

**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): November 9, 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 2.02 Results of Operations and Financial Condition.

On November 9, 2020, Harrow Health, Inc. (the “Company”) issued a press release and a letter to stockholders announcing its financial results for the period ended September 30, 2020 and an update on recent corporate events. The press release and letter to stockholders are being furnished as Exhibits 99.1 and 99.2, respectively, to this Current Report on Form 8-K.

The information furnished under this Item 2.02 of this Current Report on Form 8-K, including Exhibits 99.1 and 99.2, shall not be deemed to be “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section. The information in this Item 2.02, including Exhibits 99.1 and 99.2, shall not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent it is specifically incorporated by reference but regardless of any general incorporation language in such filing.

The information furnished under this Item 2.02 of this Current Report on Form 8-K, including Exhibits 99.1 and 99.2, shall not be deemed to constitute an admission that such information or exhibit is required to be furnished pursuant to Regulation FD or that such information or exhibit contains material information that is not otherwise publicly available. In addition, the Company does not assume any obligation to update such information or exhibit in the future.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

- 99.1 [Press Release issued by Harrow Health, Inc. on November 9, 2020](#)
 - 99.2 [Letter to Stockholders by Harrow Health, Inc. dated November 9, 2020](#)
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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: November 9, 2020

By: /s/ Andrew R. Boll

Name: Andrew R. Boll

Title: Chief Financial Officer



Harrow Health Publishes Third Quarter 2020 *Letter to Stockholders*

Nashville, TN – November 9, 2020 – Harrow Health, Inc. (NASDAQ: HROW) today reported results for the third quarter 2020. Please [click here](#) to review Harrow Health’s *Letter to Stockholders* for the third quarter 2020.

Mark L. Baum, CEO of Harrow Health, commented, “The third quarter of 2020 was the best financial quarter in the history of the Company. Our team delivered on revenues, gross margins, and nearly every other internal financial metric that we chart. Revenues in July were better than June; and each subsequent month continued to improve, resulting in a company record revenues, gross margins and adjusted EBITDA. As we move into the fourth quarter and set our sights on 2021, we are hopeful our revenue trend, which currently looks V-shaped, will quickly transition into a *checkmark-shaped* trend line into 2021. In addition to the outstanding performance of ImprimisRx, other Harrow businesses continued to hit new and major milestones, and we expect to see more value inflection events in the coming quarterly periods.”

Conference Call and Webcast

The company’s management team will host a question and answer conference call with analysts and an audio-only webcast today at 4:45 p.m. Eastern Standard Time / 1:45 p.m. Pacific Standard Time. To participate, please use the dial in or click on the link below:

- [U.S. callers](#): (844) 602-0380
- [International callers](#): (862) 298-0970
- [Audio-only webcast](#): please [click here](#)

Conference Call Replay

A dial in replay of the call will be available until December 09, 2020. The webcast replay will be available until February 09, 2021.

- [U.S. callers](#): (877) 481-4010, Replay ID: 38433
- [International callers](#): (919) 882-2331, Replay ID: 38433
- [Webcast](#): please [click here](#)

About Harrow Health

Harrow Health, Inc. (NASDAQ: HROW) owns a portfolio of healthcare businesses, including [ImprimisRx](#), the nation’s leading ophthalmology outsourcing facility and pharmaceutical compounding business. The company holds large equity positions in [Eton Pharmaceuticals](#), [Surface Ophthalmics](#), and [Melt Pharmaceuticals](#). Harrow also owns Mayfield Pharmaceuticals, Stowe Pharmaceuticals, and Visionology, all companies founded as subsidiaries of Harrow Health. The Company also owns royalty rights in certain drug candidates being developed by Surface, Melt, and Mayfield. Harrow intends to create, invest in and grow paradigm shifting healthcare businesses that put patients first. For more information about Harrow Health, please visit the Investor Relations section of the corporate website by [clicking here](#).

Forward-Looking Statements

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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Investor Contact:

ir@harrowinc.com

Source: Harrow Health, Inc.

Harrow Health, Inc.
Letter to Stockholders

November 9, 2020

To the Stockholders of Harrow Health, Inc.:

The third quarter of 2020 was the best financial quarter in the history of the Company. Our team delivered on revenues, gross margins, and nearly every other internal metric that we chart. Revenues in July were better than June; and each subsequent month continued to improve. We were also pleased that while we achieved Q3 record revenues, we also hit an Adjusted EBITDA record, an important correlative trend we expect to continue as revenues grow. Finally, from a financial perspective, we expect that an increasing percentage of each incremental dollar of additive revenue will improve our Adjusted EBITDA figure.

As we move into the fourth quarter and set our sights on 2021, we are hopeful our revenue trend, which currently looks V-shaped, will quickly transition into a “checkmark-shaped” trend line into 2021. We believe this trend of growth will be driven by expanding our core business through new customer growth, continuing to expand within the many thousands of accounts we currently serve, launching new products in our development pipeline, and adding new revenue sources - such as Dexycu® commissions and those from other strategic initiatives we’ve been working on.

In addition to the record performance of ImprimisRx, as discussed below, other Harrow businesses continued to hit new and major milestones, and we expect to see more value inflection events in the coming quarterly periods.

Lastly, once we complete the deconsolidation of Mayfield Pharmaceuticals, we intend to leverage our position in eyecare and from a strategic perspective, exclusively focus on investing in and developing eyecare-related healthcare goods and services. We believe that Harrow’s focus on eyecare will better serve our stockholders.

Consolidated Financial Highlights

Total revenues were \$14.4 million for the third quarter of 2020, compared to \$12.8 million for the same period last year, and up nearly 80% from second quarter of 2020, when we recorded \$8.1 million in revenues. Based on the revenues we recorded in the month of October, we expect that our revenue trend will be stable into the fourth quarter and grow further in 2021.

Gross margins rapidly rebounded in the third quarter of 2020, up to a new high of 74%, compared to 68% in the third quarter of 2019, and 60% in the second quarter of 2020. This increase in gross margins was primarily related to the increase in unit volumes sold, increased production efficiencies and capacity utilization during the period. Adjusted EBITDA for the third quarter of 2020 was \$3.0 million compared to \$1.5 million in the third quarter of 2019. A reconciliation of all non-GAAP financial results in this letter appears beginning on page 5.

Operating income during the third quarter of 2020 was \$1.6 million, compared to an operating loss of \$4.4 million during the same period last year. We recorded a non-cash gain related to our Eton Pharmaceuticals ownership position of \$8.6 million, which pushed other income to \$7.0 million and resulted in net income attributable to Harrow Health, Inc. of \$8.6 million during the third quarter of 2020.

One additional metric we track is the ImprimisRx segment contribution. In the third quarter of 2020, segment contribution from ImprimisRx was \$4.7 million, which includes non-cash expenses related to depreciation, amortization and stock-based compensation of \$528,000. This important metric demonstrates the earnings power of the ImprimisRx business separately from other Harrow businesses, assets and liabilities.

Selected highlights regarding operating results for the three and nine months ended September 30, 2020 and for the same periods in 2019 are as follows (in thousands, except per share data):

	For the Three Months Ended September 30,	
	2020	2019
Total Revenues	\$ 14,399	\$ 12,755
Cost of Sales	(3,696)	(4,061)
Gross Profit	10,703	8,694
Selling, General & Administrative Expenses	(8,436)	(8,608)
Research & Development Expenses	(670)	(444)
Impairment of Intangible Assets	-	(4,040)
Total Operating Expenses	(9,106)	(13,092)
Operating Income (Loss)	1,597	(4,398)
Other Income (Expense), net	7,026	(7,232)
Net Income (Loss)	\$ 8,623	\$ (11,630)
Net Loss attributable to noncontrolling interests	15	161
Net Income (Loss) attributable to Harrow Health, Inc.	\$ 8,638	\$ (11,469)
Net Income (Loss) per share of common stock, basic	\$ 0.33	\$ (0.45)
Net Income (Loss) per share of common stock, diluted	\$ 0.32	\$ (0.45)

	For the Nine Months Ended September 30,	
	2020	2019
Total Revenues	\$ 34,276	\$ 38,561
Cost of Sales	(10,526)	(13,184)
Gross Profit	23,750	25,377
Selling, General & Administrative Expenses	(23,806)	(25,399)
Research & Development Expenses	(1,822)	(1,659)
Impairment of Intangible Assets	(363)	(4,040)
Total Operating Expenses	(25,991)	(31,098)
Operating Loss	(2,241)	(5,721)
Other (Expense) Income, net	(2,319)	3,004
Net Loss	\$ (4,560)	\$ (2,717)
Net Loss attributable to noncontrolling interests	54	228
Net Loss attributable to Harrow Health, Inc.	\$ (4,506)	\$ (2,489)
Net Loss per share of common stock, basic and diluted	\$ (0.17)	\$ (0.10)

ImprimisRx, a wholly owned subsidiary founded in 2014

ImprimisRx is an ophthalmic-focused pharmaceutical company with capabilities that include formulation development, scalable production, quality systems required by the highest federal manufacturing standards, U.S. and state-specific licensure to dispense direct-to-prescriber/institution or direct-to-patient, and a national commercial team that sells to and services prescribers, institutions, and patients in all 50 states.

The third quarter was the most successful operational quarter in the history of ImprimisRx. New pharmaceutical production automation equipment came online, the team successfully launched new software systems to enhance customer experience and create additional visibility into the business, and our quality systems continued to improve. However, my favorite statistic is our Net Promoter Score – which is a measure of our customers’ willingness to recommend our business to others. After conducting over 4,000 customer surveys during the third quarter of 2020, our NPS has remained steady at 92 – *an incredible achievement*. This score shows the affinity between ImprimisRx and its customers – *which is a key directional indicator of the true value of the business*. We also saw net revenue per 503B order increase to \$1,900 per order in the third quarter of 2020 compared to \$1,770 per order in the third quarter of 2019. ImprimisRx’s President, John Saharek, and the ImprimisRx team, deserve great credit for this success. I am convinced that the ImprimisRx business can and will continue to improve and deliver more value to our customers, driving meaningful financial value to Harrow stockholders.

Late last year, we began a process to leverage the ImprimisRx platform to add new FDA-approved and soon-to-be-FDA-approved ophthalmic products to the ImprimisRx platform. Our agreement with EyePoint Pharmaceuticals (NASDAQ: EYPT) to sell Dexycu® was the first achievement in the execution of this strategy. However, we have several other revenue-expanding deals in the pipeline and our team is looking forward to making announcements on these new initiatives in the near term. The ImprimisRx commercial team has successfully initiated new customer trials of Dexycu® with some of its largest Tri-Moxi customers, and this success has led to an early expansion of the EyePoint agreement to accelerate our outreach in terms of the number of ImprimisRx customers we’re able to bring the exciting Dexycu® offering to.

In summary, our efforts to leverage the ImprimisRx platform are underway. We continue to believe ImprimisRx is at the start of a growth run that we expect to last for many years, leading to ImprimisRx achieving our goal of becoming one of the largest ophthalmic pharmaceutical companies in the U.S.

Deconsolidated Companies (Non-Controlled Investments)

- Eton Pharmaceuticals (NASDAQ: ETON), founded by Harrow in 2017, delivered with two recent FDA approvals, EM-100 (\$600 million potential addressable market) and Alkindi® Sprinkle (an Orphan Drug Designated product with a \$100 million potential addressable market). Eton was recently assigned a May 2021 PDUFA date for its Orphan Drug Designated dehydrated alcohol program, which Eton estimates is a greater than \$100 million market with one competitor, and another May 2021 PDUFA action date for its zonisamide oral suspension. In October 2020, Eton submitted a New Drug Application (or NDA) for its third neurology product candidate, ET-101 (topiramate oral solution), while completing a \$22.5 million “above-market price” capital raise to help fund the launch of these exciting products and product candidates. Harrow maintains a 3,500,000 common share position in Eton representing approximately 15% of the outstanding equity of Eton.
- Surface Ophthalmics (formerly Surface Pharmaceuticals), founded by Harrow in 2017, continues to make clinical progress in its ocular surface disease programs, with three active INDs on file. Phase 2 data on SURF-201 is expected in the next couple of months. In addition, SURF-100 is expected to generate Phase 2 data within the next 12 months and the SURF-200 clinical development program is underway. We believe that Surface is well positioned to seek and complete a Series B funding in the first part of 2021. Harrow holds approximately 30% of the equity interests in Surface along with royalty rights on all drug candidates Surface is developing.
- Melt Pharmaceuticals, founded by Harrow in 2018, began enrolling patients in its Phase 1 study during the third quarter of 2020. Melt management has indicated that it hopes to have topline data available from this study in the coming months. Here is a [link](#) to a video that depicts the promise of Melt’s pharmaceutical drug candidates, if FDA-approved. We continue to expect Melt to complete a Series B financing within the next six months. Harrow holds approximately 44% of the common stock in Melt along with royalty rights on all drug candidates Melt is currently developing.

Subsidiary Companies (Controlling Interests)

- Visionology has begun the process of pitching to potential investment partners and we hope to announce the closing of its Series A financing within the next few months. While telemedicine is a “hot” space, we believe that Visionology is much more than telemedicine, and therefore is a much more interesting business. Visionology takes advantage of everything we know about ophthalmology and eyecare along with the expertise of Drew Livingston, the co-founder and former CEO of Doxy.me, the world’s largest and fastest growing SaaS-based telemedicine business. I look forward to sharing more about how we expect Visionology to change the game for chronic eyecare health management, and how Visionology will help drive what we believe is the coming revolution in patient-driven healthcare access and transparency.

- On behalf of Stowe Pharmaceuticals, Harrow recently completed in vitro and in vivo studies on STE-006 (formerly known as MUL-1867) and a second Harrow-owned topical formulation (DS-007), at a leading U.S. academic research institution which focuses on ocular-specific investigations. The objective of these studies was to determine whether the active test articles had in vitro killing power against relevant ophthalmic isolates of bacteria, viruses, and fungi; in vivo killing power against adenovirus-5; and if they were tolerable as surface-acting agents using the Draize scale. Past anti-bacterial data for STE-006 was strong; and while our initial read on anti-viral data from these studies was positive, we were not able to replicate prior data conducted on STE-006. Therefore, while we remain keenly interested in pathogen-agnostic topical agents to treat non-specific conjunctivitis (such as DS-007), we do not intend to invest further in STE-006. We intend to update our stockholders on further progress with DS-007 and other Harrow formulations in the anti-infective category in the coming quarters.
- Mayfield Pharmaceuticals is continuing to advance its drug pipeline and programs. We expect to have more to discuss about Mayfield at the time of our next quarterly stockholder update.

Financial Outlook

We are pleased with the strength of our underlying eyecare businesses and the momentum we have established with our customers and business partners. Importantly, during the third quarter, our business produced \$2.6 million of cash from operations, helping push our cash balance to a level we have not seen since December 31, 2018. We do not believe the third quarter revenues and financial performance were a fluke and expect revenues and our cash balance to grow throughout next year. We continue to remain highly optimistic about the prospects of our business.

Even though we have hit our previous target of 70% gross margins, we are pressing the team to continue to find new efficiencies that can drive gross margins higher. As we start to see more contribution from sales of Dexycu® to our topline, there should be a corresponding expansion of our gross and operating margins even further in the near term. ImprimisRx is a powerful pharmaceutical platform that in the third quarter demonstrated the earnings capability of incremental revenue growth in the business. As we execute on our operational plan, we will continue to build upon our strategic objectives, including inorganic growth opportunities and enhancing the profitability profile of the business.

Closing

I want to thank the employees of Harrow, ImprimisRx, and every Harrow-connected business for delivering exceptional results. Business is good, and we believe it will continue to get even better. Our pipeline of deal-flow is strong, and we are working on transactions that are potentially transformative. I am confident that the work we are doing to bring in new ophthalmic products and other opportunities will change the profile of our company in a positive way. Much work is left to do. We look forward to reporting on continued execution and action in the next *Letter to Stockholders* in March of 2021.

Sincerely,

Mark L. Baum
Founder and Chief Executive Officer
Nashville, Tennessee

FORWARD-LOOKING STATEMENTS

The Company's remarks in this stockholder letter include forward-looking statements within the meaning of federal securities laws. Forward-looking statements are subject to numerous risks and uncertainties, many of which are beyond Harrow Health's control, including risks and uncertainties described from time to time in its SEC filings, such as the risks and uncertainties related to the Company's ability to make commercially available its compounded formulations and technologies, and FDA approval of certain drug candidates in a timely manner or at all.

For a list and description of those risks and uncertainties, please see the "Risk Factors" section of the Company's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and other filings with the SEC.

Harrow Health's results may differ materially from those projected. Harrow disclaims any intention or obligation to update or revise any financial projections or forward-looking statements whether because of new information, future events or otherwise. This stockholder letter contains time-sensitive information and is accurate only as of today.

Additionally, Harrow Health refers 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 is included in this letter.

No ImprimisRx compounded formulation is FDA-approved. All ImprimisRx formulations are customizable. Other than drugs compounded at a registered outsourcing facility, all ImprimisRx compounded formulations require a prescription for an individually identified patient consistent with federal and state laws.

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

Adjusted EBITDA

In addition to the Company's results of operations determined in accordance with U.S. generally accepted accounting principles (GAAP), which are presented and discussed above, management also utilizes Adjusted EBITDA, an unaudited financial measure that is not calculated in accordance with GAAP, to evaluate the Company's financial results and performance and to plan and forecast future periods. Adjusted EBITDA is considered a "non-GAAP" financial measure within the meaning of Regulation G promulgated by the SEC. Management believes that this non-GAAP financial measure reflects an additional way of viewing aspects of the Company's operations that, when viewed with GAAP results, provides a more complete understanding of the Company's results of operations and the factors and trends affecting its business. Management believes Adjusted EBITDA provides meaningful supplemental information regarding the Company's performance because (i) it allows for greater transparency with respect to key metrics used by management in its financial and operational decision-making; (ii) it excludes the impact of non-cash or, when specified, non-recurring items that are not directly attributable to the Company's core operating performance and that may obscure trends in the Company's core operating performance; and (iii) it is used by institutional investors and the analyst community to help analyze the Company's results. However, Adjusted EBITDA and any other non-GAAP financial measures should be considered as a supplement to, and not as a substitute for, or superior to, the corresponding measures calculated in accordance with GAAP. Further, non-GAAP financial measures used by the Company and the manner in which they are calculated may differ from the non-GAAP financial measures or the calculations of the same non-GAAP financial measures used by other companies, including the Company's competitors.

The Company defines Adjusted EBITDA as net income (loss) excluding the effects of interest, taxes, depreciation, amortization, stock-based compensation, other income (expense), investment (gains)/ losses, net and, if any and when specified, other non-recurring income or expense items. Management believes that the most directly comparable GAAP financial measure to Adjusted EBITDA is net income (loss). Adjusted EBITDA has limitations and should not be considered as an alternative to gross profit or net income (loss) as a measure of operating performance or to net cash provided by (used in) operating, investing or financing activities as a measure of ability to meet cash needs.

The following is a reconciliation of Adjusted EBITDA, a non-GAAP measure, to the most comparable GAAP measure, net income (loss), for the three months ended September 30, 2020 and for the same period in 2019 (in thousands):

	For the Three Months Ended September 30, 2020	For the Three Months Ended September 30, 2019
GAAP Net Income (Loss)	\$ 8,638	\$ (11,469)
Stock-based compensation and payments	917	403
Interest expense, net	498	620
Taxes	-	-
Depreciation	464	397
Amortization of intangible assets	39	52
Investment (gains)/losses, net	(7,519)	6,612
Other income, net	(5)	-
Non-recurring expenses ⁽¹⁾	-	4,845
Adjusted EBITDA	\$ 3,032	\$ 1,460

⁽¹⁾ 2019 non-recurring expenses includes costs accrued in connection with litigation settlements, impairment of long-lived assets and wind-down costs (including severance) associated with the restructuring of our Irvine, California pharmacy business.

Equity Portfolio

Company	Number of Shares of Common Stock	Estimated Value at September 30, 2020
Eton Pharmaceuticals	3,500,000	\$ 27,650,000
Surface Ophthalmics	3,500,000	\$ 11,550,000
Melt Pharmaceuticals	3,500,000	\$ 17,500,000
Estimated Total Value		\$ 56,700,000

¹ Represents a non-GAAP value, which is calculated as the conversion price of the Series A Preferred Stock (from the most recent offering of the applicable company) multiplied by the number of shares owned by Harrow.