

**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): December 6, 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 Material Agreement.

On December 6, 2021, ImprimisRx, LLC, a wholly owned subsidiary of Harrow Health, Inc. (individually or together the “Company”), entered into a letter agreement (the “Letter Agreement”) with EyePoint Pharmaceuticals, Inc. (“EyePoint”) to expand the commercial alliance previously entered into by the parties pursuant to that certain Commercial Alliance Agreement, effective as of August 1, 2020, and amended as of November 12, 2020 (the “Commercial Alliance Agreement”).

During the two-year term of the Letter Agreement, in exchange for EyePoint agreeing to pay the Company a commission based on all net sales of DEXYCU® in the United States of America (U.S.), the Company will assume full responsibility for the sales and marketing of DEXYCU (dexamethasone intraocular suspension) 9% for the treatment of post-operative inflammation following ocular surgery in the U.S., has agreed to make offers of employment to eight EyePoint employees, and will be responsible for all sales and marketing related regulatory compliance. EyePoint will retain control over all regulatory approvals and commercial rights for DEXYCU. The Letter Agreement will be effective as of January 1, 2022 and will continue through December 31, 2023, unless such term is amended by mutual agreement of the parties or terminated in accordance therewith.

The Letter Agreement also amends the Company’s required minimum sales levels based on the DEXYCU unit demand for the third quarter of 2021. The failure to achieve these minimum sales levels could result in penalties payable by the Company to EyePoint; provided however, in no event shall a penalty, if any, exceed commissions payable by EyePoint to the Company.

Upon expiration or termination of the Letter Agreement, the parties will revert to the terms of the Commercial Alliance Agreement in existence prior to the effectiveness of the Letter Agreement for the remainder of the original term of the Commercial Alliance Agreement. The Letter Agreement provides that either party may terminate the Commercial Alliance Agreement upon 30 days’ prior written notice in the event DEXYCU ceases to have Medicare Part B “pass-through” payment status for a period of not less than 6 months. The Company has an additional right to terminate the Letter Agreement with 30 days written notice if (i) a proposed or final Hospital Outpatient Prospective Payment System (HOPPS) rule issued by the Centers for Medicare & Medicaid Services (CMS) during calendar year 2022 does not contain an extension of the pass-through payment period for DEXYCU beyond December 31, 2022, and (ii) EyePoint has not otherwise waived any minimum sales for a respective quarterly period.

For more information about the Commercial Alliance Agreement, please see the Company’s current report on Form 8-K filed by the Company with the U.S. Securities and Exchange Commission on August 6, 2020, as well as the information contained in the Company’s most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q.

The foregoing is a summary description of certain terms of the Letter Agreement, is not complete and is qualified in its entirety by reference to the text of the Letter Agreement, which the Company expects to file as an exhibit to the Company’s Annual Report on Form 10-K for the fiscal year ending December 31, 2021.

Item 8.01. Other Events

The Company and EyePoint issued a joint press release announcing the expansion of their commercial alliance on December 7, 2021, a copy of which is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	ImprimisRx and EyePoint Press Release dated December 7, 2021
104	Cover Page Interactive Data File (embedded within the inline XBRL document)

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: December 9, 2021

By: /s/ Andrew R. Boll

Name: Andrew R. Boll

Title: Chief Financial Officer



**EyePoint Pharmaceuticals and Harrow Health's ImprimisRx Announce Expanded
U.S. Commercial Alliance for DEXYCU®**

– ImprimisRx to assume full responsibility for U.S. sales and marketing activities for DEXYCU® and absorb the majority of EyePoint's DEXYCU commercial organization; EyePoint to retain DEXYCU NDA, revenue recognition, manufacturing and distribution responsibilities for all markets –

WATERTOWN, Mass., NASHVILLE, Tenn. and CARLSBAD, Calif., December 7, 2021– EyePoint Pharmaceuticals, Inc. (NASDAQ: EYPT), a pharmaceutical company committed to developing and commercializing therapeutics to help improve the lives of patients with serious eye disorders, and ImprimisRx, one of the nation's leading ophthalmic-focused pharmaceutical businesses and a wholly owned subsidiary of Harrow Health, Inc. (NASDAQ: HROW), today jointly announced the expansion of their commercial alliance in which ImprimisRx will assume responsibility for U.S. sales and marketing activities for DEXYCU® (dexamethasone intraocular suspension) 9% for the treatment of post-operative inflammation following ocular surgery in the U.S. The amended agreement expands the commercial alliance previously established in August 2020 between the companies.

“EyePoint is excited to build upon our successful collaboration with ImprimisRx to promote awareness and demand for DEXYCU to cataract surgeons and patients in need of more effective treatments to manage ocular inflammation following surgery,” said Scott Jones, Chief Commercial Officer of EyePoint Pharmaceuticals. “We are dedicated to providing long-lasting solutions to all patients suffering from ophthalmic diseases. This expanded partnership enables us to fully leverage ImprimisRx's presence and tremendous expertise in ocular and cataract surgery, while allowing EyePoint to focus our efforts on advancing our retinal disease-focused pipeline. We look forward to working closely with the ImprimisRx team to accelerate DEXYCU's growth, bringing its many benefits to more physicians and patients.”

“We are pleased to expand our partnership with EyePoint to continue to bring DEXYCU, an innovative FDA-approved injectable steroid product, to patients experiencing inflammation following ocular surgery,” said John Saharek, President of ImprimisRx. “A growing number of our ophthalmologist customers experience the benefits DEXYCU offers as a sustained release treatment option that is a complement to their patients' eye drop regimen. We are pleased with the success we have had thus far in building customer demand for DEXYCU, which we expect to grow as result of the expansion of our partnership with EyePoint. We look forward to executing our U.S. commercial strategy alongside EyePoint to attain our shared goal of even greater success for many years to come.”

Under the terms of the expanded commercial alliance, ImprimisRx will assume responsibility for the sales and marketing of DEXYCU in the U.S. and will absorb the majority of EyePoint's DEXYCU commercial organization. EyePoint will continue to recognize net product revenue and maintain manufacturing and distribution responsibilities for DEXYCU along with non-sales related regulatory compliance. EyePoint will pay ImprimisRx a commission based on the net sales of DEXYCU and will retain all commercial rights for DEXYCU. This amended agreement will be effective on January 1, 2022.

About DEXYCU®

DEXYCU® (dexamethasone intraocular suspension) 9% is indicated for the treatment of postoperative inflammation and was approved by the FDA on February 9, 2018. A link to the full product label is available at: <https://dexycu.com/wp-content/uploads/2019/01/DEXYCU-PI-20181220.pdf>.

December 7, 2021

About EyePoint Pharmaceuticals

EyePoint Pharmaceuticals (Nasdaq: EYPT) is a pharmaceutical company committed to developing and commercializing therapeutics to help improve the lives of patients with serious eye disorders. The Company's pipeline leverages its proprietary Durasert® technology for sustained intraocular drug delivery including EYP-1901, a potential twice-yearly intravitreal anti-VEGF treatment initially targeting wet age-related macular degeneration. The Company has two commercial products: YUTIQ®, for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye, and DEXYCU®, for the treatment of postoperative inflammation following ocular surgery. EyePoint Pharmaceuticals is headquartered in Watertown, Massachusetts.

About ImprimisRx

ImprimisRx is one of the nation's leading ophthalmology-focused outsourcing pharmaceutical businesses, serving thousands of ophthalmologists and optometrists in all 50 states, with 40 proprietary ophthalmic formulations. For more information about ImprimisRx, including ordering instructions, please visit our website, imprimisrx.com.

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 vision care. Harrow Health also holds non-controlling equity positions in [Eton Pharmaceuticals](#), [Surface Pharmaceuticals](#), 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.

EYEPOINT PHARMACEUTICALS SAFE HARBOR STATEMENTS UNDER THE PRIVATE SECURITIES LITIGATION ACT OF 1995: To the extent any statements made in this press release deal with information that is not historical, these are forward-looking statements under the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements regarding the use of proceeds for the offering and other statements identified by words such as "will," "potential," "could," "can," "believe," "intends," "continue," "plans," "expects," "anticipates," "estimates," "may," other words of similar meaning or the use of future dates. Forward-looking statements by their nature address matters that are, to different degrees, uncertain. Uncertainties and risks may cause EyePoint's actual results to be materially different than those expressed in or implied by EyePoint's forward-looking statements. For EyePoint, this includes stock price volatility and uncertainties relating to the financial markets, the continued impact of the COVID-19 pandemic on EyePoint's business, the medical community and the global economy, and the impact of general business and economic conditions. More detailed information on these and additional factors that could affect EyePoint's actual results are described in EyePoint's filings with the SEC, including its Annual Report on Form 10-K for the fiscal year ended December 31, 2020, as revised or supplemented by its Quarterly Reports on Form 10-Q and other documents filed with the SEC. All forward-looking statements in this news release speak only as of the date of this news release. EyePoint undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

-MORE-

December 7, 2021

Harrow Health 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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