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): January 27, 2021

HARROW HEALTH, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-35814**	**45-0567010**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

102 Woodmont Blvd., Suite 610 **Nashville, Tennessee** (Address of principal executive offices)	**37205** (Zip Code)

Registrant's telephone number, including area code: **(615) 733-4730**

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

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

Title of each class	Trading Symbol(s)	Name on exchange on which registered
Common Stock, $0.001 par value per share	HROW	The NASDAQ Global Market

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Act of 1934: Emerging growth company ☐

If any 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 Information

On January 27, 2021, Surface Ophthalmics, Inc. ("Surface") issued a press release (the "Surface PR") announcing the first patient dosed in a head-to-head phase II trial for its drug candidate SURF-100 (mycophenolate sodium and betamethasone in Klarity® vehicle) for the treatment of chronic dry eye disease. The head-to-head study will compare SURF-100 against leading on-market competitors lifitegrast ophthalmic solution 5% (marketed as Xiidra®) and cyclosporine ophthalmic emulsion 0.05% (marketed as Restasis®).

Harrow Health, Inc. currently owns three million five hundred thousand (3,500,000) shares of Surface common stock, which is approximately 30% of the issued and outstanding voting interests of Surface, along with a mid-single digit royalty right on net sales of SURF-100.

The foregoing is only a brief description of the Surface PR, does not purport to be a complete description of the Surface PR and is qualified in its entirety by reference to the full text of the document, which is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

All trademarks referenced in this Current Report on Form 8-K and the Surface PR are the property of their respective owners.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Item	Description
99.1	Surface Ophthalmics Press Release Date January 27, 2021

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.

HARROW HEALTH, INC.

Dated: January 27, 2021

By: */s/ Andrew R. Boll*
Name: Andrew R. Boll
Title: Chief Financial Officer

EXHIBIT 99.1

Surface Ophthalmics Announces First Patient Dosed in Landmark Head-to-Head Phase II Trial for SURF-100 for Chronic Dry Eye Disease

Innovative head-to-head study will compare SURF-100 against leading on-market competitors lifitegrast ophthalmic solution 5% and cyclosporine ophthalmic emulsion 0.05%

PLEASANTON, California – Surface Ophthalmics, Inc., a pharmaceutical company focused on the development and commercialization of innovative therapeutics for ocular diseases, today announced that the first patient has been dosed in the Phase II clinical trial for its investigational product SURF-100 (mycophenolate sodium and betamethasone sodium phosphate in Klarity® vehicle) for the treatment of chronic dry eye disease.

SURF-100 utilizes a new and differentiated mechanism of action by combining mycophenolate sodium and betamethasone sodium phosphate, which are known to have synergistic therapeutic effects, in the patented Klarity diluent. This combination is designed to increase residence time, patient comfort and promote ocular healing in a non-blurring formulation. The landmark clinical trial will directly compare SURF-100 with the current leading treatments for dry eye disease, lifitegrast ophthalmic solution 5% (marketed as Xiidra®) and cyclosporine ophthalmic emulsion 0.05% (marketed as Restasis®). The trial will enroll about 300 patients with a primary endpoint of statistically significant Symptom Improvement between various study arms based on the University of North Carolina Dry Eye Management Scale at Day 84.

Kamran Hosseini, MD, PhD, President and CEO, Surface Ophthalmics, said "With the first patient enrolled, we're excited to be initiating this bold trial which is not only the first head-to-head trial in chronic dry eye, but also will be the most expansive Phase II trial initiated to-date including the greatest number of arms with multiple active investigational arms at different strengths. By having SURF-100 go head-to-head with the leading marketed therapies, we hope to demonstrate clear advantages in both efficacy and, perhaps even more importantly, patient comfort and tolerability. We want to provide patients with the answers they need to find the best treatment option for their dry eye disease."

"I'm thrilled to be involved in this trial – the first of its kind in dry eye disease. Current therapies for chronic dry eye disease face challenges in patient comfort and tolerability – an area where we hope to be able to demonstrate significant improvement," stated Edward Holland, MD, Director, Cornea Services/Professor of Clinical Ophthalmology at Cincinnati Eye Institute/University of Cincinnati and lead investigator for the SURF-100 clinical trial.

"We continue to deliver on our key clinical milestones as we work to advance three unique clinical programs. Last week we announced positive top-line results from our Phase II trial for SURF-201 for the treatment of pain and inflammation following ocular surgery. SURF-100 is the first treatment to utilize betamethasone in dry eye disease in the United States, and now the first patient enrolled in a landmark dry eye study," said Hosseini. "We're excited to see early success in our strategy of using fundamental building blocks to create effective, safe and well-tolerated ocular treatments for patients."

ABOUT OUR CLINCIAL PROGRAMS

Surface Ophthalmics is advancing three clinical programs: one in chronic dry eye disease (SURF-100), one in episodic dry eye disease (SURF-200), and one in pain and inflammation following ocular surgery (SURF-201). These programs utilize Klarity® as the delivery vehicle, which has a proven track record of protecting and rehabilitating the ocular surface.

In only two years, Surface has filed three unique INDs, now moved two programs (SURF-201 and SURF-100) into Phase II clinical studies, and is preparing for an additional Phase II program in the coming month.

ABOUT KLARITY®

The patented Klarity® delivery vehicle is used across Surface Ophthalmics' three current clinical programs. Developed by Richard L. Lindstrom, MD, inventor of Optisol GS (an advanced corneal preservation solution), Klarity is designed to protect and rehabilitate the ocular surface pathology for patients with moderate-to-severe dry eye disease.

ABOUT SURFACE OPHTHALMICS

Surface Ophthalmics, Inc. is a pharmaceutical company focused on development and commercialization of innovative therapeutics for ocular diseases. We are striving to solve key patient needs in eye care through leveraging deep expertise, a bold approach, an eye toward efficiency, and clear, differentiated clinical advantages. Our current drug pipeline consists of three proprietary drug candidates, all utilizing Klarity®, a patented delivery vehicle. We are led by an experienced and proven management team and board of directors with over 80 years of ophthalmology related professional experience. For more information: http://surfaceophthalmics.com/.

CONTACTS

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