In the United States, the Company received FDA Breakthrough Device Designation for this indication in 2024 and is evaluating long-term data generated from its European studies to inform its regulatory strategy.

Focal One has not been cleared or approved by the FDA for the treatment of deep infiltrating endometriosis, and its use for that indication in the United States is investigational. Breakthrough Device Designation provides for enhanced interaction with the FDA during development and review but does not guarantee or accelerate clearance or approval, and there can be no assurance that Focal One will receive clearance or approval for this indication.

Cautionary Statement on Forward-Looking Statements

In addition to historical information, this Current Report on Form 8-K contains forward-looking statements within the meaning of applicable federal securities laws, including Section 27A of the U.S. Securities Act of 1933 (the "Securities Act") or Section 21E of the U.S. Securities Exchange Act of 1934, as amended, including the information contained in the Press Release, the information contained in the Investor Presentation and the information concerning the new indications, which may be identified by words such as "believe," "can," "contemplate," "could," "plan," "intend," "is designed to," "may," "might," "potential," "objective," "target," "project," "predict," "forecast," "ambition," "guideline," "should," "will," "estimate," "expect" and "anticipate," or the negative of these and similar expressions, which reflect the Company's views about future events and financial performance. Such statements are based on management's current expectations and are subject to a number of risks and uncertainties, including matters not yet known to the Company or not currently considered material by the Company, and there can be no assurance that anticipated events will occur or that the objectives set out will actually be achieved. Important factors that could cause actual results to differ materially from the results anticipated in the forward-looking statements include, but are not limited to, uncertainties related to market conditions and those risks relating to the Company's business, which are described in the Company's filings with the SEC and in particular in the section "Risk Factors" in the Company's Annual Report on Form 10-K and Quarterly Report on Form 10-Q.

Forward-looking statements speak only as of the date they are made. Other than required by law, the Company does not undertake any obligation to update them in light of new information or future developments. These forward-looking statements are based upon information, assumptions and estimates available to the Company as of the date of this Current Report on Form 8-K, and while the Company believes such information forms a reasonable basis for such statements, such information may be limited or incomplete.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated August 11, 2026
99.2	Investor Presentation, dated August 11, 2026
104	Cover Page Interactive Data File-the cover page XBRL (embedded within the Inline XBRL document)

SIGNATURES

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

EDAP TMS S.A.

Date: August 11, 2026

By: /s/ Sanket Shah
Sanket Shah
General Counsel and Corporate Secretary

Exhibit 99.1

FocalTherics™ Reports Preliminary Financial Results for Second Quarter of 2026

AUSTIN, Texas, August 11, 2026 - FocalTherics™ (Nasdaq: FOCL) (the "Company"), a global leader in robotic focal therapy, today announced preliminary unaudited financial results for the Company's HIFU segment, reported as continuing operations, for the second quarter of 2026.

During the second quarter of 2026, the Extracorporeal Shock Wave Lithotripsy (ESWL) and Distribution segments met the criteria to be classified as held for sale under ASC 205-20, Presentation of Financial Statements — Discontinued Operations, and ASC 360-10, Property, Plant, and Equipment, and the Company determined that the planned exit represents a strategic shift that will have a significant effect on the Company's operations and financial results. Accordingly, the Company's unaudited financial results as of and for the three and six months ended June 30, 2026 reflect the Company's ESWL and Distribution operating segments as discontinued operations. The following reflect the Company's continuing operations (the Company's HIFU segment) for the second quarter of 2026:

- Revenue Between $12.7 and $13.2 million, Representing an Increase Between 34% and 39% from the Three Months Ended June 30, 2025
- Gross Margin Between 54% and 56%, Representing an Increase Between 3% and 5% from the Three Months Ended June 30, 2025

In addition, the Company reported cash, cash equivalents and short-term investments from all operations of $21.5 million as of June 30, 2026.

All figures reported above with respect to the second quarter of 2026 and as of June 30, 2026, are preliminary and are unaudited and subject to change and adjustment as the Company prepares its unaudited interim condensed consolidated financial statements for the three- and six-month periods ended June 30, 2026 and 2025. Accordingly, investors are cautioned not to place undue reliance on the foregoing information. The Company does not intend to provide preliminary results in the future. The preliminary results provided in this news release constitute "forward-looking information" and "forward-looking statements" within the meaning of U.S. securities laws, are based on several assumptions and are subject to a number of risks and uncertainties. Actual results may differ materially. See "Forward-looking Statements."

The Company intends to report full second quarter of 2026 financial results after market close on Thursday, August 13th and will hold a conference call at 4:30 pm ET that day to discuss results.

About FocalTherics

A recognized global leader in robotic focal therapy, FocalTherics develops, manufactures, and markets minimally invasive medical devices worldwide to treat various conditions using proprietary focused ultrasound technology. The Company's flagship platform, Focal One Robotic HIFU, combines advanced imaging, real-time treatment planning, robotic precision, and HIFU technology to deliver personalized focal therapy designed to optimize clinical outcomes while preserving quality of life.

Forward-Looking Statements

In addition to historical information, this press release contains forward-looking statements within the meaning of applicable federal securities laws, including Section 27A of the U.S. Securities Act of 1933 (the “Securities Act”) or Section 21E of the U.S. Securities Exchange Act of 1934, which may be identified by words such as “believe,” “can,” “contemplate,” “could,” “plan,” “intend,” “is designed to,” “may,” “might,” “potential,” “objective,” “target,” “project,” “predict,” “forecast,” “ambition,” “guideline,” “should,” “will,” “estimate,” “expect” and “anticipate,” or the negative of these and similar expressions, which reflect the Company’s views about future events and financial performance. Such statements are based on management's current expectations and are subject to a number of risks and uncertainties, including matters not yet known to the Company or not currently considered material by the Company, and there can be no assurance that anticipated events will occur or that the objectives set out will actually be achieved, and include statements such as the expected financial results for the three months ended June 30, 2026 and as of June 30, 2026. Important factors that could cause actual results to differ materially from the results anticipated in the forward-looking statements include, among others, the clinical status and market acceptance of the Company’s HIFU devices and the continued market potential for the Company’s ESWL and Distribution divisions, as well as risks associated with the current worldwide inflationary environment, the uncertain worldwide economic, political and financial environment, geopolitical instability, climate change and pandemics, or other public health crises, and their related impact on the Company’s business operations, including their impacts across the Company’s businesses or demand for its devices and services.

Other factors that may cause such a difference may also include, but are not limited to, those described in the Company's filings with the Securities and Exchange Commission and in particular, in the sections "Cautionary Statement on Forward-Looking Information" and "Risk Factors" in the Company's Annual Report on Form 10-K and Quarterly Report on Form 10-Q.

Forward-looking statements speak only as of the date they are made. Other than required by law, the Company does not undertake any obligation to update them in light of new information or future developments. These forward-looking statements are based upon information, assumptions and estimates available to the Company as of the date of this press release, and while the Company believes such information forms a reasonable basis for such statements, such information may be limited or incomplete.

Investor Contact
Louisa Smith
Gilmartin Group
investor.relations@focalone.com

FocalTherics™

Global Leader in Therapeutic Ultrasound

Statements & Disclaimer

This presentation has been prepared by EDAP TMS S.A. ("EDAP," "EDAP TMS," the "Company," "we" or "us" or "our"). This presentation, and its contents and the accompanyin discussion with management are confidential and may not be further copied, distributed or passed on, directly or indirectly, to any other person or published or reproduced or indirectly, in whole or in part, by any medium or in any form for any purpose without the Company's prior written consent. The recipient should not construe the contents presentation as legal, tax, accounting, investment advice or recommendation or business, financial or related advice. The recipient should consult its own counsel and tax ar financial advisors as to legal and related matters concerning the matters described in this presentation. This presentation does not purport to be all-inclusive or to contain a information that the recipient may require. To the maximum extent permitted by law, none of the Company, its representatives, nor any other person accepts any liability, ir without limitation, any liability arising out of fault or negligence for any loss arising from the use of the information contained in this presentation.

Forward-Looking Statements

This presentation (including oral commentary that accompanies this presentation) contains forward-looking statements, including statements related to our business, prod trials. Any statements about our expectations, beliefs, plans, predictions, forecasts, objectives, assumptions, or future events or performance are not historical facts and may forward-looking. In some cases, you can identify forward-looking statements through the use of words such as "believe," "can," "contemplate," "could," "plan," "intend," "may, "potential," "objective," "target," "project," "predict," "forecast," guideline," "should," "will," "would," "estimate," "expect," and "anticipates," or similar expressions. Although we b that the expectations reflected in these forward-looking statements are reasonable, these statements are not guarantees of future performance and involve risks and uncer which are subject to change based on various important factors, some of which are beyond our control. Important factors that could cause actual results to differ materially results anticipated in the forward-looking statements include, among others, the clinical status and market acceptance of our HIFU devices and the continued market pote our lithotripsy and distribution divisions, as well as risks associated with the current worldwide inflationary environment, the uncertain worldwide economic, political and fin environment, geopolitical instability, climate change and pandemics, or other public health crises, and their related impact on our business operations, including their impa our businesses or demand for our devices and services, and the other risks described in our Annual Report on Form 10-K for the year ended December 31, 2025, our Quarterl on Form 10-Q for the quarter ended March 31, 2026, and the other filings we make with the Securities and Exchange Commission. Should one or more of these risks or uncer materialize or should any of these assumptions prove to be incorrect, our actual future results, performance and events and circumstances may differ in material respects fr performance projected in these forward-looking statements. The forward-looking statements included in this presentation are made only as of the date hereof. The Compar not undertake any obligation to update any forward-looking statements for any reason after the date of this presentation to conform these statements to actual results or to in the Company's expectations, except as may be required by law. Accordingly, the Company cautions you not to place any undue reliance on any forward-looking statemer

Industry Data

This presentation also includes data, forecasts and information obtained from industry publications and other information available to us. Some data is also based on our go estimates, which are derived from management's knowledge of the industry and independent sources. We have not independently verified any of the data from third-party nor have we ascertained the underlying assumptions relied upon therein. While we are not aware of any misstatements regarding the industry data presented herein, estim forecasts involve uncertainties and risks and are subject to change based on various factors.


FocalTherics™
• Rebranded to **FocalTherics (NASDAQ: FOCL)**
• Executed Successful NASDAQ MarketSite Investor Day on June 1
• Announced Core Focus on High-Growth Robotic Focal Therapy
• Shift of Reporting Legacy Non-Core ESWL and Distribution Financia
To Discontinued Operations Effective Q2'26
FocalTher

FocalTherics™

Global Leader in Therapeutic Ultrasound

Redefining the Treatment of Cancer and Benign Disease through Organ Sparing, Function Preserving Focal Therapy

Preliminary Q2'26 Financial Results & Key Business Upda

Preliminary Q2'26 Financial Results	
HIFU Revenue	$12.7M – $13.2M *+34% - +39% YoY Growth*
HIFU Capital Sales	13 Focal One System Sales *+44% YoY Growth*
Global HIFU Installed Base	184 Focal One Systems *+38 vs. 146 in Q2'25*
Focal One U.S. Procedure Volume	+47% YoY Growth
HIFU Gross Margin	54% – 56% *+3% - +5% YoY Growth*
Operating Profit / (Loss)	($8.5M) – ($7.5M)
Cash	$21.5M*

Note: Financial results above reflect preliminary unaudited results.

* In April 2026, the Company drew €12.0M in Tranche B borrowings from its EIB credit facility

Growing Commercial Momentum:

- ✓ Strong commercial execution with record second quarte HIFU Revenue
- ✓ Accelerated adoption across leading hospital networks w four additional health systems purchasing a second or subsequent system during the quarter
- ✓ Growing international expansion with new installations a Imperial College Healthcare NHS Trust London, Nice Univ Hospital, and leading centers in India

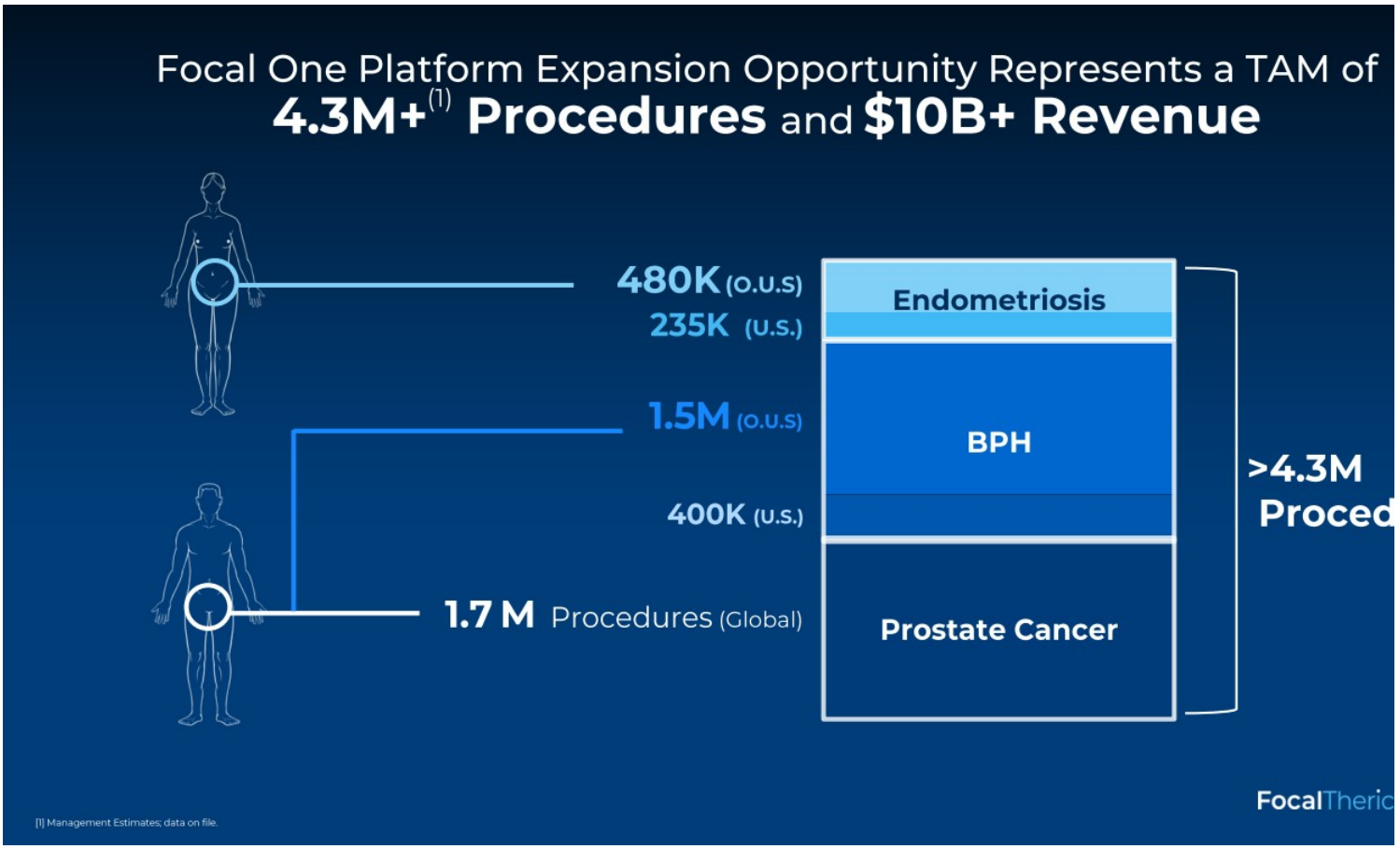
Expanding Opportunity Across Multiple Indicatior with Single Focal One Robotic Platform:

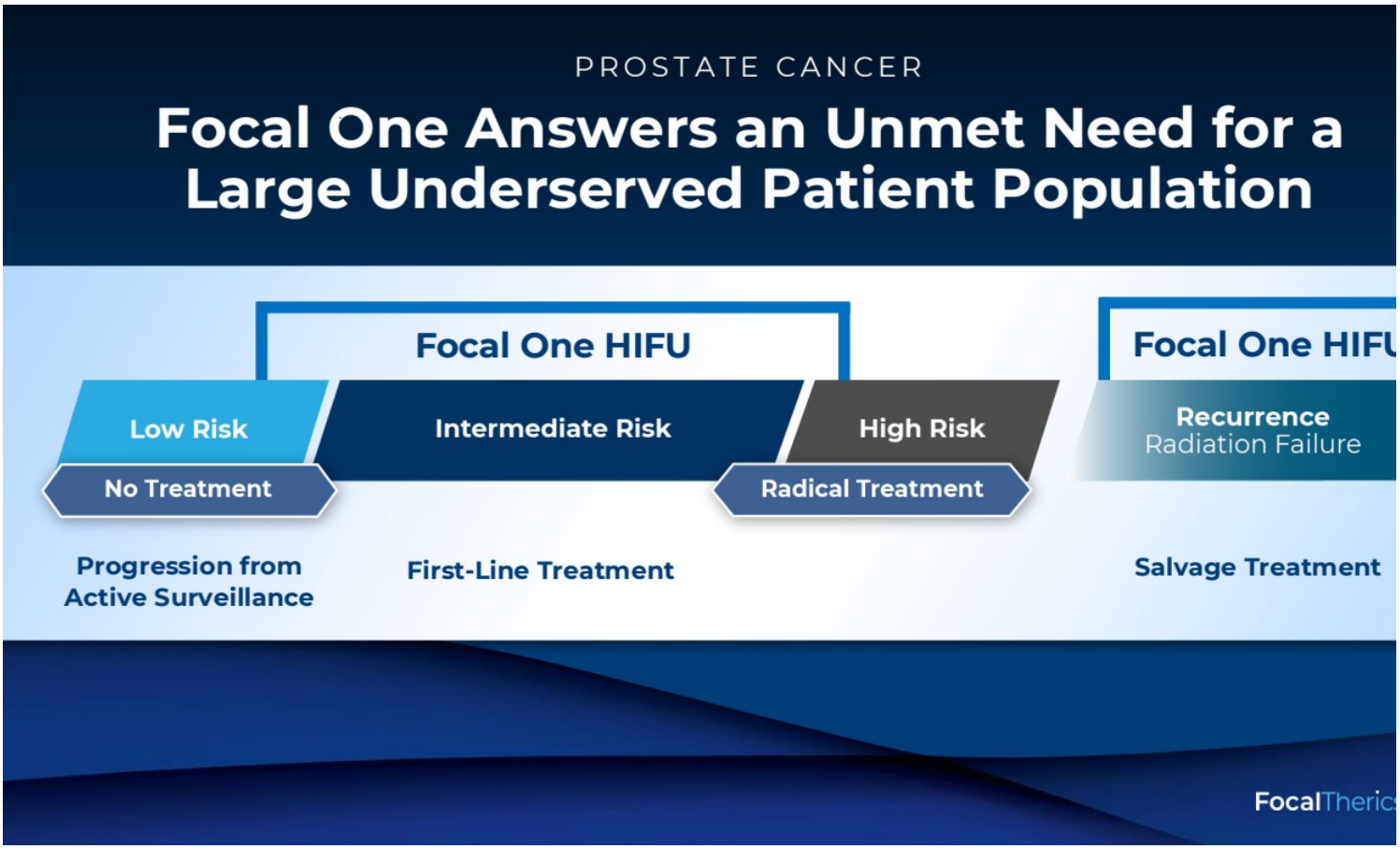
- ✓ 4 consecutive annual reimbursement increases for HIFU Prostate Cancer with proposed +11.6% 2027 OPPS
- ✓ Entering large endometriosis opportunity with launch of commercial program at Toulouse University Hospital
- ✓ Advancing BPH clinical development with parallel on-go international studies and approved IRB in the U.S.
- ✓ Continued development of proprietary Focal One-based histotripsy technology

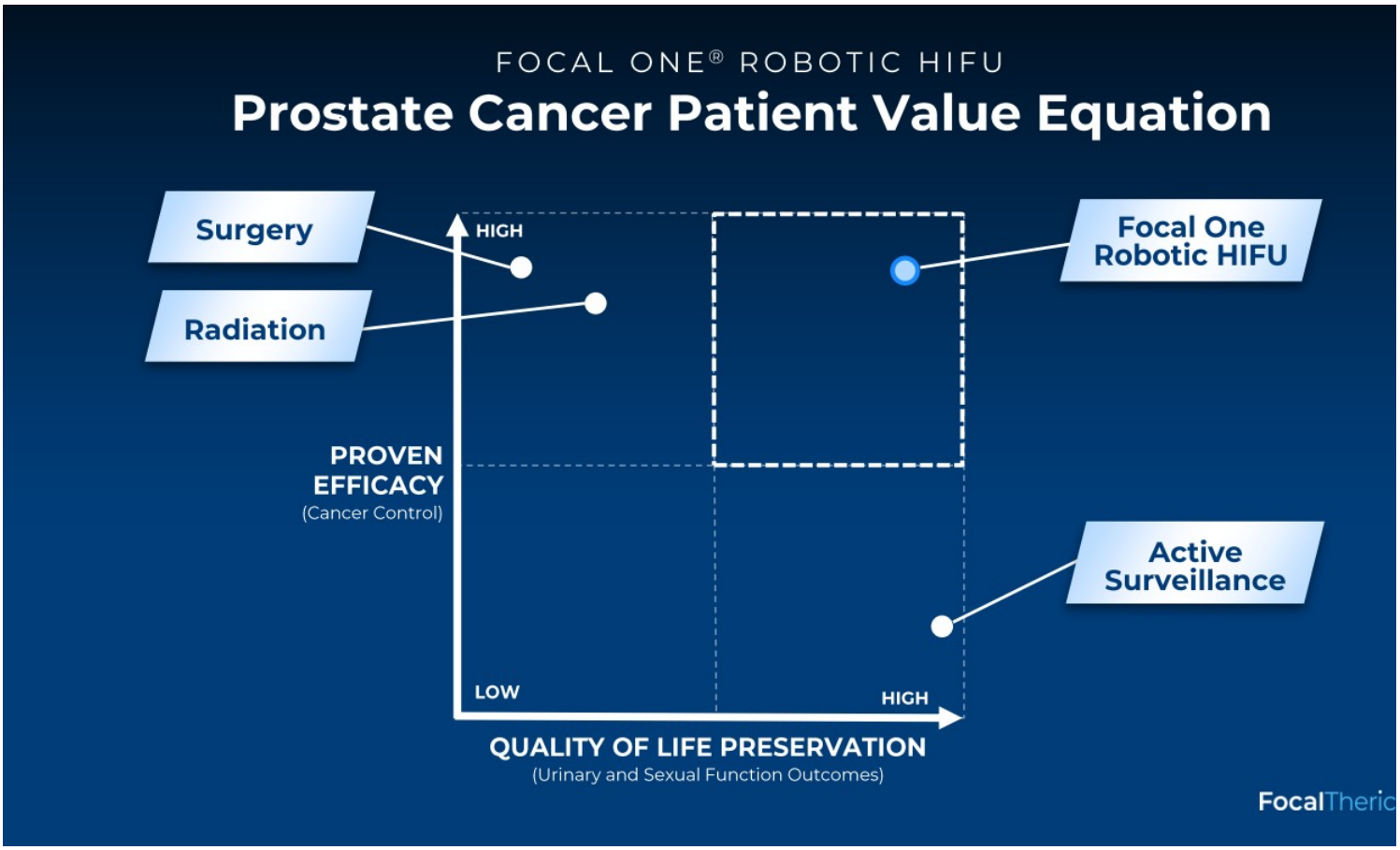
FocalTheric

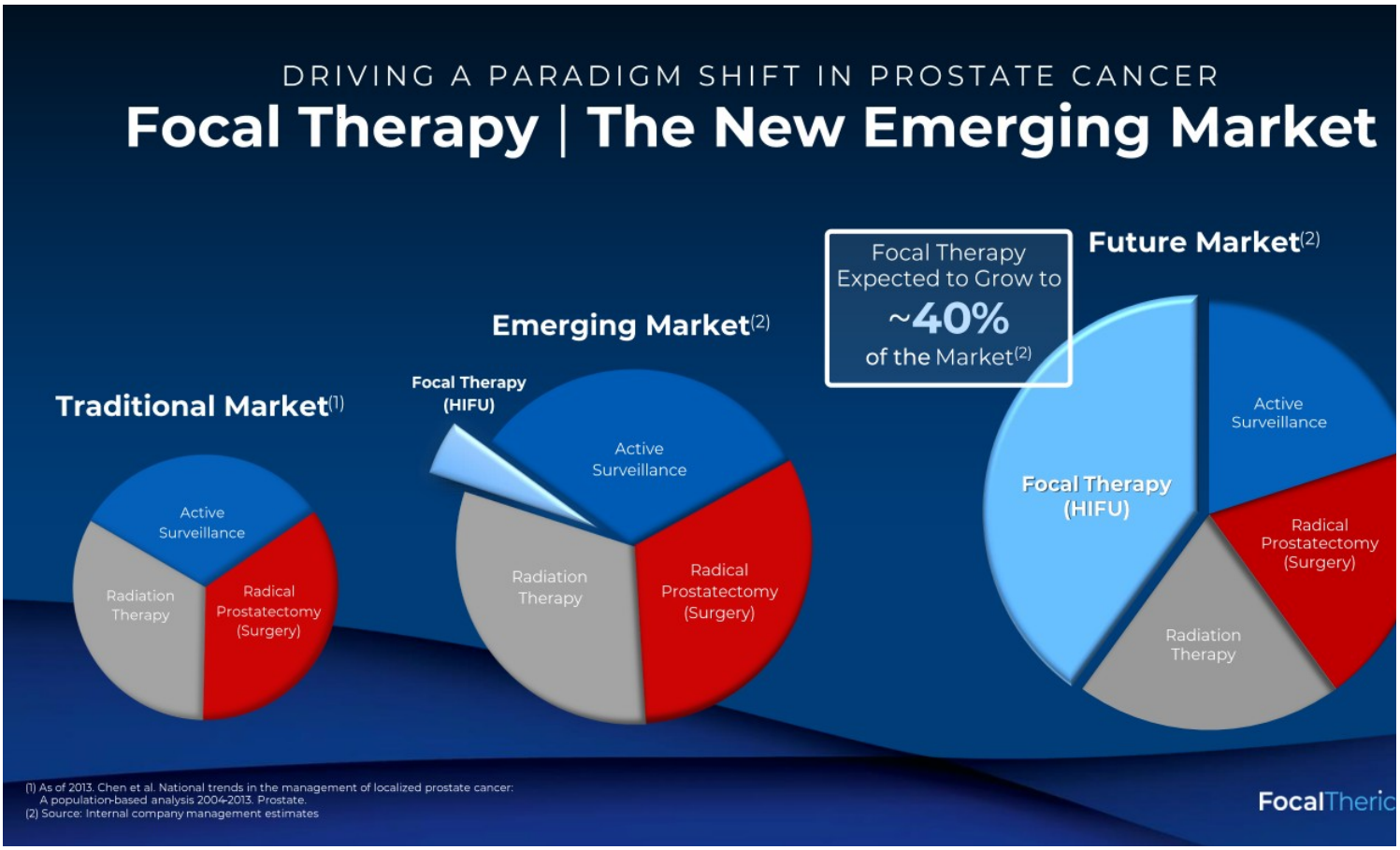
FocalTherics™

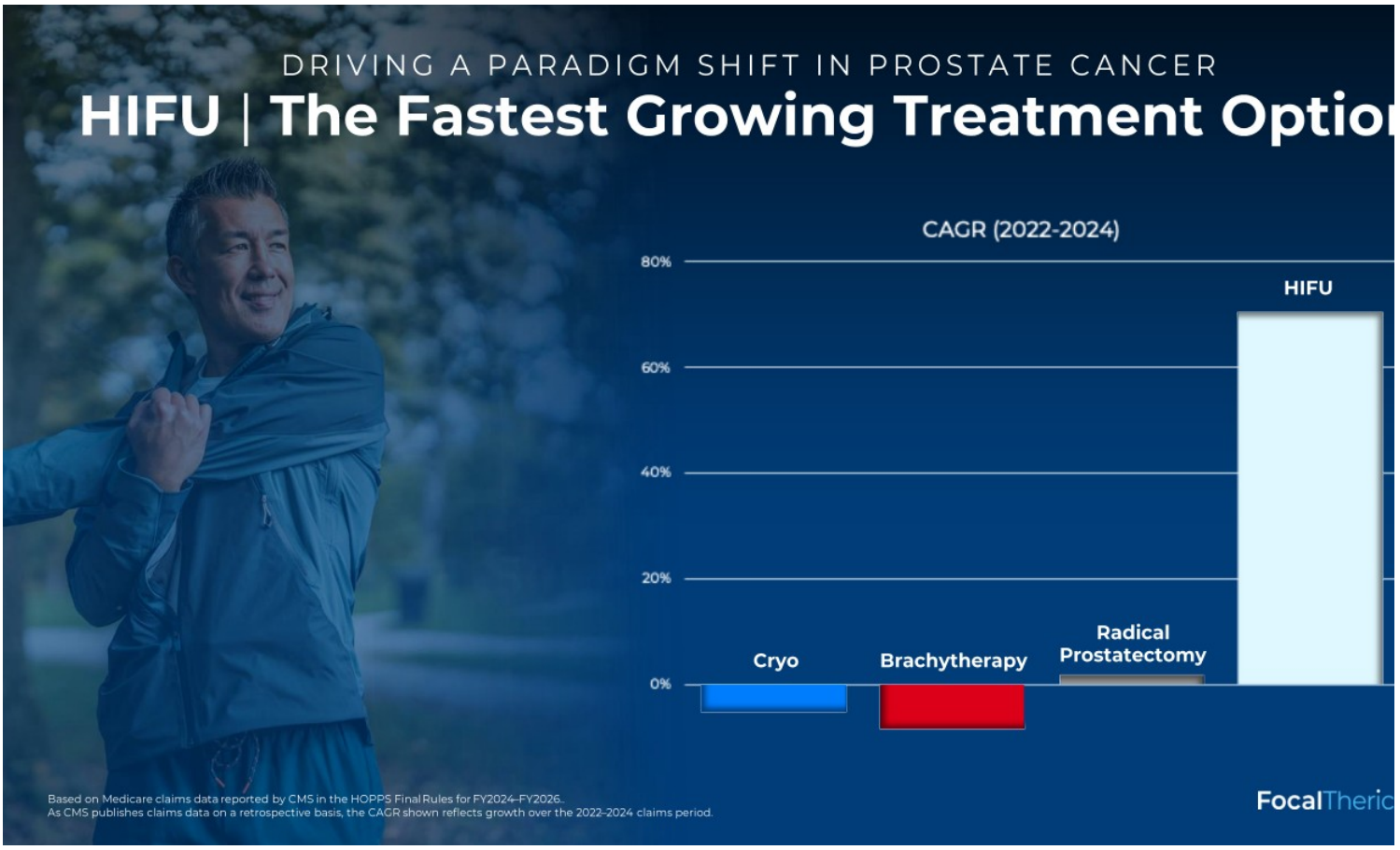
Large and Growing Market Opportunitie In Prostate Cancer, BPH and Endometriosis


Focal One Platform Expansion Opportunity Represents a TAM of
4.3M+(1) Procedures and $10B+ Revenue
480K (O.U.S)
235K (U.S.)
1.5M (O.U.S)
400K (U.S.)
1.7 M Procedures (Global)
Endometriosis
BPH
Prostate Cancer
>4.3M
Proced
[1] Management Estimates; data on file.


PROSTATE CANCER
Focal One Answers an Unmet Need for a Large Underserved Patient Population
Focal One HIFU
Low Risk
Intermediate Risk
High Risk
No Treatment
Radical Treatment
Focal One HIFU
Recurrence
Radiation Failure
Progression from Active Surveillance
First-Line Treatment
Salvage Treatment
FocalTherics


FOCAL ONE® ROBOTIC HIFU
Prostate Cancer Patient Value Equation
Surgery
Radiation
Focal One Robotic HIFU
Active Surveillance
HIGH
PROVEN EFFICACY
(Cancer Control)
LOW
HIGH
QUALITY OF LIFE PRESERVATION
(Urinary and Sexual Function Outcomes)
FocalTheric


DRIVING A PARADIGM SHIFT IN PROSTATE CANCER
Focal Therapy | The New Emerging Market
Traditional Market(1)
Active Surveillance
Radiation Therapy
Radical Prostatectomy (Surgery)
Emerging Market(2)
Focal Therapy (HIFU)
Active Surveillance
Radiation Therapy
Radical Prostatectomy (Surgery)
Focal Therapy Expected to Grow to ~40% of the Market(2)
Future Market(2)
Active Surveillance
Focal Therapy (HIFU)
Radical Prostatectomy (Surgery)
Radiation Therapy
(1) As of 2013. Chen et al. National trends in the management of localized prostate cancer: A population-based analysis 2004-2013. Prostate.
(2) Source: Internal company management estimates
FocalTherap

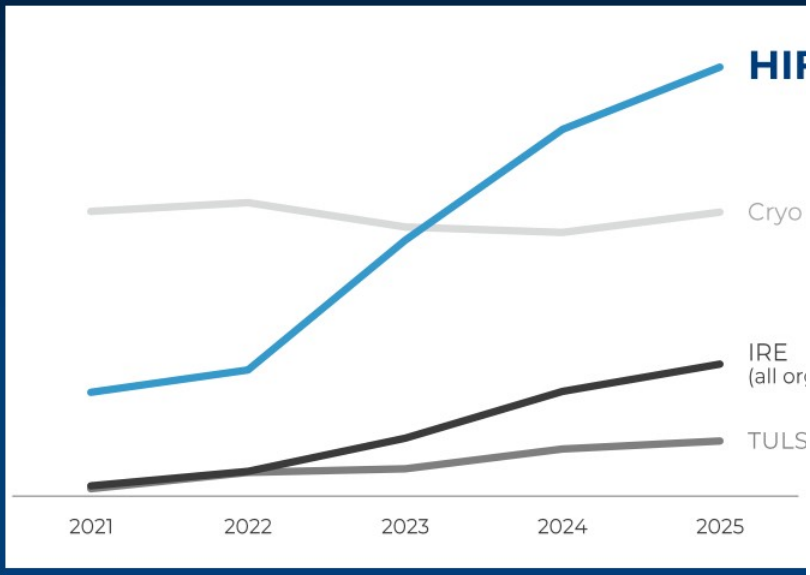

DRIVING A PARADIGM SHIFT IN PROSTATE CANCER
HIFU | The Fastest Growing Treatment Optio
CAGR (2022-2024)
80%
60%
40%
20%
0%
HIFU
Radical Prostatectomy
Brachytherapy
Cryo
Based on Medicare claims data reported by CMS in the HOPPS Final Rules for FY2024–FY2026.
As CMS publishes claims data on a retrospective basis, the CAGR shown reflects growth over the 2022–2024 claims period.
FocalTheric

PROSTATE CANCER TREATMENT MODALITIES

Ablation Therapy Market Share

Fastest Growing
Focal Therapy Treatment[1]

#1 Ablation Technology
for Prostate Cancer

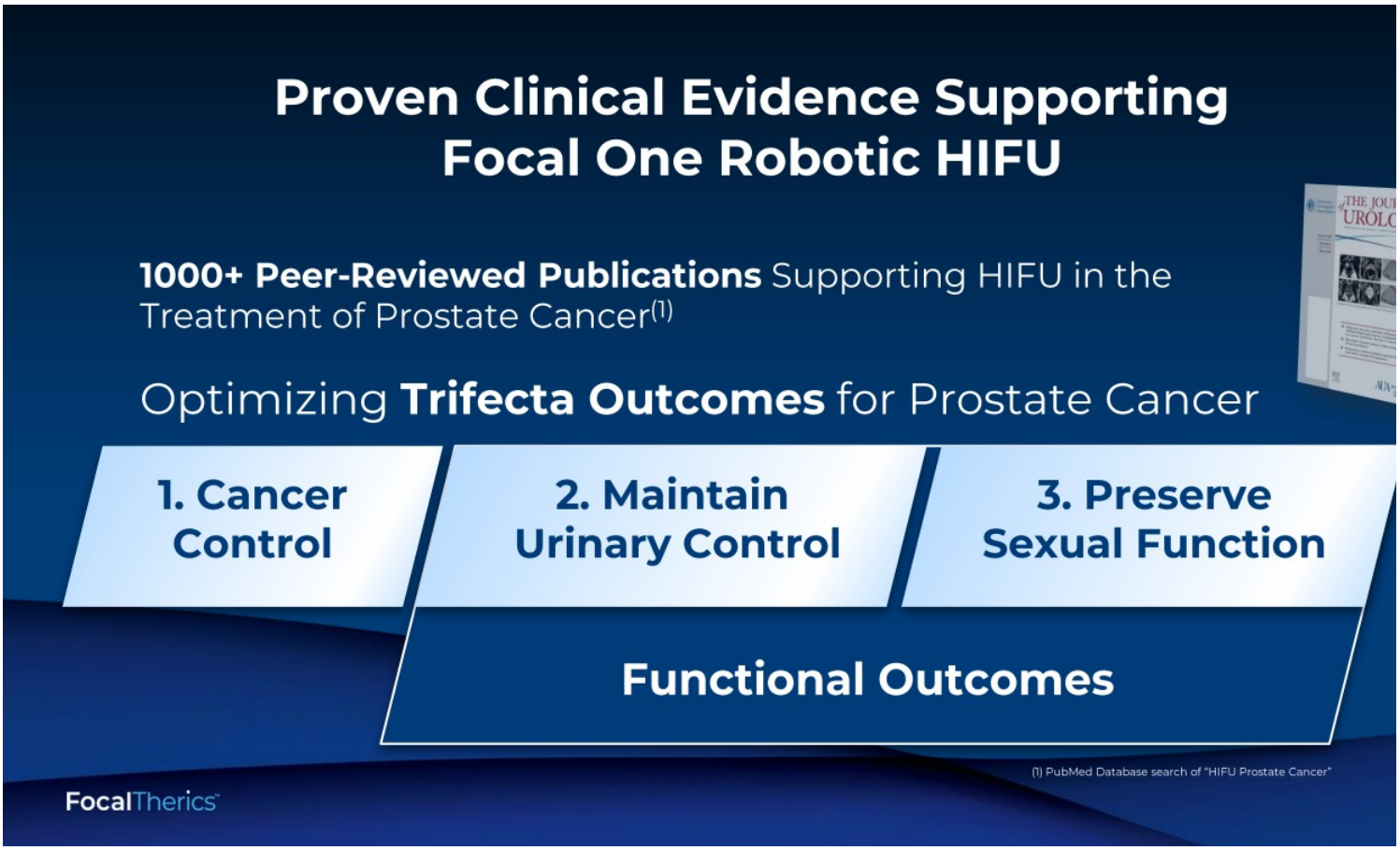


[1] Based on Medicare claims utilization data published by CMS in connection with the Hospital Outpatient Prospective PaymentSystem (HOPPS) Proposed Rules for CY 2023-CY 2027.
[2] IRE and TULSA treatment volumes may include procedures other than prostate cancer treatment, as applicable billing codes are not historically prostate-specific.

FocalTher

FocalTherics™

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
(1) PubMed Database search of "HIFU Prostate Cancer"
FocalTherics

Prostate Cancer Treatment Comparison[1]

Focal One HIFU Provides an Optimal Organ-Preserving Patient Treatment

		ORGAN-PRESERVING STRATEGY		WHOLE-GLAND RADICAL TREATMENT STRATEG	
		Active Surveillance	**Focal One® Robotic HIFU**	**Radiation**	**Surgery** Radical Prostatectom
CANCER CONTROL	**10-year Cancer Specific Survival**	N/A	**95%**[2]	91%[2]	99%[3]
QUALITY OF LIFE FUNCTIONAL OUTCOMES	**Continence Preservation**	96%[4]	**98%**[6]	96%[4]	75%[4]
	Erectile Function Preservation	82%[4]	**90%**[7]	69%[4]	49%[4]
	Ejaculation Preservation	-	**96%**[8]	28%[5]	0%
PATIENT BURDEN	**Risk of Complications**	Low	**Low**	Medium	High
	Typical Complications	-	**-**	Radiation Toxicity, Risk of Secondary Cancers	Blood Loss and Other Surgical Complications
	Treatment Process	-	**1 Session, Same Day Outpatient Procedure**	45 Sessions 45 Visits	1 Session 1-Day Hospital Stay

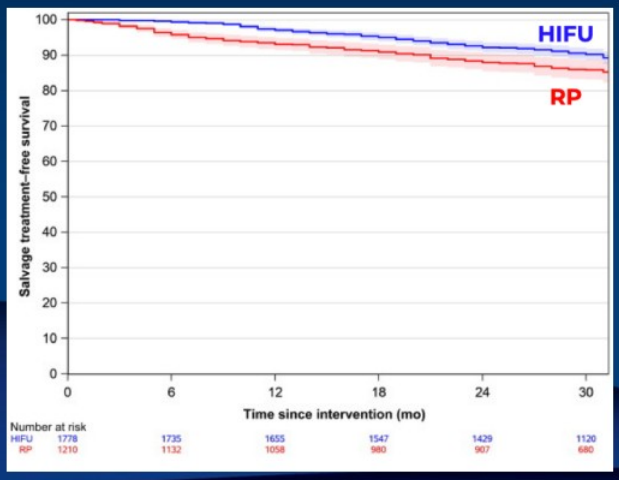
(*) Hospital stay duration for radical prostatectomy

[1] Data compiled from separate published studies; not a head-to-head comparison
[2] Yeh, HT et al. 10-year oncological outcomes of EBRT versus HIFU for stage II prostate cancer: a multicenter Chang Gung research database (CGRD) study with inverse-probability-of-treatment weighting (IPTW) analysis.Int Urol Nephrol (2025).
[3] Stensland, KD et al. National Long-term Survival Estimates After Radical Prostatectomy for Prostate Cancer. Urology. 2024 Feb;184:135-141.
[4] Donovan, JL, et al. Patient-Reported Outcomes after Monitoring, Surgery, or Radiotherapy for Prostate Cancer. N Engl J Med. 2016 Oct 13.
[5] Sullivan JF et al. Ejaculation profiles of men following radiation therapy for prostate cancer. J Sex Med. 2013 May;10(5):1410-6.
[6] Arnouil, N., et al. "Traitement focal par HIFU versus prostatectomie radicale robot-assistée pour cancer de la prostate localisé: résultats carcinologiques et fonctionnels à 1 an." Progrès en Urologie 28.12 (2018): 603-610.
[7] Haddad et al. Focal high-intensity focused ultrasound for localized prostate cancer: A single-centre experience. CUAJ • May-June 2016 • Volume 10(5-6Suppl)
[8] von Hardenberg J et al. Prostate cancer treatment by the latest focal HIFU device with MRI/TRUS-fusion control biopsies: A prospective evaluation. Urologic Oncology: Seminars and Original Investigations, Volume 36, Issue 9, 2018, Pages 401.e1-401.e9

FocalThe

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

Published in European Urology – December 2024



Prospective, Comparative, Multicentric, non-inferiority clinical t
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 at 30 months (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

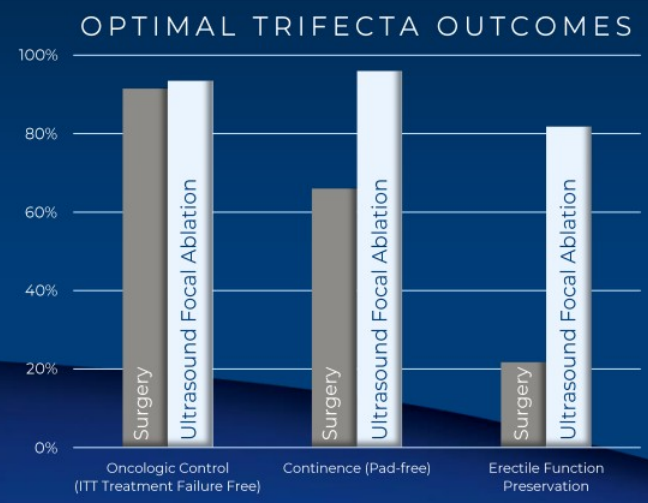
Ploussard et al. "Whole-gland or Subtotal High-intensity Focused Ultrasound Versus Radical Prostatectomy: The Prospective, Noninferiority, Nonrandomized HIFI Trial." European urology vol. 87,5 (2025): 526-533. doi:10.1016/j.eururo.2024.11.006

*STFS = Salvage Treatment Free Survival

FocalTheric

FARP - Randomized Controlled Trial
Focal Ablation vs Radical Prostatectomy

Final Results Presented at AUA 2025



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

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

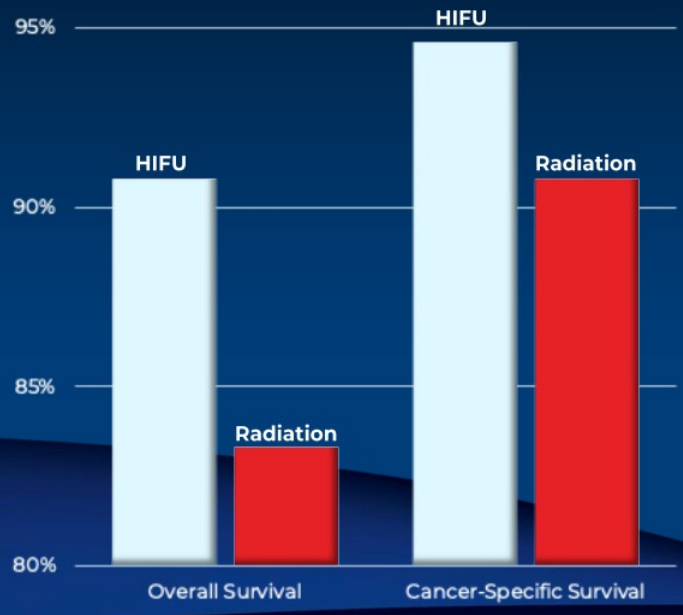
80+% of Focal Ablation patients treated with Focal One®

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

FocalTheric

HIFU Demonstrates Equivalent 10-year Survival to Radiation Therapy



10-year Oncological Outcomes of HIFU vs EB

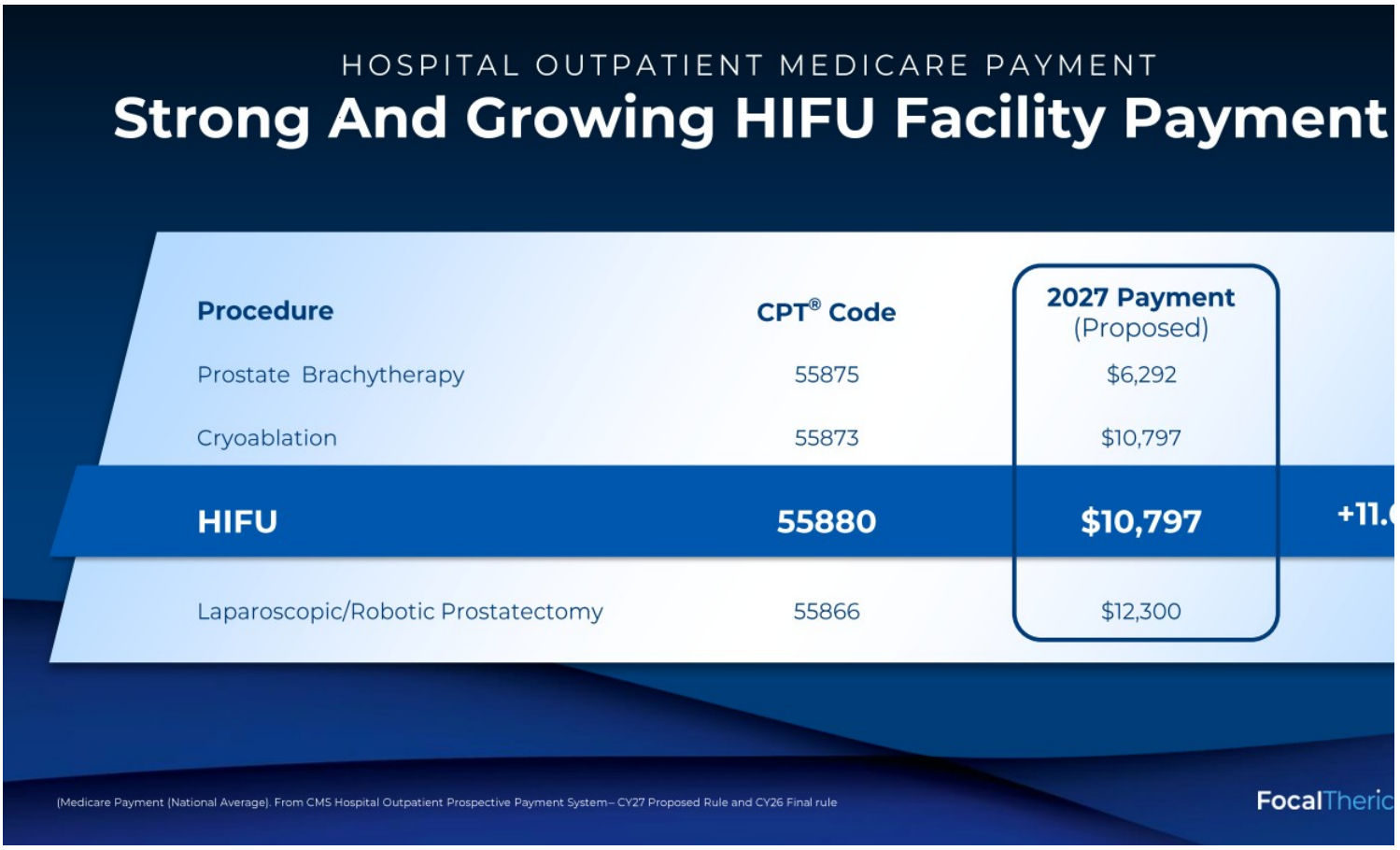
- **Lower Mortality** at 10 years post HIFU (9.
  compared to EBRT (16.7%)
- **Lower Cancer-Specific Mortality** after H
  (5.4%) compared to EBRT (9.2%)

[1] Yeh, HT., Liu, YY., Chang, Y.L. et al. 10-year oncological outcomes of EBRT versus HIFU for stage II prostate cancer: a multicenter Chang Gung research database (CGRD) study with inverse-probability-of-treatment weighting (IPTW) analysis. Int Urol Nephrol (2025). https://doi.org/10.1007/s11255-025-04805-7

FocalTheric

FocalTherics™

Strong Hospital and Physician Reimbursement


HOSPITAL OUTPATIENT MEDICARE PAYMENT
Strong And Growing HIFU Facility Payment
Procedure
CPT® Code
2027 Payment (Proposed)
Prostate Brachytherapy
55875
$6,292
Cryoablation
55873
$10,797
HIFU
55880
$10,797
+11.
Laparoscopic/Robotic Prostatectomy
55866
$12,300
(Medicare Payment (National Average). From CMS Hospital Outpatient Prospective Payment System– CY27 Proposed Rule and CY26 Final rule
FocalTheric

Favorable HIFU Physician Payment

HIFU Provides the Highest Physician Payment Amongst Focal Ablation Treatments For Prostate C

Procedure	CPT® Code	Work RVU (2026)	Physician Payment (Medicare - 2026)
Prostate Brachytherapy	55875	13.12	$693
Cryoablation	55873	13.26	$692
MRI Transurethral Ultrasound Ablation (TULSA)	55882	11.21	$530
Irreversible Electroporation (IRE)	55877	13.50	$675
HIFU	**55880**	**17.29**	**$884**
Laparoscopic/Robotic Prostatectomy	55866	21.90	$1,087

Based on CMS Physician Fee Schedule – CY 2026 Final rule

FocalTheric

FocalTherics™

Expanding Clinical Indications

Focal·One® i

Single Platform, Multiple Indications

- Prostate Cancer
- Benign Prostatic Hyperplasia (BP
- Deep Infiltrating Endometriosis

Focal One is currently being evaluated in a clinical study for treatment of benign prostatic hyperplasia (BPH). Not Available for Sale in U.S.
Focal One has received CE Mark for Treating Deep Infiltrating Endometriosis. Not Available for Sale in U.S.

FocalTher

Benign Prostatic Hyperplasia

100M+[1]

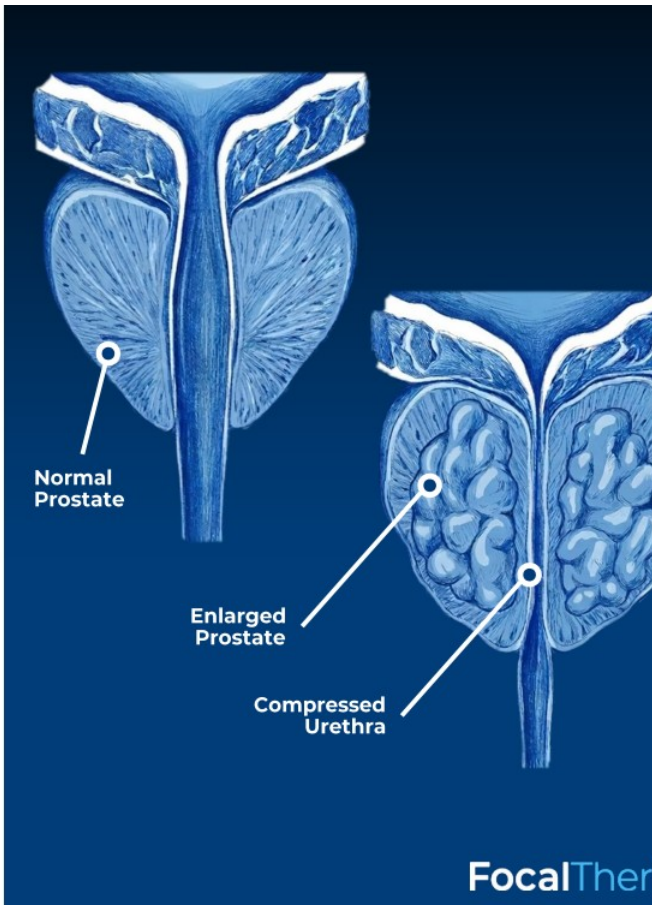
Men Living with BPH Globally

13M+[1]

New Cases Diagnosed Annually, Globally

600,000+[2]

New Cases Diagnosed in the U.S.



[1] Chen X, Yang S, He Z, Chen Z, Tang X, Lin Y, Huang Y, Hou J, Wei X. Comprehensive analysis of the global, regional, and national burden of benign prostatic hyperplasia from 1990 to 2021. Sci Rep. 2025 Feb 15;15(1):5644. doi: 10.1038/s41598-025-90229-3. PMID: 39955408; PMCID: PMC11830103.
[2] Urologic Diseases in America. 2024. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases. 2024

Focal One® Robotic HIFU is Favorably Positioned to Capture Market Share in Highly Fragmented BPH Treatment Category

Promising Clinical Advantages

- Non-Invasive, Urethra-sparing
- No Bleeding
- No Foreign Body
- No Impairment of Sexual or Ejaculatory Function

Potential For a Straightforward Regulatory Pathway

- Leverages Existing Prostate Tissue Ablation Indication
- New CPT Category 3 Code Specific to Transrectal HIFU for BPH

A Favorable Blueprint for Rapid Growth and Commercial Success

- Same Focal One Platform
- Leverages Growing Install Base
- Expands Clinical Utility of Hospital's Capital Investment
- Same Urology Call Point
- Existing Trained Physicians & Staff

FocalTher

Deep Infiltrating Endometriosis

38M

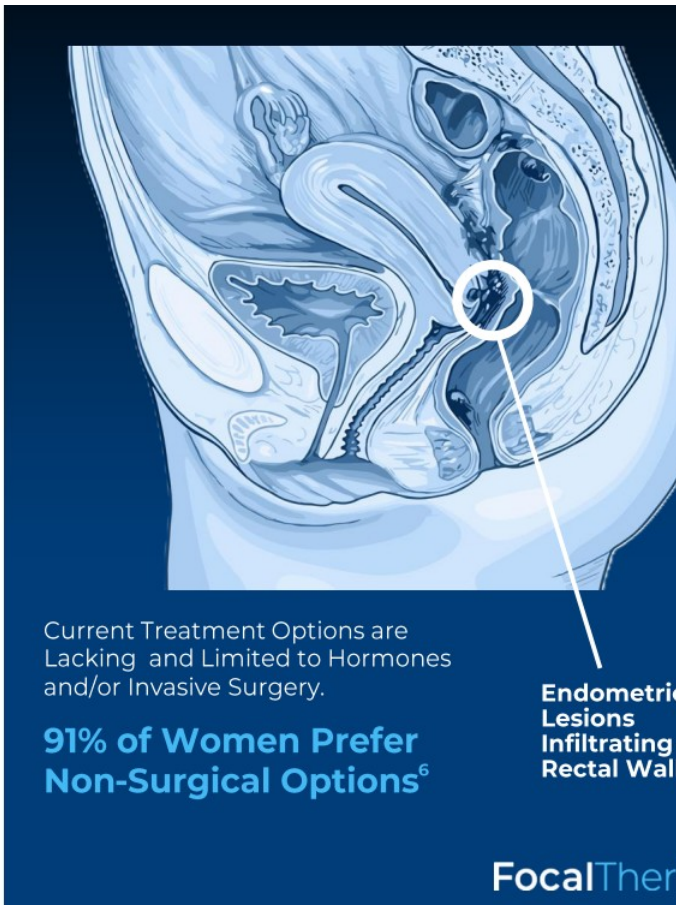
Women Living with Deep Infiltrating Endometriosis Globally[1,2,3,4,5]

783,000+

Patients Diagnosed with Deep Rectal Endometriosis Globally[1,2,3,4,5]

225,000+

Patients Diagnosed with Deep Rectal Endometriosis in U.S.[1,2,3,4,5]



[1] Abrão MS, Petraglia F, Falcone T, Keckstein J, Osuga Y, Chapron C. Deep endometriosis infiltrating the recto-sigmoid: critical factors to consider before management. Human Reproduction Update, 2015; 21(3):329-339. [2] Wenwei Li, Huiyan Feng, Qingjian Ye. Factors contributing to the delayed diagnosis of endometriosis — a systematic review and meta-analysis. Frontiers in Medicine, 2025; doi 10.3389/fmed.2025.1576490. [3] Agarwal SK, Chapron C, Giudice LC, et al. Clinical diagnosis of endometriosis: a call to action; underdiagnosis estimated at up to 60%. Della Corte L et al, 2020; cited in scoping review 2024. [4] United Nations, Department of Economic and Social Affairs, Population Division. World Population Prospects 2024. Women aged 15-49 by country, 2024 mid-year estimates. [5] Internal Company estimates and calculations based upon publicly available data [6]Vercellini P, et al. "You can't always get what you want": from doctrine to practicability of study designs for clinical investigation in endometriosis. BMC Womens Health. 2015 Oct 22;15:89.doi: 10.1186/s12905-015-0248-4. PMID: 26490454; PMCID: PMC4618787.

Focal One® Robotic HIFU Solves an Unmet Need in Women's Health

Promising Clinical Advantages

- No Surgery
- No Incision
- No Blood Loss
- Quick Return to Normal Activities

Key Regulatory Milestones

- Active CE Mark
- Commercial Launch initiated in 5 countries
- FDA-Granted Breakthrough Device Designation

Potential Growth Driver for Increased System Sales and Procedures

- Expands Use of Focal One into Women's Health
- Same Focal One Platform
- Leverages Growing Install Base
- Increases Hospital's ROI on Capital Investment

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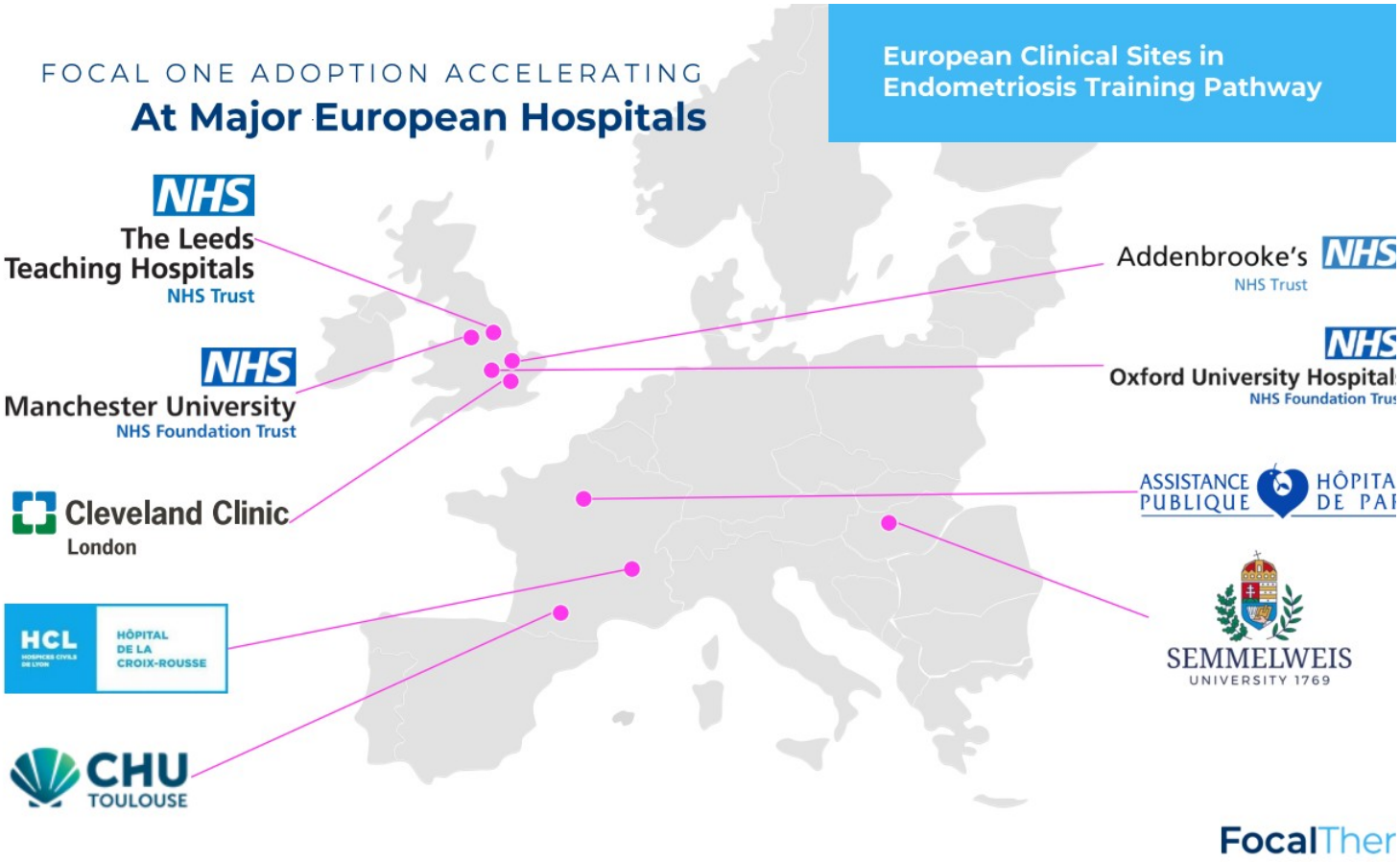
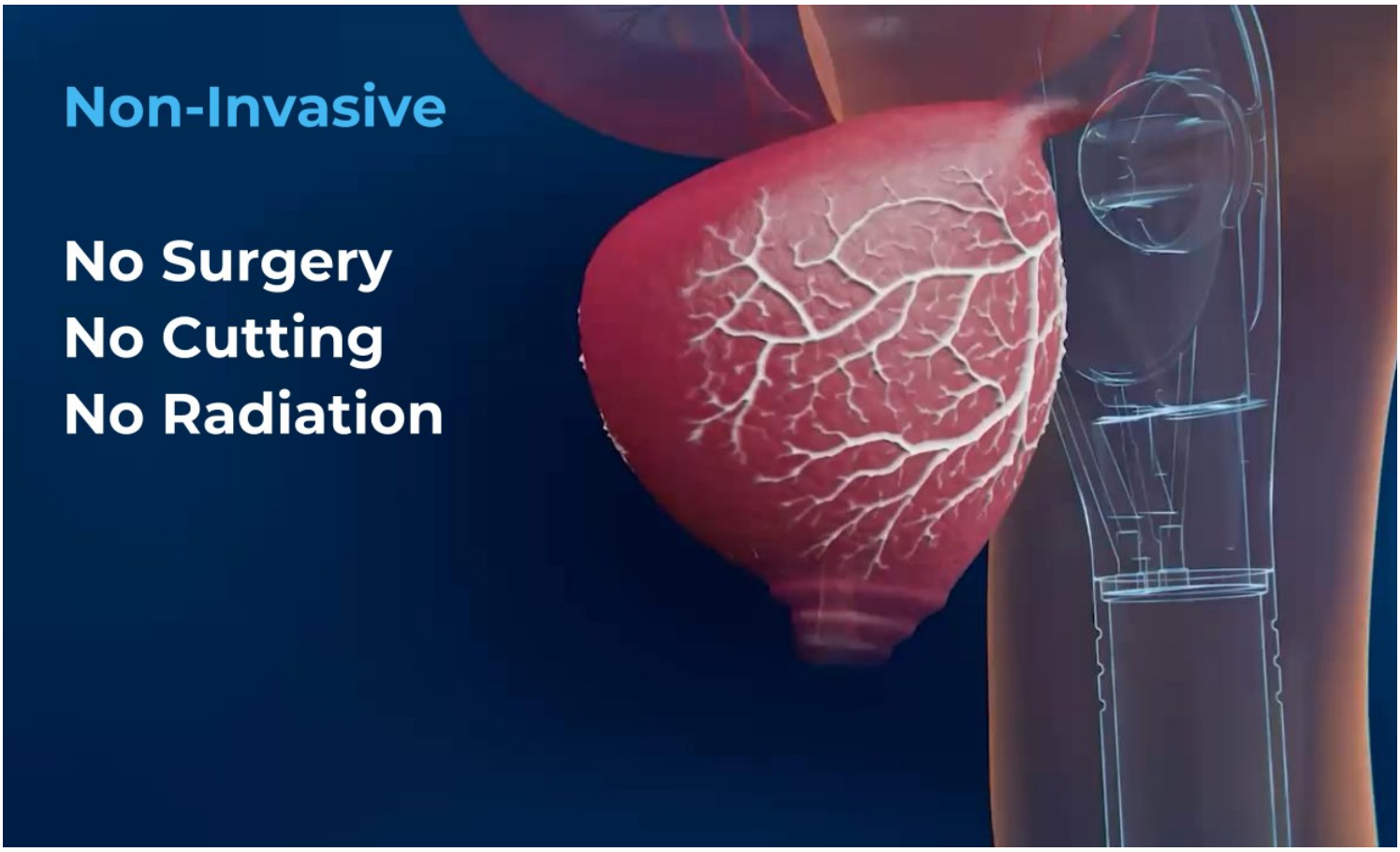
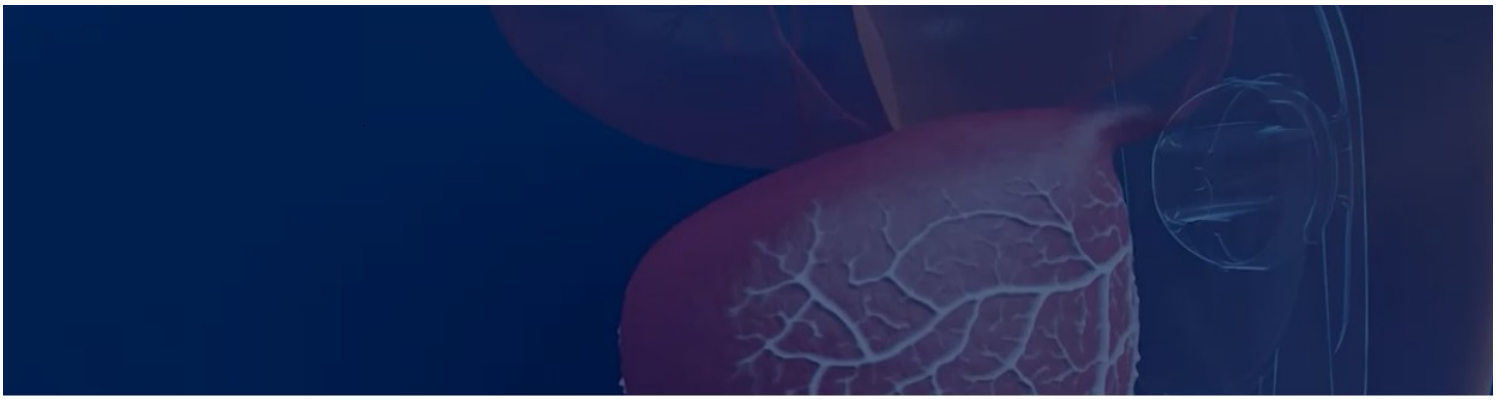

FOCAL ONE ADOPTION ACCELERATING
At Major European Hospitals
European Clinical Sites in Endometriosis Training Pathway
NHS
The Leeds Teaching Hospitals
NHS Trust
NHS
Manchester University
NHS Foundation Trust
Cleveland Clinic
London
HCL
HÔPITAL DE LA CROIX-ROUSSE
CHU
TOULOUSE
Addenbrooke's
NHS Trust
NHS
Oxford University Hospital
NHS Foundation Trus
ASSISTANCE PUBLIQUE
HÔPITA
DE PA
SEMMELWEIS
UNIVERSITY 1769
FocalTher

FocalTherics™

Technology Leadership & Innovation


Non-Invasive
No Surgery
No Cutting
No Radiation

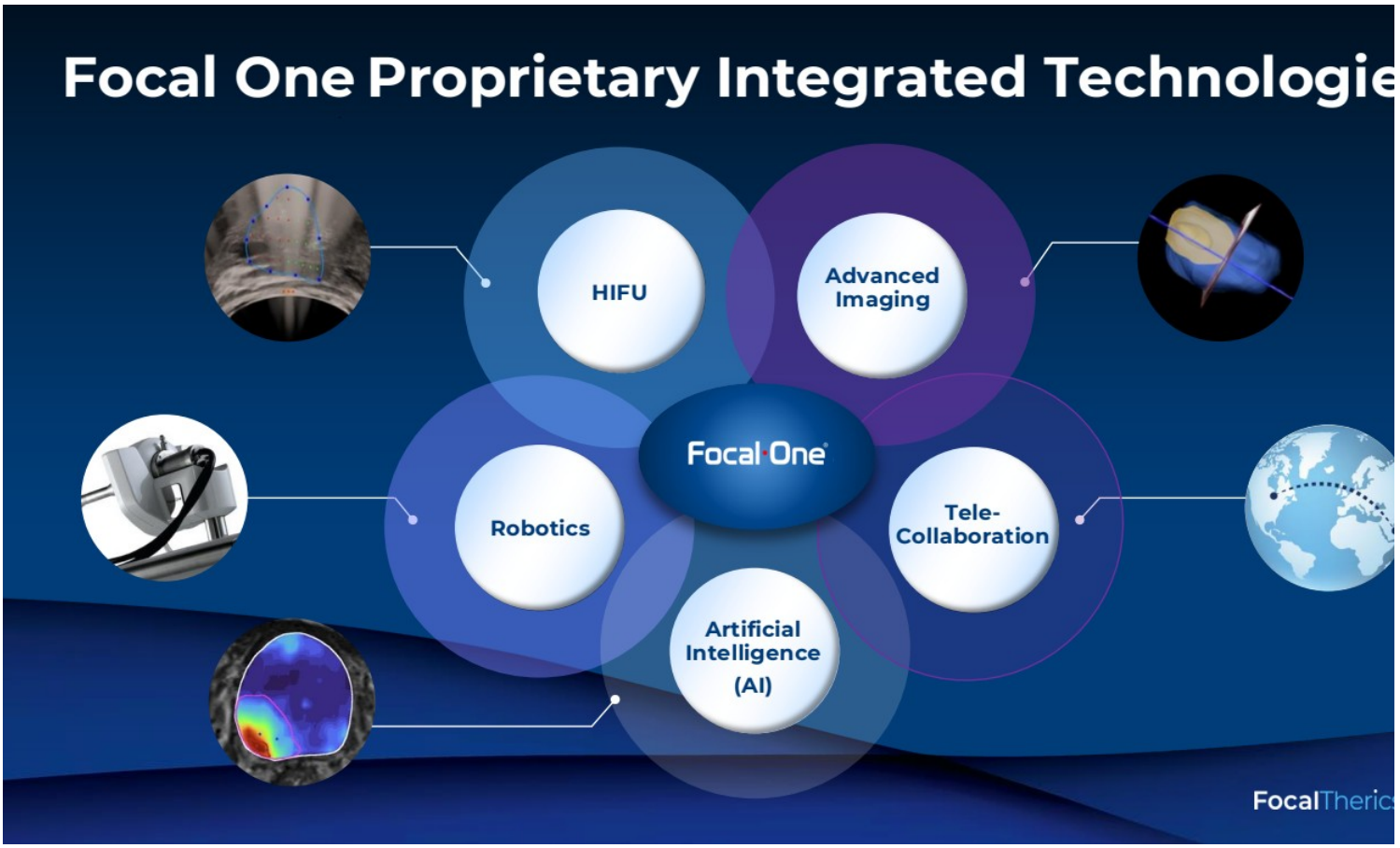


Advanced Imaging

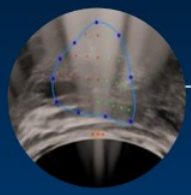
High-Intensity Focused Ultrasound (HIFU)

Precise Robotic Energy Delivery

Organ Sparing, Function Preser

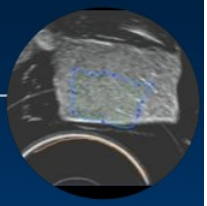

Focal One Proprietary Integrated Technologie
HIFU
Advanced Imaging
Focal One
Robotics
Tele-Collaboration
Artificial Intelligence (AI)
FocalTherics

Leading in Therapeutic Ultrasound



HIFU

Histotripsy



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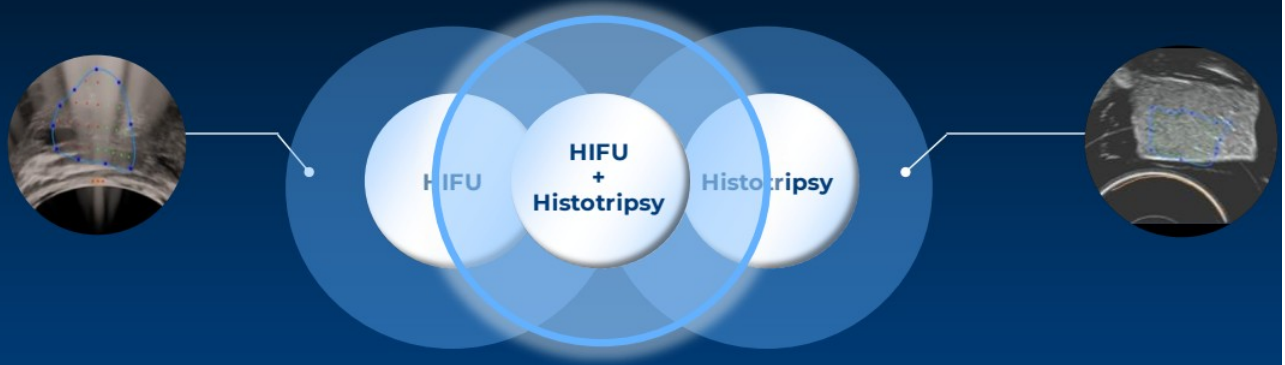
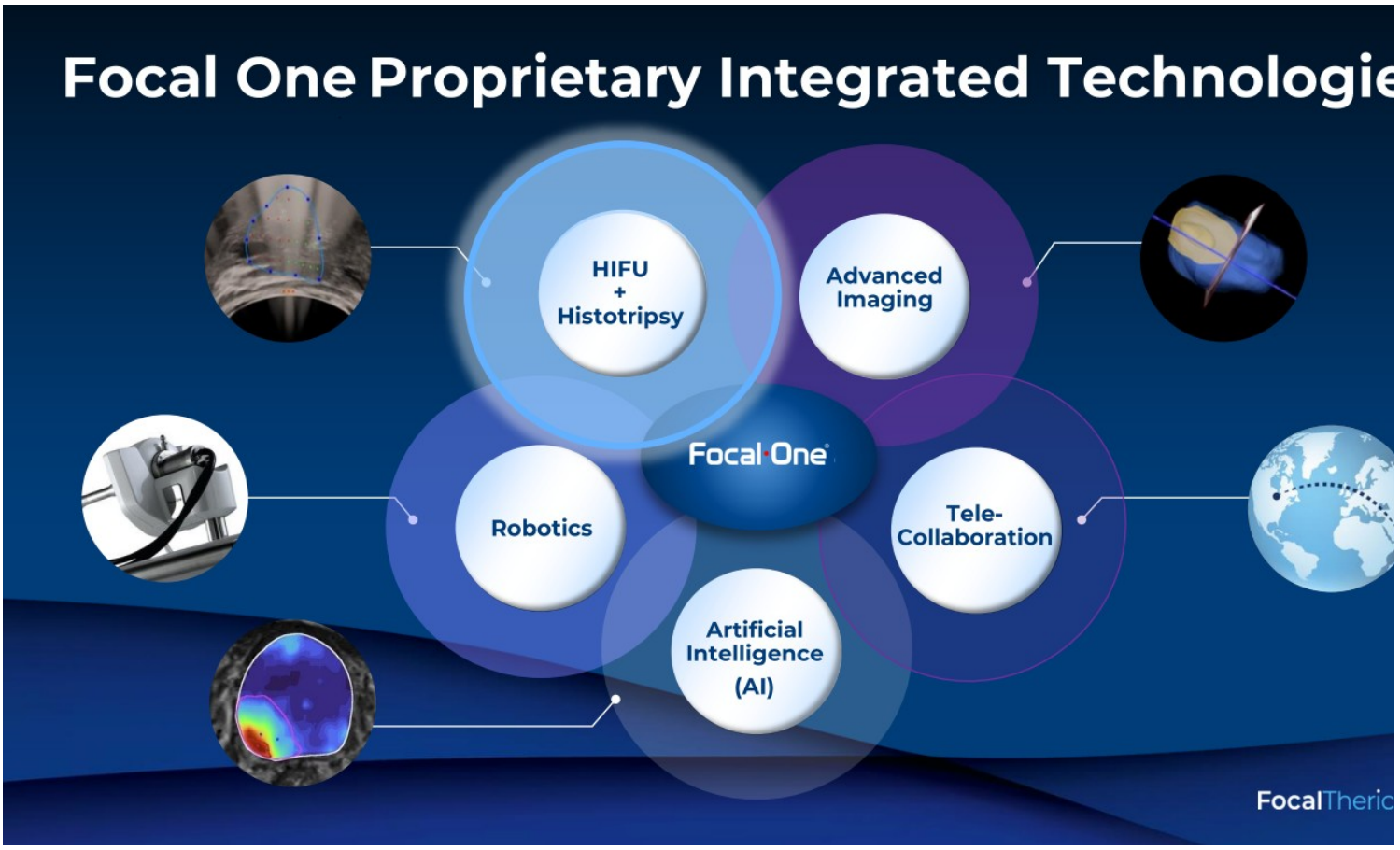
Leading in Therapeutic Ultrasound



Ideally Positioned to Combine **HIFU** and **Histotripsy** o
a **Single Platform** with an Established,
Non-Invasive Treatment Workflow

FocalTherics


Focal One Proprietary Integrated Technologie
HIFU
+
Histotripsy
Advanced
Imaging
Focal·One
Robotics
Tele-
Collaboration
Artificial
Intelligence
(AI)
FocalTheric

FocalTherics™

Accelerating Global Focal One Adoption

LEADING FOCAL THERAPY

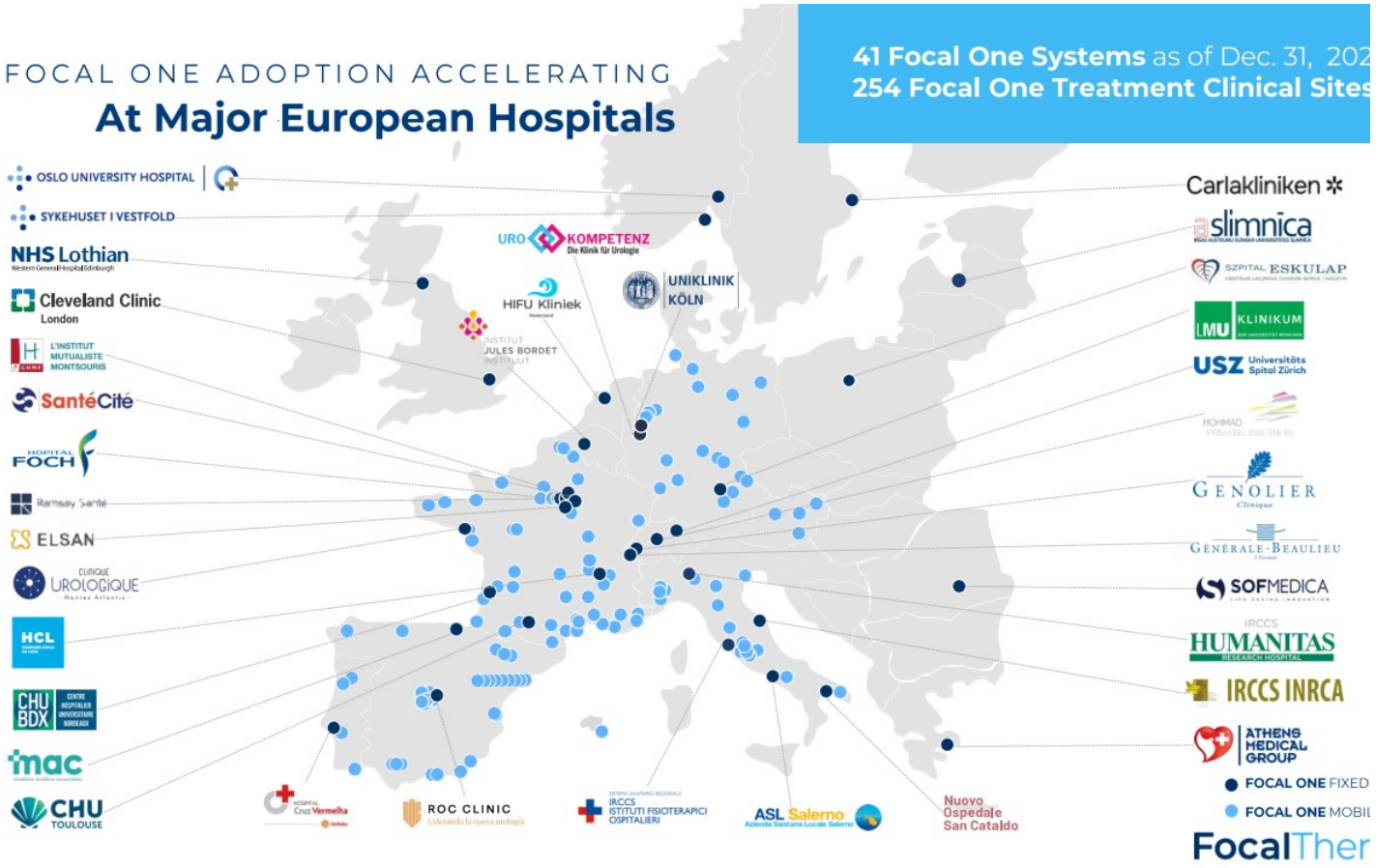
Adopted by Major U.S. Hospitals

96 Focal One Systems as of June 30, 20
(44 Academic – 52 Community)

LEADING FOCAL THERAPY

Adopted by Major U.S. Hospitals

96 Focal One Systems as of June 30, 20
300+ Hospitals in Sales Pipeline


FOCAL ONE ADOPTION ACCELERATING
At Major European Hospitals
41 Focal One Systems as of Dec. 31, 202
254 Focal One Treatment Clinical Sites
OSLO UNIVERSITY HOSPITAL
SYKEHUSET I VESTFOLD
NHS Lothian
Cleveland Clinic London
L'INSTITUT MUTUALISTE MONTSOURIS
SantéCité
HOPITAL FOCH
Ramsay Santé
ELSAN
CLINIQUE UROLOGIQUE
HCL
CHU BDX
mac
CHU TOULOUSE
URO KOMPETENZ
Die Klinik für Urologie
HIFU Kliniek
INSTITUT JULES BORDET
UNIKLINIK KÖLN
HOSPITAL Cruz Vermelha
ROC CLINIC
IRCCS ISTITUTI FISIOTERAPICI OSPITALIERI
ASL Salerno
Nuovo Ospedale San Cataldo
Carlakliniken
aslimnica
SZPITAL ESKULAP
LMU KLINIKUM
USZ Universitäts Spital Zürich
GENOLIER Clinique
GÉNÉRALE-BEAULIEU
SOFMEDICA
IRCCS HUMANITAS RESEARCH HOSPITAL
IRCCS INRCA
ATHENS MEDICAL GROUP
FOCAL ONE FIXED
FOCAL ONE MOBIL
FocalTher

FocalTherics™

Company Highlights

Investing Today to Build and Lead the Global Category of Robotic Focal Therapy

- **An Established and Growing Commercial Foundation** With Expanding Adoption In Prostate Cancer and A Clear Path to Deeper Market Penetration Across Global Markets
- **Differentiated Technology Leadership in HIFU** Supported by Continued Innovation to Include Robotic Histotripsy, With Clinical Differentiation and Opportunities Beyond Urology
- **Platform Upside Opportunity** Through New Indications of BPH and Endometriosis that Can Broaden the Addressable Market and Increase Utilization of Focal One
- **Capital-efficient Growth Strategy** Focused on Accelerating Commercial Execution, Expanding the Sales Pipeline, and Building Long-term Shareholder Value
- **Compelling Investment Opportunity** at the Growth Intersection of Image-Guided Precision Focal Therapy, Minimally Invasive Care, and Global Demand for Better Patient Outcomes

FocalTherics™

Annex

Preliminary Unaudited Estimated Financial Results as of and for the Six Months Ended June 30, 2

During the second quarter of 2026, the ESWL and Distribution segments met the criteria to be classified as held for sale under ASC 205-20, Presentation of Financia Statements — Discontinued Operations, and ASC 360-10, Property, Plant, and Equipment, and we determined that the planned exit represents a strategic shift that have a major effect on our operations and financial results. Accordingly, our unaudited financial results as of and for the six months ended June 30, 2026 will reflect ESWL and Distribution operating segments as discontinued operations. We will reclassify certain prior year amounts to conform to the current year's presentation discontinued operations.

We are in the process of finalizing our results as of and for the six months ended June 30, 2026. We have presented below ranges of certain unaudited preliminary results as of and for the six months ended June 30, 2026, as well as the comparative period for the six months ended June 30, 2025. The following information reflec our preliminary estimates with respect to such data based on currently available information and does not present all necessary information for an understanding financial condition as of and for the six months ended June 30, 2026. These estimated metrics should not be viewed as a substitute for our financial statements pre in accordance with GAAP included in our quarterly and annual filings filed with the Securities and Exchange Commission (the "SEC").

We have provided ranges, rather than specific amounts, for the information below, primarily because our financial closing and analysis procedures as of and for the months ended June 30, 2026 are not yet completed. This unaudited estimated financial information has been prepared by, and is the responsibility of, our manage and is subject to revisions based on our procedures and controls associated with our financial reporting process. Accordingly, undue reliance should not be placed these preliminary estimates. Our independent registered public accounting firm, KPMG S.A., has not audited, reviewed, examined, compiled, nor applied agreed-up procedures with respect to our preliminary results or the accounting treatment thereof and does not express an opinion or any other form of assurance with respec thereto.

While we believe that such information and estimates are based on reasonable assumptions and management's reasonable judgment, our actual results may vary we complete our closing procedures. Factors that could cause the actual results to differ include (but are not limited to) the discovery of new information that affec accounting estimates and management's judgments, or impacts valuation methodologies underlying these estimated results; and a variety of business, economic competitive risks and uncertainties, many of which are not within our control, and we undertake no obligation to update this information, unless required by law. Further, our preliminary estimates below are not necessarily indicative of the metrics to be expected for any future period as a result of various factors, including, bu limited to, those discussed in "Risk Factors" and "Special Note Regarding Forward-Looking Statements." This information should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the fiscal period ended December 2025 and in our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2026 and our consolidated financial statements and the related notes.

FocalTheric

The following tables provide detail on our preliminary unaudited estimated financial results as of and for the six months ended June 30, 202

	As of June 30, 2026 (Amounts in thousands of U.S. dollars) (unaudited)
Cash, cash equivalents and short-term investments	$ 21,542

	Six Months Ended June 30, 2025	Six Months Ended June 30, 2026	
		Low End of Range	High End of Range
	(Amounts in thousands of U.S. dollars, except percentages) (unaudited)		
Revenue from Continuing Operations	$ 16,009	$ 24,300	$ 24,800
Revenue from Discontinued Operations	$ 16,337	$ 11,600	$ 11,850
Net Loss from Continuing Operations	$(14,135)	$(24,300)	$(24,000)
Net Profit from Discontinued Operations	$ 285	$ 350	$ 450
Gross Margin from Continuing Operations	50.1%	52.0%	54.0%
Gross Margin from Discontinued Operations	34.6%	34.0%	36.0%

FocalTherics™

Global Leader in Therapeutic Ultrasound