# VISION: BECOME THE BPH TREATMENT OF CHOICE FOR ALL PROSTATES

February 2024



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# **Aquablation Therapy:**

Uniquely Positioned to Become the BPH Standard of Choice for All Prostate Sizes and Shapes

A BPH therapy that addresses the compromise between safety and efficacy of alternative surgical interventions<sup>1,2</sup>



### First-of-its-Kind Technology

Only automated robotic therapy for BPH Robust IP portfolio with high barriers to entry

### **Compelling Clinical Evidence**

Strong and growing base of clinical evidence – nearly 150 peerreviewed publications

Only BPH technology randomized against TURP, the historical standard of care for surgical intervention<sup>3</sup>

### ~95% Patients Access to Aquablation Therapy

Strong KOL support Inclusion in clinical guidelines

### Proven Commercial Strategy

Well-defined customer base and efficient sales infrastructure Capital equipment with recurring disposable and service revenues





\$20B+

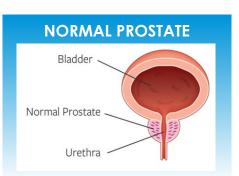
U.S. BPH

**Surgical Market** 

Opportunity

# Benign Prostatic Hyperplasia (BPH)

A Significant Men's Health Disease in the U.S.



**ENLARGED PROSTATE (BPH)** 

Bladder

Urethra

Enlarged Prostate



**#1** Reason men visit the urologist

# 1 in 2

Estimated men ages 51-60 have BPH and prevalence increases over time

# 99%

Men with BPH say symptoms impact Quality of Life<sup>1</sup>

# ~40M

**2**x

Men in the U.S. that currently have BPH<sup>2</sup>



Men >65 years old in the U.S. expected to double in the next 10 years<sup>2</sup>



# Large Market & Significant Unmet Need

# U.S. men actively **MANAGED** for BPH



### WATCHFUL WAITERS

Choose to do nothing and suffer BPH symptoms



6.7M

**1.1M** 

**400K** 

### PHARMACEUTICALS

Suffer dosing adjustments and side effects

PHARMA FALLOUT

Delay surgery despite medication failure

### **SURGERIES ANNUAL**

Compromise between safety & efficacy outcomes

\$16B

\$**3**B

**\$1B** 

8.2M

**TREATED** for BPH

\$20B+

U.S. BPH Surgical Market Opportunity

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# **Limitations: Pharmaceutical Therapy**

### **FIRST-LINE TREATMENTS**

- Alpha-blockers: relax the prostate
- 5-ARIs: shrink the prostate



### MINIMAL IMPACT ON SYMPTOMS & HIGH SIDE EFFECT PROFILE

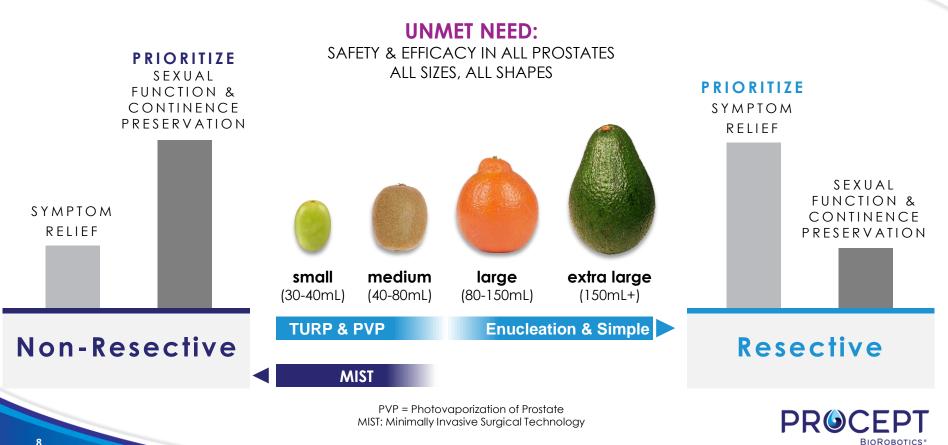
- Minimal impact on symptom relief (IPSS reduction: ~5 points) and flow improvement (~2.5 mL/s improvement)
- Side effects may include **ejaculatory dysfunction**, **erectile dysfunction**, headaches, dizziness, and loss of libido
- · Long-term use increases risk of cardiac failure and dementia



of patients stop BPH meds within 2 years



# **Unmet Need in Surgical Intervention**



# **Resective Surgery: Overview & Limitations**

290K Procedures in 2019<sup>1</sup>

### PROSTATE TISSUE <u>IS</u> REMOVED DURING PROCEDURE

- TURP
- Laser
  - PVP (Photo-vaporization of Prostate)
  - Enucleation (HoLEP, ThuLEP, GreenLEP)
- Simple (Open, Laparoscopic, Robotic)



### FAVORABLE EFFICACY BUT WEAK SAFETY PROFILE WITH MANY SIZE & SHAPE LIMITATIONS

### Efficacy

Sustained, high impact on symptom relief (IPSS reduction: ~15 points)

### Safety

• High rates of irreversible complications: incontinence, ejaculatory dysfunction, erectile dysfunction

### Procedure

- Intraoperative visualization limited to cystoscopy
- Size and shape limitations for TURP and PVP
- Manual techniques dependent on surgeon skill; variability in resection times



# **Resective Surgery: Summary of Key Safety Data**

		TURP <sup>1,2</sup>	PVP <sup>1,2</sup>	Enucleation <sup>1,2,3</sup>	Simple Prostatectomy <sup>1,4</sup>	
G	eneral Prostate Size Treated	< 80mL	< 80mL	> 80mL	> 100mL	
Irreversible Complications	Incontinence	As high as <b>2%</b>	As high as <b>2%</b>	As high as	As high as	
	Erectile dysfunction	As high as	As high as <b>20%</b>	As high as	As high as <b>2-3%</b>	
	Ejaculatory dysfunction	As high as <b>89%</b>	As high as <b>50%</b>	As high as <b>77%</b>	As high as	



# AquaBeam Robotic System

Only Image Guided, Automated Robotic Therapy for BPH

### EFFECTIVE, SAFE AND DURABLE OUTCOMES THAT ARE INDEPENDENT OF PROSTATE SIZE, SHAPE, AND SURGEON EXPERIENCE



### Real-Time Image Guidance

Intraoperative ultrasound imaging combined with cystoscopic visualization provide a multidimensional view of the treatment area



### **Personalized Treatment Planning**

Advanced planning software allows the surgeon to map the treatment contour that precisely targets the resection area



### **Automated Robotic Execution**

The robot executes the treatment plan and guides the precisely calibrated waterjet with speed and accuracy while surgeon monitors



### **Heat-Free Waterjet Resection**

Utilizing the unique power of a pulsating waterjet near the speed of sound, Aquablation therapy removes prostatic tissue with a heat-free waterjet





AQUABLATION

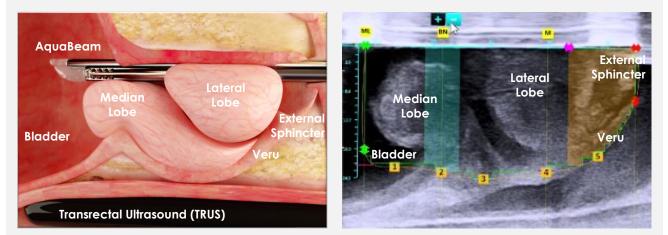
# **Real-Time Image Guidance**

Personalized Treatment Planning

### REAL-TIME, MULTI-DIMENSIONAL VISUALIZATION OF THE ENTIRE PROSTATE FOR CUSTOMIZED TREATMENT PLANNING



OTHER TREATMENTS LIMITED TO CYSTOSCOPY ONLY

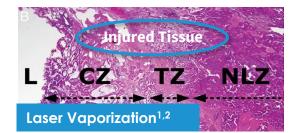


### TRANSRECTAL ULTRASOUND IMAGING SIDE VIEW



# **Heat-Free Waterjet Resection**





L- Lumen CZ- Cautery Zone TZ- Transition Zone NLZ- Non-Laser Zone Minimize variables that impact outcomes with a

precisely calibrated, heat-free waterjet

# Heat-based options can lead to thermal injury and result in:

- Highly variable depth of tissue penetration
- Necrosis which may extend deeper than cavity created
- Potential for unintended prostate capsule perforation
- Potential damage to nerve bundle
  responsible for erectile function
- Delayed healing of prostatic urethra



# Clinically Validated Efficacy, Durability & Safety

Independent of Prostate Size, Shape, and Surgeon Experience



n = 181

Only FDA pivotal study randomized to gold standard TURP for prostates

### 30 – 80 mL

- Superior safety compared to TURP due to low irreversible complications
- Superior symptom relief for subset of patients with prostates  $\geq$  50 mL



n = 101

Only prospective multicenter study successfully completed for large prostates

### 80 – 150 mL

- Only treatment for large prostates with a low irreversible complication rate
- Size independent procedure
- Significant symptom relief in large prostates



n = 178

First multicenter all-comers study with realworld results in prostates

### 20 – 150 mL

- Validates safety and efficacy in a realworld setting
- Minimal exclusion criteria







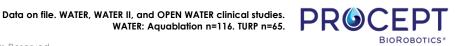
European

Canadian Urological Association



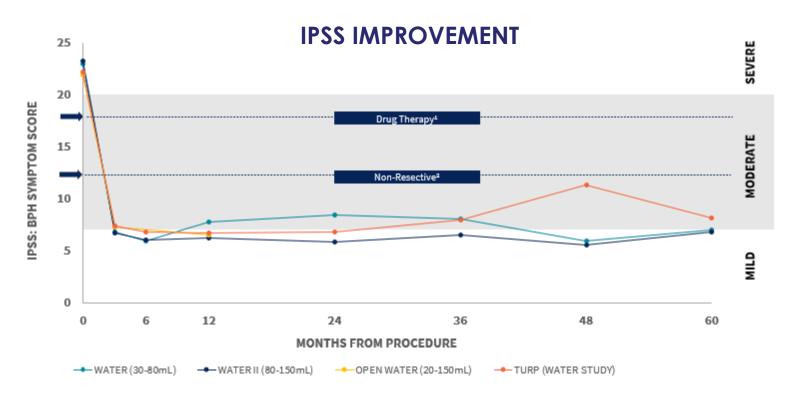


German **Urology Society** 



# **Efficacy and Durability**

Similar Outcomes to TURP, but Across ALL Prostates in Both Clinical & Commercial Studies



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# **Safety** Low Rates of Irreversible Complications in ALL Prostates<sup>1</sup>

		WA	TER				
		Aquablation	TURP	WATER II	OPEN WATER		
Mean Prostate Size		54 mL	52 mL	107 mL	59 mL		
Ob	ostructive Median Lobe	50%	52%	83%	59%		
ations	Incontinence	0.0%	0.0%	2.0%	0.0%		
Irreversible Complications	Erectile dysfunction	0.0%	0.0%	0.0%	0.0%		
sible	Ejaculatory dysfunction	6.9%	24.6%		8.4%		
Irrever		Statistical Signif	icance: p<0.05	14.9%			

Data on file. WATER, WATER II, and OPEN WATER clinical studies. 1. Compared to published rates observed for other resective surgeries **PRO**CEPT

**BIOROBOTICS\*** 

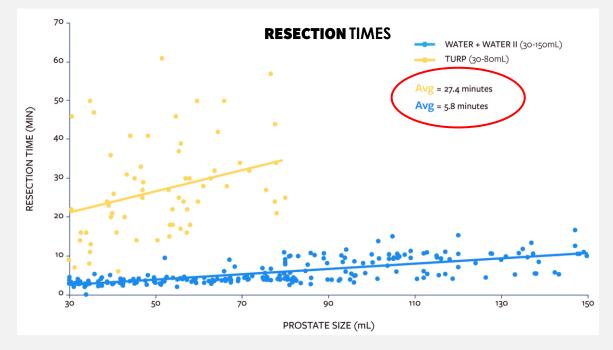
# **Surgical Standardization**

Predictable Outcomes, Consistency and Increased Efficiency

### IMPROVED EFFICIENCY IN THE OPERATING ROOM

### Clinical Outcomes are Experience Agnostic

- WATER study 14 of 17 participating surgeons had no previous experience with Aquablation therapy
- WATER II study median previous experience of 0.5 procedures with Aquablation therapy



### Data on file. WATER, WATER II, and OPEN WATER clinical studies.



# **U.S. Reimbursement Summary**

### COVERAGE

- Full U.S. Medicare Coverage effective January 2021<sup>3</sup>
- Positive Private Payor Policies:
  - United Healthcare, Aetna, Cigna, Anthem, Humana, and numerous other regional providers

### CODING

- Unique Water Jet Resection CPT Code 0421T
- Probe, Image-Guided, Robotic, Waterjet Ablation C Code C2596

### ΡΑΥΜΕΝΤ

- APC Level 6 Payment (HOPPS Medicare National Avg. CY 2023 \$8,558)
- ► APC Level 6 Payment (HOPPS Medicare National Avg. CY 2024 \$8,787)
- (1) Estimated based on data from Policy Reporter
- (2) Mean age of 65 years for BPH surgical resective patients
- (3) Subject to beneficiaries meeting certain clinical criteria set forth in local coverage determinations
- (4) In accordance to internal estimates



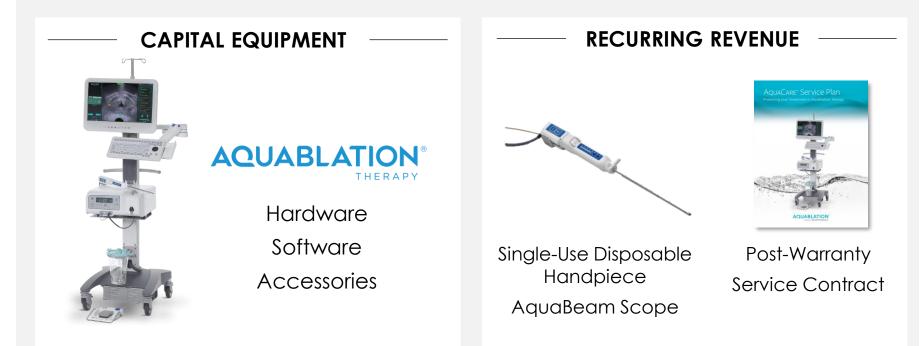
# ~50%

of hospital based resective BPH procedures are Medicare<sup>2,4</sup>



# **Capital Equipment Sales**

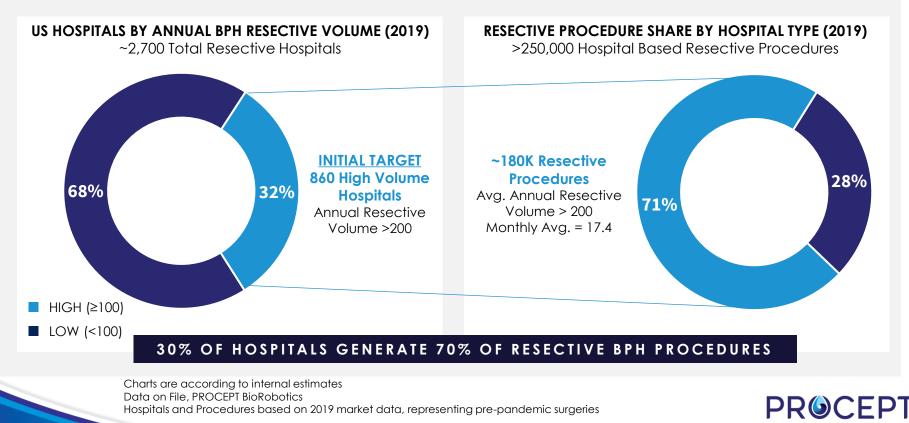
Recurring Revenue Model





# U.S. Commercial Opportunity: Segmentation

## Target High-Volume Hospitals



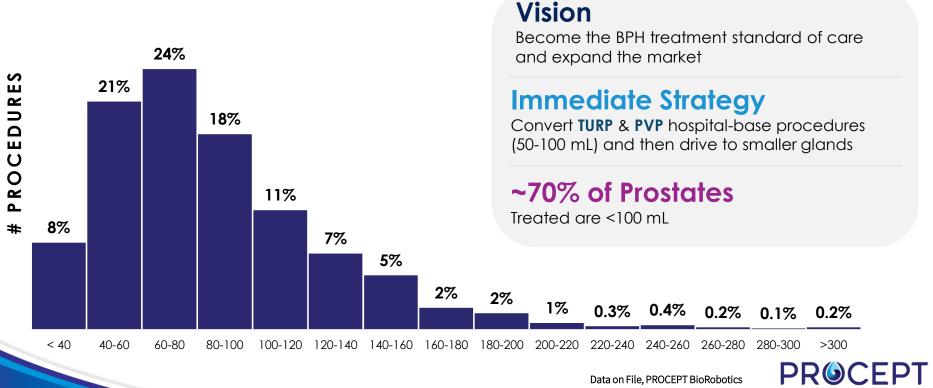
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# Aquablation Treated Prostate Sizes – U.S.

### **PROSTATE SIZE HISTOGRAM – U.S DATA**

1/1/21 to 12/31/23



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# PROSTATE CANCER UPDATE



# Aquablation Therapy + Prostate Cancer Highlights



**Prostate Cancer represents a large, attractive market** with a significant unmet clinical need



Limitations of current prostate cancer treatment options lack safety & efficacy



Prostate Cancer is **highly synergistic & logical next indication** for Aquablation Therapy



**Enrolling two single-arm clinical studies** to support future research & regulatory applications in the United States **at minimal cost** 



Leverage existing technology & sales channel to drive future growth and adoption



# **Clinical Study Design**

Investigate Safety & Efficacy

# **BPH + PCa**

Single-Arm Study

Enrollment of BPH patients who also have Prostate Cancer (Grade Group 1-3)

 $\leq$ 125 patients from up to 15 sites globally

# PCa Only

FDA – IDE Approved Single-Arm Study

Enrollment of Prostate Cancer Patients (Grade Group 1-2)

20 patients from up to 5 sites in U.S.

Total Estimated Cost of ~\$2 million in 2024



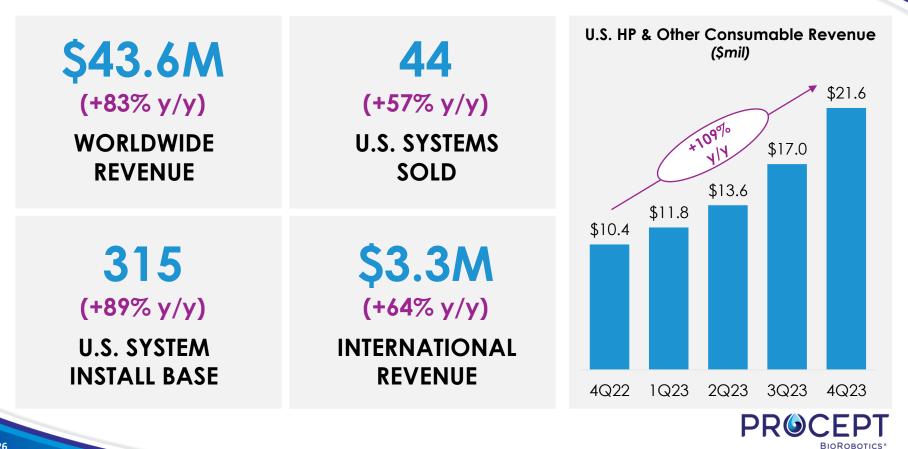


# **4Q23 FINANCIAL REVIEW**





# 4Q23 Earnings Recap



# **2024 Financial Guidance**

**Total Revenue** (\$ Mil) ~\$210.0 \$136.2 \$75.0 \$34.5

	Actual 2023	Guidance FY24 <sup>1</sup>			
Revenue	\$136.2 million	~\$210.0 million			
Revenue growth (y/y)	82%	~54%			
Gross Margin	52%	~57% to 59%			
Operating Expenses	\$180.2 million <sup>2</sup>	~\$231.5 million <sup>3</sup>			
Revenue : OPEX Growth Ratio	1.5x	~1.9x			
Adjusted EBITDA Loss	\$86.5 million⁴	~\$73.0 million⁴			

Actual



### TOTAL CASH & CASH EQUIVALENTS BALANCE OF \$257M & DEBT BALANCE OF \$52M AS OF DECEMBER 31, 2023

(1) 2024 financial guidance issued on February 27, 2024
 (2) 2023 operating expenses included approximately \$19.1 million in stock-based compensation expense
 (3) 2024 operating expense guidance includes approximately \$31.5 million in stock-based compensation expense
 (4) See appendix for reconciliation of non-GAAP financial measures



# **Non-GAAP Reconciliations**

### RECONCILIATION OF GAAP NET LOSS TO ADJUSTED EBITDA

### (in thousands) (unaudited)

	Three Months Ended December 31,			Twelve Months Ended December 31,				
		2023		2022		2023		2022
Net loss	\$	(27,504)	\$	(28,172)	\$	(105,897)	\$	(87,154)
Depreciation and amortization expense		1,318		663		3,807		2,841
Stock-based compensation expense		4,981		2,885		19,134		10,337
Interest (income) and interest expense, net		(2,079)		(320)		(3,556)		2,687
Loss on loan extinguishment		-		3,258		-		3,258
Adjusted EBITDA	\$	(23,283)	\$	(21,686)	\$	(86,512)	\$	(68,031)

### RECONCILIATION OF 2024 GAAP NET LOSS TO ADJUSTED EBITDA Guidance (in thousands) (unaudited)

 2024
\$ (103,150)
5,800
31,500
 (7,150)
\$ (73,000)
\$ \$

PROCEPT



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### Slide 5:

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 Zom KC, Bidair M, Trainer A, Arther A, Kramolowsky E, Desai M, et al. Aquablation therapy in large prostates (80–150 cc) for lower urinary tract symptoms due to benign prostatic hyperplasia: WATER II 3-year trial results. BJUI Compass. 2022;3(2):130–138.

Based on company's internal estimates.

3. WATER U.S. pivotal trial

### <u>Slide 6</u>

Roehrborn, CG, Rosen, RC. Medical therapy options for aging men with benign prostatic hyperplasia: focus on alfuzosin 10 mg once daily. Clinical Interventions in Aging 2008;3(3).

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2014, Ortman, An Aging Nation: The Older Population in the United States

1. According to internal marketing survey

2. According to internal estimates

Loughlin, K. Benign prostatic hyperplasia: epidemiology, economics and evaluation. Can J Urol. 2015 Oct;22 Suppl 1:1-6.

Vuichoud, C, Loughlin, K. Benign prostatic hyperplasia: epidemiology, economics and evaluation. Can J Urol. 2015 Oct;22 Suppl 1:1-6.

MS Health NDTI Urology Specialty Profile, July 2012-June 2013

### <u>Slide 7</u>

All numbers are approximate.

Vuichoud, C, Loughlin, K. Benign prostatic hyperplasia: epidemiology, economics and evaluation. Can J Urol. 2015 Oct;22 Suppl 1:1-6.

Data on File, PROCEPT BioRobotics

Total surgeries based on 2019 market data, representing pre-pandemic surgeries

### Slide 8:

MTOPS study, NEJM December 2003, Vol.349, No.25

Lusty et al. Cardiac Failure Associated with Medical Therapy of Benign Prostatic Hyperplasia: A Population Based Study / Vol. 205, 1430-1437, May 2021

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PSS = International Prostate Symptom Score

### <u>Slide 9</u>

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1. Procedures based on 2019 market data, representing pre-pandemic surgeries and according to internal estimates

### Slide 11

1. Leong et al. Minimizing Sexual Dysfunction in BPH Surgery. Current Sexual Health Reports (2019) 11:190–200

2. Comiter et al. Urinary incontinence after prostate treatment. Up to Date; Last update May 2020.

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4. Khera, M. Simple Prostatectomy. Medscape. 2018.

Data reported in each category is not head-to-head.



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### Slide 14:

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Bruyère F, et al. Penetration depth with the XPS GreenLight laser assessed by contrast enhanced ultrasonography. J Endourol. 2013 Oct;27(10):1282-6. doi: 10.1089/end.2013.0368. Epub 2013 Aug 21.

### Slide 16

1. Drug therapy generally provides IPSS reduction of approximately 5 points.

2. Non resective surgery generally provides IPSS reduction of approximately 10 points

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# Thank You



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