

**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): July 25, 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 July 25, 2021, Harrow Health, Inc. (the “Company”) entered into a License and Supply Agreement (the “Agreement”) with Sintetica S.A. (“Sintetica”), pursuant to which Sintetica granted the Company the exclusive license and marketing rights to its patented ophthalmic drug candidate (“AMP-100”) in the United States of America (“U.S.”) and Canada.

Pursuant to the Agreement, the Company will pay Sintetica a per unit transfer price to supply AMP-100, along with a per unit royalty for units sold. The Company is required to pay Sintetica up to eighteen million dollars (\$18,000,000) in one-time milestone payments including a five million dollar (\$5,000,000) payment due within 30 days of signing the Agreement and the balance of payments due upon achievement of certain regulatory and commercial milestones. Under the terms of the Agreement, Sintetica will be responsible for regulatory filings for AMP-100 in the U.S.

Subject to certain limitations, the term of the Agreement is ten years, and allows for a ten-year extension if certain sales thresholds are met.

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

Item 8.01 Other Events.

On July 27, 2021, the Company issued a press release announcing its exclusive North American licensing arrangement to AMP-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**

<u>Item</u>	<u>Description</u>
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99.1	Harrow Health and Sintetica Press Release dated July 27, 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: July 27, 2021

By: /s/ Andrew R. Boll

Name: Andrew R. Boll

Title: Chief Financial Officer



Harrow Health Acquires Patented Ophthalmic Surgical Drug Candidate from Sintetica

New Drug Application Expected to Be Filed in Late 2021

NASHVILLE, Tenn. and MENDRISIO, Switzerland, July 27, 2021 – Harrow Health, Inc. (NASDAQ: HROW), an ophthalmic-focused healthcare company, today announced that it has entered into an agreement with Sintetica, S.A., a growing pharmaceutical company focused on analgesics, local anesthetics and sterile injectable solutions, to acquire the marketing and supply rights in the U.S. and Canada for AMP-100, a patented ophthalmic surgical drug candidate. When approved, AMP-100 will provide ocular surface anesthesia during ophthalmic interventions such as cataract surgery and intravitreal injections, which are estimated to total over 10 million procedures annually in the U.S.⁽¹⁾

AMP-100 is a patented, innovative ocular surface anesthetic drug candidate, with safety and efficacy supported by a robust pre-clinical and clinical program, including a recently completed Phase 3 study that successfully compared the efficacy and tolerability of AMP-100 to current standards of care. Sintetica intends to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in late 2021. When approved, the active ingredient used in AMP-100 will be the first approved use of this active ingredient in the U.S. ophthalmic market.

Commenting on the acquisition, Mark L. Baum, CEO of Harrow Health, said, “This transaction reflects Harrow Health’s commitment to continued growth by adding new high-value products to our portfolio. The acquisition of rights to market and sell AMP-100 in the U.S. and Canada will further fortify our greatest commercial strength – providing thousands of U.S. eyecare professionals and their patients with *novel ophthalmic surgical products*. When approved, we expect to fully leverage our wholly owned, efficient, scalable, and tech-enabled ImprimisRx ophthalmic-focused commercial and distribution platform to market AMP-100 to our ‘front-of-the-eye-focused’ customer base, such as cataract and refractive surgeons. In addition, we intend to invest in expanding our commercial footprint to include retina-focused surgeons to fully leverage the market potential of AMP-100.”

“We have a sound business strategy for commercializing our promising and innovative products in countries around the world,” added Miro Venturi, Corporate CEO for Sintetica, S.A. “We are convinced that Harrow Health, with its knowledge and expertise in ophthalmology and commitment to providing high-quality medications, is the optimal choice for Sintetica to partner with to bring AMP-100 to the U.S. market.”

Under the terms of the agreement, Sintetica will be responsible for regulatory filings for the product in the U.S. The agreement provides for upfront and milestone payments to Sintetica as well as per unit royalties on sales of AMP-100, when successfully commercialized. Harrow Health will have marketing rights for the U.S. and Canada, while Sintetica will retain the marketing rights in other countries.

B. Riley Securities acted as financial advisors to Harrow Health for the transaction.

About Sintetica

Based in Mendrisio, Switzerland, Sintetica is a growing privately held international pharmaceutical company focused on analgesics, local anesthetics and sterile injectable solutions in ampoules, vials and IV bags for hospitals. Sintetica develops medicines in concentrated and premixed formulations, which enables healthcare practitioners to administer these products without manipulation and dilution, increasing patient safety and improving convenience for patients and HCPs. Sintetica runs sales subsidiaries in selected European markets and partners with leading distributors around the world. In 2020, Sintetica employed 277 employees and produced 52.9 million products, with revenues of close to CHF 90 million. For more information about Sintetica, please visit the corporate website, sintetica.com.

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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 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 equity positions in Eton Pharmaceuticals, Surface Ophthalmics and Melt Pharmaceuticals, all of which started as Harrow Health subsidiaries. Harrow Health also 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 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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References:

⁽¹⁾ Market Scope 2019, IOL Market Report, April 2019, and Ophthalmologica, [2018 Update on Intravitreal Injections](#), accessed 7/27/21

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