



Harrow Health Announces Launch of Mayfield Pharmaceuticals

July 31, 2019

NASHVILLE, Tenn., July 31, 2019 (GLOBE NEWSWIRE) -- Harrow Health, Inc. (NASDAQ: HROW), today announced it has filed a Form 8-K with the Securities and Exchange Commission containing a [corporate presentation](#) for its subsidiary, Mayfield Pharmaceuticals, Inc. Mayfield is focused on making a difference in women's lives by developing branded pharmaceutical products that address significant unmet needs within the women's health marketplace. Once funded, Harrow expects Mayfield to be led by Melissa Bradford-Klug, an experienced senior life science executive with a proven track record of success.

As CEO of Mayfield, Bradford-Klug will be charged with the development of Mayfield's drug candidate pipeline:

- MAY-66, a patented new chemical entity drug candidate intended to treat bacterial vaginosis (BV). MAY-66 has produced extraordinarily promising data in what we believe is a translatable pre-clinical model. Approximately 21 million women in the U.S. are estimated to suffer from BV, with 4 million treated annually, and high reoccurrence rates of BV are an ongoing need. In addition, pregnant women currently have no safe treatment options for this type of infection. The addressable market for MAY-66 is estimated at \$1 billion annually in the U.S.

- [MAY-44](#), which was acquired by Mayfield in February, will be developed through the 505(b)(2) clinical pathway for the treatment of dyspareunia in pre and post-menopausal women. MAY-44 is protected by three issued patents and could become the first FDA-approved topical non-estrogen-based product to address a market of as many as 38 million American women for whom dyspareunia is common. The dyspareunia indication Mayfield will seek approval for is an estimated \$1.5 billion annual U.S. market opportunity.

- MAY-88 is a patent-pending oral suspension that Mayfield will develop for the treatment of interstitial cystitis (IC) via the 505(b)(2) clinical pathway. An estimated 8 million U.S. patients chronically suffer from IC, with the existing IC drug market in the U.S. estimated at \$400 million annually.

Melissa Bradford-Klug commented, "I am excited to co-found and lead an exciting and needed women's health focused company with such a promising pipeline. MAY-66, our lead first in class molecule for bacterial vaginosis – based on early data generated – has the potential to be a breakthrough product in a very large underserved market. Feedback from FDA during our recent Pre-IND meeting for our patented MAY-44 drug candidate was instructive and we have important clarity about the development pathway for what we believe is a potentially high impact program. MAY-88 could finally change the treatment landscape for the millions of American women who chronically suffer from interstitial cystitis."

Harrow Health CEO, Mark L. Baum, added, "Melissa is a visionary and extremely competent biopharma leader with a record of developing and commercializing pharmaceutical women's health products that have improved the lives of millions of American women. As Mayfield's CEO, Melissa will leverage her 20+ year career – as a scientist, in business development, and in executive leadership – at some of the leading U.S. and global pharmaceutical companies. Beyond her impressive experience, Melissa has a deep reservoir of determination to drive innovation in the women's health space. I'm excited to be working with her and am confident that under her leadership, Mayfield investors and shareholders, including Harrow, will have the opportunity to not only generate great economic returns, but to also commercialize products that will uniquely benefit the sisters, daughters, mothers, aunts and grandmothers in our country and around the world."

Harrow expects Mayfield will follow a similar template of its previous subsidiaries [Eton Pharmaceuticals](#), [Surface Pharmaceuticals](#), and [Melt Pharmaceuticals](#), by pursuing a Series A financing and being separately managed and funded from Harrow.

About Mayfield Pharmaceuticals

Mayfield Pharmaceuticals, Inc. is a pharmaceutical company focused on the development and commercialization of patented or patent-pending solutions that address unmet needs in the women's health sector. Mayfield intends to seek regulatory approval for its drug candidates through the U.S. Food and Drug Administration's 505(b)(1) and 505(b)(2) regulatory pathways. Mayfield's current candidates will pursue approval for dyspareunia, bacterial vaginosis, and interstitial cystitis, addressable markets that are collectively estimated at roughly \$3 billion.

Mayfield Pharmaceuticals' vision is to become a leading provider of novel pharmaceutical solutions for unmet needs in the women's health and wellness space.

About Harrow Health

Harrow Health, Inc. (NASDAQ: HROW) owns a portfolio of healthcare businesses, including one of the nation's leading

ophthalmology pharmaceutical businesses, [ImprimisRx](#). The company holds large equity positions in [Eton Pharmaceuticals](#) (NASDAQ: ETON), [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 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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