

**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): September 10, 2020**

**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.)

**102 Woodmont Blvd., Suite 610**  
**Nashville, Tennessee**  
(Address of principal executive offices)

**37205**  
(Zip Code)

Registrant's telephone number, including area code: **(615) 733-4730**

**Not Applicable**

(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 Global 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 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 8.01 Other Events.**

On September 10, 2020, Imprimis NJOF, LLC (“Imprimis”), a wholly-owned subsidiary of the Company, received correspondence from the Centers of Medicare and Medicaid Services (“CMS”) that rejected Imprimis’ application for transitional pass-through status under CMS’s hospital outpatient prospective payment system for one of Imprimis’ compounded products.

This decision does not affect the Company’s current operations, revenues, cash flows, or the availability of this compounded product, which the Company will continue to sell in its current form.

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

<u>Item</u>	<u>Description</u>
-------------	--------------------

99.1	<a href="#">Harrow Health, Inc. Corporate Presentation dated September 2020</a>
------	---

---

**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: September 14, 2020

By: /s/ Andrew R. Boll

Name: Andrew R. Boll

Title: Chief Financial Officer

---



NASDAQ: HROW

---

OUTSTANDING COMMON STOCK:

25.6M SHARES

---

ESTIMATED MARKET CAPITALIZATION

\$167M

---

PRICE PER SHARE as of July 7, 2020

\$6.51

SEPTEMBER 2020

---

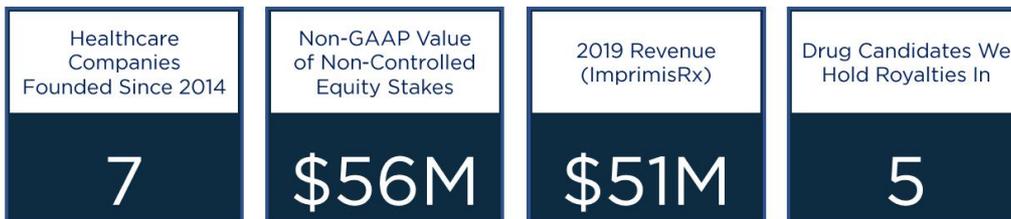
## SAFE HARBOR

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-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](http://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 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. Harrow expressly disclaims any intent or obligation to update these forward-looking statements except as required by law. Our compounded formulations are not FDA approved. All trademarks, service marks and trade names included in this presentation are the property of their respective owners.

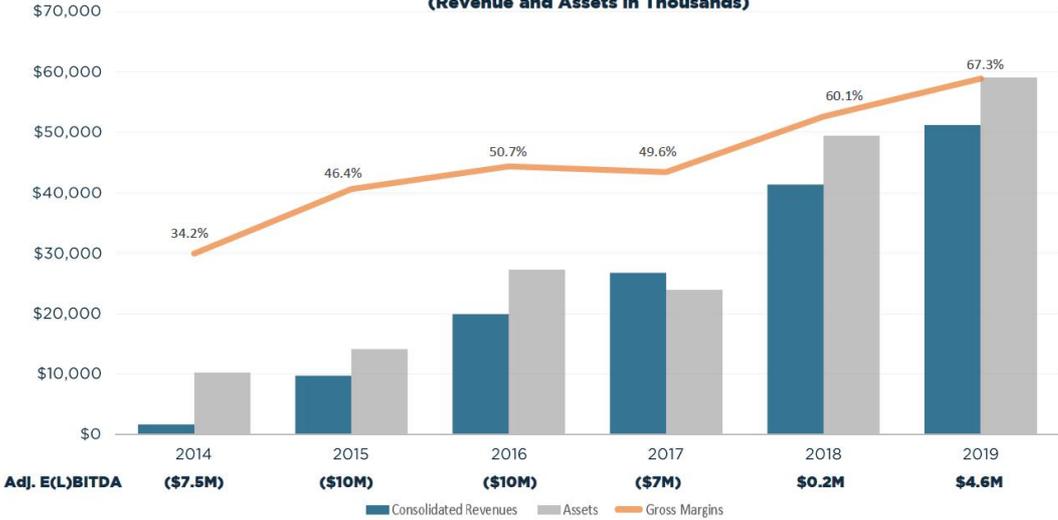




- We start-up innovative healthcare businesses *with a focus in ophthalmic pharmaceuticals*.
- We own ImprimisRx, an ophthalmology-focused prescription pharmaceutical platform.
- We actively manage our interests in six other Harrow-founded healthcare businesses.
- We own royalty streams on drug candidates being developed by several of our businesses.

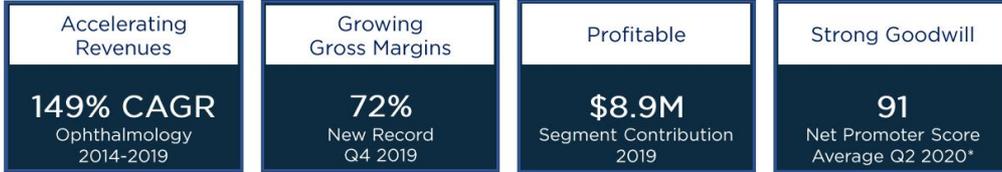


**Consolidated Revenues, Assets, and Gross Margins**  
 (Revenue and Assets in Thousands)





- 100% wholly-owned Harrow subsidiary founded in 2014.
- Nation's leading FDA-registered ophthalmology-focused cGMP pharmaceutical drug compounder and prescription drug platform serving the ocular surgery, dry eye disease, and glaucoma markets.
- Launched over 7 ophthalmic product lines during the past 5 years; 60+ patents filed.
- Over 1,500 monthly serviced accounts for over 9,000 prescribers.
- Fully-integrated national sales and customer service teams; efficient and scalable distribution platform.



\*Based on internal survey of 2,946 customers.



# Traditional Pharmaceutical Value Chain



Middle-men and intermediaries thrive.

Inefficiencies diminish value for the patient, pharmaceutical company, and the healthcare provider.

Tiered formularies and layers of intermediaries “feed” this opaque system.

“Discount cards” and other “access” programs attempt to soften consumer costs.

# ImprimisRx Value Chain

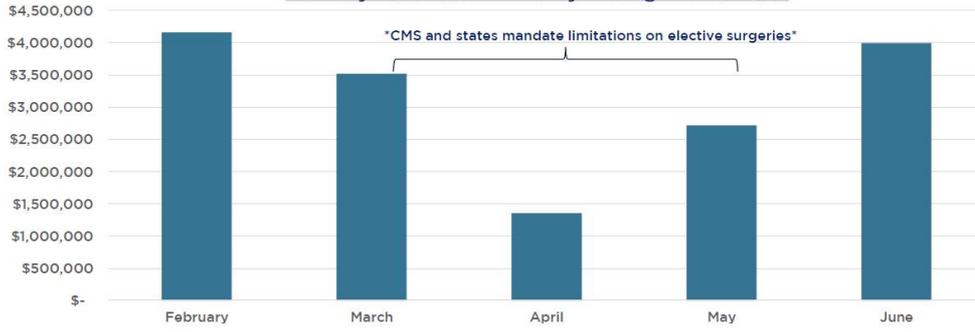


Cash-pay focused; no pharmacy benefit manager (PBM), wholesaler or distributor middlemen.  
No formulary rejections, discount cards, prior authorizations, insurance investigations, or PBM claw-backs.

The ImprimisRx model is simple and transparent – *for patients and prescribers.*



Monthly Revenues February through June 2020



- A reduction in elective procedures in response to COVID-19 had a negative impact on revenues.
- In May, states began easing restrictions associated with limitations on elective procedures.
- Revenues quickly snapped-back to near normal levels by the end of Q2.





Growth Strategy

We intend to leverage our national platform, continuing to create a dominant position in the US ophthalmic surgery market (>5 million annual procedures\*); and to make a strong push into dry eye disease, glaucoma, and other patient-specific chronic care eye conditions.

- All ImprimisRx products were developed after a doctor-customer identified an unmet need in the market.
- We will continue to develop products around what our customers need to provide better care for patients.
- We will grow inorganically, transacting to add new profitable revenue streams to better serve our customers.

Recent Transaction: Eyepoint Commercial Alliance for Dexycu®

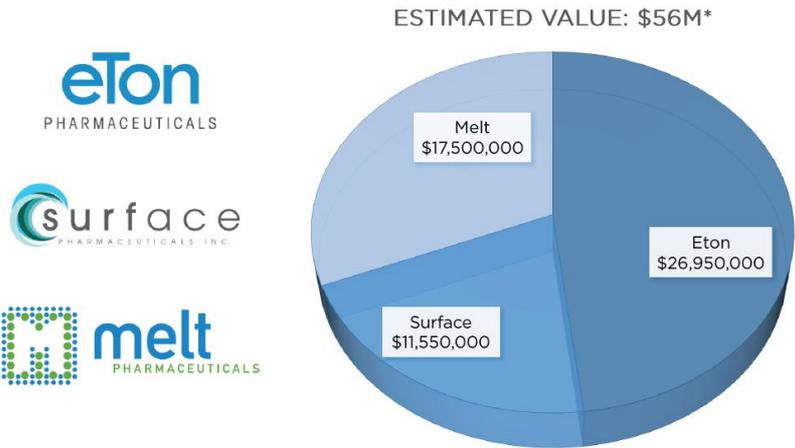
- Dexycu® is the only FDA approved single dose, sustained release, intracameral steroid (9% dexamethasone) injection for treatment of postoperative inflammation following ocular surgery.
- Through a recently announced commercial alliance with EyePoint, ImprimisRx is promoting Dexycu to its customers who in 2019 purchased more than 250,000 units of injectables used during cataract surgery.
- Conversions of ImprimisRx customers to Dexycu represent an estimated \$25 million+ annual opportunity, with an expected 85%+ contribution margin.



\*Based on internal projections using publicly available U.S. market-size estimations.



# Non-Controlled Equity Interests



\*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 September 11, 2020



Background

- Specialty pharmaceutical company; with diversified and growing pipeline.
- Deconsolidated from Harrow in June 2017, NASDAQ IPO in November 2018 ([ETON](#)).
- Harrow Health owns 3.5M shares of Eton common stock (-17%).

Opportunity\*

- \$2.5B+ aggregate market opportunity for drug candidates; multiple catalysts (next 12-18 months).

Expected Significant Events and Upcoming Catalysts\*

- EM-100: partnered with Bausch Health; FDA target action date September 15, 2020.
- Alkindi Sprinkle (orphan): PDUFA September 29, 2020.
- Additional NDAs expected to be submitted in 2H 2020.



\*According to Eton Pharmaceuticals, Inc. Corporate Presentation dated June 2020, press releases, and their corporate website: [etonpharma.com](http://etonpharma.com)



**Background**

- Clinical stage pharmaceutical development company focused on ocular surface and dry eye disease.
- Deconsolidated from Harrow May 2018 after \$21M Preferred Stock offering led by Flying L Partners.
- Harrow Health owns 3.5M shares of Surface common stock (~30% of equity interests).

**Opportunity**

- We estimate 30M+ Americans suffer from dry eye disease, with an existing multi-billion drug market.
- Harrow owns royalty rights on patented ophthalmology drug candidates SURF-100/200/201.

**Expected Significant Events and Upcoming Catalysts**

- Series B financing expected to close in 2020.
- SURF-201: Phase 2 clinical study underway (inflammation following ocular surgery); data end of 2020.
- SURF-100: Phase 2 clinical study underway (chronic dry eye disease); data expected during 2H 2021.
- SURF-200: IND effective; design and start of episodic dry eye program underway.





Background

- Clinical-stage company developing patented sublingual non-IV, non-opioid sedation drug candidates.
- Deconsolidated from Harrow in January 2019 after \$11M Preferred Stock offering.
- Harrow Health owns 3.5M shares of Melt common stock (~44% of equity interests).

Opportunity

- Cataract surgery (4.2M procedures annually in the US) with many label expansion opportunities.
- Harrow owns a royalty on the MELT-100 drug candidate and all future label extensions.

Expected Significant Events and Upcoming Catalysts

- IND effective in July 2020.
- Phase 1/PK study began enrolling in September; expected to be complete 2H 2020.
- Series B Financing expected within next 6 months.
- *Pivotal* Phase 2 study to begin in first half of 2021.





Background

Comprehensive, on-demand telemedicine chronic care ophthalmic platform.

- Innovative telemedicine 2.0 platform unites a national network of trusted eye health professionals, pharmaceutical and diagnostics companies, and pharmacy services to patients and their loved ones in a simple seamless way using our patent-pending VisionBox™ technology.
- Harrow currently controls 100% of Visionology.

Opportunity

- Partner with ImprimisRx to provide suite of proven ophthalmic medicines for chronic eye diseases.
- Other partnerships pending to deliver additional patented and patent-pending reimbursed services.

Significant Events and Upcoming Catalysts

- Led by Drew Livingston, co-founder/ex-CEO of Doxy.me (world's largest SaaS telemedicine platform).
- Regional launch expected in second half of 2020; national launch to follow in 2021.





**Background**

Women's health pharmaceutical company developing three novel drug candidates:

- MAY-66: Topical NCE for bacterial vaginosis
- MAY-44: Temporary treatment of dyspareunia
- MAY-88: Treatment for interstitial cystitis

**Opportunity**

Transformative patented therapies in three under-innovated areas of women's health.

Harrow owns royalty interests on patent-pending interstitial cystitis drug candidate MAY-88.



**Background**

Anti-infective pharmaceutical company developing lead "pathogen agnostic" drug candidate:

- NCE anti-infective (ophthalmic/otic applications)
- Preclinical data shows strong bacterial kill-times
- Ongoing in vivo anti-viral preclinical studies

**Opportunity**

Growing need for anti-infective ophthalmic NCEs.

Potential topical drop for non-specific conjunctivitis.

Expecting key preclinical data in 2H 2020.





- ImprimisRx is a cornerstone wholly-owned ophthalmology-focused commercial drug platform.
- Expect ImprimisRx to grow beyond a \$100M revenue business over the next few years.
- Leverage ImprimisRx ophthalmic drug platform to partner and inorganically expand our business.
- Positioned to capture significant income on incremental revenues as our overall business grows.
- Expect to see near-term catalysts related to our ownership stakes in Eton, Surface, and Melt.
- Anticipate near-term pivotal events for subsidiaries Visionology, Mayfield, and Stowe businesses.
- Management is strongly aligned with common shareholders through performance equity awards.

ESTABLISHED  
PLATFORM

FORESEEABLE  
GROWTH

PROFIT  
EXPANSION

INNOVATION  
LEADER



102 Woodmont Blvd. Ste 610  
Nashville, Tennessee 37205  
(615) 733-4730

**[IR@HARROWINC.COM](mailto:IR@HARROWINC.COM)**  
**[WWW.HARROWINC.COM](http://WWW.HARROWINC.COM)**

---