# Harrow Health, Inc. Letter to Stockholders

November 13, 2019

To the Stockholders of Harrow Health, Inc.:

We've decided to adopt a *Letter to Stockholders* format, which we will publish on our corporate website <a href="here">here</a>, in an effort to make quarterly conference calls more efficient. I am confident this change will better facilitate greater transparency, providing realistic expectations and commentary about our business through clear and consistent communication.

We intend to provide these letters on a quarterly basis at the time we file our quarterly and annual financial reports with the U.S. Securities and Exchange Commission. In addition to these letters, we will continue to report meaningful events in our periodic SEC reports (including Form 10-Qs, Form 10-Ks and Form 8-Ks) and/or through press releases.

#### Introduction

When you own a share of Harrow Health, you own a share of four "value trees":

- 1. Our consolidated subsidiary businesses such as ImprimisRx, Mayfield, Stowe, and Radley;
- 2. Our equity portfolio of shares in deconsolidated or spun-off businesses such as Eton, Surface, and Melt;
- 3. Potential royalty streams in drugs being developed by companies that have been (or we intend to be) deconsolidated or spun-off; and
- 4. Future businesses the Harrow leadership team is building such as Visionology<sup>®</sup>.

Harrow is a healthcare business creation company. We are a team of entrepreneurs. We build, fund and help manage the healthcare businesses we start. Our job is to grow shareholder value and eventually return capital to stockholders. We believe that our record of using modest amounts of capital to build companies, like ImprimisRx, Eton Pharmaceuticals, Surface Pharmaceuticals, Melt Pharmaceuticals and others, is a unique and efficient business building and shareholder value creation model. The kind of value we are trying to create doesn't happen overnight or even in a quarter or two; it takes time. Our team is grateful to our stockholders who see the opportunity for Harrow's stock price to appreciate as we continue to execute our strategy.

#### Consolidated Financial Results

It was about two years ago, during our third quarter 2017 earnings call, when we first described three 2021 financial goals which, if achieved, we believed would establish a compelling value opportunity for Harrow. Below are the financial goals we described:

- \$100M in annual run rate revenue;
- 70% or better gross margins; and
- 20% or better operating margins

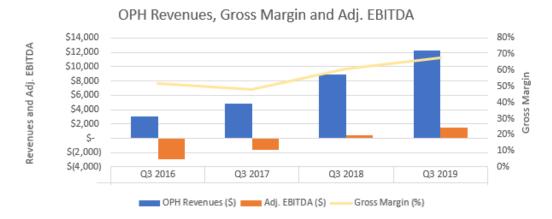
Here is where we stand to date on our path to achieve these goals:

For the first nine months of 2019, gross revenues from our ImprimisRx ophthalmology business have grown 46% compared to the same period in 2018. Our gross ophthalmology-related sales were approximately \$12.3 million and \$35.3 million for the three and nine months ended September 30, 2019, compared to \$8.9 million and \$24.1 million during the same periods last year, respectively. Consolidated net revenues were \$12.8 million for the three-month period, which grew 19% year-over-year, compared to \$10.7 million for to the same prior year period.

As we anticipated, **Gross Margins rebounded to 68%** in the third quarter versus the 61% we reported both in the second quarter of 2019 and for the third quarter of 2018. **Gross Margins Year-to-Date are 66%.** 

Adjusted EBITDA (a non-GAAP measure) totaled \$1.5 million during the third quarter 2019, setting a new company record. Our pharmaceutical compounding segment reported record Segmented Quarterly Earnings of \$2.3 million — which included non-cash-based expenses of \$529,000 related to depreciation, amortization and stock-based compensation. We've now reported adjusted earnings three quarters in a row and expect that trend to continue and grow as revenues increase. A reconciliation of adjusted EBITDA to the most comparable GAAP measure, net loss, is located at the end of this letter.

We believe our key metrics such as gross ophthalmology revenues, gross margins, and adjusted EBITDA are trending in the right direction (revenues and adjusted EBITDA listed in thousands of dollars):



Within other expenses, we recorded a loss of \$7.3 million, which was driven by a \$5.5 million reduction in the fair value of our Eton common stock position during the third quarter of 2019. Despite the reduction in fair value of our Eton position, we are still big believers in this company and its value creating potential and are excited about Eton's near and long-term prospects, especially as we get into 2020.

#### **Other Historical Items:**

On August 27, 2019, we restructured our ParkRx business and consolidated our pharmaceutical compounding operations under the ImprimisRx brand, transferring seven key formulations to our New Jersey facilities. While these formulations will help us achieve our financial goals, during the third quarter of 2019, we went roughly five weeks without revenue from that business, which we estimate had an impact on quarterly revenues of approximately \$600,000 - \$700,000. We also recorded one-time costs of \$4 million related to the *non-cash* impairment of long lived assets (e.g. goodwill, intangibles and

equipment), and we incurred approximately \$400,000 in one-time costs related to severance packages and other wind down costs in the third quarter connected with the closure of the ParkRx California-based pharmacy. Over the next six to twelve months, as we build up inventory of these seven key transferred formulations in New Jersey, and continue to re-engage with customers, we expect to recover roughly \$3 million - \$4 million of ParkRx's historical annual revenue, likely with a gross margin profile in keeping with our stated financial goals.

Selected highlights regarding operating results for the three months and nine months ended September 30, 2019 and for the same periods in 2018 are as follows (in thousands, except per share data):

	For the three months ended	For the three months ended
	September 30, 2019	September 30, 2018
Total Revenues	\$12,755	\$10,739
Cost of Sales	(4,061)	(4,191)
Gross Profit	8,694	6,548
Selling, General & Administrative Expenses	(8,608)	(6,964)
Research & Development Expenses	(444)	(233)
Impairment and disposal of long lived assets	(4,040)	
Operating Loss	(4,398)	(649)
Other Expense, net	(7,232)	(1,865)
Net Loss	\$ (11,630)	\$ (2,514)
Net Loss attributable to non-controlling interests	161	-
Net Loss attributable to Harrow Health, Inc.	\$ (11,469)	\$ (2,514)
Net Loss per share of common stock, basic and diluted	\$(0.45)	\$ (0.12)

	For the nine months	For the nine months
	ended September 30, 2019	ended September 30, 2018
Total Revenues	\$38,561	\$29,988
Cost of Sales	(13,184)	(12,419)
Gross Profit	25,377	17,569
Selling, General & Administrative Expenses	(25,399)	(20,231)
Research & Development Expenses	(1,659)	(392)
Impairment and disposal of long lived assets	(4,040)	1
Operating Loss	(5,721)	(3,054)
Other Income (Expense), net	3,004	(451)
Net Loss	\$ (2,717)	\$ (3,505)
Net loss attributable to non-controlling interests	228	-
Net Loss attributable to Harrow Health, Inc.	\$ (2,489)	\$ (3,505)
Net Loss per share of common stock, basic and diluted	\$(0.10)	\$(0.16)

#### Financial Outlook

Looking forward, we continue to see strong demand for ImprimisRx formulations and expect top line growth year-over-year, consistent with our stated revenue goals. Looking into Q4 of this year and more so into 2020 and beyond, with a number of our litigation matters out of the way (along with their expenses), our pharmaceutical compounding consolidation and ParkRx restructuring behind us, and the

growth drivers described later in this letter pushing our sales to new levels, we are projecting adjusted EBITDA to increase over the coming quarters as revenues grow and gross margins work their way to 70% and beyond. We are very close already to achieving our gross margin target of 70% and adjusted operating margins should fall in line soon as our revenues reach their target levels. Based on our growing visibility into our business, the revenue growth opportunities we foresee, and the sustainability of our profit stream, we remain confident our team is on track to achieve our 2021 goals.

#### **Subsidiaries**

#### *ImprimisRx*

ImprimisRx began operations on April 1, 2014. Back in 2014, we were attracted to an ophthalmic-focused business opportunity because our research showed that over 90 percent of ophthalmic prescribers regularly used compounded drugs in their practices. This meant, in part, that traditional gold-standard FDA-approved products were not adequately meeting the needs of a vast number of U.S. ophthalmologists, optometrists and their patients. It also convinced us that an innovative formulary of high-quality affordable products, available in every state in the U.S., could help address this market need.

Today, ImprimisRx is the market leader in ophthalmology-focused pharmaceutical compounding. Within the ophthalmic community, ImprimisRx has become an important part of over 6,000 prescribers' practices, serving them and their patients.

In addition to making product innovation and affordability cornerstones of the business, ImprimisRx has invested over \$10M in quality and manufacturing systems. The management team continues to make investments in equipment, quality systems and personnel.

From a regulatory perspective, in 2013 the Federal Food Drug and Cosmetic Act (FDCA) was amended and a new category of pharmaceutical manufacturer called an outsourcing facility was allowed to register with FDA, comply with cGMP (current good manufacturing practices – under 21 C.F.R. Parts 210 and 211) and benefit from certain operational efficiencies. Today, ImprimisRx is part of a small group of outsourcing facilities who have registered with FDA and submitted to FDA inspections. For ImprimisRx, inspections by FDA and other internal quality audits conducted regularly using third party consultants (who are usually ex-FDA inspectors) help ensure the integrity of critical quality systems and our investment in this business. John Saharek, the President of ImprimisRx, continues to foster a culture of quality and, despite having dispensed over 3.5 million sterile prescriptions, the ImprimisRx team works diligently – each day – to maintain fidelity to the highest standards.

As production, operations, personnel, and quality are upgraded and improved upon, we expect 2020 to be the most important financial inflection point for ImprimisRx as it begins to generate significant cash flow for the overall Harrow business. The value of this unique profitable commercial platform is significant and while the past five years have been outstanding for ImprimisRx, I believe the next five years will be even better and below are several reasons for my optimism:

Longer product expiration dates. A new ImprimisRx policy has recently been operationalized that
will allow for increased cGMP dispensing systemwide, providing our customers with greater
access to products made to the highest federal drug manufacturing standards and with longer
beyond use dating ("BUD" or expiration dating). This is an important strategic advantage over
competitors and, because our outsourcing facility products generally have higher gross margins,
this should further help ImprimisRx reach its gross margin goals.

- 2. CMS. The Centers for Medicare and Medicaid Services (CMS) recently clarified its policies on the prescribing of intraocular or periocular injections of combinations of anti-inflammatory drugs and antibiotic formulations, allowing ophthalmologists to counsel patients about the benefits and potential drawbacks of Dropless® formulations and, if the patient elects, to have Dropless prescribed. This policy may lead to a meaningful impact on revenues from these formulations which we hope to begin seeing during 2020.
- 3. New equipment and software will make it easier to do business with ImprimisRx. The integration of a new piece of automated filling equipment, which is expected to come on-line in the first quarter of 2020, will expand our outsourcing facility's capacity by nearly 5 times. And ImprimisRx recently launched a new patient pay portal that will allow customers to more easily transact with ImprimisRx with limited-to-no interaction with a customer service agent.
- 4. ImprimisRx is pursuing expanding sales with an international strategy. Outside of a small presence in Canada and the Philippines, ImprimisRx does not have a footprint outside of the U.S. Because we have been able to extend the BUDs for many of our 503B outsourcing facility products, ImprimisRx intends to pursue sales partners in other countries, taking additional advantage of our increased production capabilities.
- 5. Increased regulatory and legal clarity and trends in reimbursement. While we've been building the leading ophthalmology-focused pharmaceutical compounding franchise in the U.S., the FDA has steadily made regulatory progress for outsourcing facilities. In addition, certain litigation matters have provided additional clarity regarding our business model, including not only what we can and can't make, but also how we market to customers. Also, trends in reimbursement with high deductibles for pharmaceutical benefits and increasing co-pays favor our simple no-hassle cash pay business model. We believe these factors will further drive new customer adoption and increase our footprint within current customers' practices.

# Mayfield Pharmaceuticals

The process of deconsolidating Mayfield Pharmaceuticals has begun and is expected to conclude by the end of the year. Mayfield's pipeline of product candidates is clinically compelling and commercially relevant and, when approved, each product and related indication will make a tremendous impact in the lives of women across our country and beyond. We have a great CEO, Melissa Bradford-Klug, and I believe few pharmaceutical industry executives know the women's health space better than Melissa. Mayfield has a committed cornerstone investment from Solas Bioventures, and David Adair, M.D. has agreed to join the Mayfield board of directors. Dr. Adair is a Co-Founder and Managing Director at Solas with 21 years as an OB/GYN Department Professor and Vice Chairman at the University of Tennessee College of Medicine in Chattanooga, so we are pleased to have someone with a strong women's health background provide a vote of confidence for what Melissa and her team will be pursuing.

# Stowe Pharmaceuticals

We have begun the process of interviewing senior executive candidates for Stowe Pharmaceuticals. We have also begun initial outreach to investors. We have been pleased with the

interest we have received from premier pharmaceutical industry executives and from leading investment groups thus far. Stowe will seek to develop Zian™, which its lead drug candidate STE-006 will be based upon, and which has shown tremendous promise pre-clinically as an anti-infective, efficiently killing broad spectra bacteria colonies, viruses, fungi and mold. We believe there is a mounting need in ophthalmology and otology for new anti-infective products, particularly for orphan indications, and the FDA is supporting the development of these types of programs through incentives such as the Orphan Drug Designation (ODD) and the Qualified Infectious Disease Product (QIDP), which we believe some of the Stowe programs may qualify for. Because of its blockbuster potential and the interest level in the Zian™ molecule, we are very bullish on Stowe and look forward to sharing more about our plans for Stowe in the coming months.

# Radley Pharmaceuticals

We continue to support two major healthcare institutions who are conducting investigator-initiated studies on RAD-100. Additionally, we have submitted a Type C meeting request with FDA for Radley's RAD-100 program in order to seek guidance on our proposed clinical development plan. We believe that following our meeting with FDA, we should have clarity regarding the status for the RAD-100 program and execute the requisite clinical development program to seek approval for this potentially important drug development candidate.

# **Equity Portfolio**

We are continuing to build a portfolio of equity positions in deconsolidated former subsidiaries. At September 30, 2019, our portfolio includes:

Company	Number of	Estimated
	Common	Value
	Shares	
Eton Pharmaceuticals	3,500,000	\$22,120,000
Surface Pharmaceuticals	3,500,000	\$11,550,000 <sup>1</sup>
Melt Pharmaceuticals	3,500,000	\$17,500,000 <sup>1</sup>
Estimated Total Value		\$51,170,000

In October, Eton had its first drug approved by the FDA, Biorphen®, which is the first and only FDA-approved ready-to-use formulation of phenylephrine for hypotension resulting primarily from vasodilation during anesthesia. Eton believes this could be a \$50 million or greater opportunity. ET-105 has a PDUFA date of March 17, 2020, which could be a real inflection point, as the estimated market size for that opportunity exceeds \$700 million. According to Eton's recent press releases, it has either submitted or plans to submit seven NDAs or ANDAs by the end of 2019 and plans to submit four more NDAs by the end of 2020. We continue to be excited about the value of Eton and the growth that we expect as the company begins to monetize its growing portfolio of unique products.

Surface Pharmaceuticals is executing a clinical development strategy for dry eye drug candidates that we believe provides multiple ways to demonstrate primary endpoint clinical trial success, with the goal of increasing the odds of yielding an approvable product. We anticipate Surface will have its promised INDs in place in the next few months and, hopefully, human clinical data in 2020. Positive

<sup>&</sup>lt;sup>1</sup> 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.

human clinical data could create a significant value inflection point. The dry eye disease market continues to garner attention from Wall Street and the pharmaceutical industry with Oyster Point, a dry eye disease focused development stage company, pricing its IPO recently at approximately a \$385 million pre-money value and the Novartis's purchase of the Xiidra® dry eye franchise for more than \$5 billion that closed in the summer of 2019.

Melt Pharmaceuticals had a positive pre-IND meeting with FDA in January, and they are expecting to file INDs for MELT-100 and MELT-200 during 2020, with human clinical data shortly thereafter. Greg Madison, CEO at Melt, and his team have developed a strategy that we believe gives Melt a great chance to end up with an approvable product, leveraging the real world experience we have with the MKO Melt as a compounded drug to help minimize the clinical development risk for Melt's drug development programs. A recent internal commercial survey of several therapeutic areas validated our belief that Melt's formulations would likely find strong commercial appeal within large potential markets. Melt has also secured consulting agreements with the leading authorities on reimbursement and third-party payment which also gives us confidence that any approved Melt product will produce great value for not only the clinical community, but also for Melt stockholders. In addition to this, as a result of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act passed last year, there is significant support from Congress, CMS and FDA for non-opioid or opioid sparing drugs and drug candidates, that we think will create more momentum for Melt Pharmaceuticals and its drug development programs over the next few years.

And last, but certainly not least, we are also building the foundations of an exciting business called Visionology which we've been working on for over two years and that we will discuss more during 2020.

# Royalty Portfolio

In addition to the equity positions listed above, another aspect of our strategy is to own royalty interests in drug development candidates. We believe that as these programs mature and eventually become commercialized, the streams of potential cash may be significant, allowing the company to have yet another source to create value for our stockholders. Below is the current portfolio of royalty interests we own:

COMPANY	DRUG CANDIDATE	PROPOSED INDICATION	MARKET OPPORTUNITY	ROYALTY RATE
SURFACE	SURF-100	CHRONIC DRY EYE	\$1.5B+	4%
SURFACE	SURF-200	EPISODIC DRY EYE	\$1B+	4%
SURFACE	SURF-300	DRY EYE	\$1B+	6%
MELT	MELT-100	CONSCIOUS SEDATION	S SEDATION \$1B+	
MAYFIELD	MAY-88	INTERSTITIAL CYSTITIS	\$400M+	N/A
RADLEY	RAD-100	RARE DISEASES/ORPHAN INDICATIONS	N/A	N/A

#### Prospects for Growing Asset Values and Other Value Catalysts

In order to achieve our long-term goals, we intend to grow our capital base. We expect to achieve this through the earnings of the businesses we own, increased equity values in our equity portfolio and, in the future, with royalties from drug development programs already underway.

Our business establishment process has been incredibly efficient, illustrated by the fact that in addition to the creativity and motivation of the Harrow senior management team, each of the deconsolidated businesses previously described required only a few hundred thousand dollars of out-of-pocket costs to launch. While we expect the equity positions we hold in our deconsolidated businesses and those that we consolidate to appreciate during 2020 and beyond, we also expect to see value creation catalysts in several of these businesses that could mark significant value inflection points for stockholders. Over time, and as significant value is realized, our intention will be to return capital back to our stockholders (i.e. through stock-buy backs, dividends, etc.).

# Closing

When we changed our name to Harrow Health at the end of 2018, the objective was to "prepare the ground for planting seeds" in the form of building paradigm shifting healthcare companies that put patients first. We believed then, and do today, that these seeds we've planted will eventually sprout and begin to create significant value for stockholders. As we have highlighted in this inaugural *Letter to Stockholders*, while our wholly-owned subsidiary, ImprimisRx, continues to perform well and consistent with plan, new "green shoots" of value are emerging at Eton, Surface, Melt, Mayfield, and others we intend to discuss in the future.

I look forward to updating stockholders about progress that has been made when we publish our next *Letter to Stockholders* in 2020.

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 most recent annual report on Form 10-K and subsequent quarterly reports on Form 10-Q filed 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 EBITDA, a non-GAAP measure, to the most comparable GAAP measure, net loss, for the three months ended September 30, 2019 and for the same period in 2018 (in thousands):

	For the Three Months Ended September 30, 2019	For the Three Months Ended September 30, 2018
GAAP Net Loss	\$(11,469)	\$ (2,514)
Stock-based compensation and payments	402	591
Interest expense, net	620	705
Taxes	-	-
Depreciation	397	423
Amortization of intangible assets	50	59
Investment loss from Eton, Surface, Melt, net	6,612	1,160
Other Expense, net	-	-
Non-recurring expenses (1)	4,845	-
Adjusted EBITDA	\$1,457	\$424

<sup>(1)</sup> 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 ParkRx business.