



Harrow Health Subsidiary, Mayfield Pharmaceuticals, Inc., Acquires Patented Dyspareunia Drug Candidate and Other Intellectual Property

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SAN DIEGO, Feb. 07, 2019 (GLOBE NEWSWIRE) -- Harrow Health, Inc. (NASDAQ: HROW), today announced that its subsidiary, Mayfield Pharmaceuticals, Inc., has acquired drug formulation assets and intellectual property, including three recently issued patents, from Elle Pharmaceutical, LLC, for MAY-44, a drug candidate for the treatment of dyspareunia, or pain experienced by women during sexual intercourse.

"Dyspareunia is a common condition significantly affecting the quality of life of millions of women, but is often unacknowledged, undiagnosed, and untreated," said Lauren J. Oshry, MD, Chief Medical Officer of Elle. "As a physician, it is gratifying to work with Mayfield to bring attention to this condition and expand women's options with this novel treatment that is non-hormonal and which, through my clinical experience with lidocaine-based topical preparations, that were the cornerstone of developing our patented formulation, have provided exceptional clinical benefits."

Harrow Health CEO, Mark L. Baum, commented, "The MAY-44 drug development program, including the patents and other assets Mayfield acquired in this transaction, will require minimal Harrow investment because they are advanced to the point of having clinical trial material successfully built and shown to be stable. We also have accumulated considerable market research, positive anecdotal evidence of the clinical value of compounded lidocaine-based gel formulations, and we're in negotiations with experienced candidates to join the Mayfield team in key leadership positions. We look forward to advancing the Mayfield business, including the MAY-44 program and other assets that are now a part of Mayfield. I anticipate we will be speaking more about this exciting women's health focused company throughout 2019."

ABOUT MAY-44

MAY-44 is a non-estrogen topical analgesic gel containing a patented pH-balanced formulation of 3.75% lidocaine and other essential excipients designed for use on mucosal surfaces. If FDA-approved, MAY-44 could become the first topical non-estrogen-based product indicated for this large underserved medical need. Anecdotal evidence has shown topical lidocaine, which only needs to be applied immediately prior to intercourse, can be highly effective (90%) for moderate to severe dyspareunia^{1, 2}. In a 46-patient randomized, controlled, double-blinded trial, users of 4% aqueous lidocaine reported significantly less pain during intercourse compared to a control group (median score of 1.0 compared to 5.3 on a 0-10 scale for pain, respectively)¹.

ABOUT DYSPAREUNIA

There are an estimated 32 million women in the U.S. who suffer from moderate-to-severe dyspareunia, and 64 million post-menopausal women in the U.S. for whom dyspareunia is common³. Other estimates suggest dyspareunia affects greater than one in ten women⁴. In a proprietary market research report completed in December 2017, a survey of OB/GYN practices estimated that one in every four patients complained of some level of dyspareunia each month. It was also estimated that two-thirds of women complaining of dyspareunia are post-menopausal and one-third are pre- or peri-menopausal.

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 health care businesses that put patients first. For more information about Harrow Health, please visit the Investor Relations section of the corporate website by [clicking here](#).

SAFE HARBOR

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.

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2. Harvard Health Publishing. (2012, May). When sex gives more pain than pleasure. Retrieved December 27, 2018 from <https://www.health.harvard.edu/pain/when-sex-gives-more-pain-than-pleasure>
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4. Mitchell KR, et al. (2017, October). Painful sex (dyspareunia) in women: prevalence and associated factors in a British population probability survey. *BJOG An International Journal of Obstetrics and Gynaecology*, 124(11), 1689-1697.

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