



## Harrow Announces Closing of Acquisition of Melt Pharmaceuticals

November 18, 2025

NASHVILLE, Tenn., Nov. 18, 2025 (GLOBE NEWSWIRE) -- Harrow (Nasdaq: HROW), a leading provider of ophthalmic disease management solutions in North America, today announced that it has completed the acquisition of Melt Pharmaceuticals, Inc. (Melt), a clinical-stage pharmaceutical company pioneering non-opioid, non-IV therapies for sedation for medical procedures in the hospital, outpatient, and in-office settings. Melt's product candidates, MELT-210, MELT-300, and MELT-400, are based on the proprietary Zydis® ODT (oral dissolving tablet) drug delivery platform. The closing of the Melt acquisition marks a strategic expansion of Harrow's portfolio and reinforces its commitment to delivering innovative therapies that improve patient outcomes.

With global patent coverage and potential applications in ophthalmology, gastroenterology, dental care, and a wide range of outpatient procedures where sedation or anxiety management is needed, from diagnostic imaging to endoscopy procedures to pre-anesthesia, Melt's drug candidates, including MELT-300, position Harrow to enter the multi-billion-dollar annual U.S. and global procedural sedation and anxiety market.

MELT-300 represents a transformative opportunity, building on more than a decade of real-world experience with MKO Melt® — a compounded sublingual sedation product sold by Harrow's ImprimisRx subsidiary and currently administered by over 800 U.S. ophthalmic institutions, primarily for cataract surgery. As a potential FDA-approved successor, MELT-300 is a patented, sublingually delivered formulation of a fixed dose of midazolam (3mg) and ketamine (50mg) designed to provide rapid, predictable sedation without the need for intravenous administration. The MELT-300 [Phase 2](#) and [Phase 3](#) clinical programs previously demonstrated statistical *superiority* to midazolam alone. The innovative approach to sedation MELT-300 offers has the potential to transform patient experiences across a wide range of office-based and outpatient procedures, addressing the healthcare system's growing demand to reduce exposure to opioids, including fentanyl.

"The development of MELT-300 marks a defining milestone for Harrow — our first product taken from ideation to the brink of commercialization. I still remember the first call we received about this novel concept of non-IV, non-opioid sedation, and the immediate sense that it could truly change the patient experience for procedural sedation. From helping shape the early formulation, to supporting and funding the clinical program, to now executing the remaining pharmacokinetics (PK) studies and preparing to submit our first NDA — this journey showcases Harrow's ability to recognize promising opportunities early and execute to deliver meaningful value," said Mark L. Baum, Chief Executive Officer of Harrow. "We're incredibly excited about MELT-300's potential to transform procedural sedation, reduce opioid exposure, and expand safe, accessible sedation options across medical specialties. It's not just a scientific or commercial achievement — it's a meaningful step forward for patients and for the US healthcare system."

Harrow's Chief Scientific Officer, Amir Shojaei, added, "In addition to the MELT-300 program, in parallel, our clinical development team is also excited to advance the MELT-210 drug candidate in procedural sedation, which we have rarely spoken about, but which nevertheless remains an important part of the rationale behind this acquisition. MELT-210 is a sublingual dosage of midazolam (3mg) in the Zydis ODT technology and has been studied in both Phase 2 and Phase 3 trials as a comparator drug in the MELT-300 program. Due to the advantageous characteristics of MELT-210, including its rapid uptake and short half-life, compared to current market alternatives, we believe MELT-210 will have strong commercial potential. We look forward to engaging with FDA to discuss next steps for this advanced drug development program, and in due course, to have a second product in the market from the Melt portfolio."

"I've relied on MKO Melt for years because it delivers what both clinicians and patients want — effective, needle-free sedation without opioids or the need for IV access. The workflow efficiencies and safety profile have made it a cornerstone of our surgical suite," said Dr. Lawrence Woodard, M.D., Medical Director of Omni Eye Services of Atlanta. "Seeing this innovation advance toward FDA approval with MELT-300 reinforces its importance, not only for ophthalmology but for a wide range of outpatient and office-based procedures. Beyond individual practices, the societal impact of reducing opioid exposure while expanding access to safe, convenient sedation could be enormous."

### Next Steps for MELT-300

The MELT-300 program was the subject of a Special Protocol Assessment (SPA), confirming that the completed Phase 3 study design, statistical approach, and endpoints adequately support a future regulatory submission. Having completed the Phase 3 program, Harrow's focus now turns to advancing MELT-300 toward FDA approval and commercialization.

- **Integration into Harrow:** Melt Pharmaceuticals will be fully integrated into Harrow's operations to ensure a seamless transition and accelerate progress toward NDA submission, approval, and market launch.

- **Supporting Studies:** In support of an NDA filing, Harrow will be initiating one non-clinical animal study and three PK studies to generate the balance of the data necessary for an NDA package.
- **NDA Submission (H1 2027):** Prepare and submit the NDA for MELT-300.
- **Regulatory Review and Approval (H1 2028):** Engage collaboratively with the FDA through the review process, with potential approval in the first half of 2028.
- **Commercial Readiness and Launch (H2 2028):** Leverage Harrow's existing commercial infrastructure and MKO Melt customer network to execute launch preparations — including manufacturing scale-up, packaging, supply-chain validation, reimbursement, market-access planning, and much more.
- **Market Expansion Strategy:** Build on Harrow's established ophthalmic footprint to drive adoption initially in cataract and other ophthalmic procedures, followed by expansion into additional outpatient and in-office settings where opioid-free, needle-free sedation can improve patient experience and workflow efficiency.

Together, these next steps position MELT-300 to become the first FDA-approved, non-opioid, non-IV sublingual sedation therapy in the U.S., representing a meaningful growth opportunity for Harrow and a major advancement in patient-centric procedural care.

### 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](http://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 “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 website at [sec.gov](http://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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