



Harrow Announces Availability of Fortisite™ Formulations for In-Office Use

January 5, 2023

NASHVILLE, Tenn.--(BUSINESS WIRE)--Jan. 5, 2023-- Harrow (Nasdaq: HROW), a leading U.S. eyecare pharmaceutical company, today announced the availability, for in-office use, of Fortisite™ (compounded Tobramycin 1.5% + Vancomycin 5%) from its FDA-registered and FDA-inspected ImprimisRx® 503B outsourcing facility. Fortisite formulations are patent-pending high-concentration, refrigeration-stable, fortified antibiotic formulations, in solution. The availability of Fortisite for in-office use represents the first time eyecare professionals have been able to stock a fortified or high-concentration compounded antibiotic formulation for the immediate treatment of patients in need.

This press release features multimedia. View the full release here: <https://www.businesswire.com/news/home/20230105005349/en/>



Fortisite, available from Harrow's ImprimisRx 503B outsourcing facility. (Photo: Business Wire)

ImprimisRx offers a robust Fortisite patient access program and a 100% replacement guarantee for any expired 503B Fortisite product, ensuring all prescribing U.S. eyecare

professionals can continuously stock Fortisite formulations in their offices. Eyecare professionals can [order](#) Fortisite online or call ImprimisRx Customer Care at (844) 446-6979.

In commenting on the announcement, Mark L. Baum, Chairman and Chief Executive Officer of Harrow, said, "The availability of Fortisite formulations will provide eyecare professionals with new and important tools in their pharmaceutical armamentarium as they consider how to treat potentially sight-threatening infections. Until there is an FDA-approved product to meet these needs, Fortisite formulations have the potential to become the standard of care for ophthalmology and optometry practices across the country.

"Because Fortisite is now available for in-office use from our FDA-registered 503B outsourcing facility, each bottle must strictly adhere to rigorous analytical testing protocols that are not required for locally regulated 503A compounding pharmacies."

Comments from eyecare professionals regarding Fortisite (*none of whom are consultants to Harrow*):

- At a recent panel discussion at the annual Ocular Surgery News (OSN) New York conference, [Dr. Eric Donnenfeld](#), an internationally recognized refractive and cataract surgeon at Ophthalmic Consultants of Long Island, NY, said, "Every ophthalmologist who has an anterior segment practice should have Fortisite available in their refrigerator for that ounce of protection you need on that Friday afternoon for that patient that comes in with infection that you say, 'what do I do next?' To have this available from Harrow's ImprimisRx [division] is a really nice thing to have."
- [Dr. Brian Shafer](#), a cataract, refractive, cornea, and glaucoma surgeon with Chester County Eye Care, added, "The commercial availability of Fortisite is truly a game changer in the management of certain serious infectious eye diseases. Gone are the days of sending patients to compounding pharmacies hours away. Now, we can provide patients with the care they need and deserve *directly from the office refrigerator!*"
- [Dr. Terrence O'Brien](#), distinguished professor of ophthalmology at Bascom Palmer Eye Institute, said, "Topical broad-spectrum ophthalmic antibacterial agents are an essential therapy for severe, sight-threatening ocular infections. Finally, a reliable source for stable, commercially available, shelf-ready potent formulations for immediate application is changing traditional access and reliability challenges while allowing more rapid achievement of microbicidal concentrations in ocular tissues for potentially enhancing treatment response."

Compounded medications are not reviewed by the FDA for safety or efficacy. ImprimisRx does not compound copies of commercially available products.

PLEASE REVIEW THE FORTISITE [PACKAGE INSERT](#) BEFORE USING.

About Harrow

Harrow (Nasdaq: HROW) is a leading U.S. eyecare pharmaceutical company that serves eyecare professionals by providing both branded FDA-approved and innovative compounded prescription medicines that are accessible and affordable. Harrow meets its mission by serving ophthalmologists and optometrists as they protect the gift of sight for their patients. For more information about Harrow, please visit the Investors section of the corporate website, 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 the continued 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 FDA-approved products and compounded formulations and technologies in a timely manner or at all; market acceptance of the Company’s products and challenges related to the marketing of the Company’s products; risks related to our 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 products; 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 products; 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’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 website 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 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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