



Harrow Health Provides \$13.5 Million Senior Secured Loan to Melt Pharmaceuticals

September 2, 2021

Melt Expects to Dose First Patient in MELT-300 Phase 2 Study During September 2021

NASHVILLE, Tenn.--(BUSINESS WIRE)--Sep. 2, 2021-- Harrow Health, Inc. (Nasdaq: HROW), an ophthalmic-focused healthcare company, and Melt Pharmaceuticals, Inc., a clinical-stage pharmaceutical company developing first-in-class medicines for sedation and analgesia, today announced that Harrow Health has provided a \$13.5 million senior secured loan to Melt Pharmaceuticals.

This press release features multimedia. View the full release here: <https://www.businesswire.com/news/home/20210902005101/en/>

Melt Pharmaceuticals plans to use the proceeds to conduct its pivotal Phase 2 efficacy study for the company's lead drug candidate, MELT-300, a patented combination of midazolam and ketamine in a rapidly dissolving, sublingual tablet to provide sedation and analgesia for patients undergoing cataract surgery. Melt's [IV-free and non-opioid approach](#) seeks to replace the current practice of IV-delivered sedation and analgesia medication, including the use of fentanyl intraoperatively and other opioids prescribed for pain post-operatively. Melt expects to dose its first patient in September 2021 and to report topline clinical results in the spring of 2022. Pending the outcome of the Phase 2 clinical study, Melt Pharmaceuticals anticipates beginning a Phase 3 clinical study, which compares MELT-300 to a placebo, in the second half of 2022. Melt also expects to file with the U.S. Food and Drug Administration (FDA) two investigational new drug applications (INDs) for its MELT-210 and MELT-400 programs in the latter part of 2021.

"We are pleased to have secured this non-dilutive funding that allows us to complete our Phase 2 clinical study of MELT-300 and execute our overall clinical strategy, which we expect to generate data to ultimately support a new drug application (NDA) submission to the FDA," said Larry Dillaha, M.D., CEO of Melt Pharmaceuticals. "Recent estimates are that as many as 50% of the over four million annual cataract surgeries in the U.S. involve patients being exposed to opioids perioperatively. If FDA approved, MELT-300 will be a new surgical protocol that should virtually eliminate opioid exposure during cataract surgery, ameliorating, in part, the devastating public health effects of the U.S. opioid crisis. As a result of this funding, we will now also be able to advance our goal of leveraging our patented technology in other short-duration procedures in medical fields such as pediatrics, dermatology, plastics, and women's health."

Mark L. Baum, Harrow Health CEO, added, "As Melt Pharmaceuticals' largest shareholder, an owner of royalty rights of potential MELT-300 sales, and given our domain expertise in commercializing ophthalmic surgical pharmaceutical products, Harrow is delighted to provide the capital for Melt's flagship MELT-300 program and to advance other valuable Melt development programs. Dr. Dillaha has an impressive 505(b)(2) drug approval track record, and we believe strongly in his team's strategy with the MELT-300 program. For Harrow, I can think of few near-term events that could deliver the magnitude of value as MELT-300, a multi-patented drug development candidate with a billion-dollar annual revenue opportunity in the growing ophthalmic surgery market. I am very excited about what this potential paradigm shift away from opioids and IVs could mean clinically for patients and ophthalmologists and financially for Harrow shareholders."

The senior secured loan, funded with approximately \$12.5 million of new cash and about \$1 million of existing amounts owed to Harrow Health, has a one-year term with no principal payments due until maturity and no pre-payment penalties. The loan carries an annual interest rate of 12.5%, which can be paid-in-kind in the form of additional principal balance. The loan is secured against nearly all of Melt's assets, including all patents issued in the U.S., Australia, Japan and South Korea related to Melt's platform technologies. Concurrent with entering into the loan agreement, Harrow Health was also provided a five-year, right-of-first-refusal option related to third-party commercialization rights of Melt's drug candidates.

Harrow Health owns approximately 44% of the equity interests in Melt Pharmaceuticals along with a 5% royalty right on sales of MELT-300.

About Melt Pharmaceuticals

Melt Pharmaceuticals, Inc. is a clinical-stage pharmaceutical company focused on the development and commercialization of patented non-intravenous and non-opioid sedation and analgesia medicines for short-duration medical procedures in outpatient and in-office settings. Melt's core technology is a series of combination non-opioid sedation drug formulations that may replace or supplement current sedation modalities for more than 100 million medical procedures in the United States. To learn more about Melt, please visit their website, www.meltpharma.com.

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.

View source version on [businesswire.com](https://www.businesswire.com/news/home/20210902005101/en/): <https://www.businesswire.com/news/home/20210902005101/en/>

Investor Contact:

Jamie Webb, Director of Communications and IR
jwebb@harrowinc.com
615-733-4737

Source: Harrow Health, Inc.