



Company: Harrow Health, Inc.
Industry: Rx Eye Drugs
Price (2/21/2023 close): US\$ 16.96/share

Nasdaq: HROW
URL: <https://www.harrow.com/>
Market Cap: ~US\$ 500 million

1. U.S. DEPARTMENT OF JUSTICE INVESTIGATED DEXYCU SALES & MARKETING PRACTICES
2. FDA HURRICANE: REGULATORY MEETING, RECALL, INSPECTION, WARNING LETTER
3. HROW LICENSED UNPOPULAR LEGACY NOVARTIS DRUGS WITH LITTLE/NO RX GROWTH
4. IHEEZO FACES ESTABLISHED COMPETITION – FDA APPROVED COMPOUND SINCE 1955
5. LOSSES FROM PREVIOUS DRUG INVESTMENT FAILURES – HISTORY OF BAD ACTORS

Harrow Health, Inc. (“Harrow”, “HROW”) primarily sells ophthalmic prescription pharmaceuticals (“drugs”) using the ImprimisRx brand in the United States. Historically Harrow sold only bespoke compound drugs mixed at its compound pharmacies. In the past decade compound pharmacies have come under increased scrutiny due to fatalities from quality control issues without regulatory oversight. In recent years, Harrow tried to transition from a bespoke compound pharmacist to become a pharmaceutical development company through a variety of initiatives such as:

- Signed a deal with EyePoint Pharmaceuticals, Inc. (“Eyepoint”) (Nasdaq: EYPT) to sell, market, and promote Dexycu, EYPT’s drug approved by the Food and Drug Administration (“FDA”).
- Acquired a total of nine (9) licensed drugs from Novartis AG (“Novartis”) (NYSE: NVS) in two separate transactions paying over US\$ 215 million in December 2021 and January 2023.
- Received FDA approval for another licensed drug, Iheezo, an ocular anesthetic in September 2022.
- Invested in drug development entities and spin-offs since 2017.

While investors have bought into the story of change, our findings suggest that at best, Harrow is an unprofitable stock promotion neglecting risk disclosures and quality control standards at its compounding pharmaceutical operations.

1. U.S. Department of Justice (“DOJ”) Investigation into Dexycu sales practices: In August 2022, Eyepoint received a DOJ subpoena seeking the production of documents related to sales, marketing, and promotional practices related to Dexycu. **Harrow did not disclose this subpoena to investors despite being the responsible party for Dexycu sales, marketing, and promotional practices.**
2. Harrow has not disclosed to investors recent FDA actions: In June 2022, Harrow received a FDA Warning Letter for false and misleading marketing claims. In August 2022 Harrow received a FDA Form 483 inspection report which cited unsanitary conditions and drug quality issues. **Harrow did not disclose any such actions to investors.** A few months later following these actions, the company issued a nationwide recall with the FDA.
3. Acquired Novartis drugs show abysmal growth: We reviewed Rx unit growth reported for Harrow’s nine licensed drugs from Novartis. Despite Harrow’s claim that sales of the FDA-approved Novartis drugs are an exciting growth opportunity, our research showed that these drugs have suffered from a massive decline in Rx unit fulfillments due to competition from alternative branded and generic drugs. To us, this suggests that Harrow licensed unpopular legacy Novartis drugs with little Rx unit count growth.
4. Iheezo does not look like a beacon of growth: Despite Harrow’s bullish comments about Iheezo, we expect the first branded ocular anesthetic in 14 years to have a tough time becoming a successful growth story. Iheezo’s compound was initially approved by the FDA in 1955 (~68 years ago) and faces established competition in a very mature category that shows little Rx unit count growth.
5. Off balance sheet drug development entities filled with losses: In recent years, Harrow made five off balance sheet investments into former Harrow subsidiary spin-offs (the “Fab Five”) generating significant losses for Harrow shareholders. One of Harrow’s investments, Surface Ophthalmics (“Surface”), was written down to zero as of FYE 2021. Another Harrow investment, Melt Pharmaceuticals (“Melt”) filed and withdrew its S-1, implying limited interest since September 2022. These investments follow a similar pattern whereby Harrow insiders receive personal stock incentives in, employment and consulting fees from, Harrow’s former subsidiaries to enrich themselves.

Harrow burns cash from operations and relies on external financing for survival. We think Harrow did not disclose to investors the existence of a DOJ investigation because it would have compromised Harrow’s ability to raise capital. With significant liabilities managed by bad actors willing to enrich themselves at the expense of minority Harrow shareholders, we are short Harrow and think its stock is going lower.

THIS RESEARCH REPORT EXPRESSES SOLELY OUR OPINIONS. WE ARE SHORT. WE ARE BIASED. DO YOUR OWN WORK. Use Bonitas Research LLC's research opinions at your own risk. You should do your own research and due diligence before making any investment decisions. We have a short interest in Harrow Health (\$HROW) stock and stand to realize significant gains in the event that the price of such instrument declines. Please refer to our full disclaimer located on the last page of this report.

U.S. DEPARTMENT OF JUSTICE INVESTIGATED DEXYCU SALES & MARKETING PRACTICES

Harrow did not disclose to investors a government investigation into Dexycu sales.

In August 2022, Eyepoint received a subpoena from the U.S. Attorney's Office for the District of Massachusetts seeking production of documents related to sales, marketing and promotional practices of Dexycu ("DOJ investigation").¹

Eyepoint is a United States drug developer that owns and manufactures FDA-approved drug Dexycu. In March 2019 Eyepoint commercially launched Dexycu.

On August 1, 2020, Eyepoint signed a 5-year agreement for Harrow to sell Dexycu. Initial agreement terms required Harrow receive final approval from Eyepoint for marketing materials used in promoting sales of Dexycu.²

On December 6, 2021, the agreement was amended, and Harrow assumed full responsibility for U.S. sales and marketing activities for Dexycu, including control over all regulatory approvals and commercial rights for Dexycu, while Eyepoint retained control over revenue recognition, manufacturing, and distribution responsibilities as of January 1, 2022.³ The consulting firm Eyepoint originally appointed to help with Promotional Review Committee oversight was replaced by a Harrow appointee.

Harrow agreed to indemnify and hold Eyepoint harmless from and against all liabilities resulting from any third-party claim "for all current Dexycu Sales, Marketing and Medical Science Liaison (MSL) functions, including compliance with all applicable laws or regulations related to such responsibilities... and all associated costs for the Promotional Review Committee (PRC), Compliance (Sunshine Act, SOPs, training, etc.), Speaker Programs, Trade Shows, and Customer Training."⁴

Considering Harrow was responsible for Dexycu promotional activity since August 2020, and assumed full responsibility for all Dexycu sales and marketing related regulatory compliance as of January 1, 2022, we think it is reasonable to suspect Harrow management was (and/or will be) also questioned by the DOJ about Dexycu sales.

Eyepoint's 3Q'22 10-Q included disclosure about the DOJ investigation. Harrow made no mention of the DOJ or any active investigation, subpoena, or request for information.

DOJ INVESTIGATION – August 2022

We received a subpoena from the U.S. Attorney's Office for the District of Massachusetts seeking production of documents related to sales, marketing and promotional practices, including as pertain to DEXYCU®. If the DOJ commences an action against us, the action could have a material adverse effect on our business, financial condition, results of operations and cash flows. In addition, we have expended and expect to continue to expend significant financial and managerial resources responding to the DOJ subpoena, which could also have a material adverse effect on our business, financial condition, results of operations and cash flows.

In August 2022, the Company received a subpoena from the U.S. Attorney's Office for the District of Massachusetts seeking production of documents related to sales, marketing and promotional practices, including as pertain to DEXYCU®. We are cooperating fully with the government in connection with this matter. We cannot predict the outcome of the DOJ Investigation, and there can be no assurance that the DOJ will not commence an action against us, or as to what the ultimate outcome of any such DOJ Investigation might be. Under applicable law, the DOJ has the ability to impose sanctions on companies which are found to have violated the provisions of applicable laws, including, civil monetary penalties and other remedies. The resolution of any such enforcement action, should there be one, could have a material adverse effect on our business, financial condition, results of operations and cash flows. We have expended and expect to continue to expend significant financial and managerial resources responding to the DOJ subpoena, which could also have a material adverse effect on our business, financial condition, results of operations and cash flows.

Source: 3Q'22 10-Q EYPT – p.37 <https://www.sec.gov/ix?doc=/Archives/edgar/data/1314102/000095017022022141/eypt-20220930.htm>

¹ <https://www.sec.gov/ix?doc=/Archives/edgar/data/1314102/000095017022022141/eypt-20220930.htm>

² https://www.sec.gov/Archives/edgar/data/1314102/000156459020051654/eypt-ex101_120.htm

³ <https://investors.harrow.com/news-releases/news-release-details/eyepoint-pharmaceuticals-and-harrow-healths-imprimisrx-0>

⁴ https://www.sec.gov/Archives/edgar/data/1314102/000156459022009929/eypt-ex1045_1565.htm

FDA REGULATORY MEETING, FDA RECALL, FDA INSPECTION, FDA WARNING LETTER

Harrow did not disclose that both of its compound pharmacy facilities are under review by the FDA.

Based on the scope and range of multiple drugs mentioned in various FDA observations, we suspect that Harrow's entire compounding business is under review.

As of today, Harrow operates two compound pharmacies in New Jersey with two separate designations, 503A and 503B, to distribute to retail and institutional customers, respectively. ImprimisRx NJ is Harrow's 503A facility to compound drugs for patients and individual prescriptions. Imprimis NEOF, LLC is Harrow's 503B facility to compound drugs for institutions, hospitals, physician groups, etc.⁵

In 2017, Harrow's 503B facility was inspected and violations were observed by the FDA.⁶

In June 2019, Harrow received a FDA Warning Letter about quality control issues and noted serious deficiencies in practices for producing sterile drug products which put patients at risk.⁷

From September 2020 to January 2021, Harrow's 503B facility was inspected again. Inspectors cited twelve (12) observations, of which five were "repeat observations."⁸

On June 30, 2022 Harrow received a FDA Warning Letter regarding false and misleading marketing claims for Pred-Moxi-Brom that "*fails to adequately and truthfully convey risk and efficacy information about the products, despite concerns previously expressed by the FDA.*"⁹

In December 2017 Harrow received a FDA Warning Letter related to sales, marketing and promotional materials used for various Harrow products.¹⁰

On September 25, 2018, ImprimisRx NJ, LLC was found by the FDA to be in violation of producing drugs that violate the FDCA.¹¹

On August 5, 2022, Harrow received FDA Form 483 inspection results of its 503A ImprimisRx NJ compound facility which cited nine (9) observations of failure including unsanitary conditions and drug quality issues. The FDA Form 483 investigation dates were from 7/11/2022-8/5/2022.¹²

On August 29, 2022, the FDA held a Regulatory Meeting regarding Harrow's 503B Imprimis NEOF, LLC compound facility.¹³ The results of this action have yet to be disclosed, but Regulatory Meetings tend to be held when there are violations of the law.¹⁴

On November 9, 2022, Harrow and 503A ImprimisRx NJ initiated a nationwide recalled Timolol-Latanoprost product shipped between 7/7/2022 and 10/31/2022 due to sub-potency of the labeled amount of latanoprost.¹⁵

It is unclear whether Harrow's November 2022 FDA product recall was reactive, proactive, or coincidental and unrelated to the FDA's inspection of both of Harrow's facilities, repeated FDA Warning Letters, or its most recent FDA Regulatory Meeting.

⁵ <https://www.sec.gov/Archives/edgar/data/1360214/000149315218003095/ex21-1.htm>

⁶ <https://www.fda.gov/media/107150/download>

⁷ <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/imprimis-njof-llc-553322-06072019>

⁸ <https://www.fda.gov/media/151431/download>

⁹ <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/imprimis-rx-llc-627802-06302022>

¹⁰ <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/imprimis-pharmaceuticals-540678-12212017>

¹¹ <https://www.fda.gov/media/120640/download>

¹² <https://www.fda.gov/media/162966/download>

¹³ <https://www.fda.gov/drugs/human-drug-compounding/registered-outsourcing-facilities>

¹⁴ <https://www.fda.gov/media/71765/download>

¹⁵ <https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=197020>

FDA WARNING LETTER – June 30, 2022

These violations are concerning from a public health perspective because they create a false or misleading impression about the safety and effectiveness of this drug product. This is especially concerning in light of the many known risks associated with the active ingredients in this drug product, as reflected in ImprimisRx's own Product Information website and the prescribing information for FDA-approved drug products containing the same active ingredients, as well as potential safety risks of using these drug products together.

Prior Communication

The FDA has expressed concerns regarding promotional materials for compounded drug products from Imprimis Pharmaceuticals Inc.² in a previous letter. On December 21, 2017, the FDA sent Imprimis Pharmaceuticals Inc. a Warning Letter based on a firm website and social media posts that misbranded the firm's "Dropless," "LessDrops," "Simple Drops," and "Klarity C-Drops" products by omitting important risk information and otherwise making false or misleading claims regarding the safety and efficacy of these products. We are concerned that ImprimisRx is continuing to promote its products in a manner that similarly fails to adequately and truthfully convey risk and efficacy information about the products, despite concerns previously expressed by the FDA.

Source: <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/imprimis-rx-llc-627802-06302022>

FDA FORM 483 DEFICIENCY OBSERVATIONS – August 5, 2022

ImprimisRx Gets Form 483 for Unsanitary Conditions, Drug Quality Issues

November 15, 2022

PHARMACEUTICALS

INSPECTIONS AND AUDITS

The FDA issued a nine-observation Form 483 to ImprimisRx's Ledgewood, N.J., facility for unsanitary conditions and other deficiencies observed during a July 11 to Aug. 5 inspection.

Source: <https://www.fdanews.com/articles/210185-imprimisrx-gets-form-483-for-unsanitary-conditions-drug-quality-issues?v=preview>

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax: (973) 331-4969 ORAPHARM1_RESPONSES@fda.hhs.gov		DATE(S) OF INSPECTION 7/11/2022-8/5/2022*	
		FEI NUMBER 3003348498	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Ms. Suja Alum, PharmD, General Manager and Pharmacist-in-Charge			
FIRM NAME ImprimisRx NJ		STREET ADDRESS 1705 Route 46 West, Ste 4	
CITY, STATE, ZIP CODE, COUNTRY Ledgewood, NJ 07852-9720		TYPE ESTABLISHMENT INSPECTED Producer of sterile and non-sterile drug products	
This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, please see the instructions on page 2 of this Form 483.			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Sena G Dessimyer, Investigator Tekalign Wondimu, Investigator Amy N Chen, Investigator		DATE ISSUED 8/5/2022
X		Sena G Dessimyer Investigator Imprimis Rx, Sena G. Dessimyer d Date Signed: 08-05-2022 17:28:58	
FORM FDA 483 (09/08)		PREVIOUS EDITION OBSOLETE	
		INSPECTIONAL OBSERVATIONS	
		PAGE 1 of 7 PAGES	

Source: <https://www.fda.gov/media/162966/download>

FDA REGULATORY MEETING – August 29, 2022

Facility Name	Contact Name and Phone Number	Initial Date of Registration as an Outsourcing Facility ¹	Date of Most Recent Registration as an Outsourcing Facility ¹	End Date of Last FDA Inspection Related to Compounding ²	Was a Form FDA-483 issued? ³	Other Action, if Any, Based on Last Inspection ^{4,5}	Intends to Compounds Sterile Drugs From Bulk Drug Substances ⁶
Imprimis NJOF, LLC, Ledgewood, NJ	Jeffrey Palmer +1-973-804-1635 	11/12/2016	11/19/2022	1/29/2021	<u>Yes</u>	Regulatory Meeting Held 8/29/22	Yes

Source: <https://www.fda.gov/drugs/human-drug-compounding/registered-outsourcing-facilities>

10-3 REGULATORY MEETINGS

A Regulatory Meeting is a meeting requested by FDA management at its discretion, to inform responsible individuals or firms about how one or more products, practices, processes, or other activities are considered to be in violation of the law. FDA is not

Source: <https://www.fda.gov/media/71765/download>

FDA RECALL NOTICE – November 9, 2022

Product Type ▲	Recently Updated Record**	Product Description ▲	Classification ▲	Code Information ▲	Reason for Recall ▲	Recalling Firm ▲
 Drugs	No	Timolol-Latanoprost (0.5/0.005%) ophthalmic drops, Compounded, 5 mL bottle, Imprimis Rx, Ledgewood, NJ.	Class II	Lot # 06272022@3, Exp. date 11/24/2022 Lot # 08302022@1, Exp. date 01/27/2023	Subpotent Drug: The batches contain less than 90% of the labeled amount of latanoprost.	ImprimisRx NJ 1705 Us Highway 46 Ste 4 Ledgewood, NJ 07852-9720

Product Details

Product Description:

Timolol-Latanoprost (0.5/0.005%) ophthalmic drops, Compounded, 5 mL bottle, Imprimis Rx, Ledgewood, NJ.

Reason for Recall:

Subpotent Drug: The batches contain less than 90% of the labeled amount of latanoprost.

Product Quantity:

960 bottles

Recall Number:

D-0060-2023

Code Information:

Lot # 06272022@3, Exp. date 11/24/2022 Lot # 08302022@1, Exp. date 01/27/2023

Classification:

Class II

Event Details

Event ID:

[91140](#)

Voluntary / Mandated:

Voluntary: Firm initiated

Product Type:

Drugs

Initial Firm Notification of Consignee or Public:

Letter

Status:

Ongoing

Distribution Pattern:

Nationwide in the USA

Recalling Firm:

ImprimisRx NJ
1705 Us Highway 46 Ste 4
Ledgewood, NJ 07852-9720
United States

Press Release URL(s):

Source: <https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=197020>

Harrow's former California compounding pharmacy, Park Compounding, experienced a similar chain of events that ultimately led to Harrow's former pharmacist getting her California license revoked and the pharmacy closed.¹⁶

In September 2013, Harrow's California pharmacy recalled product.¹⁷

In July 2014, the FDA issued a Form 483 with negative observations.¹⁸

In June 2015 a referral letter was sent by the FDA to the California State Board of Pharmacy raising awareness of numerous violations.¹⁹

In March 2016 the FDA issued another Form 483 with repeat observations of quality control issues.²⁰

In 2017 the FDA investigated two serious adverse events associated with ImprimisRx's compounded curcumin emulsion product for injection, including one patient fatality.

On June 23, 2017, ImprimisRx recalled all unexpired products containing ungraded PEG 40 castor oil.²¹

In March 2019 Harrow received a FDA Warning Letter about its CA 503A facility.²²

In May 2019, the Company's California facility surrendered its license as regulators forced the sale or closure of the facility.²³

In 2019 Nadia Mohamed Ibrahim Elsayed Ibrahim was ultimately found in violation of 21 causes for discipline by the State of California Board of Pharmacy Department of Consumer Affairs.²⁴

ImprimisRx CA Inc. (dba ImprimisRx), Irvine CA - 503A Facility - Out of business

- [Warning Letter \(03/26/2019\)](#)
- Compounding Risk Alert: [A Case of Hemorrhagic Occlusive Retinal Vasculitis \(HORV\) Following Intraocular Injections of a Compounded Triamcinolone, Moxifloxacin, and Vancomycin Formulation \(10/3/2017\)](#)
- Compounding Risk Alert: [FDA Investigates Two Serious Adverse Events Associated with ImprimisRx's Compounded Curcumin Emulsion Product for Injection \(8/4/2017\)](#)
- [483 Issued 03/31/2017 \(PDF - 558KB\)](#)
- [Warning Letter \(03/20/2017\)](#)

Imprimis NJOF, LLC, Ledgewood, NJ - 503B Facility

- [483 Issued 01/29/2021 \(PDF - 5.35MB\)](#)
- [Warning Letter \(06/07/2019\)](#)
- [483 Issued 07/10/2017 \(PDF - 1.6MB\)](#)

ImprimisRx NJ, Ledgewood, NJ - 503A Facility

- [483 Issued 08/05/2022 \(PDF - 1.57MB\)](#)
- [483 Issued 04/09/2019 \(PDF - 305KB\)](#)
- [Untitled Letter \(09/25/2018\)](#)
- [483 Issued 07/10/2017 \(PDF - 190KB\)](#)

Source: <https://www.fda.gov/drugs/human-drug-compounding/compounding-inspections-recalls-and-other-actions>

¹⁶ <https://www.fda.gov/drugs/human-drug-compounding/compounding-inspections-recalls-and-other-actions>

¹⁷ <https://web.archive.org/web/20170112025126/http://www.fda.gov/Safety/Recalls/ArchiveRecalls/2013/ucm367838.htm>

¹⁸ <https://www.fda.gov/media/89982/download>

¹⁹ <https://www.fda.gov/media/92296/download>

²⁰ <https://www.fda.gov/media/97132/download>

²¹ <https://www.fda.gov/drugs/human-drug-compounding/fda-investigates-two-serious-adverse-events-associated-imprimisrxs-compounded-curcumin-emulsion>

²² https://ipq.org/wp-content/uploads/2019/06/2019_03_26_Imprimis-Rx.pdf

²³ <https://www.mass.gov/doc/mariam-saad-fouad-bekhit-elgawly-license-no-ph238026-consent-agreement-for-voluntary-surrender/download>

²⁴ https://www.pharmacy.ca.gov/enforcement/fy1718/ac176271_rph55103

HROW LICENSED UNPOPULAR LEGACY NOVARTIS DRUGS WITH LITTLE/NO RX GROWTH

It's much less risky for doctors to use FDA-approved drugs versus non-FDA approved bespoke compound formulations.

Compound pharmacies have come under increased scrutiny in the past decade due to fatalities from quality control issues inherent in non-FDA approved products.

Harrow's 2017 10-K addressed the risks associated with an FDA Warning Letter it received about the use of curcumin in emulsions.²⁵

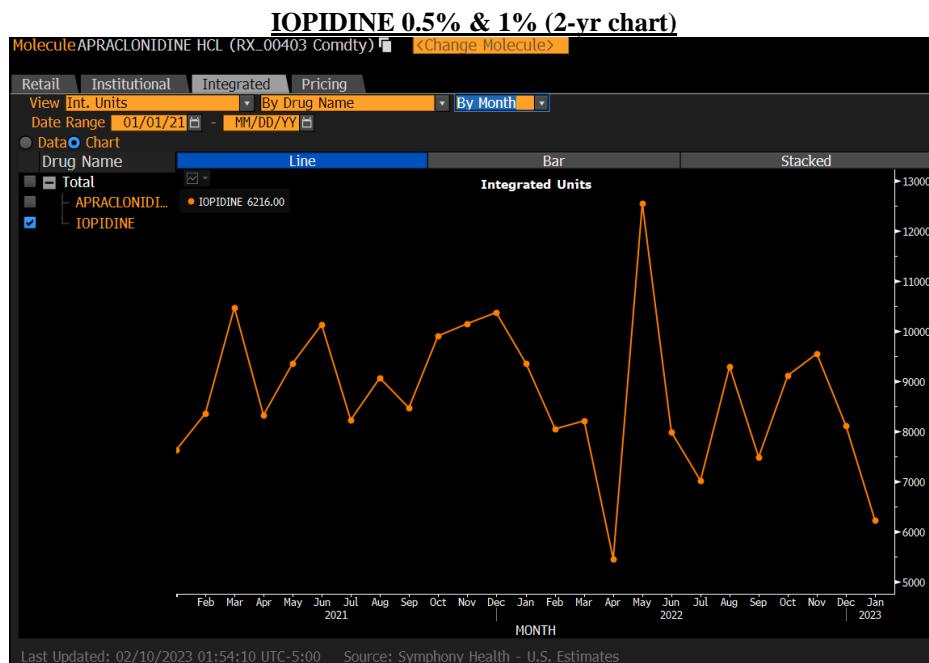
As of today, quality control issues for compounded drugs continues to exist which is why it was so important for Harrow to transition away from selling bespoke compounded non-FDA approved drugs towards FDA-approved drugs.

In December 2021, Harrow acquired exclusive U.S. commercial rights to four (4) FDA-approved ophthalmic products from Novartis for up to US\$ 14.3 million.²⁶

Bloomberg Terminal users have access to United States Prescription data from Symphony Health Solutions ("Rx data") (<https://symphonyhealth.com>) which includes specific information such as number of Rx count written per month per drug, competing drug list, pricing list, category info, etc.

The Symphony Health Solutions monthly integrated drug dataset tracks the volume and dollar amount of prescription drugs sold through combined retail and institutional channels. In this report we reference "*Integrated Units*" for Rx data for specific Novartis drugs and their respective categories.²⁷

Rx data shows a decline in year-over-year growth in Rx units since Harrow acquired U.S. commercial rights for IOPIDINE 0.5% & 1%, MOXEZA, and MAXITROL from Novartis.



²⁵ <https://www.sec.gov/Archives/edgar/data/1360214/000149315220003862/form10-k.htm>

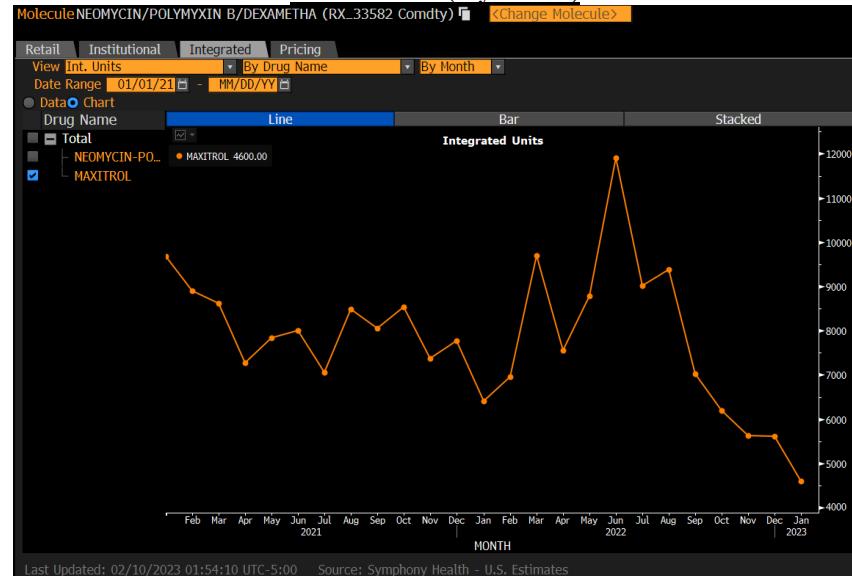
²⁶ <https://www.businesswire.com/news/home/20211220005121/en/Harrow-Health-Acquires-U.S.-Commercial-Rights-to-Four-Branded-Eye-Drops>

²⁷ Bloomberg defines *Integrated Units* as "the combined metrics of Total Prescription (TRx) Quantity and Non-Retail Volume Units. (Note: Units can only be added at the Product/Form level. For example, while a product may have both an inject-able and a capsule form, adding those units together would not be sensible, so the products are broken out into forms for unit addition.) This represents the most granular unit metric for a drug - # of pills, mls, mgs, etc."

MOXEZA (2-yr chart)



MAXITROL (2-yr chart)



In January 2023, Harrow acquired exclusive U.S. commercial rights to an additional five (5) FDA-approved ophthalmic products from Novartis for up to US\$ 175 million.²⁸

Rx data revealed sales declining for most Novartis drugs that Harrow sells due to significant competition from other branded and generic drugs. The following images compare Rx units by category versus Harrow sold Novartis drugs.

To us, the evidence suggests that Harrow licensed unpopular legacy Novartis drugs with little/no Rx count growth.

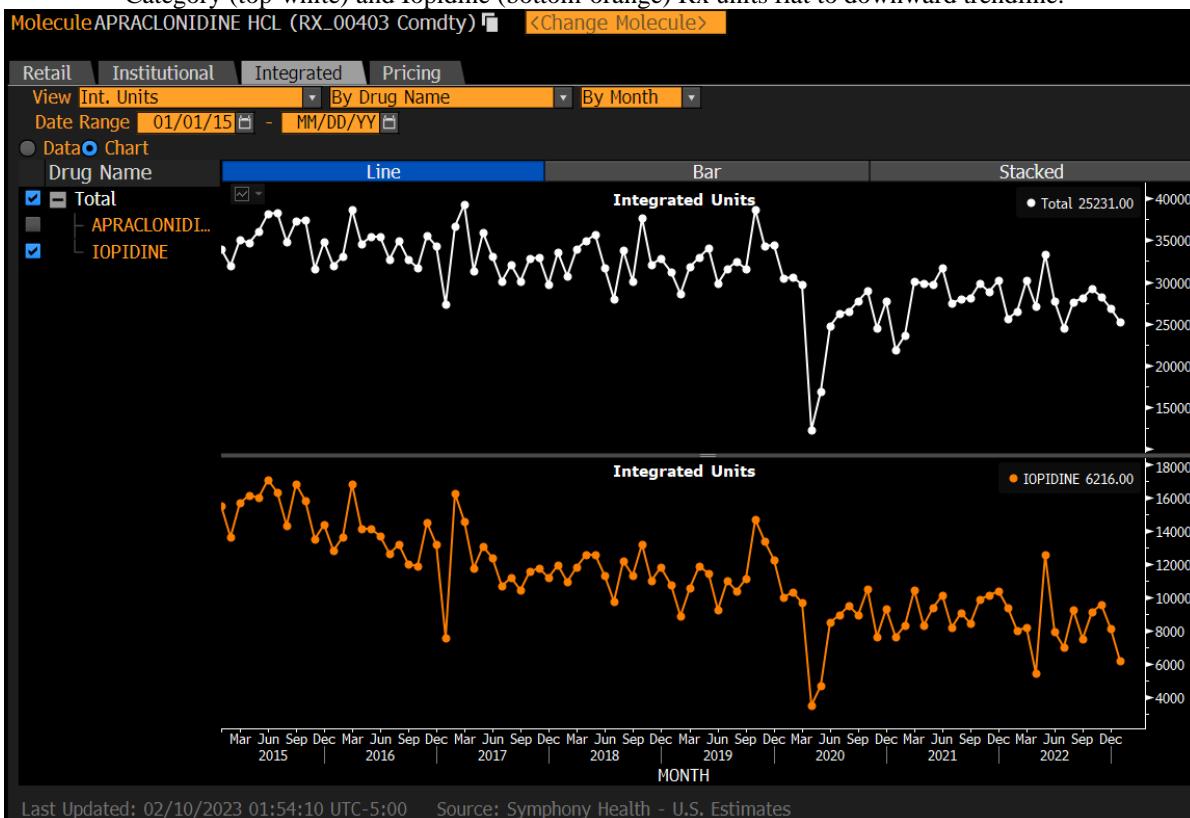
Product	ILEVRO NEPAFENAC SUSPENSION 0.3% OPHTHALMIC	NEVANAC NEPAFENAC OPHTHALMIC SUSPENSION 0.1%	MAXIDEX DEXAMETHASONE OPHTHALMIC SUSPENSION 0.1%	TRIESENCE TRIAMCINOLONE ACETONIDE INJECTABLE SUSPENSION 40 MG/ML	VIGAMOX MOXIFLOXACIN HYDROCHLORIDE OPHTHALMIC SOLUTION 0.5%
Year of FDA Approval	2012	2005	Pre-1982	2007	2003

Source: <https://www.sec.gov/Archives/edgar/data/1360214/00014931522035374/ex99-3.htm>

²⁸ <https://www.sec.gov/Archives/edgar/data/1360214/000149315223002125/ex99-1.htm>

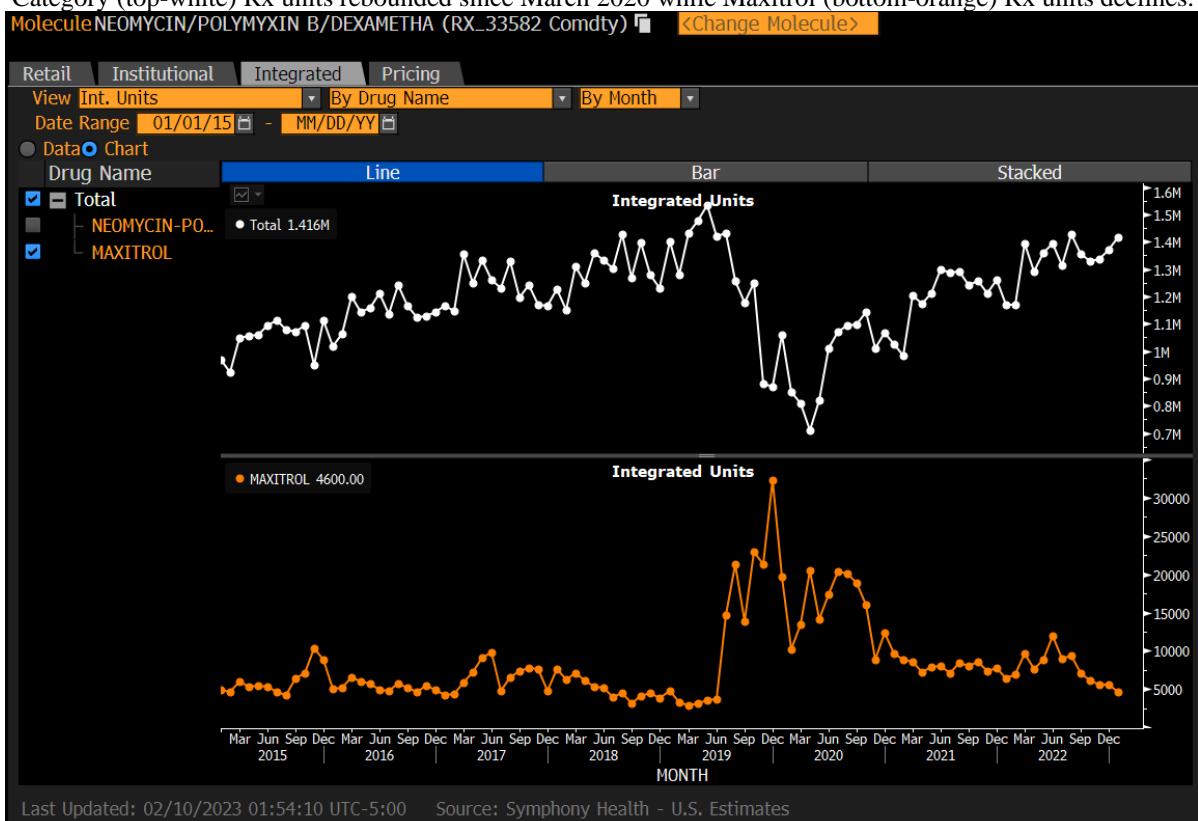
IOPIDINE 0.5% & 1%

Category (top-white) and Iopidine (bottom-orange) Rx units flat to downward trendline.



MAXITROL

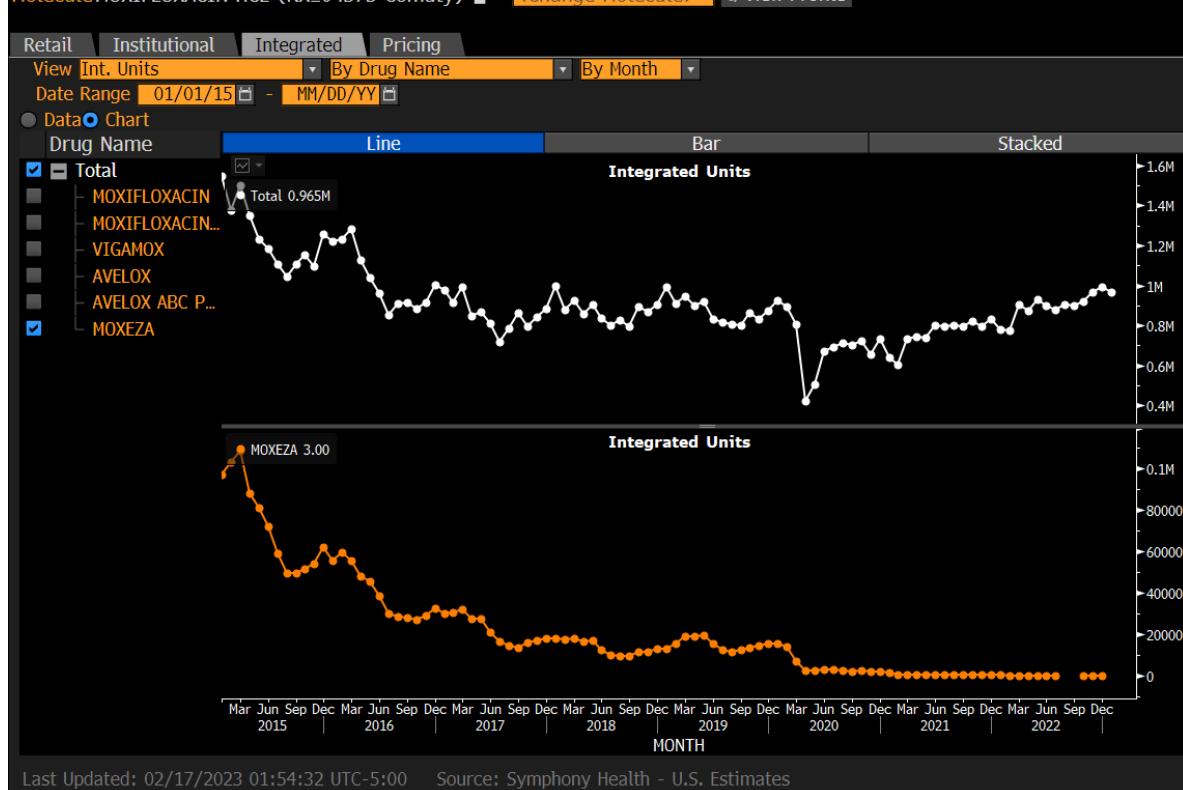
Category (top-white) Rx units rebounded since March 2020 while Maxitrol (bottom-orange) Rx units declines.



MOXEZA

Category (top-white) Rx units rebounded since March 2020 while Moxeza (bottom-orange) Rx units declined.

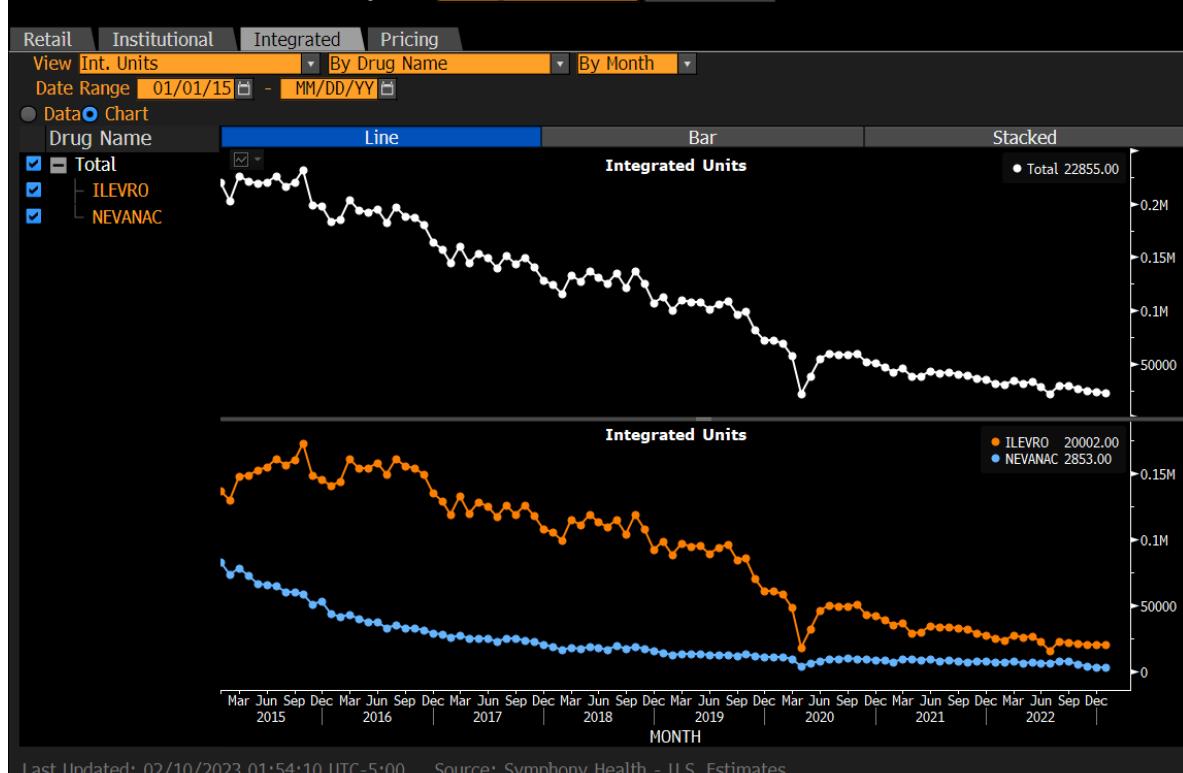
Molecule MOXIFLOXACIN HCL (RX_04373 Comdty) [Change Molecule](#) [View Profile](#)



ILEVRO & NEVANAC

Category (top-white), Ilevro (bottom-orange) and Nevanac (bottom-blue) Rx units decline.

Molecule NEPAFENAC (RX_04671 Comdty) [Change Molecule](#) [View Profile](#)



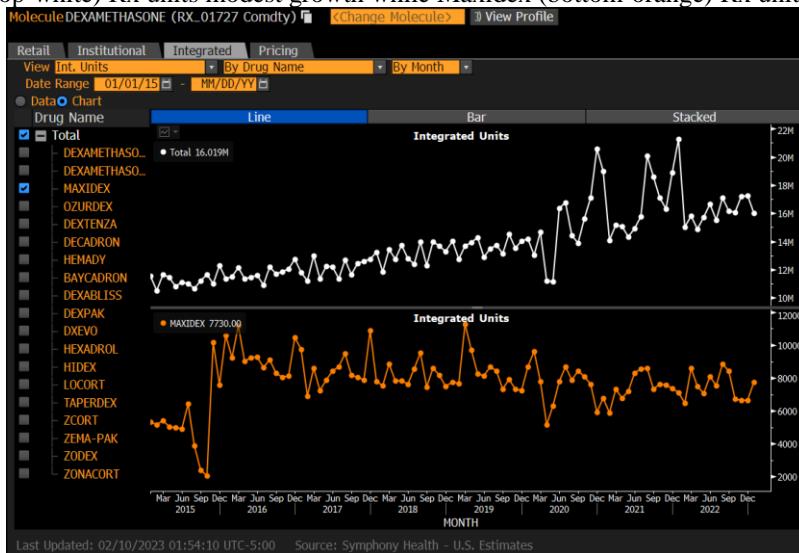
VIGAMOX

Category (top-white) Rx units rebounded since March 2020 while Vigamox (bottom – orange) Rx units declined.



MAXIDEX

Category (top-white) Rx units modest growth while Maxidex (bottom-orange) Rx units remain flat.



TRIESENCE

Triesence (orange) Rx units flatlined in 2022.



IHEEZO FACES ESTABLISHED COMPETITION – COMPOUND FDA APPROVED IN 1955

In July 2021, Harrow licensed Iheezo (formerly AMP-100) from international pharmaceutical company Sintetica S.A. for exclusive marketing and supply rights in the U.S. and Canadian markets (<https://www.sintetica.com/>).

Iheezo is a chloroprocaine hydrochloride ophthalmic gel 3% for topical ophthalmic use.

In September 2022, the FDA approved Iheezo and Harrow paid Sintetica fees of ~US\$ 8.1 million as was committed to milestone payments up to US\$ 18 million under the terms of the agreement.

Iheezo represents the first FDA-approved use of chloroprocaine hydrochloride in the U.S. ophthalmic market and the first branded ocular anesthetic approved in nearly 14 years.

We think the real reason Iheezo is the first FDA-approved drug in the U.S. ophthalmic market in 14 years is because there is little need for a new drug solution in the category.²⁹

Iheezo's formal FDA approval cited initial U.S. approval in the year 1955.³⁰

“Local anesthetics in this class have an ester linkage to benzoic acid or its derivatives. The amino ester-linked local anesthetics most commonly used clinically are procaine, chloroprocaine, and tetracaine. All of these agents were introduced into clinical practice by 1955.”³¹

Topical ocular anesthetics are the most commonly used method of anesthesia for cataract surgery in the US. “The most widely used topical agents are proparacaine, tetracaine, cocaine, lidocaine, and bupivacaine. Ophthalmologists use proparacaine daily.”³²

Iheezo faces established competition in a very mature little/no growth drug category.

Harrow will need to increase its marketing spend significantly to get any support for Iheezo and compete in such a mature drug category.

Given the lack of mind-blowing improvements over pre-existing FDA-approved drugs, we anticipate a low probability of success that Iheezo supplants established incumbents in a little/no growth category.³³

The next page includes Symphony Health data via Bloomberg Terminal for each of the incumbent molecules which shows little/no growth in the category.

²⁹ <https://www.drugs.com/drug-class/ophthalmic-anesthetics.html>

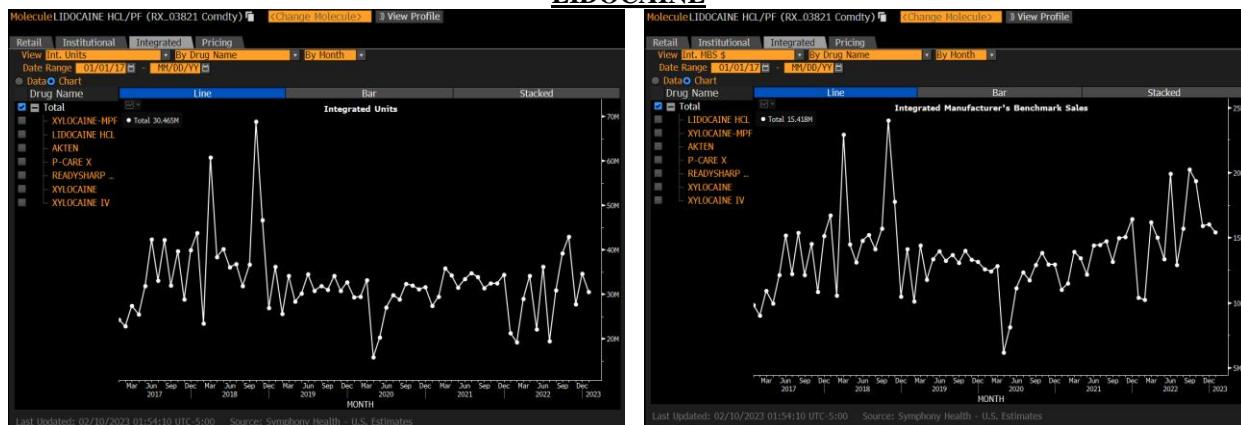
³⁰ https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/216227s000lbl.pdf

³¹ <https://accessanesthesiology.mhmedical.com/content.aspx?bookid=490§ionid=40114732&jumpsectionid=40124532>

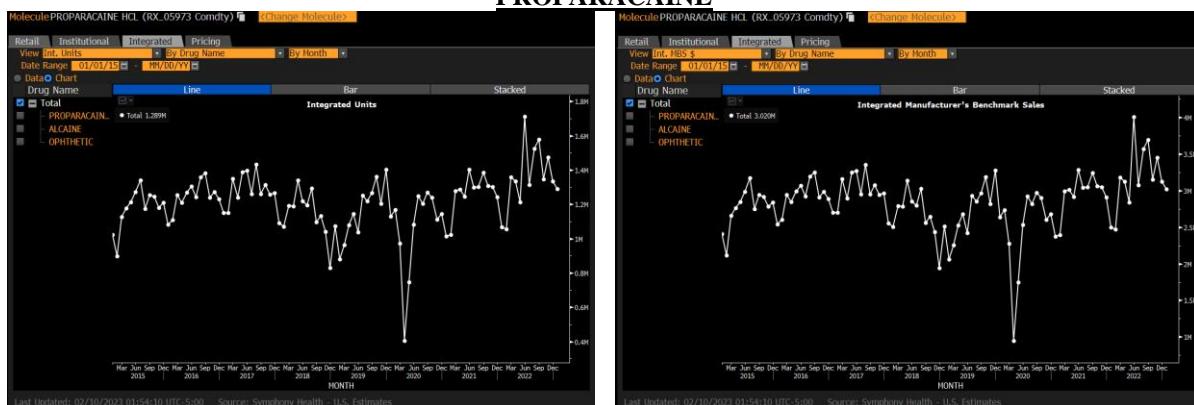
³² https://crstoday.com/articles/2002-sep/0902_301-html

³³ https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/216227s000lbl.pdf

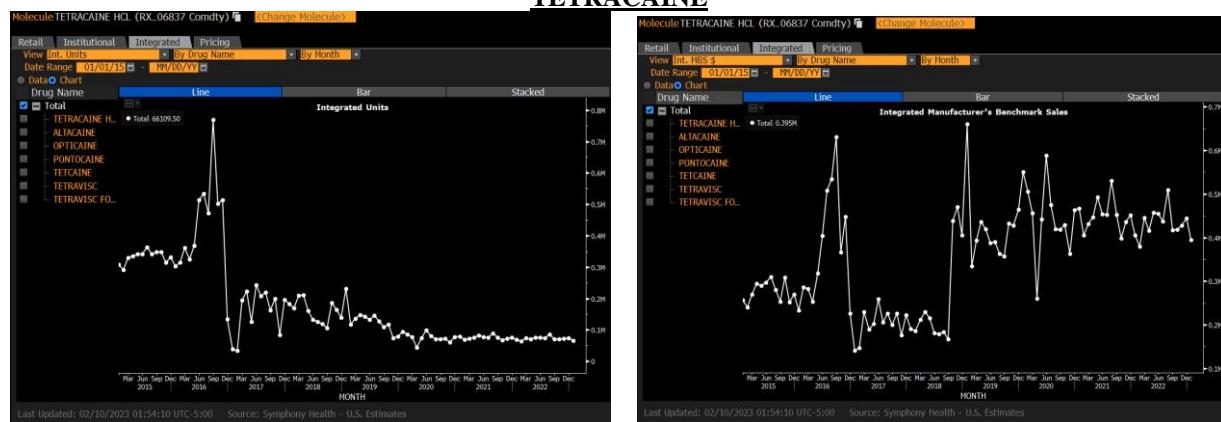
LIDOCAINE



PROPARACAIN



TETRACAIN



LOSSES FROM PREVIOUS DRUG INVESTMENT FAILURES – HISTORY OF BAD ACTORS

Harrow has made a habit of spinning out formerly consolidated subsidiaries that are allegedly developing drugs.

Harrow insiders received a mixture of personal stock options, employment/board member and/or consulting agreements in these off balance sheet entities to avoid scrutiny and obfuscate expenses paid to personally benefit Harrow insiders at the expense of HROW shareholders.

In recent years, Harrow made five off balance sheet investments into five former Harrow subsidiary spin-offs (the “Fab Five”) generating significant losses for Harrow shareholders.

The Fab Five consisted of Radley Pharmaceuticals, Inc. (“Radley”), Mayfield Pharmaceuticals, Inc. (“Mayfield”), Stowe Pharmaceuticals, Inc. (“Stowe”), Surface Ophthalmics (“Surface”), and Melt Pharmaceuticals (“Melt”).

In 2020, Harrow stopped all operating activities and terminated all licensing agreements related to Radley, Mayfield, and Stowe.³⁴

In 2021, Harrow valued its Surface equity at zero incurring US\$ 12.1 million in losses since 2020.³⁵

Harrow’s cumulative investment in Melt was ~U\$S 19.3 million with a net carrying value of US\$ 2.1 million as of September 30, 2022.³⁶

Melt’s sole creditor is Harrow. Melt used to be a Harrow subsidiary. Harrow’s CEO Mark Baum is Melt’s Chairman of the Board and Harrow’s Chief Medical Officer Larry Dillaha is Melt’s CEO.³⁷

Melt’s shareholders include Harrow executives, founders and shareholders.³⁸

Melt is a pre-revenue company without any approved products and has no customers.

Harrow’s CEO Baum, Harrow’s CFO Boll, and Harrows Chief Operating Officer John P. Sharek are each personally incentivized with Melt stock options plus any additional existing employment or consulting arrangements.³⁹

On September 21, 2022, Melt filed an S-1 for an initial public offering with Aegis Capital as sole bookrunner.⁴⁰

On January 4, 2023, Melt withdrew its S-1 filings “*due to prevailing market conditions*” and requested that “*all fees paid be credited for future use*.⁴¹”

Opaleye Management (“Opaleye”) is the largest institutional holder of HROW, Melt and Eton Pharmaceuticals (Nasdaq: ETON), a Harrow minority investment.

James Silverman is the principal and manager of Opaleye.

In 2011 James Silverman was accused by Massachusetts officials of using inside information on clinical trials to generate profits for his hedge fund Risk Reward Capital Management, RRC Bio Fund LP.⁴²

In 2015 a cross-complaint disclosed that Harrow Chairman and Founder Robert J. Kammer purchased 295,000 shares of Harrow stock that was pledged as collateral to a note held by known fraudster Barry Honig.

³⁴ <https://www.sec.gov/ix?doc=/Archives/edgar/data/1360214/000149315222006525/form-10k.htm>

³⁵ <https://www.sec.gov/ix?doc=/Archives/edgar/data/1360214/000149315222032076/form10-q.htm>

³⁶ <https://www.sec.gov/ix?doc=/Archives/edgar/data/1360214/000149315222032076/form10-q.htm>

³⁷ <https://www.meltpharma.com/our-company/leadership>

³⁸ <https://www.sec.gov/Archives/edgar/data/1767398/000149315222026500/forms-1.htm>

³⁹ <https://www.sec.gov/Archives/edgar/data/1360214/000149315218015757/ex10-1.htm> ;

⁴⁰ <https://www.sec.gov/Archives/edgar/data/1767398/000149315222026500/forms-1.htm>

⁴¹ <https://www.sec.gov/Archives/edgar/data/1767398/000149315223000357/formrv.htm>

⁴² <https://www.bloomberg.com/news/articles/2011-03-09/massachusetts-charges-hedge-fund-with-insider-trading-on-biotech-research> ;
http://archive.boston.com/business/articles/2011/03/10/hedge_fund_paid_for_inside_data_state_says/

The cross-complaint pleaded that “Kammer and other ImprimisRx insiders engaged in a number of wrongful actions constituting securities fraud, undue influence and duress, to acquire a substantial portion of her Imprimis stock and restrict her from freely selling other Imprimis stock she owned... Baum expressly directed Kammer and [outside counsel] to obtain a "lock up and leak out" agreement from Merlyn.”⁴³

In September 2018 the SEC found that Barry Honig and his associates engaged in illegal promotional activity and manipulative trading to artificially boost each issuer’s stock price and to give the stock the appearance of active trading volume.⁴⁴

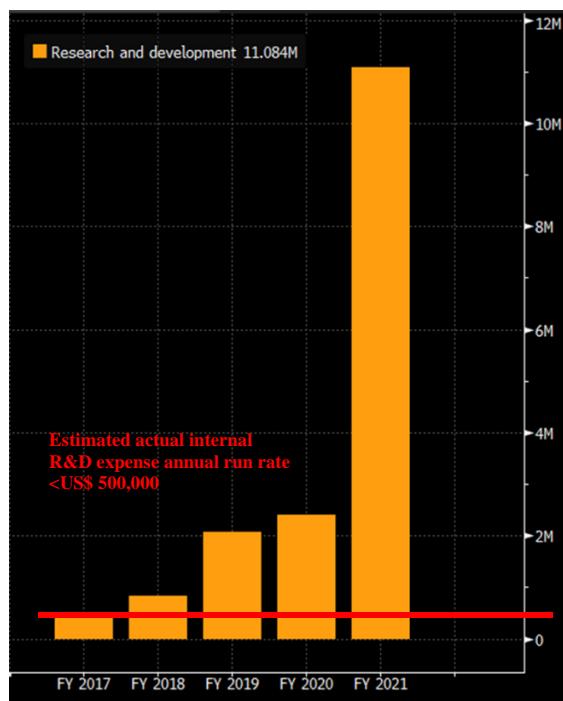
Investor interest increased as Harrow started to increase investment into research and development (“R&D”). Since 2018, Harrow’s reported sequential yr/yr R&D expense growth exceeded revenue growth. However, a more detailed review of the R&D expense revealed the vast majority of increased R&D expenditures was due to investments in former Harrow subsidiary spin-offs.

As a brazen example of self-enrichment, we estimate Harrow’s actual current internal R&D expense annual run rate to be slightly lower than what Melt paid Larry Dillaha in cash compensation as Melt CEO in 2021.⁴⁵

From 2018 to 2020, Harrow disclosed that sequential year-over-year R&D expense increased primarily from clinical development programs for Radley, Mayfield, Stowe, and Melt.⁴⁶ Harrow included investments into former subsidiary spin-offs and minority equity investments which Harrow accounted for on its income statement as R&D expenses.

In 2021, 94% of its sequential year-over-year R&D expense growth was towards the license to distribute Iheezo.⁴⁷

If we exclude R&D expenses that went to Harrow related party off-balance sheet entities, we estimate Harrow’s actual current internal R&D expense annual run rate is ~US\$ 500,000/yr.



Source: Bloomberg; HROW SEC Filings

⁴³ <https://www.courtlistener.com/opinion/3156297/kammer-v-corwin-ca41/>

⁴⁴ <https://www.sec.gov/news/press-release/2018-182>

⁴⁵ <https://www.sec.gov/Archives/edgar/data/1767398/000149315222026500/forms-1.htm>

⁴⁶ <https://www.sec.gov/ix?doc=/Archives/edgar/data/0001360214/000149315221005583/form10-k.htm> ;

<https://www.sec.gov/Archives/edgar/data/1360214/000149315220003862/form10-k.htm> ;

<https://www.sec.gov/Archives/edgar/data/1360214/000149315219003188/form10-k.htm>

⁴⁷ <https://www.sec.gov/ix?doc=/Archives/edgar/data/0001360214/00014931522006525/form-10k.htm>

DISCLAIMER

We are short sellers. We are biased. So are long investors. So is Harrow Health, Inc. (HROW). So are the banks that raised money for HROW. If you are invested (either long or short) in HROW, so are you. Just because we are biased does not mean that we are wrong. We, like everyone else, are entitled to our opinions and to the right to express such opinions in a public forum. We believe that the publication of our opinions about the public companies we research is in the public interest.

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