

**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 18, 2021

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

Delaware
(State or other jurisdiction
of incorporation)

001-35814
(Commission
File Number)

45-0567010
(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
8.625% Senior Notes due 2026	HROWL	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 1.01 Entry Into a Material Definitive Agreement.

On August 18, 2021, Harrow Health, Inc. (the “Company”) entered into a License Agreement and a Basic Sale and Purchase Agreement (together, the “Agreements”) with Wakamoto Pharmaceutical Co., Ltd. (“Wakamoto”), pursuant to which Wakamoto granted the Company the exclusive license and marketing rights to its ophthalmic drug candidate (“MAQ-100”) in the United States of America (“U.S.”) and Canada.

Pursuant to the Agreements, Wakamoto will supply MAQ-100 to the Company, and the Company will pay Wakamoto a per unit transfer price to supply MAQ-100. In addition, the Company is required to pay Wakamoto various one-time milestone payments totaling up to two million dollars (\$2,000,000) upon the achievement of certain regulatory milestones and up to six million two hundred thousand dollars (\$6,200,000) upon the achievement of certain commercial milestones. Under the terms of the Agreements, the Company will be responsible for regulatory filings and fees for MAQ-100 in the U.S. and Canada

Subject to certain limitations, the term of the Agreements is for five years from the date of the U.S. Food and Drug Administration’s (or FDA’s) market approval of MAQ-100 and allows for a five-year extension if certain unit sales thresholds are met.

The foregoing is a summary description of certain terms of the Agreements, is not complete and is qualified in its entirety by reference to the text of the Agreements, which the Company expects to file as an exhibit to the Company’s Quarterly Report on Form 10-Q for the quarter ending September 30, 2021.

Item 8.01 Other Events.

On August 18, 2021, the Company issued a press release announcing its exclusive arrangement to MAQ-100. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Item	Description
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99.1	Harrow Health and Wakamoto Press Release dated August 18, 2021
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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: August 18, 2021

By: /s/ Andrew R. Boll

Name: Andrew R. Boll

Title: Chief Financial Officer



Harrow Health Acquires Ophthalmic Surgical Drug Candidate from Wakamoto Pharmaceutical Co., Ltd.

NASHVILLE, Tenn. and TOKYO, August 18, 2021 – Harrow Health, Inc. (NASDAQ: HROW), an ophthalmic-focused healthcare company, today announced that it has entered into an agreement with Wakamoto Pharmaceutical Co., Ltd. to acquire the U.S. and Canadian commercial rights for drug candidate MAQ-100, a preservative-free triamcinolone acetonide ophthalmic injection.

MAQ-100 is marketed and sold by Wakamoto in Japan as MaQaid[®]. Following Japan’s Ministry of Health Labor and Welfare (or MHLW) approval, MaQaid was launched in Japan in 2010, indicated as an intravitreal injection for visualization for vitrectomy. Since its initial MHLW approval, the indication for MaQaid was expanded to include (a) treatments for alleviation of diabetic macular edema, (b) macular edema associated with retinal vein occlusion (or RVO), and (c) non-infectious uveitis. Harrow intends to leverage the clinical data used for Japanese market approval of MaQaid, initially to support a clinical program and U.S. market NDA submission of MAQ-100 for visualization during vitrectomy.

Mark L. Baum, CEO of Harrow Health, stated, “We are indeed honored to work with our new partners at Wakamoto to bring MAQ-100 to the U.S. and Canadian markets. This transaction is an excellent strategic fit with our recent commitment to expand our footprint to include retina-focused surgeons and follows our recent announcement of the acquisition of AMP-100, a patented, innovative ocular surface anesthetic drug candidate. Both transactions represent progress towards the execution of our strategic goal to grow Harrow through the addition of high-value products to our pharmaceutical portfolio. And both transactions allow us to leverage our wholly owned, efficient, scalable, and tech-enabled ImprimisRx ophthalmic-focused platform to expand the portfolio of ophthalmic pharmaceutical products we provide to the thousands of prescribers we serve across the country.”

Norihisa Kojima, CEO for Wakamoto Pharmaceuticals, stated, “We are very glad to have an opportunity to collaborate with Harrow Health. We believe Harrow Health’s exclusive focus on ophthalmology and commitment to thousands of American ophthalmic surgeons, providing high-quality and innovative medications, make Harrow an excellent selection for potential expansion to the U.S. and Canada markets.”

Under the terms of the agreement, Wakamoto will receive payments based on the achievement of commercial milestones and supply Harrow with MAQ-100. Harrow Health will have marketing rights for the U.S. and Canada, while Wakamoto Pharmaceuticals will retain MAQ-100 marketing rights in other countries.

B. Riley Securities acted as financial advisors to Harrow Health and MP Advisors acted as strategic advisors to Wakamoto on the transaction.

About Wakamoto Pharmaceutical Co., Ltd.

Wakamoto Pharmaceutical Co., Ltd. (Head office: Tokyo, CEO: Norihisa Kojima), a Japanese pharmaceutical company, started in 1929. Wakamoto Pharmaceuticals manufactures and sells various kinds of ethical drugs in ophthalmology, OTC products and food supplements.

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About Harrow Health

Harrow Health, Inc. (NASDAQ: HROW) is an ophthalmic-focused healthcare company. The Company owns and operates ImprimisRx, one of the nation's leading ophthalmology-focused pharmaceutical businesses, and Visionology, a direct-to-consumer eye care subsidiary focused on chronic eye disease. Harrow Health also holds non-controlling equity positions in [Eton Pharmaceuticals](#), [Surface Ophthalmics](#) and [Melt Pharmaceuticals](#), all of which started as Harrow Health subsidiaries, and owns royalty rights in four clinical-stage drug candidates being developed by Surface Ophthalmics and Melt Pharmaceuticals. For more information about Harrow Health, please visit the Investors section of the corporate website, harrowinc.com.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Any statements in this release that are not historical facts may be considered such "forward-looking statements." Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties which may cause results to differ materially and adversely from the statements contained herein. Some of the potential risks and uncertainties that could cause actual results to differ from those predicted include the impact of the COVID-19 pandemic and any future health epidemics on our financial condition, liquidity and results of operations; our ability to make commercially available our compounded formulations and technologies in a timely manner or at all; market acceptance of the Company's formulations and challenges related to the marketing of the Company's formulations; risks related to our compounding pharmacy operations; our ability to enter into other strategic alliances, including arrangements with pharmacies, physicians and healthcare organizations for the development and distribution of our formulations; our ability to obtain intellectual property protection for our assets; our ability to accurately estimate our expenses and cash burn, and raise additional funds when necessary; risks related to research and development activities; the projected size of the potential market for our technologies and formulations; unexpected new data, safety and technical issues; regulatory and market developments impacting compounding pharmacies, outsourcing facilities and the pharmaceutical industry; competition; and market conditions. These and additional risks and uncertainties are more fully described in Harrow Health's filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K and its Quarterly Reports on Form 10-Q. Such documents may be read free of charge on the SEC's web site at www.sec.gov. Undue reliance should not be placed on forward-looking statements, which speak only as of the date they are made. Except as required by law, Harrow Health undertakes no obligation to update any forward-looking statements to reflect new information, events or circumstances after the date they are made, or to reflect the occurrence of unanticipated events.

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