



Harrow Health Announces FDA Acceptance of New Drug Application for AMP-100

February 22, 2022

Receives PDUFA Date of October 16, 2022

NASHVILLE, Tenn.--(BUSINESS WIRE)--Feb. 22, 2022-- Harrow Health, Inc. (Nasdaq: HROW), an ophthalmic-focused healthcare company, today announced that the U.S. Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) filing for AMP-100, the Company's drug candidate for ocular surface anesthesia and intraoperative pain management during ocular surgery. The FDA has assigned the application standard review and a Prescription Drug User Fee Act (PDUFA) target action date of October 16, 2022.

In commenting on the announcement, Mark L. Baum, Chief Executive Officer of Harrow Health, said, "The FDA's acceptance of the AMP-100 NDA is a major step forward for Harrow Health Inc. and our commitment to make this patented, innovative drug candidate available. The non-opioid active pharmaceutical ingredient used in AMP-100, if approved, would be the first approved use of this ingredient in the U.S. ophthalmic market. We look forward to working with the FDA during the review process, and we are excited about making AMP-100, if approved, commercially available to the thousands of ophthalmologists, optometrists, hospitals, and ambulatory surgery centers we serve throughout the United States."

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 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, www.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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Source: Harrow Health, Inc.