Harrow to Acquire Melt Pharmaceuticals

September 26, 2025

NASHVILLE, Tenn., Sept. 26, 2025 (GLOBE NEWSWIRE) -- Harrow (Nasdaq: HROW), a leading provider of ophthalmic disease management solutions in North America, today announced that it has entered into an agreement to acquire **Melt Pharmaceuticals, Inc.**, a clinical-stage pharmaceutical company pioneering non-opioid, non-IV therapies for sedation for medical procedures in the hospital, outpatient, and in-office settings. The closing of this acquisition is subject to customary closing conditions, including approval by Melt stockholders, excluding Harrow and Harrow-affiliated parties.

Melt's lead investigational therapy, **MELT-300**, is a patented, sublingually delivered formulation of a fixed dose of midazolam (3mg) and ketamine (50mg) designed to provide rapid, predictable sedation and analgesia without the need for intravenous administration. This innovative approach has the potential to transform patient experiences across a wide range of office-based and outpatient procedures and address the healthcare system's growing demand to reduce exposure to opioids.

In November 2024, Melt announced positive topline results from its pivotal LOUISE (Lower Opioid Use and Improve the Sedation Experience) Phase 3 Study, which demonstrated that MELT-300 was statistically superior to both sublingual midazolam alone (P=0.009) and placebo (P=<0.0001) in providing successful procedural sedation. In addition, the proportion of patients requiring rescue sedation was nearly twice as high for sublingual midazolam compared with MELT-300 (P=0.003).

The LOUISE Phase 3 Study was conducted under a Special Protocol Assessment ("SPA") agreement with the U.S. Food and Drug Administration ("FDA"), which confirmed the study design would adequately support a future regulatory submission. Further, results from a recently completed cardiac safety study indicated that MELT-300 did not alter normal heart rhythm, supporting the therapy's safety profile.

Harrow plans to submit a New Drug Application ("NDA") to the FDA in 2027, with a potential U.S. commercial launch in 2028.

Strategic Rationale

- **Immediately Accretive Launch**: Harrow, through its ImprimisRx subsidiary, has successfully marketed the MKO Melt®, a compounded sublingual sedation product widely used by ophthalmologists for more than a decade, with the product used in over *500,000* cataract surgeries. This long-standing, positive experience, by over 700 U.S. ophthalmologists, provides a strong foundation of physician trust and market familiarity with this mode of sedation delivery. Upon FDA approval of MELT-300, Harrow intends to ensure customer access to an FDA-approved product and discontinue the MKO Melt.
- **Market Opportunity**: Entry into the multi-billion-dollar U.S. procedural sedation market. MELT-300's novel formulation has the potential to replace and/or supplement IV sedation in medical interventions, with applications in ophthalmic surgery and potential label expansion opportunities into tens of millions of other procedures annually, including claustrophobia during MRIs, sedation for colonoscopies, dental procedures, gastroenterology procedures, and other interventions.
- **Added Diversification**: Strengthens Harrow's perioperative portfolio of surgical solutions and diversifies Harrow's business as MELT-300 is utilized outside of its core US ophthalmic business.
- **Operational Synergies**: Harrow's existing commercial and regulatory infrastructure provides the scale to accelerate Melt's market introduction and potential to replace opioid-based intravenous sedation during the more than 4,000,000 annual U.S. cataract surgeries.
- **Improved Patient Experience**: MELT-300's under-the-tongue delivery, using Catalent's ZYDIS® oral dissolving tablet technology – which is used in over 35 FDA-approved products – offers a less invasive, needle-free, non-opioid option that could reduce anxiety, improve comfort, and simplify care.
- **Expanded Accessibility**: Enables physicians to perform procedures comfortably in office and outpatient settings, reducing reliance on operating rooms.
- **Global Application**: The MELT 300 product candidate has patents issued in North America, Australia, Europe, Asia, and the Middle East. Harrow intends to identify suitable development and commercialization partners to make this technology available outside the U.S. market.

"We are excited to welcome Melt Pharmaceuticals *back* into the Harrow family. This acquisition represents another important step in our mission to deliver innovative, patient-focused ophthalmic disease management solutions that go beyond the limitations of traditional care," said Mark L. Baum, Chief Executive Officer of Harrow. "MELT-300 has the potential to redefine the standard of care for millions of patients by providing a convenient, non-opioid alternative for procedural sedation. By reducing reliance on opioids, MELT-300 not only addresses a critical public health need but also opens the door to significant market expansion opportunities across a wide range of medical procedures. With this acquisition, Harrow continues to strengthen its pipeline of transformative therapies and reinforces our commitment to improving outcomes for patients and providers alike."

Larry Dillaha, MD, Chief Executive Officer of Melt Pharmaceuticals, added, “Sedation hasn’t changed much over the past few decades. Having demonstrated the clinical superiority of the MELT-300 drug candidate over its individual components, including midazolam, we believe the standards of care for sedation will change when the MELT-300 drug candidate is FDA-approved. By re-joining Harrow, we gain the resources and expertise needed to accelerate our programs and bring MELT-300 closer to the patients and physicians who need it most. Together, we are committed to transforming the state of the art in the massive US and global procedural sedation market.”

About Harrow

Harrow, Inc. (Nasdaq: HROW) is a leading provider of ophthalmic disease management solutions in North America, offering a comprehensive portfolio of products that address conditions affecting both the front and back of the eye, such as dry eye disease, wet (or neovascular) age-related macular degeneration, cataracts, refractive errors, glaucoma and a range of other ocular surface conditions and retina diseases. Harrow was founded with a commitment to deliver safe, effective, accessible, and affordable medications that enhance patient compliance and improve clinical outcomes. For more information about Harrow, please visit harrow.com.

About Melt Pharmaceuticals

Melt Pharmaceuticals, Inc. is a clinical-stage pharmaceutical company focused on developing proprietary non-IV, non-opioid, sedation, and analgesia therapeutics for human medical procedures in the hospital, outpatient, and in-office settings. Melt intends to seek regulatory approval through the FDA’s 505(b)(2) regulatory pathway for its proprietary, patented small-molecule product candidates, where possible. Melt’s core intellectual property is the subject of multiple granted patents in North America, Europe, Asia, and the Middle East. Melt Pharmaceuticals, Inc. is a former subsidiary of Harrow, Inc. (Nasdaq: HROW) and was carved out as a separately managed business in 2019. To learn more about Melt, please visit their website, www.meltpharma.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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