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): March 13, 2020

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.)
102 Woodmont Dlvd Suite 610		
102 Woodmont Blvd., Suite 610 Nashville, Tennessee		37205
(Address of principal executive offic	es)	(Zip Code)
r r	,	(1)
Registrant's	s telephone number, including area code: (61	15) 733-4730
	Not Applicable	
(Former N	ame or Former Address, if Changed Since I	Last Report)
Securities registered pursuant to Section 12(b) of the A	rt:	
securities registered pursuant to occurr 12(0) of the 11		
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 fi following provisions:	ling is intended to simultaneously satisfy	the filing obligation of the registrant under any of the
] Written communications pursuant to Rule 425 und	er the Securities Act (17 CFR 230.425)	
] Soliciting material pursuant to Rule 14a-12 under t	he Exchange Act (17 CFR 240.14a-12)	
] Pre-commencement communications pursuant to R	tule 14d-2(b) under the Exchange Act (17 C	FR 240.14d-2(b))
] Pre-commencement communications pursuant to R	tule 13e-4(c) under the Exchange Act (17 Cl	FR 240.13e-4(c))
ndicate by check mark whether the registrant is an en Securities Act of 1934: Emerging growth company []	nerging growth company as defined in Rule	405 of the Securities Act of 1933 or Rule 12b-2 of the
f any emerging growth company, indicate by check ma or revised financial accounting standards provided purs		e extended transition period for complying with any new

Item 2.02 Results of Operations and Financial Condition.

March 13, 2020, Harrow Health, Inc. (the "Company") issued a press release and a letter to stockholders announcing its financial results for the year and quarter ended December 31, 2019. 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 March 13, 2020
- 99.2 <u>Letter to Stockholders by Harrow Health, Inc. dated March 13, 2020</u>

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: March 13, 2020 By: /s/ Andrew R. Boll

Name: Andrew R. Boll
Title: Chief Financial Officer



Harrow Health Publishes Fourth Quarter 2019 Letter to Stockholders

Nashville, TN – March 13, 2020 – Harrow Health, Inc. (NASDAQ: HROW) today reported results for the fourth quarter 2019. Please <u>click here</u> to review Harrow Health's *Letter to Stockholders* for the fourth quarter 2019.

Mark L. Baum, CEO of Harrow Health, commented, "During 2019, we plowed the ground for the next leg up for the company and our shareholders. We own a powerful and valuable group of businesses, all with significant milestones expected in 2020. Operationally, in Q4 we hit the ball out of the park on gross margin – delivering on our target a year ahead of schedule. New equipment coming online in a few weeks and additional efficiencies we expect shortly should secure the gross margin targets we promised to deliver going forward. We have numerous ways to meet or even exceed expectations on revenue and are catching up quickly. And financially, we are making money; with record-highs in adjusted EBITDA and cash flow from operations during the fourth quarter – and we still have no interest in or need to (especially at our current stock price) sell Harrow stock to raise capital. All of these items, and much more, are discussed in our Letter to Stockholders."

Statement Regarding COVID-19 (Novel Coronavirus)

The company is not expecting disruptions in its business or supply chain as a result of the recent COVID-19 virus concerns in the US and around the world. The company has double checked inventories and its sources of key active pharmaceutical ingredients and other materials. It believes that it has ample supplies, and access to supplies, for the duration of 2020 and, in most cases, into 2021. In addition, the company has been in contact with its insurance provider and believes it has adequate coverage through its various risk management policies that could help supplement any losses in the unlikely event a potentially recoverable claim was to occur. Every ophthalmic product ImprimisRx dispenses is tested for sterility, endotoxin, and other contaminants as is required under the highest federal drug production standards (21 CFR Parts 210 and 211). The company has also messaged statements of confidence regarding our business continuity to our customers, employees and other stakeholders.

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 8:30 a.m. Eastern Daylight Time / 5:30 a.m. Pacific Daylight Time. To participate, please use the dial in or click on the link below:

<u>U.S. callers</u>: (844) 602-0380

International callers: (862) 298-0970

Audio-only webcast: please <u>click here</u>

Conference Call Replay

A dial in replay of the call will be available until April 13, 2020. The webcast replay will be available until June 13, 2020.

• <u>U.S. callers</u>: (877) 481-4010, Replay ID: 33135

• International callers: (919) 882-2331, Replay ID: 33135

• 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 Pharmaceuticals, Melt Pharmaceuticals, Mayfield Pharmaceuticals, Stowe Pharmaceuticals, and Radley Pharmaceuticals, all companies founded as subsidiaries of Harrow Health. The Company also owns royalty rights in certain drug candidates being developed by Surface, Melt, Mayfield and Radley. 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

###

Investor Contact:

Jon Patton jpatton@harrowinc.com 858-704-4587

Source: Harrow Health, Inc.

Harrow Health, Inc. Letter to Stockholders

March 13, 2020

To the Stockholders of Harrow Health, Inc.:

I am pleased to present our Q4 2019 Letter to Stockholders which includes an update about 2020 and beyond. For the year 2019, which marked our fifth year of commercial operations, Harrow delivered record highs in *three of our most important financial metrics – revenues, gross margin, and adjusted EBITDA*. We ended 2019 with \$54 million of equity value in deconsolidated subsidiaries¹ (on a non-GAAP basis), more than \$1 million of cash flow generated from operations during Q4, a record high adjusted EBITDA figure, and a more predictable financial position which allowed us to successfully renegotiate our debt facility. One of our former subsidiaries, Melt Pharmaceuticals, raised \$11 million in a Preferred Stock offering and is executing its clinical development plans for its novel conscious sedation drug candidates. Harrow owns 44% of the equity interests in Melt and is entitled to a 5% royalty on sales of its lead drug candidate. Our other subsidiaries are doing well, and in most cases even better than we expected; and as I summarize in the *Closing* below, 2020 is expected to be filled with value catalysts.

Consolidated Financial Results

For the full year 2019, gross revenues from our ophthalmology business grew 40% compared to 2018. Our fourth quarter 2019 gross ophthalmology-related sales were approximately \$12.4 million and \$47.7 million for the year, compared to \$10 million and \$34.1 million during the same periods last year, respectively. In the fourth quarter, revenue from our 503B outsourcing facility grew 63% to \$9.1 million, compared to \$5.6 million in the fourth quarter of 2018. For the fourth quarter of 2019, consolidated net revenues were \$12.6 million, which grew 11% year-over-year, compared to \$11.4 million during the same period in 2018, *keeping in mind the 2018 figure included non-ophthalmology revenue historically attributable to our Park business which was restructured late in the third quarter of 2019*. From 2014 to 2019, we've grown ophthalmology revenues at a 149% compound annual growth rate (CAGR) and aggregate revenues at a 99% CAGR.

Here are a few additional financial metrics:

• Gross margin increased to a record high of 72% in the fourth quarter, putting us on a par with other ophthalmic pharmaceutical company peers. The fourth quarter was a marked improvement over the 68% we reported in the third quarter of 2019, and the 64% reported in the fourth quarter of 2018. Gross margin for the full year was 67%, a new record on an annual basis, and a strong increase over the 60% gross margin we reported for 2018.

¹ Represents a non-GAAP measure that calculates the value of equity positions of Harrow deconsolidated subsidiaries as the price per share (and conversion price) of the Series A Preferred Stock (from the most recent offering of Melt Pharmaceuticals and Surface Pharmaceuticals) multiplied by the number of common shares owned by Harrow. As an example, Harrow owns 3,500,000 shares of Surface Pharmaceuticals common stock and the value we ascribe is based on the price per share of Series A Preferred Stock paid by third party investors in May 2018 (the Surface Series A financing event) – not inclusive of any positive or negative value associated with the operations of the business subsequent to the financing.

- Income from operations, on a GAAP basis, was positive for the first time in the history of the company, coming in at \$900,000 for the fourth quarter 2019.
- Adjusted EBITDA (a non-GAAP measure) totaled \$2.1 million during the fourth quarter, setting a new company high, which was previously set last quarter (Q3) at \$1.5 million. During the fourth quarter of 2018, we recorded adjusted EBITDA of (\$264,000). A reconciliation of adjusted EBITDA to the most comparable GAAP measure, net loss, is located at pages 13-14.
- Our pharmaceutical compounding segment reported record segmented quarterly earnings of \$2.2 million a figure that includes deductions for non-cash-based expenses of \$600,000 related to depreciation, amortization and stock-based compensation. We think of this metric, which in the aggregate would be approximately \$2.8 million, as the profit the compounding business produced as a "stand-alone" business.
- We reported cash flow from operations during the fourth quarter of nearly \$1.7 million, which we view as a significant development for the prospects of the business going forward.
- We reported adjusted EBITDA for every quarter in 2019, with adjusted EBITDA totaling \$4.6 million for the year ended December 31, 2019, and because of the progress we've made in 2019, as we add incremental revenue in 2020 and beyond, a significant portion of that new revenue should continue to fall to our bottom line.

In the first part of the fourth quarter 2019, we experienced an unexpected, but temporary setback when we launched a series of software upgrades and related tools. The roll-out of these new tools, which were designed to improve our operations, transaction process, and customer service capabilities, was not as successful as we expected, leading to stock outs of some products, missed orders and customer service complications *primarily associated with the ImprimisRx patient-specific business*. These issues were resolved quickly, and we're now getting the benefit we intended from these new tools. Critically, beginning in February and to this point in March 2020, our patient-specific business bounced back towards historical growth rates, and again, record numbers of customers are partnering with ImprimisRx to treat their patients.

These software upgrades are allowing us to more easily interact with chronic care patients and process prescription orders with efficiencies we've never had. As an example – within days of launching a recent targeted campaign using these new tools, with response and conversion rates that were *an order of magnitude better* than our historical results, we were able to acquire over 1,300 chronic care and auto-refill orders, totaling nearly \$175,000 in new revenues, and \$875,000 of potential revenues from future refills. Also, patient-specific prescription processing that took, in many cases, <u>days</u> to process are now being processed in a matter of <u>minutes</u>! Our software upgrade enabled this campaign and these results, but it is capable of much more, adding value that should more than make up for the temporary setback we experienced, making it easy to do business with us, and allowing us to grow our market share, generate new customer wins, and accelerate revenue growth.

During the fourth quarter, within "Other Expenses," we recorded a net investment gain of approximately \$2.2 million, which was driven primarily by an increase in the fair value of our Eton common stock position during the quarter, helping push our net income to \$2.66 million, or \$0.10 a share.

Selected highlights regarding operating results for the three months and year ended December 31, 2019 and for the same periods in 2018 are as follows (in thousands, except per share data):

	For the three		For the three	
	months ended		months ended	
	December 31, 2019		December 31, 2018	
Total Revenues	\$	12,604	\$	11,384
Cost of Sales		(3,565)		(4,102)
Gross Profit		9,039		7,282
Selling, General & Administrative Expenses		(7,697)		(9,012)
Research & Development Expenses	(424)		(433)	
Operating Income (Loss)		918		(2,163)
Other Income, net		1,674		20,293
Net Income	\$	2,592	\$	18,130
Net Loss attributable to non-controlling interests		65		-
·	\$	2,657	\$ \$	18,130
······································	\$	0.10		0.89
Net Income per share of common stock, diluted	\$ 0.10		\$	0.78
,				
,				
•		For the year ended		For the year ended
		For the year ended December 31, 2019		For the year ended December 31, 2018
Total Revenues		3	\$	· ·
		December 31, 2019	\$	December 31, 2018
Total Revenues		December 31, 2019 51,165	\$	December 31, 2018 41,372
Total Revenues Cost of Sales Gross Profit Selling, General & Administrative Expenses		December 31, 2019 51,165 (16,749)	\$	December 31, 2018 41,372 (16,521)
Total Revenues Cost of Sales Gross Profit Selling, General & Administrative Expenses Research & Development Expenses		December 31, 2019 51,165 (16,749) 34,416	\$	December 31, 2018 41,372 (16,521) 24,851
Total Revenues Cost of Sales Gross Profit Selling, General & Administrative Expenses		December 31, 2019 51,165 (16,749) 34,416 (33,096)	\$	December 31, 2018 41,372 (16,521) 24,851 (29,243)
Total Revenues Cost of Sales Gross Profit Selling, General & Administrative Expenses Research & Development Expenses Impairment and disposal of long-lived assets Operating Loss		December 31, 2019 51,165 (16,749) 34,416 (33,096) (2,083)	\$	December 31, 2018 41,372 (16,521) 24,851 (29,243)
Total Revenues Cost of Sales Gross Profit Selling, General & Administrative Expenses Research & Development Expenses Impairment and disposal of long-lived assets		December 31, 2019 51,165 (16,749) 34,416 (33,096) (2,083) (4,040)	\$	December 31, 2018 41,372 (16,521) 24,851 (29,243) (825)
Total Revenues Cost of Sales Gross Profit Selling, General & Administrative Expenses Research & Development Expenses Impairment and disposal of long-lived assets Operating Loss Other Income, net		December 31, 2019 51,165 (16,749) 34,416 (33,096) (2,083) (4,040) (4,803)	\$ \$	December 31, 2018 41,372 (16,521) 24,851 (29,243) (825) (5,217)
Total Revenues Cost of Sales Gross Profit Selling, General & Administrative Expenses Research & Development Expenses Impairment and disposal of long-lived assets Operating Loss Other Income, net Net Income (Loss) Net Loss attributable to non-controlling interests	\$	December 31, 2019 51,165 (16,749) 34,416 (33,096) (2,083) (4,040) (4,803) 4,678		December 31, 2018 41,372 (16,521) 24,851 (29,243) (825) (5,217) 19,842
Total Revenues Cost of Sales Gross Profit Selling, General & Administrative Expenses Research & Development Expenses Impairment and disposal of long-lived assets Operating Loss Other Income, net Net Income (Loss) Net Loss attributable to non-controlling interests Net Income attributable to Harrow Health, Inc.	\$	December 31, 2019 51,165 (16,749) 34,416 (33,096) (2,083) (4,040) (4,803) 4,678 (125)		December 31, 2018 41,372 (16,521) 24,851 (29,243) (825) (5,217) 19,842
Total Revenues Cost of Sales Gross Profit Selling, General & Administrative Expenses Research & Development Expenses Impairment and disposal of long-lived assets Operating Loss Other Income, net Net Income (Loss) Net Loss attributable to non-controlling interests Net Income attributable to Harrow Health, Inc. Net Income per share of common stock, basic	\$	December 31, 2019 51,165 (16,749) 34,416 (33,096) (2,083) (4,040) (4,803) 4,678 (125) 293	\$	December 31, 2018 41,372 (16,521) 24,851 (29,243) (825) (5,217) 19,842 14,625

Subsidiaries

ImprimisRx

ImprimisRx continues to leverage two macro trends in the ophthalmic pharmaceutical business: (1) an increasing number of Americans have healthcare and prescription drug plans² with high deductibles requiring high out-of-pocket costs for patients; and (2) physician and facility fees for Medicare-centric surgical cases (such as cataract surgery) are fixed by government payors. To soften the blow of these realities for both patients and providers, many pharmaceutical companies use coupons, discounts, and/or rebates to supposedly lower costs.

² According to the Kaiser Family Foundation's Employer Health Benefits Survey, in 2018, the average worker contributed \$5,547 towards total premium costs of \$19,616 per family. Also, anecdotally, a senior executive at a major regional healthcare insurer and provider recently told me that over 80% of their \$5,000 deductible plans never reset (i.e. they never reach the entirety of the deductible).

Transacting with ImprimisRx is completely different because there are no insurance payments, coupons, discounts, or rebates – things are much simpler: *a fair cash price* – more often than not less than the out-of-pocket costs for having to go through the rigmarole of dealing with third party payment. For "bundled fee" surgical cases, ImprimisRx is a low-cost, high-quality provider of a growing *suite* of perioperative formulations. Patients, physicians, and facilities appreciate this simplicity.

By addressing the unmet needs of patients, physicians, and facilities, the ImprimisRx model has changed the ophthalmology prescription drug market, and with approximately 7,000 prescribers (and growing) who regularly use and prescribe ImprimisRx products, it has become a trusted partner within the ophthalmic and optometric community. We've dispensed well over 3.5 million sterile prescriptions and are currently shipping over 100,000 compounded ophthalmic pharmaceutical products per month from our FDA/DEA-registered and inspected 503B outsourcing facility. This trust and success – *in less than six years of existence* – has led to ImprimisRx becoming one of the largest ophthalmic prescription pharmaceutical companies in the United States. And we have the infrastructure, systems, and processes to continue our growth for many years to come³.

Recent ImprimisRx Customer Wins and Focusing on Growth

As proof points for the growth we expect this year and next, we've announced a few of the supply agreements we've recently signed, including one with Vision Center Network of America (VCNA), whose nine ophthalmic ambulatory surgery centers (ASCs) perform approximately 100,000 cataract procedures annually (about 2.5% of the U.S. market), iOR Partners, a progressive office-based surgery suite provider, and EyeCare Services Partners, a partnership of 30+ ophthalmologic, optometric brands, and ASCs across multiple states. Other exclusive or preferred provider supply agreements recently signed include leading ASC groups, LASIK/PRK providers, and ophthalmic practices, including one with a leading provider of LASIK eye procedures that performs over 150,000 procedures annually, and another with one of the nation's largest surgery center operators. These agreements and others will begin contributing to revenues in the near term as we begin to provide products used in these hundreds of thousands of ophthalmic procedures.

Additionally, since our last earnings call, after receiving our California 503B outsourcing facility license in December, we've seen ophthalmology *revenues from the California market more than double.* Given the size of the California market and our ability to efficiently service to scale, we see growth continuing in the Golden State for years to come.

³ The company is not expecting disruptions in its business or supply chain as a result of the recent COVID-19 (novel coronavirus) concerns in the US and around the world. The company has double checked inventories and its sources of key active pharmaceutical ingredients and other materials. It believes that it has ample supplies, and access to supplies, for the duration of 2020 and, in most cases, into 2021. In addition, the company has been in contact with its insurance provider and believes it has adequate coverage through its various risk management policies that could help supplement any losses in the unlikely event a potentially recoverable claim was to occur. Every ophthalmic product ImprimisRx dispenses is tested for sterility, endotoxin, and other contaminants as is required under the highest federal drug production standards (21 CFR Parts 210 and 211). The company has also messaged statements of confidence regarding our business continuity to our customers, employees and other stakeholders.

We also expect that during the first quarter 2020, we will reach our goal of re-acquiring half of the revenue that was formerly attributable to Park – and based on current trends, we expect this line of business could show even more growth over the coming quarters.

Finally, our improving gross margin story was achieved by our team rolling up its sleeves with the equipment we had. However, in a few short weeks we expect to have new bottle filling production equipment coming online which we expect should increase our capacity by about 5X. In order to meet anticipated demand this year and next, we are adding another production shift in our New Jersey 503B facility and we've increased our physical footprint in New Jersey which now totals seven ISO Class 7 clean rooms and approximately 30,000 square feet of space.

The Next Stage of Growth for ImprimisRx

- We are currently in discussions with a handful of pharmaceutical companies that may benefit from leveraging the ImprimisRx commercial and distribution footprint within the ophthalmology space, with the intent to acquire, license or otherwise access FDA-approved ophthalmic products and drug candidates. To these potential partners, ImprimisRx offers near immediate access to a critical mass of customer relationships, a national sales organization, cost-effective distribution (i.e. a better gross-to-net), and customer service infrastructure. We expect to advance our discussions to definitive agreements sometime this year, and that these agreements will increase our revenue and profitability, leading to the transition of ImprimisRx from a pharmaceutical drug compounder to an ophthalmic pharmaceutical drug company.
- Another important development is a program undertaken to ensure access to ImprimisRx surgical formulations which may be eligible for temporary pass-through payment from the U.S. Centers for Medicare and Medicaid Services (CMS). Related to this, during the fourth quarter of 2019, leadership at ImprimisRx met with CMS and, based on the outcome of that meeting, ImprimisRx applied for temporary pass-through payment for an NDC-coded surgical formulation. We expect to know if this pass-through payment application is approved by July 1, 2020.
- We are introducing a handful of new formulations that could drive meaningful revenue growth during the second half of 2020 and into 2021. As an example, one large existing customer is in the process of "trialing" one of these new products in parts of its network. If successful, the expected revenue impact from this *one patented product*, from this *one customer* could be nearly \$1 million per year in new revenue. There are many other large accounts we intend to extend this and other formulations to and initial customer feedback has been very favorable.
- Finally, we're transitioning the ImprimisRx sales organization from a primarily contracted group to a primarily dedicated direct sales representative model. *We do not expect this change to have much impact from an expense standpoint*; however, we do expect to gain additional depth from our sales team that we believe will drive ImprimisRx revenue growth, specifically in the glaucoma and dry eye markets, which combined, represent over 43 million prescriptions annually in the US.

VisionologyTM

Since 2018, we've been working on a way to leverage the thousands of ophthalmic prescribers our ophthalmic businesses serve, our experience in developing ophthalmic prescription pharmaceuticals, as well as our manufacturing and sales infrastructure. With this in mind, this year we will launch Visionology – an eye health platform trusted by both our partner physicians and patients alike – that we believe has the potential to dramatically improve care and patient access to affordable medications prescribed to treat a variety of chronic and acute conditions.

One example of Visionology's service will be to offer a patent-pending formulation we've developed with Dr. Richard L. Lindstrom in order to treat presbyopia. The presbyopia market is the largest unaddressed pharmaceutical market in ophthalmology – with over 65 million Americans (and an estimated 1.8 billion worldwide) potentially being eligible for some type of vision-correcting pharmaceutical medication. Based on feedback from a select group of patients, when available, our formulations may provide benefits we do not believe other potential entrants into this market may be able to offer. Because of this, and with the help of a world-class ophthalmic and optometric advisory board, we are in the process of designing initial clinical studies to gather human clinical data to support the potential of our formulations. We intend to provide more color on the Visionology presbyopia program, and other details about this exciting new business, over the coming quarters.

Stowe Pharmaceuticals

Stowe Pharmaceuticals is developing STE-006, a multi-patent protected NCE drug candidate which has shown tremendous promise pre-clinically as an anti-infective – *quickly killing broad spectra ophthalmic-specific bacteria colonies*, *viruses*, *fungi*, *and mold*. Stowe is nearing completion of a series of studies with an internationally recognized ophthalmic infectious disease research laboratory which were designed to "pressure test" our molecule, crystalizing its scientific value, and ultimately, the investment opportunity we believe STE-006 and Stowe presents. The data so far are what we'd hoped for – and we have a growing confidence we may have a "category killer" prescription ophthalmic drug candidate for several very large unserved ophthalmic markets.

We expect to file a Stowe corporate presentation with the SEC in the coming quarter and inform our shareholders about the initial Stowe management team and board. We expect to complete a deconsolidating transaction soon thereafter.

Mayfield Pharmaceuticals

We continue to make significant progress with Mayfield Pharmaceuticals, including recruiting a prominent senior pharmaceutical executive as Mayfield's new CEO and positively renegotiating a licensing agreement for Mayfield's dyspareunia program. Now more than ever, we are excited about the prospects of Mayfield's drug candidates, particularly with Mayfield's recurrent bacterial vaginosis (BV) program. BV is a tremendous problem for women who do not have access to a safe and effective bactericidal product. We believe our lead program is going to change the landscape for this large and unmet need for millions of American women – as well as women across the globe. We intend to work to conclude a deconsolidating transaction for Mayfield this year.

Radley Pharmaceuticals

An artifact of the work we did in 2015 with the molecule pyrimethamine was the discovery of a new and stable delivery system for pyrimethamine. This discovery was formulated into what has become RAD-100. An important feature of RAD-100 is that, unlike current FDA-approved versions of pyrimethamine, it may be titrated based on the needs of specific patients and we believe it may provide better absorption characteristics compared to currently available forms of this medication. In January of 2020, Radley completed a Type C meeting with FDA for its RAD-100 program and received guidance on its proposed clinical development plan and initial label indication. We are happy to report that following our meeting with FDA, RAD-100 was granted a path forward that could condense the traditional clinical development process.

This February, the United States Patent and Trademark Office (USPTO) informed us that our RAD-100 composition of matter and methods of use claims are being allowed.

With the recent successful Pre-IND Meeting with FDA and USPTO news, I can add more color on the RAD-100 work we are pursuing, including supporting investigator-initiated human *in vivo* and *in vitro* studies of RAD-100 at two major healthcare institutions in Boston and New York:

- In Boston, investigators at the Dana-Farber Cancer Institute (DFCI) have shown that RAD-100 blocks the effects of the transcription factor STAT3, which is commonly over-active in cancer cells, and they have initiated clinical trials using RAD-100 in cancer patients. Radley is also collaborating with scientists at DFCI to determine if RAD-100 is effective in targeting STAT3 in animal models of cancer and related disorders. We expect to provide more information this year about this important collaboration.
- In New York, a RAD-100 human clinical study is being sponsored by Montefiore Medical Center in collaboration with the Albert Einstein College of Medicine. Radley began supplying its RAD-100 formulation for a Phase 1 human clinical study as a STAT3 inhibitor for the treatment of intermediate/high-risk Myelodysplastic Syndromes (MDS). This Phase 1 study is designed to assess the maximum tolerated dose of RAD-100 and provide the recommended Phase 2 dose for the treatment of intermediate/high-risk MDS that is refractory to or relapsed after treatment with azanucleosides. The objective of this study is to determine the safety, dose tolerance, pharmacokinetics and pharmacodynamics of RAD-100 in intermediate/high-risk/relapsed or azanucleoside-refractory MDS within the confines of a Phase 1 study. To date, all participants have tolerated the RAD-100 therapy well and enrollment will continue through the third quarter of 2020.

These studies are being conducted through agreements between these institutions and Radley. Harrow has agreed to supply the RAD-100 study drug and will maintain other rights connected to intellectual property and other drug development rights. Harrow maintains royalty rights on the RAD-100 drug candidate. Once we round out the portfolio of Radley's drug development pipeline, we intend to prepare it for and execute a deconsolidating transaction.

Equity Portfolio

We are continuing to create a portfolio of equity positions in deconsolidated subsidiaries. At December 31, 2019, our portfolio includes:

	Number of	
Company	Common Shares	 Estimated Value
Eton Pharmaceuticals	3,500,000	\$ 25,200,000
Surface Pharmaceuticals	3,500,000	\$ 11,550,0004
Melt Pharmaceuticals	3,500,000	\$ 17,500,0004
Estimated Total Value		\$ 54,250,000

⁴ 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.

Eton Pharmaceuticals

Eton (NASDAQ: ETON) has numerous value catalysts coming in the near term that we believe will continue to make it appealing to investors. Because of the business development prowess of the Eton team, in a few short years since we founded the company, Eton now has nine active programs – including one approved product, three under FDA review, and another five in late stage development. The aggregate reference product market size for these opportunities exceeds \$4 billion annually. We have a high degree of confidence that the Eton regulatory and commercial team will improve results and take advantage of the immense opportunity that the current pipeline of programs represents. We also believe that with Sean Brynjelsen at the helm as CEO, more accretive deals and deal making seem likely. Harrow Health's 3.5 million shares of Eton common stock represent an approximately 20% ownership stake in the company.

Surface Pharmaceuticals

Surface Pharmaceuticals is developing a total of four ophthalmic drug candidates *and* is poised to reach a significant inflection point this year. During the summer, we expect to see data readout from its Phase 2 study of SURF-201, a novel steroid drug candidate for the treatment of pain and inflammation following ocular surgery. And Surface's SURF-100 Phase 2 study, which is expected to begin enrolling in a few months and should be completed during Q1 2021, will be what we believe is the most "complete" dry eye disease clinical study ever conducted – with *three* potential approvable dry eye disease drug candidates in a single study. Surface has very favorable public company comps, making Harrow Health's 3.5 million Surface common shares (representing a 30% ownership stake) and royalty rights on each of Surface's drug candidates a very attractive asset and potential future cash flow producer.

Melt Pharmaceuticals

The team at Melt Pharmaceuticals is focused on revolutionizing the surgical experience through needle-free and opioid-free procedural sedation. Recently completed market research with cataract surgeons and anesthesiologists validated our conviction that there is a great deal of interest in Melt's non-IV approach for patients. Over the next few years Melt is focused on three goals:

- Gaining FDA approval for its lead drug candidate MELT-100
- Gaining reimbursement under Medicare Part B for MELT-100, and
- Capitalizing the company through its next clinical milestones.

Melt is scheduled to have a Type C meeting with FDA in May to discuss its proposed Phase 3 program. Shortly after this meeting with FDA, Melt intends to file an IND for MELT-100 and begin enrolling its Phase 1/PK study. If successful, Melt intends to move into its Phase 3 activities in mid-2021. The initial label Melt intends to seek will be for sedation and analgesia related to cataract surgery, and fortunately, from a clinical development perspective, an acute care study such as this can be completed efficiently without long and costly patient follow up periods.

Melt's Opioid Sparing Conscious Sedation MELT-100 Program

After discussions with some of the top legal, regulatory and policy advisors in Washington DC, the Melt leadership continues to believe MELT-100 should not only be eligible for transitional pass-through status under Medicare Part B, but also for "longer-term pass-through" status as a non-opioid analgesic in the ambulatory care setting. ⁵

⁵ Additionally, the Non-Opioids Prevent Addiction in the Nation Act referred to as the NOPAIN Act was introduced during Q4 in both the U.S. House of Representatives and the Senate. This bipartisan legislation is designed to remove payment disincentives put in place by CMS that currently restrict the ability of practitioners to prescribe non-opioid treatment alternatives in surgical settings. With 7 Senate and 16 house bipartisan sponsors and cosponsors, the NOPAIN Act is gaining momentum. Supported by the congressional Bipartisan Opioid Task Force, the NOPAIN Act also enjoys strong advocacy from grassroots organizations led by voices for non-opioid choices; and is supported by a diverse coalition, including professional organizations of physicians and nurses and other groups fighting for common sense solutions to pain management. If passed, the legislation would provide separate payment status for 5 years.

A recently commissioned survey performed by the Ophthalmology and Anesthesiology Society (OAS), which is comprised of approximately three hundred ophthalmology and anesthesiology professionals, indicated that over 50% of patients undergoing cataract surgery today are given an opioid at some point during the surgical procedure. We believe that, if approved, MELT-100 can dramatically reduce or even eliminate the need for opioid medications for cataract surgery.

Given the progress the Melt team has made, and the enormous impact MELT-100 could have if approved, we expect Melt to successfully raise additional capital this year to take the MELT-100 program through to a Phase 3 readout and NDA filing.

Harrow Health's 3.5 million shares of Melt common stock represent an approximately 44% ownership stake in the company and Harrow has royalty rights on MELT-100.

Financial Outlook

While we achieved our gross margin target a year ahead of schedule, we are presently about six to twelve months behind on revenue targets. March has always been our best month and this March looks to be another record, especially after just hitting another record week of revenue. Barring anything unforeseen, we expect net revenues in the first quarter of 2020 to be slightly ahead of where we finished in the fourth quarter 2019, and to grow further over the remaining part of the year.

On revenue growth, we have multiple new drivers that may allow us to meet or exceed our 2021 revenue targets, including revenue contribution from new products we're launching this year, new product supply agreements, the addition of revenue from acquired or in-licensed FDA-approved products, and/or potential pass-through payment for a key high volume ophthalmic surgical product.

We anticipate adjusted EBITDA continuing to increase over the coming quarters as revenues bounce back and accelerate. We will continue to target gross margins of 70%, expecting some slight volatility in that metric as new formulations, equipment and personnel are added to our production queue this year. We still believe we are positioned to reach our operating margin target during 2021.

Closing

During 2019, we prepared for the next leg up – in terms of growth and hopefully the price of Harrow's stock, and here are a few examples of what I mean:

- Benefitting from a more assertive approach to growth, ImprimisRx is poised to deliver on expectations, as it transitions from an ophthalmic compounding business to an ophthalmic pharmaceutical company.
- Visionology should launch, generate revenue, and we believe change the eye health experience for millions of American patients with an impactful healthcare platform that includes services and prescription products.
- Eton now has nine active programs, including one that is FDA-approved, three accepted NDAs in review with FDA, and a handful of other late stage large market products; and we believe we will see improvements in the Eton team's execution on the their prolific business development translating into growing value for holders of Eton shares.
- Melt, which has great public company comps, will file its MELT-100 IND and enter the clinic; and the use of drug candidates that reduce opioid use is being encouraged through federal policy and legislation and is overwhelmingly desired by a recently polled groups of prescribers making Melt's potential commercial opportunity greater than ever.
- Mayfield's pipeline, which includes a preferred format (topical) NCE BV drug candidate that has shown tremendous translatable pre-clinical
 promise and two 505(b)(2) large market high commercial impact drug candidates should be ready for a deconsolidating transaction in 2020.
- Radley, which is in the clinic working with two of the most prominent research organizations in the world for two separate orphan indications for a soon-to-be patented drug candidate, may be ready for a deconsolidating transaction in 2020.
- Surface, which has great public company comps, and is seeking approval for drug candidates that our ImprimisRx business has dispensed (as compounded drugs) to cash-pay customers (i.e. there is meaningful anecdotal information about whether they might work and are safe), should reach major clinical and value inflection milestones this year beginning this summer.
- Stowe, which we expect to deconsolidate this year, has produced translatable anti-infective data from the #1 ophthalmic research laboratory in the world on a patented NCE molecule that appears to rapidly kill ophthalmic-specific isolates of bacteria, mold, viruses and fungi; and we view the Stowe assets which presently have no meaningful balance sheet value as having the potential be one of the most valuable businesses we've started.

We know not everything will go our way and that growth and value creation is not always a linear process. That said, just a handful of years ago, we started Harrow with an idea and a small amount of investor capital, and today we've built an efficient business model with major 2020 catalysts for all our businesses, wholly owned and deconsolidated. Importantly, from my perspective, I see multiple ways to deliver, and hopefully exceed, our shareholders' expectations.

Last, but certainly not least, I want to thank our shareholders for reaching out to check on us after the tragic tornadoes that hit Nashville a few short weeks ago. While we escaped any damage, others did not, and anyone interested in assisting those in need, consider donating to the Second Harvest Food Bank and giving what you can. I look forward to updating stockholders in a couple of months when we publish our next *Letter to Stockholders* in May.

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 and older 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) and, if any and when specified, other non-recurring income or expense items. The company believes that the most directly comparable GAAP financial measure to adjusted EBITDA is net loss. Adjusted EBITDA has limitations and should not be considered as an alternative to gross profit or net 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 E(L)BITDA, a non-GAAP measure, to the most comparable GAAP measure, net income, for the three months ended December 31, 2019 and for the same period in 2018 (in thousands):

	Eı	nree Months nded er 31, 2019	 Three Months Ended lber 31, 2018
GAAP Net Income	\$	2,657	\$ 18,130
Stock-based compensation and payments		465	536
Interest expense, net		561	689
Taxes		-	-
Depreciation		571	385
Amortization of intangible assets		34	59
Investment gains/losses from Eton, Melt and Surface, net		(2,235)	(21,017)
Other Expense, net		-	35
Non-recurring expenses ⁽¹⁾		75	918
Adjusted E(L)BITDA	\$	2,128	\$ (264)

(1) Non-recurring expenses in 2019 includes costs in connection with the wind-down of and restructuring of Park.

The following is a reconciliation of adjusted EBITDA, a non-GAAP measure, to the most comparable GAAP measure, net loss, for the year ended December 31, 2019 (in thousands):

	For the Year Ended December 31, 2019	
GAAP Net Income	\$ 168	
Stock-based compensation and payments	2,023	
Interest expense, net	2,500	
Taxes	-	
Depreciation	1,849	
Amortization of intangible assets	209	
Investment gains/losses from Eton, Melt and Surface, net	(6,548)	
Other Expense, net	-	
Non-recurring expenses ⁽¹⁾	4,383	
Adjusted E(L)BITDA	\$ 4,583	

⁽¹⁾ Non-recurring expenses includes costs in connection with the impairment of long-lived assets and wind-down costs (including severance) associated with the restructuring of our Park business, litigation settlements, and costs Melt incurred during the period presented that were consolidated in the Company's financial statements, that were reimbursed to the Company following the deconsolidation of Melt in the first quarter of 2019.