# 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 21, 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**<br>**Nashville, Tennessee**<br>(Address of principal executive offices) | **37205**<br>(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 21, 2021, Surface Ophthalmics, Inc. ("Surface") issued a press release (the "Surface PR") reporting positive top-line results from a Phase II trial of its drug candidate SURF-201, a 0.2% betamethasone, preservative-free ophthalmic solution in the Klarity® delivery vehicle for the treatment of post cataract surgery pain and inflammation. According to the Surface PR, SURF-201 was dosed twice daily, and met its primary endpoints of absence of inflammation at both Day 8 and Day 15 and was found to be safe and well-tolerated by the patient group. In addition, a secondary endpoint showed almost 90% of patients given SURF-201 were pain free at Day 15. SURF-201 marks the first ophthalmic therapeutic in the United States to utilize betamethasone as well as being the first preservative-free unit dose therapy for the treatment of post-operative pain and inflammation.

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-201.

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.

**Item 9.01. Financial Statements and Exhibits**

**(d) Exhibits**

| Item | Description |
|---|---|
| 99.1 | Surface Ophthalmics Press Release Date January 21, 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 21, 2021

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

**Exhibit 99.1**

**Surface Ophthalmics Announces Positive Top-Line Results from Phase II Trial for SURF-201 (Betamethasone 0.2% in Klarity® vehicle) for the Treatment of Post-Cataract Surgery Pain and Inflammation**

*Investigational therapy SURF-201 met all primary endpoints for the treatment of pain and inflammation following cataract surgery*

**PLEASANTON, California –** Surface Ophthalmics, Inc., a pharmaceutical company focused on the development and commercialization of innovative therapeutics for ocular diseases, today announced positive top-line results from the Phase II trial for SURF-201, an investigational therapy for the treatment of post-cataract surgery pain and inflammation. With twice-daily dosing, SURF-201 met its primary endpoints of absence of inflammation at both Day 8 and Day 15.

SURF-201 is 0.2% betamethasone, a unique and potent corticosteroid, formulated as a solution in Surface's patented Klarity vehicle, and is intended to provide improved efficacy and safety when compared to currently used corticosteroids. SURF-201 marks the first ophthalmic therapeutic in the United States to utilize betamethasone, as well as being the first preservative-free unit dose therapy for the treatment of post-operative pain and inflammation.

The trial involved 91 patients and met the primary endpoints of complete clearance of anterior chamber cells, which is a marker for inflammation, at both Day 8 and Day 15 with p-values of 0.01 and 0.001, respectively. While SURF-201 was dosed at only twice a day, a higher percentage of patients were inflammation free by the end of the dosing when compared to the previously reported results of all other branded corticosteroids. In addition to inflammation, when looking at the secondary endpoint, an unprecedented high percentage of almost 90% of patients were pain free at Day 15. Overall, SURF-201 was found to be safe and well-tolerated and there was zero incidence of intraocular pressure increase of more than 10 mm/Hg from the base and exceeding the 22 mm/Hg mark.

"The extremely positive data for SURF-201 affirms not only the potential for this product, but also the merit of the common building blocks found across the therapies in our pipeline," said Kamran Hosseini, MD, PhD, President and CEO, Surface Ophthalmics. "This is a critical point in time for Surface Ophthalmics – over the coming months, we will be moving forward with SURF-201 as well as advancing our pipeline of SURF-100 (Chronic Dry Eye) and SURF-200 (Episodic Dry Eye) into Phase II trials. Based on the data we received from this study, we feel even more confident that our building block approach to product development will continue to demonstrate positive results and allow us to fully recognize the potential of our robust pipeline to offer innovative solutions for unmet patient needs in the ophthalmic space."

*For more information on the 2021 outlook for Surface Ophthalmics, read the release here.*

"These results are, to me, extremely promising – showing impressive reduction in pain and inflammation – giving us strong Phase II evidence that SURF-201 has benefits for patients following ocular surgery," said Richard Lindstrom, MD, internationally recognized leader in corneal, cataract, refractive and laser surgery. "With SURF-201, I'm excited to see betamethasone, a potent and safe corticosteroid popular in many countries, advance through clinical trials in the United States. I expect SURF-201 to be a significant new treatment option for the eyecare community, particularly in its unique unit-dose, preservative-free solution with the comforting Klarity vehicle."

**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, moved one program (SURF-201) into Phase II clinical studies, and is preparing for two additional Phase II programs 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**

**Media Inquiries**
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