



Letter to Stockholders

November 14, 2022

Dear Harrow Stockholders:

I am pleased to report third quarter results that included 22% year-over-year revenue growth and the company remaining “in the black” while we prepare to launch IHEEZO™, generate new high-value revenues from our portfolio of FDA-approved branded pharmaceutical products (BPPs), and advance our market-leading ImprimisRx compounded pharmaceuticals products (CPPs) brand. Here are a few recent noteworthy events connected to the continued execution of our Five Year Strategic Plan:

- On September 27th, we [announced](#) the approval of IHEEZO (previously known as AMP-100), Harrow’s first NDA product which was approved by the U.S. Food and Drug Administration (FDA) for ocular surface anesthesia.

I remain confident that within 24 months of our launch of IHEEZO, with our market access strategy in place, Harrow’s revenues should more than double, and our core gross margins should begin to float meaningfully higher. Page 5 of this Stockholder Letter has additional color on IHEEZO.

- On September 29th, we launched [Fortisite](#)™ which is a patent-pending suite of compounded high-concentration refrigeration-stable fortified antibiotics.

The reception for the Fortisite portfolio has been extraordinary! Page 6 of this Stockholder Letter has additional color on Fortisite.

- On October 5th, we [announced](#) the sale of our non-ophthalmology compounded product line, adding cash to our balance sheet in the fourth quarter, and giving us the prospect of extra cash coming next year from an earn-out.

This asset sale marked the achievement of a strategic imperative because, as we embark upon this next stage of development, we believe that Harrow must be a “pure-play” company to be a leading U.S. ophthalmic pharmaceutical company. As a result of this transaction, we are now 100% invested and focused in the U.S. ophthalmic pharmaceutical market.

- On October 27th, our former subsidiary, Melt Pharmaceuticals, [announced](#) that it had completed its pivotal Phase 2 efficacy study for its MELT-300 program.

The MELT-300 clinical study took longer than we anticipated and was over budget. It is done now; and while one cannot predict the outcome of a blinded clinical study, we believe the MELT-300 phase 2 study design should yield a dataset for an approvable product candidate (either MELT-300 and/or MELT-210), allowing Harrow to eventually convert our 46% equity interest in Melt into further value for Harrow’s stockholders. Given the clinical [promise](#) of Melt’s technology, I have 100% confidence in the commercial potential of Melt’s product candidates. As a reminder, Harrow owns 3.5 million shares of Melt common stock, a \$13.5 million senior secured note receivable from Melt, and royalty rights on MELT-300.

- We recently [announced](#) the launch of [atropine.com](#)[™] to commercialize our compounded atropine formulations and address a significant unmet need for millions of Americans.

Page 7 of this Stockholder Letter has additional color on atropine.com – and our intention to “plant a flag” in the compounded atropine market.

- I want to add that in the last 30 days, we’ve made critical progress with product acquisition opportunities we have been pursuing for quite some time.

Related to our M&A strategy, we are focused on assets that are either (i) FDA-approved and “under-loved” (or non-strategic) where they currently are, or (ii) have been substantially de-risked from a development perspective. Our objective is to leverage our commercial platform and our U.S. ophthalmic market expertise. We can’t guarantee any one of these deals will get done, or that Harrow’s stockholders will be as excited as we are about these assets. Be forewarned that we are getting close and that we believe completing any one of these acquisitions would expand the revenue growth we are expecting over the coming years.

Chief among my objectives in authoring these Stockholder Letters is to give current and prospective stockholders sufficient transparency to make an informed decision as to whether to entrust this management team with their investable capital. Despite never being more bullish on Harrow – because so much is going “right” as we make critical long-term investments and push to execute on a once-in-a-generation opportunity we see for a small company like Harrow to rapidly blossom into a leading U.S. ophthalmic pharmaceutical company – this past quarter presented a heck of a challenge as we worked through a combination of operational issues, including a return to seasonal/summer demand fluctuations, supply chain issues, increased operating costs, and a nearly \$1 million revenue order backlog by the end of the third quarter. Page 3 in the *Financial Highlights and Commentary* of this Stockholder Letter has additional detail on these issues.

Now let’s look at our financial results for the three and nine months ended September 30, 2022, and the same periods in 2021.

Third Quarter Core Results

Beginning in 2022, we began providing additional non-GAAP financial metrics – *Core Results*, which we define as the after-tax earnings and other operational and financial metrics generated from our principal business.

	For the Three Months Ended		For the Nine Months Ended	
	September 30,		September 30,	
	2022	2021	2022	2021
Net revenues	\$ 22,823,000	\$ 18,711,000	\$ 68,266,000	\$ 52,288,000
Gross margin	71%	74%	72%	75%
Core gross margin ⁽¹⁾	72%	74%	73%	75%
Net loss	(6,464,000)	(8,328,000)	(15,141,000)	(11,061,000)
Core net loss ⁽¹⁾	(1,531,000)	(5,359,000)	(564,000)	(828,000)
Adjusted EBITDA ⁽¹⁾⁽²⁾	2,483,000	(78,000)	11,928,000	9,896,000
Diluted net loss per share	(0.24)	(0.31)	(0.55)	(0.42)
Core diluted net loss per share ⁽¹⁾	(0.06)	(0.20)	(0.02)	(0.03)

⁽¹⁾ Core gross margin, core net loss, core diluted net loss per share (collectively, “Core Results”), and Adjusted EBITDA are non-GAAP measures. For additional information, including a reconciliation of such Core Results and Adjusted EBITDA to the most directly comparable measures presented in accordance with GAAP, see the explanation of non-GAAP measures and reconciliation tables [at the end](#) of this Letter to Stockholders.

⁽²⁾ The Company recently made a change to its methodology for reporting of Adjusted EBITDA to include acquired in-process R&D (“IPR&D”) charges. During the 2021 reporting periods, similar IPR&D transactions were excluded from Adjusted EBITDA for reporting purposes. This change is the result of the U.S. Securities and Exchange Commission’s recent industry correspondence on this matter.

Financial Highlights and Commentary

Revenues of \$22.8 million for the third quarter of 2022 represent a 22% increase over the prior-year period revenues of \$18.7 million and a slight decrease from the second quarter of 2022. During the third quarter of 2022, we saw modest seasonality return to our business, with surgical volumes slowing down in the third quarter vs. the second quarter as customers returned to their historical patterns of taking time for summer vacation and travel, leading to fewer surgical procedures, and therefore, fewer revenue generating opportunities for Harrow.

Our revenues in the third quarter were also impacted by our supply chain – including vendors who supply us with pharmaceutical ingredients and third-party laboratories who we rely on for mandated end-product analytical testing. On top of this, our regulators requested new testing regimens for some of our products, exacerbating analytical testing delays. And finally, like many American businesses, we've seen the costs to build our products slowly creep up before we could offset them with pricing adjustments.

With the above said, our third quarter headline revenue number belies a key fact of merit – *we had nearly \$1 million in firm orders that we could not fill at the end of the period because of the aforementioned supply chain impacts*. On the positive side, we successfully managed these supply chain issues and cleared up our backlog only a few weeks into the fourth quarter, and our stockholders “rang the register” on these orders. **In sum, despite decreased surgical volumes in the third quarter, without these supply chain issues, we would have been able to continue delivering sequential revenue growth.**

I am happy we ultimately took care of customer backorders in the fourth quarter; however, our job is to fill orders rapidly without any backorders. To resolve this issue, our team is doing something we've had to do many times over the years as market demands for our products grew – *scale up our production batches and generate additional operational efficiencies*. Currently, we are qualifying larger batch sizes on our highest volume products and optimizing our production scheduling. The outcome of this work should be increased availability of our products and improved gross margins. Also, our team is collaborating with key vendors and a few new vendors to resolve the remaining supply chain issues we experienced. Because of this effort, we are now seeing more finished goods inventory being released – faster and in keeping with the inbound order flow our commercial team has resolutely delivered, quarter after quarter, for more than eight years. Fortunately, demand for our products has never been greater!

Our third quarter revenues included product revenues from sales of IOPIDINE® and MAXITROL® as well as commissions from sales of DEXYCU®, which we promote under a Commercial Alliance Agreement between Harrow and EyePoint Pharmaceuticals. We recently mutually agreed with EyePoint to end this relationship. The DEXYCU agreement will be terminated effective January 1, 2023, as a result of the decision by the CMS in their CY 2023 Payment Rule for Hospital Outpatient Services and Ambulatory Surgery Centers (ASCs) that DEXYCU will no longer qualify as a separately payable product in an ASC or outpatient setting and will instead be bundled into the general cataract procedure code, effective January 1, 2023. As we have previously stated, *we do not expect the status of DEXYCU to affect our business materially, and any decrease in our revenues related to DEXYCU commissions should be replaced by products Harrow currently sells as well as anticipated organic and inorganic growth expected during 2023.*

Revenue per shipping day was \$355,000 in the third quarter of 2022, a 21% increase over the prior-year period's revenue per shipping day of \$292,000.

The total product units distributed was approximately 703,000 for the third quarter of 2022, a 21% increase over the prior-year period total product units of 582,000.

Core gross margin was 72% in the third quarter of 2022 compared with a core gross margin of 74% in the prior-year third quarter. In part, gross margins during the third quarter of 2022 were affected by some minor production challenges at our New Jersey facility, coupled with supply chain challenges that ended up driving some costs up and adding new expenses (e.g., rush fees). Ultimately, the supply chain challenges also hindered our ability to release all of the inventory we had hoped, resulting in the previously mentioned order backlog of almost \$1 million, which we have since realized in the fourth quarter.

Selling, general and administrative expenses for the third quarter of 2022 increased to \$15.4 million over the prior-year quarter's \$11.4 million. This increase was primarily a result of our continued initiatives to add key talent, support the transition and implementation of recently acquired branded products, and increased commercial and regulatory expenses related to the ongoing preparation for our launch of IHEEZO. In addition, supply chain struggles also led to increased transitory costs in operating expenses – such as increased customer service support to manage product delays and backlogs.

Research and development costs were \$775,000 in the third quarter of 2022 compared with \$6.1 million in the prior-year quarter. The decrease was primarily the result of acquired research and development costs incurred in the third quarter of 2021 related to the acquisition of IHEEZO.

GAAP operating loss was (\$94,000) for the third quarter of 2022, compared with a GAAP operating loss of (\$3.7) million during the same period last year.

Adjusted EBITDA was \$2.5 million for the third quarter of 2022 compared with Adjusted EBITDA of (\$78,000) reported in the prior-year quarter, primarily due to lower gross profit and increased operating expenses. During the third quarter of 2021, the company incurred a \$5.0 million IPR&D charge associated with an upfront payment related to the execution of a licensing and supply arrangement for IHEEZO. These charges are now included in both GAAP and non-GAAP operating expenses, which is a change versus the company's previous methodology during 2021, where similar IPR&D transactions were excluded from Adjusted EBITDA and related non-GAAP reporting purposes. This change is the result of the U.S. Securities and Exchange Commission's recent industry correspondence on this matter.

Core net loss was (\$1.5) million for the third quarter of 2022 compared with a core net loss of (\$5.4) million in the third quarter of 2021.

Core diluted net loss per share for the third quarter of 2022 was (\$0.05) compared with core diluted net loss of (\$0.20) during the same period last year.

A reconciliation of all non-GAAP financial measures in this letter begins on page 10.

Selected highlights regarding GAAP operating results for the three months and nine months ended September 30, 2022, and for the same periods in 2021 are as follows:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Total revenues	\$ 22,823,000	\$ 18,711,000	\$ 68,266,000	\$ 52,288,000
Cost of sales	6,721,000	4,947,000	19,218,000	13,134,000
Gross profit	16,102,000	13,764,000	49,048,000	39,154,000
Selling, general and administrative	15,421,000	11,356,000	43,004,000	28,643,000
Research and development	775,000	6,125,000	2,347,000	7,142,000
Total operating expenses	16,196,000	17,481,000	45,351,000	35,785,000
(Loss) income from operations	(94,000)	(3,717,000)	3,697,000	3,369,000
Total other expenses, net	(6,335,000)	(4,611,000)	(18,763,000)	(13,958,000)
Income taxes	35,000	-	75,000	-
Net loss attributable to Harrow Health, Inc.	(6,464,000)	(8,328,000)	(15,141,000)	(10,589,000)
Preferred dividends and accretion of preferred stock discount	-	-	-	(472,000)
Net loss attributable to Harrow Health, Inc. common stockholders	\$ (6,464,000)	\$ (8,328,000)	\$ (15,141,000)	\$ (11,061,000)
Net loss per share of common stock, basic and diluted	\$ (0.24)	\$ (0.31)	\$ (0.55)	\$ (0.42)

More Commentary on IHEEZO, Fortisite, and Atropine.com

IHEEZO

IHEEZO is the first approved use in the U.S. ophthalmic market of chloroprocaine hydrochloride and the first branded ocular anesthetic approved for the U.S. ophthalmic market *in nearly 14 years*. IHEEZO is protected by a patent, now listed in the Orange Book, which is valid until 2038.

We are very excited about the potential to offer our customers a new ocular anesthesia solution. Our market research has validated diverse approaches to ocular anesthesia for various ocular procedures, with doctors using different active pharmaceutical ingredients at different time intervals. We believe IHEEZO has the potential to provide ophthalmologists with a market-differentiated and *unifying solution*.

Here are a few of the essential product attributes that we believe make IHEEZO an attractive product in the ophthalmic anesthesia market:

- IHEEZO is a single-patient use, physician-administered, ophthalmic gel preparation containing no preservatives that is safe and effective for ocular surface anesthesia.
- Clinical studies supporting IHEEZO's FDA-approval demonstrated that it worked rapidly (about 1 to 1.5 minutes) and provided sufficient anesthesia to successfully perform cataract surgeries, which lasted on average, about 22 minutes.
- Critical to the potential commercial success of IHEEZO was that *no patient dosed with IHEEZO required a supplemental treatment to complete the surgical procedure (i.e., the cataract surgery)*.
- We believe IHEEZO will be used to streamline practice performance with setting-specific billing options and reliable, direct reimbursement.

Once IHEEZO was approved by FDA at the end of September, we wasted no time and initiated our market access strategy – actively assessing the landscape of opportunities for IHEEZO. We are concentrating our efforts on our core competency – the ophthalmic surgical and office-setting markets, with an emphasis on the cataract surgery segment and other high-volume procedures where the benefit of IHEEZO could be impactful. We also intend to leverage our status as a primary vendor for, what we estimate is, about 20% of all cataract procedures in the U.S.

According to a 2021 report by *Market Scope*, U.S. ocular surgeries will approach 5 million procedures this year, and the market is expected to grow consistently for many years. Because we already participate meaningfully in this market with other products, as we successfully educate doctors about the clinical benefits of IHEEZO, at a minimum, revenues from IHEEZO should be transformative to Harrow.

Finally, our market access team is also working through the pricing methodology for IHEEZO and we expect to have their pricing recommendations later this year – within a sufficient time to set pricing that is in keeping with Harrow’s corporate values, including generating value for our stockholders.

Fortisite

At the American Academy of Ophthalmology (AAO) meeting in Chicago, September 30 – October 3, we launched our compounded Fortisite line of products, led by a patent-pending compounded combination of Tobramycin 1.5% and Vancomycin 5%, in solution, that is uniquely stable at refrigerated temperatures (5°C) for up to 180 days and tested for both potency and sterility before it is dispensed. Fortisite is now available, by prescription, as a cash-pay product, for \$299 per bottle.

I was excited to “work the floor” with the Harrow team at the AAO meeting every day, meeting with customers to get a bead on what we were doing right and what we needed to improve upon. This included seeing firsthand what the reaction was to our new Fortisite offering.

Two learnings of note:

1. Over the years, we have launched quite a few compounded formulations – so I have seen many do well and some fizzle out. *I can say without any hesitation, after having seen our team present Fortisite to over 100 ophthalmologists, I have never seen such a positive reception for any new compounded formulation.* Our customers appreciated the value of Fortisite, and the paucity of detractors for prescribing this formulation emboldened our team, including me! Nearly universally, the eyecare professionals we met with appreciated what Fortisite could do for their patients battling sight-threatening conditions.

We recently asked an early Fortisite prescriber for clinical feedback, and his response was emphatic – “*Awesome.*” I also heard from many prescribers that they would use Fortisite formulations more broadly than was anticipated by our market research. Here is a recent [video](#) perspective of Fortisite from a key opinion leader. While it is still early in the launch, I am expecting (a) Fortisite sales to build consistently during 2023, (b) the development of our core Fortisite technology into a family of products by next year, and (c) that Fortisite revenues will – as I predicted earlier this year – “move the needle” for Harrow.

2. Because of its uniqueness and potential clinical impact, Fortisite is a “door-opening new-account-building product.” We have already opened several new accounts, including at three of the most prestigious ophthalmic institutions in the United States. This should allow our sales organization to create awareness within these new accounts of the entirety of the Harrow ophthalmic pharmaceutical portfolio. This is a good thing!

Atropine.com

Since the COVID pandemic, customer interest in compounded atropine has grown significantly.

A recent [article](#) in the *Review of Myopia Management* on compounded atropine concluded, “There were a wide variety of formulation methods in the United States, which may affect atropine stability and potency,” and that “the median beyond-use date [of those pharmacies surveyed] was 65 days.” We saw an opportunity to build a national brand around atropine, take advantage of our 180 days beyond-use dating, elevate the manufacturing quality of compounded atropine, and ensure patient access to this growing chronic market need.

The Harrow Team, including our research and development group, went to work. Their effort allowed us to recently launch our national atropine campaign based on our current compounded atropine formulations, *which are stable at a biologically comfortable pH and undergo validated analytical tests to ensure consistency, potency, and stability*. These formulations are now available for individual patients through our ImprimisRx 503A national mail-order pharmacy and by accessing the atropine.com portal.

We aren’t done though. We intend to launch our next-generation compounded atropine formulations, which do not contain either preservatives or boric acid, through our 503B outsourcing facility – *with or without a patient prescription* – in the coming quarterly period. These new atropine formulations are patent pending and allow us to offer a differentiated compounded atropine formulation to serve this large, underserved, and growing chronic market need.

From a digital marketing perspective, what better brand could you have than *atropine.com*? Fortunately, we own this domain name and are using it to support our compounded atropine launch. I am very excited about our new atropine.com business, and I believe that as prescriptions grow consistently, including refills, this product family will be a revenue “needle mover” for Harrow for many years to come.

Investments and Royalties

Harrow owns non-controlling equity positions in Surface Ophthalmics, Melt Pharmaceuticals, and Eton Pharmaceuticals, companies founded as Harrow subsidiaries before being deconsolidated into independent and separately managed companies.

- We own approximately 3.5 million shares of [Surface Ophthalmics](#) common stock, or about 20% of the outstanding equity interests. Surface, a pre-commercial private company, focuses on ocular surface disease, specifically dry eye disease. The U.S. market for dry eye disease is large and growing and, importantly, continues to be underserved by the current weak array of available FDA-approved products. Harrow also owns royalty rights on all three active Surface drug development programs.

Little has changed since my commentary about Surface in my [last Stockholder Letter](#); however, there has recently been a couple of remarkable transactions in the dry eye disease space, so we believe market interest in this category within eyecare is a good thing for Surface given the success of their programs to date.

- We own approximately 3.5 million shares of [Melt Pharmaceuticals](#) common stock or about 46% of the outstanding equity interests. We also hold a \$13.5 million senior secured note receivable from Melt and royalty rights on its flagship drug candidate, MELT-300.

MELT-300, a patented non-opioid sublingually delivered sedation and analgesia drug candidate, has the potential to transform the way U.S. cataract surgery patients are sedated. In addition, Melt's drug candidates and related patented technologies may have a far broader application beyond ophthalmic surgery and could potentially serve a global market.

We have tremendous confidence in the commercial viability of Melt's product candidates. Why? Because our ImprimisRx brand has dispensed over 400,000 compounded MKO Melt® troches which, as a compounded formulation, is similar to the MELT-300 product candidate. Customers seem to love the MKO Melt – so much so that they pay for it out of their capitated cataract surgery procedure fees. If we can provide them with an FDA-approved product – like the MELT-300 or MELT-210, I believe they will choose it over an IV and opioids (and as this recent [publication](#) made clear, opioids remain all too frequently used in cataract surgery).

Melt recently completed the enrollment of patients in a Phase 2 efficacy and safety study of MELT-300 and is expected to report top-line clinical results in a matter of weeks.

- We own just under 2.0 million shares of common stock of [Eton Pharmaceuticals](#) (Nasdaq: ETON), an innovative rare disease pharmaceutical company. We remain patiently optimistic about our investment in Eton and believe in its mission.

Closing

We would not be where we are today without the efforts of every single member of the Harrow Family – many of whom have been with us through thick and thin. I am equally appreciative of the newest members of the Harrow Family, who are committed to our shared goal of becoming a leading U.S. ophthalmic pharmaceutical company. Finally, we can't do this without our stockholders and their capital – so thank you for your continued confidence and support. I promise we are hustling to convert this unique opportunity we see – *clear as day* – into value for you!

The Harrow Family is truly energized. While remaining adjusted EBITDA positive, we are investing to take advantage of the next leg of growth we plainly see on our horizon. We are resolute in our conviction that we are making progress toward achieving our strategic goal – *to become a leading U.S. ophthalmic pharmaceutical company*.

I look forward to updating you on our accomplishments and progress in my next Letter to Stockholders in March of 2023.

Sincerely,

Mark L. Baum
Founder, Chairman of the Board, and Chief Executive Officer
Nashville, Tennessee

About IHEEZO™ (chloroprocaine hydrochloride ophthalmic gel) 3%

INDICATIONS AND USAGE

IHEEZO™ is indicated for ocular surface anesthesia.

CONTRAINDICATIONS

IHEEZO™ is contraindicated in patients with a history of hypersensitivity to any component of this preparation.

WARNINGS AND PRECAUTIONS

IHEEZO™ should not be injected or intraocularly administered. Patients should not touch the eye for at least 10 to 20 minutes after using an anesthetic as accidental injuries can occur due to insensitivity of the eye. Prolonged use of a topical ocular anesthetic may produce permanent corneal opacification and ulceration with accompanying visual loss. Do not touch the dropper tip to any surface as this may contaminate the gel. IHEEZO™ is indicated for administration under the direct supervision of a healthcare provider. IHEEZO™ is not intended for patient self-administration.

ADVERSE REACTIONS

The most common adverse reaction is mydriasis (approximately 25%).

For additional information about IHEEZO™, including important safety information, please see the Full Prescribing Information.

FORWARD-LOOKING STATEMENTS

Management'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 FDA-approved products and 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 measures, specifically Adjusted EBITDA, adjusted earnings, core gross margin, core net (loss) income, and core diluted net (loss) income per share. A reconciliation of non-GAAP measures with the most directly comparable GAAP measures is included in this letter.

No compounded formulation is FDA-approved. All compounded formulations are customizable. Other than drugs compounded at a registered outsourcing facility, all 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.

Non-GAAP Financial Measures

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 and Core Results, unaudited financial measures that are not calculated in accordance with GAAP, to evaluate the Company's financial results and performance and to plan and forecast future periods. Adjusted EBITDA and Core Results are considered "non-GAAP" financial measures within the meaning of Regulation G promulgated by the SEC. Management believes that these non-GAAP financial measures reflect an additional way of viewing aspects of the Company's operations that, when viewed with GAAP results, provide a more complete understanding of the Company's results of operations and the factors and trends affecting its business. Management believes Adjusted EBITDA and Core Results provide meaningful supplemental information regarding the Company's performance because (i) they allow for greater transparency with respect to key metrics used by management in its financial and operational decision-making; (ii) they exclude 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) they are used by institutional investors and the analyst community to help analyze the Company's results. However, Adjusted EBITDA, Core Results, 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 way 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.

Adjusted EBITDA

The Company defines Adjusted EBITDA as net loss attributable to Harrow Health, Inc., excluding the effects of stock-based compensation and expenses, interest, taxes, depreciation, amortization, investment loss, net, gain on forgiveness of debt, 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 loss attributable to Harrow Health, Inc. 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.

Included in Adjusted EBITDA for the third quarter of 2021 is an in-process R&D (IPR&D) charge of \$5.0 million associated with an upfront payment related to the execution of a licensing and supply arrangement with Sintetica, S.A. for IHEEZO. This \$5.0 million charge was previously excluded in the prior year reporting periods from Adjusted EBITDA and has been adjusted to account for a change in the Company's methodology to now include similar IPR&D transactions for Adjusted EBITDA, non-GAAP disclosure and reporting purposes. This change is the result of the U.S. Securities and Exchange Commission's recent industry correspondence on this matter.

The following is a reconciliation of Adjusted EBITDA, a non-GAAP measure, to the most comparable GAAP measure, net loss, for the three and nine months ended September 30, 2022, and for the same periods in 2021:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
GAAP net loss	\$ (6,464,000)	\$ (8,328,000)	\$(15,141,000)	\$(10,589,000)
Stock-based compensation and expenses	1,932,000	1,697,000	5,941,000	3,630,000
Interest expense, net	1,800,000	1,685,000	5,386,000	3,512,000
Taxes	35,000	-	75,000	-
Depreciation	247,000	399,000	1,090,000	1,275,000
Amortization of intangible assets	398,000	43,000	1,200,000	122,000
Investment loss, net	4,535,000	2,926,000	13,377,000	11,606,000
Other expenses, net	-	1,500,000 ⁽¹⁾	-	340,000 ⁽²⁾
Adjusted EBITDA	\$ 2,483,000	\$ (78,000)	\$ 11,928,000	\$ 9,896,000

⁽¹⁾ Includes \$1,500,000 of litigation settlement expenses.

⁽²⁾ Includes \$756,000 for early extinguishment of loan, \$1,500,000 of litigation settlement expenses, and a gain on forgiveness of debt of \$1,976,000.

Core Results

Harrow Health Core Results, including core gross margin, core net (loss) income, core operating (loss) income, core basic and diluted loss per share, and core operating margin, exclude all amortization and impairment charges of intangible assets, excluding software development costs, net gains and losses on investments and equity securities, including equity method gains and losses and equity valued at fair value through profit and loss ("FVPL"), preferred stock dividends, and gains/losses on forgiveness of debt. In other periods, Core Results may also exclude fair value adjustments of financial assets in the form of options to acquire a company carried at FVPL, obligations related to product recalls, certain acquisition-related items, the integration and divestment-related income and expenses, divestment gains and losses, restructuring charges/releases and associated items, related legal items, gains/losses on early extinguishment of debt or debt modifications, impairments of property, plant and equipment and software, as well as income and expense items that management deems exceptional and that are or are expected to accumulate within the year to be over a \$100,000 threshold.

The following is a reconciliation of Core Results, a non-GAAP measure, to the most comparable GAAP measure for the three and nine months ended September 30, 2022, and for the same periods in 2021:

For the Three Months Ended September 30, 2022

	GAAP Results	Amortization of Certain Intangible Assets	Investment Losses	Core Results
Gross profit	\$ 16,102,000	\$ 341,000	\$ -	\$ 16,443,000
Gross margin	71%			72%
Operating (loss) income	(94,000)	398,000	-	304,000
(Loss) income before taxes	(6,429,000)	398,000	4,535,000	(1,496,000)
Taxes	(35,000)	-	-	(35,000)
Net (loss) income	(6,464,000)	398,000	4,535,000	(1,531,000)
Basic and diluted loss per share ⁽¹⁾	(0.24)			(0.06)
Weighted average number of shares of common stock outstanding – basic and diluted	27,349,642			27,349,642

For the Nine Months Ended September 30, 2022

	GAAP Results	Amortization of Certain Intangible Assets	Investment Losses	Core Results
Gross profit	\$ 49,048,000	\$ 1,023,000	\$ -	\$ 50,071,000
Gross margin	72%			73%
Operating income	3,697,000	1,200,000	-	4,897,000
(Loss) Income before taxes	(15,066,000)	1,200,000	13,377,000	(489,000)
Taxes	(75,000)	-	-	(75,000)
Net (loss) income	(15,141,000)	1,200,000	13,377,000	(564,000)
Basic and diluted loss per share ⁽¹⁾	(0.55)			(0.02)
Weighted average number of shares of common stock outstanding – basic and diluted	27,293,756			27,293,756

For the Three Months Ended September 30, 2021

	GAAP Results	Amortization of Certain Intangible Assets	Investment Losses	Core Results
Gross profit	\$ 13,764,000	\$ -	\$ -	\$ 13,764,000
Gross margin	74%			74%
Operating (loss) income	(3,717,000)	43,000	-	(3,674,000)
(Loss) income before taxes	(8,328,000)	43,000	2,926,000	(5,359,000)
Taxes	-	-	-	-
Net (loss) income	(8,328,000)	43,000	2,926,000	(5,359,000)
Basic and diluted loss per share ⁽¹⁾	(0.31)			(0.20)
Weighted average number of shares of common stock outstanding – basic and diluted	27,112,531			27,112,531

For the Nine Months Ended September 30, 2021

	GAAP Results	Amortization of Certain Intangible Assets	Investment Losses	Other Items	Core Results
Gross profit	\$ 39,154,000	\$ -	\$ -	\$ -	\$ 39,154,000
Gross margin	75%				75%
Operating income	3,369,000	122,000	-	-	3,491,000
(Loss) income before taxes	(10,589,000)	122,000	11,606,000	(1,967,000)	(828,000)
Taxes	-	-	-	-	-
Net (loss) income attributable to common stockholders	(11,061,000)	122,000	11,606,000	(1,495,000)	(828,000)
Basic and diluted loss per share (\$) ⁽¹⁾	(0.42)				(0.03)
Weighted average number of shares of common stock outstanding – basic and diluted	26,626,722				26,626,722

- ⁽¹⁾ Core basic and diluted loss per share is calculated using the weighted-average number of shares of common stock outstanding during the period. Core basic and diluted loss per share also contemplates dilutive shares associated with equity-based awards and warrants as described in Note 2 and elsewhere in the Condensed Consolidated Interim Financial Statements filed with the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2022.

**Investment Portfolio
(includes Non-GAAP Values)**

Company	September 30, 2022	
	Number of Shares of Common Stock	Management Estimated Value
Eton Pharmaceuticals	1,982,000	\$ 4,162,200
Surface Ophthalmics	3,500,000	15,750,000 ⁽¹⁾
Melt Pharmaceuticals	3,500,000	17,500,000 ⁽²⁾
Melt Pharmaceuticals – Secured Loan + PIK	-	15,495,000 ⁽³⁾
Estimated Total Value		\$ 52,907,200

- ⁽¹⁾ Represents a non-GAAP value, calculated as the purchase and conversion price (\$4.50) of the Series A-1 Preferred Stock (the most recent equity offering) multiplied by the number of common shares owned by Harrow at September 30, 2022.
- ⁽²⁾ Represents a non-GAAP value, calculated as the purchase and conversion price (\$5.00) of the Series A Preferred Stock (the most recent equity offering) multiplied by the number of common shares owned by Harrow at September 30, 2022.
- ⁽³⁾ Represents the principal balance owed under the loan agreement, including interest paid in kind (or PIK). In accordance with ASC 323, Harrow's presentation of this loan receivable on its consolidated balance sheet is presented at its carry value less reductions in the carrying value related to Harrow's share of Melt equity losses.