# 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): May 22, 2019

#### HARROW HEALTH, INC.

(Exact name of registrant as specified in its charter)

001-35814

**Delaware** 

45-0567010

(State or other jurisdiction	(Commission	(IRS Employer		
of incorporation)	File Number)	Identification No.)		
12264 El Camino Real, Suite 350				
San Diego, CA		92130		
(Address of principal executive offices)		(Zip Code)		
Registrant's tel	lephone number, including area code: <b>(858)</b> 7	<b>'04-4040</b>		
	N/A			
(Former na	me or former address if changed since last re	port.)		
theck the appropriate box below if the Form 8-K filing is i rovisions:	intended to simultaneously satisfy the filing o	obligation of the registrant under any of the following		
] Written communications pursuant to Rule 425 under the	e Securities Act (17 CFR 230.425)			
] Soliciting material pursuant to Rule 14a-12 under the E	exchange Act (17 CFR 240.14a-12)			
] Pre-commencement communications pursuant to Rule	14d-2(b) under the Exchange Act (17 CFR 24	40.14d-2(b))		
] Pre-commencement communications pursuant to Rule	13e-4(c) under the Exchange Act (17 CFR 24	I0.13e-4(c))		

#### Item 7.01. Regulation FD Disclosure

Attached as Exhibit 99.1 to this Item 7.01 is a presentation of Harrow Health, Inc. (the "Company"), that is being used by the management of the Company at investor conferences and at meetings describing 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.

#### Item 9.01. Financial Statements and Exhibits

(d)	Exhibits
Item	Description
99.1	Harrow Health, Inc. Corporate Presentation dated May 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: May 22, 2019 By: /s/ Andrew R. Boll

Name: Andrew R. Boll
Title: Chief Financial Officer



#### 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 (the "Company" or "Harrow") 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; its ability to generate profits from sales of its formulations; risks related to research and development activities; its estimates of the current and potential market size for its technologies and formulations; unexpected data, safety and technical issues; regulatory and market developments impacting compounding pharmacies, outsourcing facilities and the pharmaceutical industry, competition, and market conditions. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements is set forth in the Company's filings with the Securities and Exchange Commission, including its Annual 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. This presentation may refer to non-GAAP financial metrics, specifically adjusted EBITDA and/or adjusted earnings. A reconciliation of any non-GAAP measures with the most directly comparable GAAP measures are included in the Company's press releases, available on its website. All forward-looking stateme



### **TOPICS COVERED**

Introduction to Harrow Health, Inc.

Financial Metrics

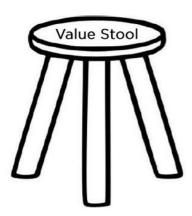
Harrow Health Equity Interests

- ImprimisRx Operating Business
- Passive Equity Holdings
- · Other Subsidiaries

Defining Success in 2021



### **Harrow Health Introduction**

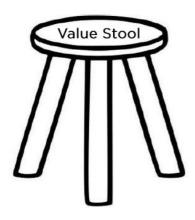


- · We found pharmaceutical companies;
- · We finance and manage them; and
- · We own:
  - · large equity stakes, and
  - royalties on many of the drug candidates they develop





### **Harrow Health Introduction**



- Core operating business: ImprimisRx
  - · Leading ophthalmic pharmaceutical compounder
  - Thousands of ophthalmologists using platform
  - Growing rapidly
  - · Generating segmented earnings

LEG 2

- Equity positions in spin-out businesses
  - Three deconsolidated start-ups
  - Valued at ~\$57M\*
  - Two+ new drug development subsidiaries

LEG 3

- Royalties and patent estate
  - Ten+ 505(b)(2) drug development candidates
  - 60+ drug patents issued or pending



HARROW HEALTH INC. Eton value is calculated based on the conversion price of Series A preferred stock (the most recent financing; and not a U.S. GAAP measure) Eton value is calculated based on the closing stock market price of Eton's common stock as of March 29, 2019.



### **Harrow Health Introduction**







<sup>\*</sup> Pursuing a deconsolidating transaction

\*\* Includes all future label extensions

† Does not include ParkRx subsidiary, which Harrow is reviewing strategic options to divest

# **FINANCIAL METRICS**



### **Consolidated Financials**

#### Revenue Growth:

- \$100M rev run rate goal in 2021
- 123% revenue CAGR 2014-2018
- 55% consolidated annual revenue growth (2017-2018)
- 57% ophthalmology year-over-year revenue growth (20 2019)
   Five ophthalmology products launched in May 2019; more planned for 2019-2020

#### **Gross Margins:**

- Continued expansion; hit 68%
- in Q1 2019, an all-time high

  Medium-term (2020-21) gross margin target of ≥70%

#### Earnings:

- Q1 2019 Adj. EBITDA \$750K
- Pharmaceutical compounding segment earnings \$2.6M (Q1-19)
   Aggregate GAAP Net Income last
- two quarters of \$29M







## **EQUITY INTERESTS**















### **ImprimisRx Subsidiary**

#### WHAT IS IT?

- · Founded by Harrow in 2014
- 100% owned by Harrow
- Leading ophthalmology pharmaceutical compounder
- Two facilities (30,000 ft<sup>2</sup>) producing ~25 SKUs
- · IP focused; 60+ patents filed
- 3,000+ physician customers in all 50 states
- 187% revenue CAGR (2014 through 2018)
- \$10M+ CAPEX invested
- · FDA-registered and inspected outsourcing facility

#### WHAT IS THE OPPORTUNITY?

- Growing, cash flowing and scalable
- Expectation to expand GMs beyond 68%
- Goal of \$100M revenue run rate in 2021
- Goal of 25% operating margins in 2021
- Continued and significant new product development expected in '19-'20





# ImprimisRx Subsidiary

	Opportunity in U.S.	
OCULAR SURGERY	Antibiotics, anti-inflammatories, sedatives, mydriatics, and anesthetics	
	<ul> <li>\$1+ billion drug market</li> <li>-4.6M ocular surgeries and other procedures <sup>1-14</sup></li> <li>Demographic growth in the overall market -6% per yr<sup>15</sup></li> </ul>	
GLAUCOMA	Prostaglandin analogs, beta blockers, alpha agonists, carbonic anhydrase inhibitors	
	<ul> <li>\$2 billion drug market</li> <li>19+ million targeted Rxs<sup>11</sup> for patients taking &gt;1 Rx</li> <li>4 million Americans<sup>16</sup></li> </ul>	
DRY EYE	Immunosuppressive agents (cyclosporine) and steroids	
	<ul> <li>\$2 billion drug market</li> <li>4 million prescriptions<sup>11</sup></li> <li>-30 million Americans suffer from some form of dry eye<sup>17</sup></li> </ul>	



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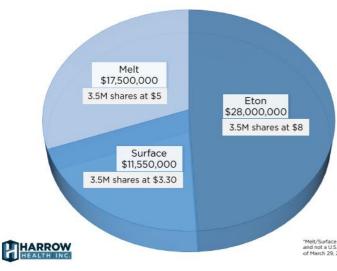


- \* Pursuing a deconsolidating transaction
  \*\* Includes all future label extensions
  † Does not include ParkRx subsidiary, which Harrow is reviewing strategic options to divest



### **Passive Equity Holdings**

HARROW'S DECONSOLIDATED EQUITY PORTFOLIO ESTIMATED VALUE: \$57M\*









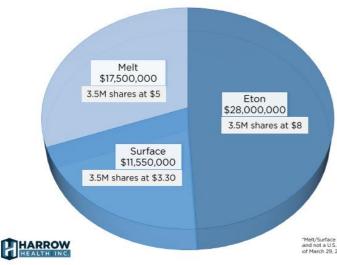
- · Eton was formed by Harrow in 2017
- · Led by CEO Sean Brynjelsen
- · 20+ years of pharma leadership
- Eton has:
  - 11 drug candidates in pipeline
  - 7 NDAs submitted or expected to be submitted by the end of 2019
- Eton is NASDAQ listed under "ETON"
- ~\$140M market capitalization

'Melt/Surface equity values estimated based on the conversion price of Series A preferred stock (the most recent financing; and not a U.S. GAAP measure); Eton value is calculated based on the closing stock market price of Eton's common stock as of March 29, 2019.



### **Passive Equity Holdings**

HARROW'S DECONSOLIDATED EQUITY PORTFOLIO ESTIMATED VALUE: \$57M\*









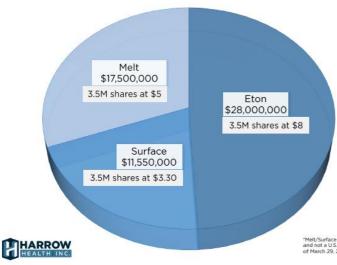
- · Led by CEO Kamran Hosseini, MD, PhD
- · 20+ years of senior ophthalmology drug development experience
- · Developing three ocular surface disease drug candidates for dry eye and blepharitis
- Three INDs expected by Q4 2019 and Q1 2020
- \$21M Series A led by Flying L Partners
- 4-6% Net Sales royalties (on all programs)

'Melt/Surface equity values estimated based on the conversion price of Series A preferred stock (the most recent financing; and not a U.S. GAAP measure); Eton value is calculated based on the closing stock market price of Eton's common stock as of March 29, 2016.



### **Passive Equity Holdings**

HARROW'S DECONSOLIDATED EQUITY PORTFOLIO ESTIMATED VALUE: \$57M\*









- · Led by CEO Greg Madison
- Ex-CEO of Keryx Biopharmaceuticals
- 15+ years senior pharma leadership
- · Developing non-opioid, non-IV, sedation and analgesia drug candidates
- · MELT-100 for conscious sedation and analgesia (cataract surgery)
- \$11M Series A should fund MELT-100 to PIII
- Up to 8% Net Sales royalties (on all programs)

'Melt/Surface equity values estimated based on the conversion price of Series A preferred stock (the most recent financing; and not a U.S. GAAP measure); Eton value is calculated based on the closing stock market price of Eton's common stock as of March 29, 2019.



### **Other Subsidiaries**



- · Women's health-focused
- May-44, a patented non-estrogen topical anesthetic drug candidate for dyspareunia
- Positive anecdotal evidence for May-44 candidate; side effects may be less severe when compared to drug incumbents<sup>18</sup>
- ~64M women in the U.S. suffer from dyspareunia<sup>19</sup>
- May-88, a patent-pending oral liquid drug candidate to treat interstitial cystitis (IC)
- As many as 12% of U.S. women suffer from IC<sup>20</sup>

#### **Progress**

- PIND meeting with FDA scheduled in June
- Additional drug development programs being reviewed for inclusion



- Focused on 505(b)(2) drug candidates for rare and orphan drug indications
- RAD-100, RAD-101 are anti-infective drug candidates
- RAD-200, RAD-300 are drug candidates as treatments for certain forms of cancer

#### **Progress**

- Pre-IND filed for RAD-100
- Investigator-IND study planned with NY-based healthcare institution for RAD-200
- Pre-clinical and Investigator-IND studies expected to begin in 2019 for RAD-300 with Boston-based healthcare institution

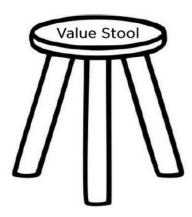




# **DEFINING SUCCESS IN 2021**



### **Defining Success in 2021**



#### **History of Executing**

- 187% ophthalmology revenue CAGR\*
- 123% consolidated revenue CAGR\*
- 68% gross margins (Q1-2019), an all-time high
- \$57M balance sheet value\*\* from deconsolidated entities

#### 2021 Vision

- · ImprimisRx operating business
  - \$100M revenue run rate goal
  - · 70% gross margin goal
  - · 25% operating margin goal
- New drug development companies to launch in 2019-2021
- · Potential significant value inflection in equity holdings
- Potential significant royalty income from 10+ spin-out drug candidates







# Company Profile\*

TRADING SYMBOL: NASDAQ: HROW	PRICE PER SHARE: \$6.57	AVG. DAILY Q1-2019 TRADING VOLUME: 277,000 SHARES	
OUTSTANDING COMMON STOCK:  24.8M SHARES	MARKET CAP: \$163 MILLION	STRONG CEO/CFO INCENTIVE THRU PERFORMANCE STOCK UNITS TO ACHIEVE \$9 - \$15 SHARE PRICE	



\* As of May 20, 2019



# **APPENDIX AND REFERENCES**



### **Published Clinical Data**

#### Kindle, Trevor, MD, et al. (2018, January). Safety and efficacy of intravitreal injection of steroid and antibiotics in the setting of cataract surgery and trabecular microbypass stent. Journal of Cataract and Refractive Surgery.

In a study of 483 eyes undergoing cataract surgery with concomitant trabecular microbypass stent insertion, there were no statistically significant differences in the safety profiles of a study group of 234 eyes receiving an intravitreal injection (pars plana) of 0.2mL of Dropless\* at the time of surgery compared to a control group of 249 eyes that received a standard topical regimen postoperatively. To measure safety, intraocular pressure was recorded as were cases of inflammation, cystoid macular edema, infection, or retinal detachments.

#### Lindstrom, R.L., et al. (2017, February). Dropless Cataract Surgery: An Overview. Current Pharmaceutical Design.

Compliance issues are diminished with Dropless Therapy compared to standard post-surgery topical drop regimens. Cost savings to patients can range from \$200 to \$600 per cataract procedure. Staff time is reduced without patient, insurance and pharmacy callbacks about eye drop substitutions and confusion over topical regimens. A retrospective review of Dropless Therapy cases found no postoperative endophthalmitis. Post-surgery infection and inflammation rates were similar to reported rates with other alternative prophylactic therapies, such as topical drops.

### Tyson, S. L., et al. (2017, January). Clinical outcomes after injection of a compounded pharmaceutical for prophylaxis after cataract surgery: a large-scale review. Current Opinion in Ophthalmology.

No major intraoperative complications associated with the transzonular injection technique. There were no cases of postoperative endophthalmitis. Rates of infection and inflammation reported in this retrospective review of 1,541 cases from 922 patients receiving a transzonular injection of Tri-Moxi-Vanc for prophylaxis after cataract surgery appear similar to reported rates with alternative prophylactic therapies such as topical drops.

### Fisher, B. L., & Potvin, R, (2016, July 18). Transzonular vitreous injection vs a single drop compounded topical pharmaceutical regimen after cataract surgery. Current Pharmaceutical Design.

Review of the rationale for reducing topical therapy in cataract surgery prophylaxis, and what is known to date about the efficacy and safety of the Dropless approach. Both groups expressed similar satisfaction with surgery, but patients who received Dropless preferred the overall experience (P=0.01).



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### References

- Market Scope, LLC, Comprehensive Report on the Global IOL Market (2013, May).
- Allen, A. (2007). Vasectomy Risks and Benefits. Retrieved November 08, 2016, from http://www.webmd.com/men/features/vasectomy-risks-
- US Market Report Suite for Gastrointestinal Endoscopic Devices 2017 MedSuite. (2016, August 01). Retrieved January 08, 2017, from https://idataresearch.com/product/us-market-report-suite-for-gastrointestinal-endoscopic-devices-2017-medsuite/
- 4. Endodontic Facts by the American Association of Endodontists. (n.d.). Retrieved January 07, 2017, from http://www.aae.org/ about-aae/newsroom/endodontic-facts.aspx
- 5. Sklavos, M. M., Spracklen, C. N., Saftlas, A. F., & Pinto, L. A. (2014, February 23). Does Loop Electrosurgical Excision Procedure of the Uterine Cervix Affect Anti-Müllerian Hormone Levels? Retrieved January 08, 2017, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3953513/6. Centers for Disease Control and Prevention -United States, 2013, (2016, November 24), Retrieved January 7, 2017 from
- https://www.cdc.gov/mmwr/volumes/65/ss/ss6512a1.htm
- Voigt, J., & Mosier, M. (2013, September). A powered bone marrow biopsy system versus manual methods: a systematic review and meta-analysis of randomised trials. Retrieved January 08, 2017, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3756462/
   ASPS 2015 Plastic Surgery Statistics Report American Society of Plastic Surgeons. (2015). Retrieved January 8, 2017, from
- https://d2wirczt3b6wjm.cloudfront.net/News/Statistics/2015/plastic-surgery-statistics-full-report-2015.pdf
  9. IMV Medical Information Division, Inc. Benchmark Report MR2013 (2013, July). Retrieved December 15, 2016.
  10. Number of LASIK surgeries in the United States from 1996 to 2020. Retrieved February 9, 2016 from
- https://www.statista.com/statistics/271478/number-of-lasik-surgeries-in-the-us/
- 11. Harrow Health internal business data, including IMS data, 2015-2019, and proprietary surveys, 2015-2019
  12. Friedman, J. W. (2007, September). The Prophylactic Extraction of Third Molars: A Public Health Hazard. Retrieved January 08, 2017, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1963310/
- 13. Elmore, J. G., MD, Longton, G. M., MS, & Carney, P. A., PhD. (2015, March 17). Diagnostic Concordance in Interpreting Breast Biopsies. Retrieved January 08, 2017, from http://jamanetwork.com/journals/jama/fullarticle/2203798
- 14. Irwin, K. (2012, December 10). Prostate cancer now detectable using imaging-guided biopsy, UCLA study shows. Retrieved January 08, 2017, from http://newsroom.ucla.edu/releases/prostate-cancer-now-detectable-241575



### References

- Market Scope, Steady Growth in Cataract Surgical Procedures is Expected Over the Next 5 Years, July 27, 2017, https://market-scope.com/pressrelease/steady-growth-in-cataract-surgical-procedures-is-expected-over-the-next-5-years/
   Glaucoma Research Foundation. Glaucoma Facts and Stats. Retrieved February 9, 2017 from http://www.glaucoma.org/glaucoma/facts-

- statistics/glaucoma-facts-and-stats.php

  17. Schott, Chris, J.P. Morgan, "Eye' ideally Positioned to Expand the Dry Eye Market . . ." August 14, 2017

  18. Mayo Clinic Staff. (2018, May). Hormone therapy: Is it right for you? Retrieved December 11, 2018 from https://www.mayoclinic.org/diseases-conditions/menopause/in-depth/hormone-therapy/art-20046372
- Wysocki et al. Management of Vaginal Atrophy: Implications from the REVIVE Survey. Clinical Medicine Insights: Reproductive Health 2014:8 23-30
- $20. Centers for Disease Control and Prevention United States. (2015, January). Retrieved February \ 27, 2019, from \ 20. Centers for Disease Control and Prevention United States. (2015, January). Retrieved February \ 27, 2019, from \ 27,$ https://www.cdc.gov/ic/index.html





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