

**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): July 28, 2019

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.)

12264 El Camino Real, Suite 350
San Diego, CA
(Address of principal executive offices)

92130
(Zip Code)

Registrant's telephone number, including area code: **(858) 704-4040**

N/A

(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 Capital 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 1.01 Entry into a Material Definitive Agreement.

On July 28, 2019, Mayfield Pharmaceuticals, Inc. (“Mayfield”), a subsidiary of Harrow Health, Inc. (the “Company”) entered into a License Agreement (the “TGV License”) with TGV-Health, LLC and TGV-Gyneconix, LLC (collectively, “TGV”), to acquire intellectual property rights for use in the women’s health field, related to Mayfield’s proprietary drug candidate MAY-66. The TGV License provides that TGV will cooperate with Mayfield in transferring all embodiments of the intellectual property (including know-how) related to the TGV License, assist in obtaining and protecting its patent rights for the acquired intellectual property and that Mayfield will use commercially reasonable efforts to research, develop and commercialize products based on the acquired intellectual property. In connection with the TGV License, Mayfield is obligated to make royalty payments to TGV equal to a low single digit percentage of net sales received by Mayfield in connection with the sale or licensing of any product based on the licensed intellectual property. In addition, Mayfield issued 300,000 shares of its common stock to TGV and is required to make certain milestone payments to TGV over the development of MAY-66 and any related products based on the licensed intellectual property.

The foregoing is only a brief description of the material terms of the TGV License and does not purport to be a complete description of the rights and obligations of the parties thereunder.

Item 7.01. Regulation FD Disclosure

Attached as Exhibit 99.1 to this Item 7.01 is a presentation of Mayfield, a subsidiary of the Company, that is being used by the management of the Company at investor conferences and at meetings describing Mayfield and the Company.

The information contained in Item 7.01 of this report and in Exhibit 99.1 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Cautionary Note Regarding Forward-Looking Statements

This Form 8-K, including the exhibits filed with this Form 8-K, contains certain forward-looking statements regarding the proposed transaction between the Company and the Buyers. Actual events or results may differ materially from those contained in these forward-looking statements. Among the important factors that could cause future events or results to vary from those addressed in the forward-looking statements include, without limitation, risks and uncertainties arising from the possibility that the closing of the transaction may be delayed or may not occur; difficulties with the integration process or the realization of the expected benefits of the transaction; and general regulatory developments impacting compounding pharmacies, outsourcing facilities and the pharmaceutical industry. In addition, please refer to the documents that the Company files with the Securities and Exchange Commission on Forms 10-K, 10-Q and 8-K, which identify and address other important factors that could cause events and results to differ materially from those contained in the forward-looking statements set forth in this Form 8-K and in the Company’s other filings. The Company is under no duty to update any of the forward-looking statements after the date of this Form 8-K to conform to actual results.

Item 9.01. Financial Statements and Exhibits**(d) Exhibits**

99.1 [Mayfield Pharmaceuticals, Inc. Corporate Presentation dated August 2019](#)

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: July 31, 2019

By: /s/ Andrew R. Boll
Name: Andrew R. Boll
Title: Chief Financial Officer



August 2019



SAFE HARBOR



This presentation contains express "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. You are cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from Harrow Health, Inc.'s ("Harrow") and Mayfield Pharmaceuticals, Inc.'s ("Mayfield"), and collectively with Harrow the "Company") expectations and projections. Some of these risks and uncertainties include, but are not limited to: the Company's ability to make commercially available its 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; its ability to obtain intellectual property protection for its assets; its ability to accurately estimate its expenses and cash burn and raise additional funds when necessary; the Company's ability to generate profits from sales of its formulations; risks related to research and development activities and any related regulatory approvals; the Company's estimates of the current and potential market size for its technologies and formulations; unexpected data, safety and technical issues; regulatory and market developments impacting the pharmaceutical industry; competition; and market conditions. More detailed information about Harrow and the risk factors that may affect the realization of forward-looking statements is set forth in the Harrow's filings with the Securities and Exchange Commission, including its Annual Reports on Form 10-K and its Quarterly Reports on Form 10-Q filed with the SEC. Such documents may be read free of charge on the SEC's web site at www.sec.gov. All forward-looking statements are qualified in their entirety by this cautionary statement. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The Company expressly disclaims any intent or obligation to update these forward-looking statements except as required by law. Harrow's compounded formulations are not FDA approved.

All trademarks, service marks and trade names included in this presentation are the property of their respective owners.

This presentation 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.



Mayfield Senior Leadership

		Experience	Background
	<p>Melissa Bradford-Klug <i>Chief Executive Officer</i></p>	<p>20+ years</p>	<ul style="list-style-type: none"> ▪ Strategic planning, licensing and business development expertise in the life sciences industry ▪ Chief Business Officer, Keryx; Senior VP, Business Development, AMAG Pharmaceuticals; VP Business Development & Licensing, Mallinckrodt ▪ Leadership roles at Baxter International and Eli Lilly ▪ MBA (DePaul); B.S. Chemistry (Maryville University)
	<p>Mark L. Baum <i>Director (Co-Founder)</i></p>	<p>20+ years</p>	<ul style="list-style-type: none"> ▪ Founder of Harrow Health (NASDAQ: HROW) and Eton Pharmaceuticals (NASDAQ: ETON); Founder of Melt Pharmaceuticals, ImprimisRx, Surface Pharmaceuticals, and YesRx ▪ 2017 E&Y Life Sciences Entrepreneur of the Year

Harrow Health, Inc. Overview

- Harrow Health, Inc. (NASDAQ: HROW) owns a portfolio of healthcare businesses, including one of the nation's leading ophthalmology pharmaceutical businesses, ImprimisRx
- Harrow's business model is to Found, Fund and Spin-Out healthcare businesses and to return capital to shareholders through the ownership of equity and royalty interests
- Since 2017, Harrow Health has spun-out three separately financed and managed drug development companies (below) and intends to complete additional similar transactions over the coming years

eTon

PHARMACEUTICALS

Spun-out of Harrow June 2017
\$20M Series A financing (\$3/share);
Nov. 2018 IPO
NASDAQ (ETON) at \$6/share

surface

PHARMACEUTICALS INC.

Spun-out of Harrow May 2018
\$21M Series A financing by leading
ophthalmic PE firm
Flying L Partners

MELT

PHARMACEUTICALS

Spun-out of Harrow Jan. 2019
\$11M Series A financing
*S-1 Registration Statement to be filed
Q3 2020*

Mayfield Pharmaceuticals

Our vision is to improve women's lives by developing products that address significant and conspicuous unmet needs



Products that matter

Products that enhance women's health and address large unmet needs in the marketplace.



Low risk development

Our development programs focus on using known molecules in dosage forms for new indications, and by developing new chemical entities with a known mechanism of actions



Lean business model

Bring together the best inside and outside experts to advance development programs in capital efficient ways. We look to offset our operating expense by collaborating with partners for markets outside the US.



Commercial strategy

Ease of access to healthcare providers and convenience to patients by directly shipping drugs to the patient's door with reliable & timely delivery.

Mayfield's Drug Candidates

MAY
66

Lead drug candidate for bacterial vaginosis, a \$1 Billion+ market opportunity

- A patented new chemical entity with a broad spectrum antimicrobial active
- Strong translatable preclinical data in various models and applications
- Bacterial vaginosis is most prevalent US gynecological infection
- 4+ million women treated annually with high rate of recurrence

MAY
44

505(b)(2) non-hormonal drug candidate for temporary relief of moderate to severe dyspareunia

- Over 38 million women in US are estimated to suffer from dyspareunia/painful intercourse
- Key market advantage is that, if approved, would be only non-hormonal drug used to treat symptoms of dyspareunia
- Peer reviewed, 46-patient study providing strong signals of efficacy

MAY
88

Unique approach to proven molecule for treatment of interstitial cystitis

- Patent-pending oral anhydrous extend release suspension of pentosan polysulfate sodium
- Estimated over 8 million patients in US suffer from interstitial cystitis
- Expect condensed 505(b)(2) clinical pathway

MAY-66 for Bacterial Vaginosis

MAY
66

THE PROBLEM:

A large percentage of women suffering from Bacterial vaginosis (BV) need more efficacious treatment options

- No treatment options for reoccurrence of bacterial vaginitis
- **Pregnant** women have no safe treatment options for BV
- Potential embarrassing signs and symptoms include thin, gray, white or green vaginal discharge; unpleasant odor; vaginal itching; and burning during urination



21+
MILLION¹

Women in the US are estimated to suffer from BV

BV Market Dynamics

BV is the most prevalent US gynecological infection³

- If untreated can cause serious health problems
 - 2x increased risk of acquiring and 3x risk of transmitting HIV
 - 2x more likely to have preterm birth
 - Reduces fertility during IVF

BV is a \$1 Billion Market that is undertreated and underpromoted Today²

Over 7.5M US prescriptions written for bacterial vaginosis and growth 4%⁴

Over 4 million women are treated annually with high rate of reoccurrence that results in many repeat sufferers⁵

Attractive pricing average cost of per day of therapy \$325⁶

Limited competition in the pipeline and companies promoting products

Unmet needs include prevention of recurrent BV and safe product that can be used in pregnant women

- Estimated 1.5-2M women have BV and are pregnant⁷

Note: Prevalence of Bacterial vaginosis 21M, Vaginal Candidiasis 8.1M, Trichomoniasis 6.5M and Yeast infections 3.2M.

MAY-66

DRUG CANDIDATE OVERVIEW

- Novel broad spectrum antimicrobial active against all gram positive, gram negative bacteria and fungi
- First in class, small molecule
- Effective against **ALL** pathogens associated with vaginitis including multi-resistant bacteria; multi-resistant fungi; microbial biofilms and enveloped and non-enveloped viruses
- Need for more efficacious BV treatment options and safe options for pregnant women suffering from bacterial vaginosis
- Patents cover matter of composition, methods of production, use and molecule until 2038
- Potential indications include treatment of recurrent bacterial vaginosis, vaginal candidiasis and trichomoniasis
- Clinical Program expectations: 505(b)(1) clinical program, with IND filing in 2021, Phase II completion in 2022



MAY-66 Proven Efficacy

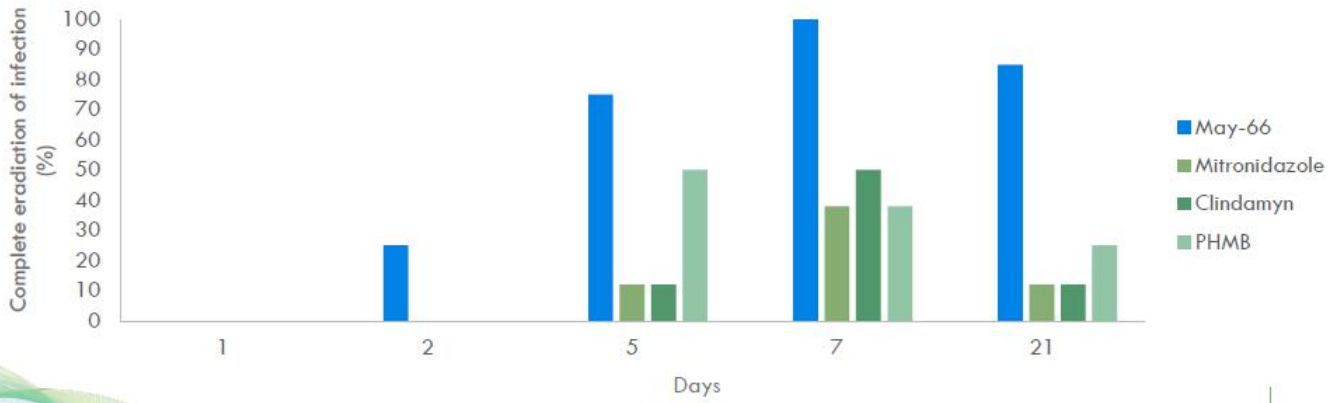
In preclinical models, MAY-66 was significantly more effective against all pathogens of BV compared to conventional therapy

Pathogen	Number of strains	MAY-66	Metronidazole	Clindamycin	Biguanides
<i>Gardnerella vaginalis</i>	25	0.06-1	2->256	0.125->1	8->256
<i>Mobiluncus</i> spp.	20	0.25-2	64->256	0.25->256	8->256
<i>Prevotella</i> spp	20	0.125-1	1-64	1-256	8->256
<i>Peptoniphilus</i> spp	15	0.06-2	1-8	0.25-128	16-128
Fungi					
<i>Candida</i> spp	40	0.06-0.25	Ineffective	Ineffective	1-128
Bacteriophages					
<i>Lactobacillus</i> bacteriophages	10	0.06-0.25	Ineffective	Ineffective	Ineffective

MAY-66 Mouse Model

MAY-66 was the most effective drug in a translatable bacterial vaginosis mouse model (Polymicrobial *G.vaginalis* + *P.bivia*)

MAY-66 treatment resulted in **complete elimination of BV in 100%** of the animals by Day 7 and prevented recurrence of the infection



MAY-44 for Dyspareunia (painful intercourse)

MAY
44

THE PROBLEM:

A large percentage of women suffering from dyspareunia do not have treatments options:

- No treatment options exist for premenopausal and postmenopausal women
- Etiology is different for women depending on the stage of their life
- 50-70% of breast cancer survivors experience dyspareunia -- no treatment options



38+
MILLION⁸

Patients in the US are estimated to suffer from dyspareunia

Dyspareunia Market Dynamics

A \$1.5 Billion Market Today¹⁰

Opportunity to expand into pre-menopausal women with over 13 million patients

Large market opportunity pre- and post-menopausal women with no options for products to treat of both segments

Ability to drive direct to patient treatment options and therapy is in it's nascency and expected to grow

Proactive market segment driven by political movement of women empowerment and satisfaction of needs

Over 1.5M prescriptions written for dyspareunia-based products and growing for post menopausal uses¹²

Attractive pricing average cost of per day of therapy \$1¹³

- \$1,700 per year per patient

10.4M Women are not advised to use hormonal therapies, so they have no options for dyspareunia and would be candidates for MAY 44¹¹

All current treatment options have black box warning or contraindications for use in breast cancer survivors and women at risk for cardiovascular disease

MAY-44

DRUG CANDIDATE OVERVIEW

- Non-estrogen gel containing a patented pH-balanced formulation of 3.75% lidocaine and excipients designed for use on mucosal surfaces
- **Goetich** proof of concept study in 46-patient randomized, double-blinded study in breast cancer survivors. 87.5% reduction in pain during intercourse after 1 month of use of aqueous 4% lidocaine vs. 38% pain reduction with placebo⁹
- MAY-44 advantages compared to products on the market:
 - “only” product for temporary relief of moderate to severe dyspareunia
 - “only” product for use in both pre- and post- menopausal women
 - “only” product without black box warning or precaution related to certain cancers
- Market research indicates 87% of OB/GYNs will prescribe MAY-44 to their current patients and 98% will prescribe MAY-44 to new patients*
- 3 newly issued patents protected through 2036
- Clinical program expectations: PIND meeting held in June 2019, IND filing within 12 months of closing of a capital raise & Phase II completion in 2021



*D.S. Howard & Associates, Inc. Market Research December 2017

MAY-88 for Interstitial Cystitis



THE PROBLEM:

A large percentage of women suffering from Interstitial Cystitis (IC) could benefit from faster onset and lower dose or who have dysphagia

- Clinical syndrome characterized by daytime and nighttime urinary frequency, urgency, and pelvic pain and is sometimes described as painful bladder syndrome
- Treatment includes pharmacological, intravesical, surgical, electrical stimulation and diet



8+
MILLION¹⁴

Patients in the US are estimated to suffer from interstitial cystitis

IC Market Dynamics

\$400 Million Market Today; highly underserved and under promoted¹⁶

Proactive market segment driven with limited treatment options

Over 380K prescriptions written for Elmiron®¹⁷ with other drugs recommended for off-label use (annually)

Obstetricians/Gynecologist and Urologists write the majority of Rx's 60%¹⁸

- Concentrated prescriber base ~ 24,000¹⁹

Generic entry difficulties due to challenges with measuring plasma concentrations

Ability to grow the market by promoting and patient education. Limited competition, Elmiron is not actively promoted

Attractive pricing average cost of per day of therapy \$32²⁰

- 56% of Rx's are from commercial payors²¹

MAY-88

DRUG CANDIDATE OVERVIEW

- First oral anhydrous extended release suspension of pentosan sulphate indicated women that have difficulty swallowing
- Anecdotal evidence has shown the oral suspension may have favorable pharmacokinetic profile 15 including faster onset and extended release properties that may allow for a lower therapeutic dose to be administered
- Stability data supports long-term expiration dating
- Pentosan originally qualified for orphan exclusivity. Work to determine a subpopulation can be identified to qualify for orphan designation
- 505(b)(2) clinical program expectations: IND filing and Phase I start in 2021, followed by single Phase 3 study to allow for NDA submission



Summary

Mayfield Pharmaceuticals is a **women's health focused** subsidiary of Harrow Health, Inc.

Potential to disrupt **large multiple billion-dollar markets**, with differentiated drug candidates

Led by an **experienced** and **proven** management team and board of directors

Near term and **minimal cash outlay** to reach significant human clinical trial event driven milestones

Focused on patented 505(b)(2) drugs and new chemical entities with **known mechanisms of action**

Drug candidates will target areas of the market where patients needs are **conspicuously not being satisfied**

Timeline and Use of Proceeds

Drug Candidate	Market Size	Patent Protection Thru	Target IND Filing	Target Phase 2 Completion	Est. Capital Outlay thru Value Inflection ¹
MAY-66 Patients with recurrent bacterial vaginosis	\$1B+	2038	2021	2022	\$5.5M - \$6.7M
MAY-44 Patients pre and post menopausal with dyspareunia	\$1.5B	2036	2020	2020/2021	\$4.0M - \$5.6M
MAY-88 Patients suffering from interstitial cystitis	\$400M+	2039 (pending)	2020	2021*	\$2.8M - \$3.8M

*We do not expect Phase 2 studies to be required for this program, this date indicates completion of Phase 2 meeting with FDA.
¹ - MAY 66 through Phase 1, MAY-44 through Phase 2, MAY-88 to Phase 3 ready

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