

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 9, 2021

HARROW HEALTH, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-35814
(Commission
File Number)

45-0567010
(IRS Employer
Identification No.)

102 Woodmont Blvd., Suite 610
Nashville, Tennessee
(Address of principal executive offices)

37205
(Zip Code)

Registrant's telephone number, including area code: **(615) 733-4730**

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name on exchange on which registered
Common Stock, \$0.001 par value per share	HROW	The NASDAQ Global Market

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Act of 1934: Emerging growth company

If any emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01. Other Information

On February 9, 2021, Melt Pharmaceuticals, Inc. (“Melt”) issued a press release (the “Melt PR”) reporting results of a phase 1 study of its drug candidate MELT, a patented combination of midazolam and ketamine in a rapidly dissolving sublingual tablet, to provide sedation and analgesia for patients undergoing cataract surgery. According to the Melt PR, the data from the phase 1 study met Melt’s study objectives, including establishing relative bioavailability and pharmacokinetic parameters, characterizing absorption rates following administration, and was well tolerated by patients. Melt expects to begin its phase 2 clinical study in the third quarter of 2021.

Harrow Health, Inc. owns three million five hundred thousand (3,500,000) shares of Melt common stock, which is approximately 44% of the issued and outstanding voting interests of Melt, along with a mid-single digit royalty right on net sales of MELT.

The foregoing is only a brief description of the Melt PR, does not purport to be a complete description of the Melt PR and is qualified in its entirety by reference to the full text of the document, which is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

All trademarks referenced in this Current Report on Form 8-K and the Melt PR are the property of their respective owners.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Item	Description
99.1	Melt Pharmaceuticals Press Release Date February 9, 2021

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

HARROW HEALTH, INC.

Dated: February 9, 2021

By: /s/ Andrew R. Boll

Name: Andrew R. Boll

Title: Chief Financial Officer



**Melt Pharmaceuticals Completes Phase 1 Study
for Sublingual, Non-Opioid Pain and Sedation Drug Candidate**

Company Expects to Begin Phase 2 Clinical Study in the Third Quarter of 2021

Boston (February 9, 2021) – Melt Pharmaceuticals, Inc., a clinical-stage pharmaceutical company developing first-in-class medicines for sedation and analgesia, announced results from its MELT Phase 1 study, a comparative bioavailability study with the objective of characterizing the pharmacokinetic parameters of two dosage strengths of the patented MELT technology (midazolam 3 mg/ketamine 25 mg and midazolam 6 mg/ketamine 50 mg) in healthy volunteers and comparing it to IV-administered formulations of both midazolam and ketamine.

“We are pleased with the results of our Phase 1 MELT study, which marks another important milestone for the Company,” said Greg Madison, CEO of Melt Pharmaceuticals. “The data established relative bioavailability and important pharmacokinetic parameters, including characterizing absorption rates following administration. Importantly, MELT was well tolerated by patients. With the Phase 1 study successfully meeting its objectives, in the coming months, we look forward to meeting with the FDA, finalizing our clinical protocol in patients undergoing cataract surgery, and initiating the Phase 2 clinical study in the third quarter of 2021.”

“Recent estimates are that more than 50% of the over four million annual cataract surgeries in the U.S. involve patients being exposed to opioids to manage pain,” added Maggie Jeffries, M.D., Board Certified Anesthesiologist, Eye Center of Texas, and Partner at Avanti Anesthesia. “If FDA approved, the potential for a pain-free, IV-free, opioid-free option for sedation and analgesia in cataract surgery is dramatic, providing benefits to patients and clinicians alike as we reduce our reliance on opioids.”

About MELT

MELT is a patented combination of midazolam and ketamine in a rapidly dissolving, sublingual tablet to provide sedation and analgesia for patients undergoing cataract surgery. This needle-free and opioid-free approach seeks to replace the current practice of IV-delivered sedation medication for patients. Melt is being developed in partnership with Catalent using its proprietary Zydis[®] orally disintegrating tablet (ODT) technology to create a freeze-dried tablet that disperses almost instantly in the mouth without water.

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. Melt Pharmaceuticals, Inc. was carved out of Harrow Health, Inc. (NASDAQ: HROW) 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 our ability to make commercially available our compounded formulations and technologies in a timely manner or at all; physician interest in prescribing our 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. 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, Melt Pharmaceuticals 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.

Zydis® and all other trademarks, service marks and trade names included or referenced in this press release, are the property of their respective owners.

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Investor Contact:

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