Harrow Health Announces $11 Million Series A Financing for Melt Pharmaceuticals Subsidiary

February 5, 2019
align="justify">SAN DIEGO and BOSTON, Feb. 05, 2019 (GLOBE NEWSWIRE) -- Melt Pharmaceuticals, Inc., an affiliated company of Harrow Health, Inc. (NASDAQ: HROW), today announced it has entered into definitive stock purchase agreements with accredited and institutional investors to raise proceeds of approximately $11 million in a private placement sale of its Series A preferred stock at $5 per share. Proceeds from the Series A financing will advance the development of MELT-100, Melt's patented flagship 505(b)(2) drug candidate. Melt Pharmaceuticals will be located in Boston, MA.

Concurrent with the financing, Greg Madison has been hired as CEO of Melt Pharmaceuticals. Most recently, Mr. Madison was CEO of Keryx Biopharmaceuticals where he led the company's transformation from development stage to a fully integrated 200+ employee commercial organization and drove impressive revenue growth by expanding the label for the company's lead product. Before Keryx, he was Chief Commercial Officer at specialty pharma company AMAG Pharmaceuticals and spent 12 years at Genzyme/Sanofi, ending as Vice-President and General Manager of the Renal division.

Mr. Madison commented, "I am excited to lead the Melt Pharmaceuticals team as we embark upon our mission to bring to market innovative therapies used for conscious sedation and pain that are non-opioid and non-IV. The market opportunity for a sublingual formulation for use in conscious sedation and pain is large, as there are numerous procedures where this technology could be a potential alternative to traditional IV-based therapies. Our initial focus will be in use prior to cataract surgeries, of which there are approximately 4.4 million procedures in the U.S. each year. As a non-opioid alternative, this formulation could help tackle one of the biggest issues today, with citizens, physicians, and lawmakers in the U.S. concerned about opioid addiction and overdoses. We have assembled an excellent Board of Directors and clinical advisory team to help guide us as we bring MELT-100 and the relevant data to FDA with the goal of ultimately supplying physicians and patients with a much-needed alternative, or supplement to, IV sedation."

Madison concluded, "Two weeks ago, we met with FDA in a planned Pre-IND meeting to discuss our clinical program for MELT-100. We are pleased with the dialogue with FDA and outcome of the meeting. We believe this Series A capital may be sufficient to take us to Phase 3 activities for the MELT-100 program. We look forward to executing the next phases of our clinical program for MELT-100, with the expectation of having our IND application for MELT-100 submitted during 2020 along with starting patient enrollment in our clinical studies thereafter."

Following this close of the Series A financing, Melt Pharmaceuticals will be deconsolidated from Harrow Health and Harrow will hold approximately 44% of the ownership interests in Melt, consisting of 3,500,000 shares of common stock. Harrow also owns a mid-single digit percent royalty on sales of all current drug assets owned by Melt (including MELT-100).

Harrow Health CEO, Mark L. Baum, added, "This marks the third time we've successfully taken Harrow Health drug formulations, know-how and other IP, founded a new company, hired an experienced and focused management team, and brought in third party capital to fund the development of drug candidates for FDA approval. Also, at $5 per share, the value of Harrow's ownership stake in Melt is greater in value than what we retained after the Series A financings of either Eton or Surface, our two previous spin-outs. I am highly confident that through Greg's leadership and execution of the MELT-100 development program, Harrow's equity holdings and royalties in Melt could create significant value for Harrow shareholders for many years to come. With Harrow and Melt shareholders now positioned for success, we look forward to completing work on our two other drug development subsidiaries, Mayfield Pharmaceuticals and Radley Pharmaceuticals."

Lake Street Capital Markets was the exclusive placement agent for the financing.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy any securities described herein, nor shall there be any sale of any such securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such jurisdiction.

ABOUT MELT PHARMACEUTICALS

Melt Pharmaceuticals, Inc., is a development stage pharmaceutical company focused on the development and commercialization of patented non-opioid and non-intravenous (or non-IV) sedation and anesthesia therapeutics for human medical procedures in hospital, outpatient, and in-office settings. Melt intends to seek regulatory approval through the U.S. Food and Drug Administration's 505(b)(2) regulatory pathway for these proprietary technologies. 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' vision is to be the leading provider of non-opioid, non-intravenous conscious sedation and analgesia pharmaceuticals used for human medical procedures in hospital, outpatient, and in-office settings.

ABOUT MELT-100

MELT-100 is the patented lead drug candidate of Melt Pharmaceuticals, Inc. and was developed as a means for providing moderate conscious sedation without an IV or opioids for patients undergoing cataract surgery and other in-office, out-patient and hospital-based procedures. The MELT-100 drug candidate is designed to be administered sublingually, whereby the medication dissolves under the tongue for absorption into the bloodstream.

ABOUT HARROW HEALTH

Harrow Health, Inc. (NASDAQ: HROW) owns a portfolio of healthcare businesses, including the nation's leading ophthalmology pharmaceutical compounding business, ImprimisRx. The company holds large equity positions in Eton Pharmaceuticals, Surface Pharmaceuticals, Melt Pharmaceuticals, Mayfield Pharmaceuticals and Radley Pharmaceuticals, all companies founded as subsidiaries of Harrow Health. The Company also owns royalty rights in certain 505(b)(2) drug candidates being developed by Eton, Surface, Melt, Mayfield and Radley. Harrow intends to create, invest in and grow paradigm shifting healthcare businesses that put patients first. For more information about Harrow Health, please visit the Investor Relations section of the corporate website by clicking here.

ABOUT LAKE STREET CAPITAL MARKETS

Lake Street Capital Markets is a full-service investment bank based in Minneapolis, MN. Lake Street provides Investment Banking, Research, Trading, and Sales services to clients. Lake Street was founded on the premise that a clear focus and a collaborative approach with both investors and corporations is the best strategy for creating value for clients.

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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. 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 its 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.

CONTACTS

Investor Contact for Melt:
Greg Madison
gmadison@meltpharma.com

Investor Contact for Harrow Health:
Jon Patton
jpatton@harrowinc.com
858-704-4587

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