



PROCEPT BioRobotics Announces FDA Clearance of the HYDROS™ Robotic System, the Next-Generation, AI-Powered Platform for Aquablation® Therapy

August 21, 2024

Designed to improve efficiency, enhance surgeon and staff experience and deliver a more accurate and consistent treatment plan for better clinical outcomes

SAN JOSE, Calif., Aug. 21, 2024 (GLOBE NEWSWIRE) -- [PROCEPT BioRobotics® Corporation](#) (Nasdaq: PRCT) (the "Company"), a surgical robotics company focused on advancing patient care by developing transformative solutions in urology, today announced FDA 510(k) clearance of its next-generation platform, the HYDROS™ Robotic System. Leveraging insights from over 50,000 procedures, HYDROS features *FirstAssist AI™* treatment planning, advanced image guidance, robotic resection, and a streamlined workflow. HYDROS is designed to improve efficiency, enhance surgeon and staff experience and deliver a more accurate and consistent treatment plan for better clinical outcomes.

"We are pleased to bring the HYDROS Robotic System to the U.S. market," said Reza Zadno, CEO of PROCEPT BioRobotics. "This milestone marks a pivotal moment for PROCEPT as Aquablation therapy continues its rapid adoption, with over 400 robotic systems now installed across the United States. After years of research and development, HYDROS introduces significant technological advancements designed for mass-market adoption, and we believe will power the next phase of our growth."

"As a urologist, my goal is to treat my patients' symptoms while preserving their quality of life. Aquablation therapy has been instrumental in helping me achieve this for patients struggling with BPH," said Dr. Steven Kaplan, Icahn School of Medicine at Mount Sinai. "The HYDROS Robotic System advances this further by utilizing the power of AI to better read and interpret ultrasound for optimal surgical planning."

The HYDROS Robotic System represents the next evolution in the delivery of Aquablation therapy, combining cutting-edge technology with user-friendly features designed to deliver better clinical outcomes for patients and healthcare providers.

Key Features of the Fully Integrated HYDROS Robotic System Include:

- **AI-Powered Treatment Planning:** *FirstAssist AI*, built from a library of real-world Aquablation therapy procedures, uses advanced image recognition software to accurately identify critical anatomy on ultrasound and suggest an optimal treatment plan for each patient.
- **Advanced Image Guidance:** The system integrates next-generation ultrasound imaging, digital cystoscopy, and dual high-definition touchscreens providing enhanced visualization of the anatomy and simultaneous viewing of ultrasound and cystoscopy images.
- **Robotic Resection:** Utilizing a heat-free waterjet, the robot executes the surgeon-defined treatment plan to resect obstructive tissue while protecting critical anatomy. This enables efficient and predictable waterjet execution, standardizing the operative experience across a wide range of prostate sizes and shapes.
- **Streamlined Workflow:** Designed to improve the surgeon and staff experience at every stage of the Aquablation therapy procedure. With a single-footprint, the integrated tower facilitates efficient operating room setup and turnover. The adjustable touchscreen improves surgeon ergonomics with midline placement, and the instinctive software interface simplifies procedural workflow.

"The HYDROS Robotic System is a game-changer for new surgeons. I believe the streamlined system along with the system's intraoperative AI capabilities provide a tool to suggest an optimal treatment, helping surgeons learn the procedure faster and with greater precision," said Dr. Brian Helfand, NorthShore's Chief of Urology and Clinical Professor at the University of Chicago.

"The HYDROS Robotic System is a testament to our commitment to innovation. By integrating AI and advanced imaging into the robotic platform, we are providing surgeons with the tools they need to deliver precise, efficient, and high-quality care," said Sham Shibliq, Chief Commercial Officer. "HYDROS will move to full market release within the current quarter and be available immediately to hospitals across the United States."

2024 Financial Guidance Update:

In conjunction with today's announcement, the Company is reaffirming its 2024 financial guidance, which was initially provided on the most recent second quarter 2024 earnings conference call on August 1, 2024.

Webcast and Conference Call Information

PROCEPT BioRobotics will host a conference call on Wednesday, August 21, 2024, at 8:00 a.m. Eastern Time to discuss the HYDROS Robotic System key features, benefits, and commercial launch plans.

Investors interested in listening to the conference call may do so by following one of the below links:

Webcast link for interested listeners:

- <https://edge.media-server.com/mmc/p/q3dbybx5/>

Dial-in registration for sell-side research analysts:

- <https://register.vevent.com/register/BI4959cac15c6540aa97a4d156af947d55>



For more information on the HYDROS Robotic System, visit www.procept-biorobotics.com/hydros

About Aquablation Therapy and the HYDROS Robotic System

The HYDROS Robotic System is the only AI-powered platform that delivers Aquablation therapy for BPH. The clinically proven procedure uses real-time ultrasound imaging combined with cystoscopy to provide the surgeon with a multi-dimensional, detailed view of the entire prostate, enabling personalized treatment planning tailored to each patient's unique anatomy. With the HYDROS Robotic System, the surgeon can now use AI to specify which areas of the prostate to resect while avoiding the anatomy that controls erectile function, ejaculatory function, and continence. Once the treatment plan is mapped by the surgeon, the predictable robotic-assisted waterjet execution enables prostate tissue to be resected in a precise, targeted, and controlled fashion.

Aquablation therapy is backed by two 5-year clinical trials demonstrating significant durable symptom relief while preserving sexual function and continence across prostates of all shapes and sizes.

About PROCEPT BioRobotics Corporation

PROCEPT BioRobotics is a surgical robotics company focused on advancing patient care by developing transformative solutions in urology. The HYDROS Robotic System is the only AI-Powered, robotic technology that delivers Aquablation therapy. PROCEPT BioRobotics designed Aquablation therapy to deliver effective, safe, and durable outcomes for males suffering from lower urinary tract symptoms or LUTS, due to BPH that are independent of prostate size and shape or surgeon experience. BPH is the most common prostate disease and impacts approximately 40 million men in the United States. The Company has developed a significant and growing body of clinical evidence with over 150 peer-reviewed publications, supporting the benefits and clinical advantages of Aquablation therapy.

Forward Looking Statements

This release contains forward-looking statements within the meaning of federal securities laws, including with respect to the Company's projected financial performance for full year 2024 and statements regarding the potential utilities, values, benefits and advantages of Aquablation® therapy

performed using PROCEPT BioRobotics' products, including HYDROS™ Robotic System, which involve risks and uncertainties that could cause the actual results to differ materially from the anticipated results and expectations expressed in these forward-looking statements. You are cautioned not to place undue reliance on these forward-looking statements. Forward-looking statements are only predictions based on our current expectations, estimates, and assumptions, valid only as of the date they are made, and subject to risks and uncertainties, some of which we are not currently aware. Forward-looking statements may include statements regarding financial guidance, market opportunity and penetration, the Company's possible or assumed future results of operations, including descriptions of the Company's revenues, gross margin, profitability, operating expenses, installed base growth, commercial momentum, reimbursement coverage, overall business strategy, or information regarding the impact of other global events on the Company and its operations. Forward-looking statements should not be read as a guarantee of future performance or results and may not necessarily be accurate indications of the times at, or by, which such performance or results will be achieved. These forward-looking statements are based on the Company's current expectations and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties. These risks and uncertainties are described more fully in the section titled "Risk Factors" in the Company's filings with the Securities and Exchange Commission (the "SEC"), including the Company's annual report on Form 10-K filed with the SEC on February 28, 2024. PROCEPT BioRobotics does not undertake any obligation to update forward-looking statements and expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein. These forward-looking statements should not be relied upon as representing PROCEPT BioRobotics' views as of any date subsequent to the date of this press release.

Important Safety Information

All surgical treatments have inherent and associated side effects. For a list of potential side effects visit <https://aquablation.com/safety-information/>.

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