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 17, 2025

HARROW, 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.)

1A Burton Hills Blvd., Suite 200 **Nashville, Tennessee** (Address of principal executive offices)	**37215** (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 Stock Market LLC
8.625% Senior Notes due 2026	HROWL	The Nasdaq Stock Market LLC
11.875% Senior Notes due 2027	HROWM	The Nasdaq Stock Market LLC

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 Items.

On July 17, 2025, Harrow, Inc., through a wholly-owned subsidiary (together, "Harrow"), announced that it had entered into a development and commercialization agreement (the "Agreement") with Samsung Bioepis Co., Ltd. ("Samsung"). Under the terms of the Agreement, following completion of the transition of commercial rights from Biogen back to Samsung, Samsung will develop, manufacture, and supply BYOOVIZ® (ranibizumab-nuna) and OPUVIZ™ (aflibercept-yszy) (individually, a "Product" and together, the "Products") for Harrow to commercialize in the U.S. market (the "Rights"). In consideration of such Rights, Harrow will make a one-time upfront payment to Samsung, and Samsung will be eligible to receive additional one-time payments based on the achievement of net sales-based milestones of the Products. In addition to other mutually agreed terms, Harrow shall pay to Samsung a share of net sales from the Products generated in the U.S. market.

A copy of the press release announcing the Agreement is filed as Exhibit 99 to this report.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99	Press Release of Harrow, Inc. dated July 17, 2025
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, INC.

Dated: July 17, 2025

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

Harrow Enters into Commercialization Agreement with Samsung Bioepis for Ophthalmology Biosimilars Portfolio in the United States

Harrow to assume full commercial responsibility for BYOOVIZ® and OPUVIZ™ by the end of 2025

NASHVILLE, Tenn., July 17, 2025 – Harrow (Nasdaq: HROW), a leading North American eyecare pharmaceutical company, today announced that it has entered into a definitive agreement with Samsung Bioepis Co. Ltd. (hereafter "Samsung Bioepis") to secure the exclusive U.S. commercial rights to the ophthalmology biosimilar portfolio of Samsung Bioepis — BYOOVIZ® (ranibizumab-nuna), an FDA-approved biosimilar referencing LUCENTIS[i] (ranibizumab), and OPUVIZ™ (aflibercept-yszy), an FDA-approved biosimilar referencing EYLEA[ii] (aflibercept) — two of the most widely used anti-VEGF therapies for retinal diseases.

BYOOVIZ has been commercialized by Biogen in the U.S. since its initial launch in June 2022. In October 2024, Biogen notified Samsung Bioepis of their decision to terminate the 2019 Development and Commercialization Agreement within the U.S. and Canada. Samsung Bioepis has been closely working with Biogen on the transfer of commercialization rights for BYOOVIZ and OPUVIZ back to Samsung Bioepis in these regions. Harrow will assume full responsibility for commercialization of BYOOVIZ in the U.S. upon completion of the transition of commercial rights from Biogen back to Samsung Bioepis. The transition is expected to be completed by the end of 2025.

This strategic acquisition enhances Harrow's position as the leading full-spectrum ophthalmic pharmaceuticals provider in the U.S., expands its pipeline with high-value biosimilars for sight-threatening retinal diseases, and reinforces its commitment to delivering value-oriented innovation to the U.S. eyecare market.

"This transformational acquisition marks a pivotal moment for Harrow and reinforces our commitment to delivering innovation, accessibility, and value to the U.S. ophthalmology community," said Mark L. Baum, Chairman and Chief Executive Officer of Harrow. "We are excited to leverage our growing commercial presence within the retina specialist community, built over the past year, and partner with Samsung Bioepis, globally recognized for its scientific excellence in biologics and biosimilars. These ophthalmic assets are among the most highly regarded in the market, and we are looking forward to bringing these products to U.S. physicians and patients."

Transaction Highlights

- **Acquired Rights**: Harrow gains exclusive U.S. commercial rights to Samsung Bioepis' portfolio of ophthalmic biosimilars, including BYOOVIZ® ("bio-viss") and OPUVIZ™ ("op-u-vis"):
    - **BYOOVIZ (ranibizumab-nuna) 0.05mL injection,** the first FDA-approved LUCENTIS biosimilar indicated for the treatment of patients with Neovascular (Wet) Age-Related Macular Degeneration (AMD), Macular Edema following Retinal Vein Occlusion (RVO), and Myopic Choroidal Neovascularization (mCNV).
    - **OPUVIZ (aflibercept-yszy) 0.05mL injection**, an FDA-approved EYLEA biosimilar indicated for the treatment of patients with Wet AMD, Macular Edema following RVO, Diabetic Macular Edema (DME), and Diabetic Retinopathy (DR).
- **Market Opportunity**: The retinal disease treatment market represents a $9 billion opportunity[iii] in the U.S., with biosimilars expected to expand patient access and affordability.
- **Execution-Ready Platform:** Harrow will leverage its established commercial infrastructure and national reach to accelerate the market impact of these biosimilars.

Harrow is committed to reshaping the Wet AMD treatment landscape by offering an FDA-approved, on-label, and affordable alternative to existing anti-VEGF therapies. The market is dominated by EYLEA, LUCENTIS, VABYSMO, and compounded Avastin, which continues to be used off-label due to its low cost, despite not being formulated or approved for ocular administration. Current anti-VEGF therapies are among the most expensive drug categories covered under Medicare Part B, with annual spending in the U.S. exceeding $4.2 billion[iv]. Harrow's acquisition of these products has the potential to substantially lower the financial burden on Medicare and commercial plans, while improving access and affordability for patients.

i Lucentis is a trademark of Genentech, Inc.
ii Eylea is a trademark of Regeneron Pharmaceuticals, Inc.
iii Company annual reports & Biopharma AVASTIN estimates
iv https://www.reviewofoptometry.com/news/article/annual-medicare-expense-for-antivegf-injections-tops-4-billion-study-finds

About BYOOVIZ (ranibizumab-nuna)

BYOOVIZ (ranibizumab-nuna) injection, for intravitreal use.

BYOOVIZ (ranibizumab-nuna) is biosimilar to LUCENTIS (ranibizumab injection).

BYOOVIZ, a vascular endothelial growth factor (VEGF) inhibitor, is indicated for the treatment of patients with:

Neovascular (Wet) Age-Related Macular Degeneration (AMD)

Macular Edema Following Retinal Vein Occlusion (RVO)

Myopic Choroidal Neovascularization (mCNV)

Select Important Safety Information

WARNING AND PRECAUTIONS

Endophthalmitis and retinal detachments may occur following intravitreal injections. Patients should be monitored following the injection.

Increases in intraocular pressure (IOP) have been noted both pre- and post-intravitreal injection.

There is a potential risk of arterial thromboembolic events following intravitreal use of VEGF inhibitors.

ADVERSE REACTIONS

The most common adverse reactions (reported more frequently in ranibizumab treated subjects than control subjects) are conjunctival hemorrhage, eye pain, vitreous floaters, and increased IOP.

Please see Prescribing Information for BYOOVIZ (ranibizumab-nuna) HERE.

About OPUVIZ (aflibercept-yszy)

OPUVIZ (aflibercept-yszy) injection, for intravitreal use.

OPUVIZ (aflibercept-yszy) is biosimilar to EYLEA (aflibercept).

OPUVIZ is a vascular endothelial growth factor (VEGF) inhibitor, indicated for the treatment of patients with:

Neovascular (Wet) Age-Related Macular Degeneration (AMD)

Macular Edema Following Retinal Vein Occlusion (RVO)

Diabetic Macular Edema (DME)

Diabetic Retinopathy (DR)

Select Important Safety Information

WARNING AND PRECAUTIONS

Endophthalmitis, retinal detachments, and retinal vasculitis with or without occlusion may occur following intravitreal injections. Patients and/or caregivers should be instructed to report any signs and/or symptoms suggestive of endophthalmitis, retinal detachment, or retinal vasculitis without delay and should be managed appropriately.

Increases in intraocular pressure have been seen within 60 minutes of an intravitreal injection.

There is a potential risk of arterial thromboembolic events following intravitreal use of VEGF inhibitors.

ADVERSE REACTIONS

The most common adverse reactions (≥5%) reported in patients receiving aflibercept were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and intraocular pressure increased.

Please see Prescribing Information for OPUVIZ (aflibercept-yszy) HERE.

About Harrow

Harrow, Inc. (Nasdaq: HROW) is a leading eyecare pharmaceutical company engaged in the discovery, development, and commercialization of innovative ophthalmic pharmaceutical products for the North American market. Harrow helps eyecare professionals preserve the gift of sight by making its portfolio of pharmaceutical products accessible and affordable to millions of patients each year. For more information about Harrow, please visit harrow.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, among others, risks related to: liquidity or results of operations; our ability to successfully implement our business plan, develop and commercialize our products, product candidates and proprietary formulations in a timely manner or at all, identify and acquire additional products, manage our pharmacy operations, service our debt, obtain financing necessary to operate our business, recruit and retain qualified personnel, manage any growth we may experience and successfully realize the benefits of our previous acquisitions and any other acquisitions and collaborative arrangements we may pursue; competition from pharmaceutical companies, outsourcing facilities and pharmacies; general economic and business conditions, including inflation and supply chain challenges; regulatory and legal risks, including litigation matters, and other uncertainties related to our pharmacy operations and the pharmacy and pharmaceutical business in general; physician interest in and market acceptance of our current and any future formulations and compounding pharmacies generally. These and additional risks and uncertainties are more fully described in Harrow's filings with the Securities and Exchange Commission (SEC), including its Annual Report on Form 10-K for the year ended December 31, 2024, subsequent Quarterly Reports on Form 10-Q, and other filings with the SEC. Such documents may be read free of charge on the SEC's web site at 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 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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