

**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 21, 2024

PROCEPT BIOROBOTICS CORPORATION
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-40797
(Commission
File Number)

26-0199180
(IRS Employer
Identification Number)

150 Baytech Drive
San Jose, California 95134
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (650) 232-7200

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
Common Stock, \$0.00001 par value per share	PRCT	The Nasdaq Global Market

Indicate 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 8.01 Other Events.

On August 21, 2024, PROCEPT BioRobotics Corporation (the “Company”) announced that the U.S. Food and Drug Administration’s (the “FDA”) has granted 510(k) clearance of the Company’s next-generation platform, the HYDROS™ Robotic System (“HYDROS”).

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

HYDROS 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. It utilizes a handpiece that comes pre-assembled with a single-use digital scope, eliminating the need for scope reprocessing.

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 setup and operating room turnover. The adjustable touchscreen enhances surgeon ergonomics with midline placement, and the instinctive software interface simplifies procedural workflow.

Cautionary Statement Regarding Forward Looking Statements

This report contains forward-looking statements within the meaning of federal securities laws. 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. Undue reliance should not be placed 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 the Company is not currently aware. Forward-looking statements may include statements regarding market opportunity and penetration, the Company’s possible or assumed future results of operations, including descriptions of the Company’s overall business strategy or information regarding 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. The Company 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 the Company’s views as of any date subsequent to the date of this press release.

SIGNATURES

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

August 21, 2024

PROCEPT BIROBOTICS CORPORATION

By: /s/ Alaleh Nouri

Alaleh Nouri

Chief Legal Officer and Secretary