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Harrow Health (HROW): Honig-Tied Reverse Merger Just Promoted a Felon to the C-Suite, Now Faces A Harrowing Outlook Amidst Regulatory Crackdown

- (1) Harrow went public via reverse merger with ties to Barry Honig, while Chairman and CEO Mark Baum has been heavily involved in least 7 public “zeroes.” HROW primarily compounds post-op ophthalmic injections, which is already its third strategy after its first two failed.
- (2) In May 2019, the Company’s California Facility surrendered its license as regulators forced the sale or closure of the facility on 21 causes for discipline. Management called this a “strategic alternatives process.” This business was acquired from a 2-count felon who was just promoted to the C-suite in June 2019. Moreover, the CA facility’s issues are emblematic of the entire business.
- (3) In remaining facilities, investors have ignored a myriad of safety, quality, litigation, regulatory, and licensing issues – the same issues that forced license surrender of the California facility. Regulators are already intervening, putting the entire business at risk.
- (4) We also found aggressive product marketing. Products have already caused 2 deaths and more patients allege blindness. Harrow appears heavily involved with “alternative medicine” providers, while its exclusive Midwest distributor was accused by the DOJ of bribes and kickbacks just 8 months after signing with HROW. Finally, the Company hired the CMO of now bankrupt opioid company Insys Therapeutics as its CMO in June 2019.
- (5) Harrow’s 2 remaining pharmacy facilities were acquired for just \$1 million, while the market now awards a \$140 million valuation (excluding investment stakes). Investors mistakenly believe that HROW is a pharmaceutical business; it’s just 2 subpar pharmacies. Pharmacies trade at 0.2x to 0.8x revenues, suggesting 63% near-term downside to HROW shares. However, given management’s track record, we view shares as uninvestible.

Investment Summary

Harrow Health (formerly Imprimis Pharmaceuticals, also doing business as ImprimisRx), is a pharmaceutical compounding business. Compounding is the process of creating a drug which replaces a standard drug when either (1) a patient cannot tolerate the standard for one reason or another, or (2) the standard is not available. Pharmacists commonly “customize” the drug by removing a non-essential ingredient (ex: gluten or lactose) or change the form (ex: from drops to injection). Harrow has built its business primarily in ophthalmology, where its eye injections intend to replace the need for eye drops, which can be burdensome to administer (ex: a patient with Parkinson’s).

We believe that management’s history is one to be aware of, as CEO and Director Mark Baum appears to have been a mattress salesman at his father’s store prior to his involvement in public equities. He holds a patent for a truck that sells mattresses, while appears to have been CEO of “BuglessBeds.com.” He graduated to the public equities business around the late 1990’s, when we find Baum listed in 1999 as a consultant to a stock promotion. Prior to Harrow, we have counted at least 7 companies where Baum was a listed executive, often as Chairman, CEO and/or CFO, which went effectively to zero.

We discovered a lawsuit filed against the Company that reveals that notorious fraudster Barry Honig provided a loan to one of the early backers of the Company, who pledged his shares to Honig. The Company also has ties to

paid promoters, which we believe explains, at least in part, the entirely unjustified 224% run in the stock over the past year despite numerous adverse regulatory developments.

The Company currently operates two pharmacies. The first is in New Jersey and is an outsourcing facility (disclosed 54% of 2018 revenues). The second also does business in New Jersey but is licensed and does business as ImprimisRx (author estimated 16% of 2018 revenues). The Company just sold its third facility for \$8.0 million, which previously did business as Park Compounding, Inc. (author estimated 31% of 2018 revenues, disclosed 9% of Q1 2019 revenues).

The remaining two New Jersey facilities were acquired for just \$1.0 million, yet the market now ascribes a \$140 million valuation to these assets (excluding investment stakes). We believe that the market not only misunderstands the true nature of Harrow's business – as that of a compounding pharmacy, not a pharmaceutical company – but also ignores numerous risks to its model. Chief among these is the market's understanding of the cause for the Park Compounding sale / "strategic alternatives process."

The strategic alternatives process is being framed by investors as the disposal of the slower-growing, non-core asset, which misses the bigger picture. In May 2019, the Company's California facility d/b/a Park Compounding, Inc. surrendered its license to the California Board of Pharmacy, whose complaint accused the Company on a remarkable 21 causes for discipline. On the Q1 2019 call, management described the situation as a "strategic alternatives process," which we believe has led many investors to mistakenly buy the stock on the misinformed expectation of a positive catalyst. On the contrary, we believe Park represented 31% of 2018 revenues (disclosed just 9% in Q1 2019) and was cash flow positive. On July 30, 2019, the Company [disclosed](#) via an 8-K that it sold Park to "Noice Rx, LLC" via an \$8.0 million seller's note. Noice Rx is owned by Robert Haywood, who also purchased the Company's Texas facility for \$10,000 in February 2017. In exploring potential explanations for why Haywood was behind both purchases, we were perplexed to find that his previous experience was entirely in the consumer products industry, while he seemed to hide his related involvement in pharmacies, of which it appears he now owns three. We also detail our findings with respect to related entities, which also have ties to "alternative medicine / therapy" providers, and believe it is highly puzzling that a former Mattel marketing executive has taken a sudden interest in purchasing Imprimis's pharmacies.

Note that the Park sale is also contingent upon temporary licenses being granted to the buyer which are not guaranteed, especially given the facility's ongoing issues. We believe this is a clear negative read-through to the value in the Company's remaining New Jersey facilities, which the market implies are worth \$140 million, even as they were only acquired for just \$1.0 million.

Investors ought to know that Park Compounding was acquired from Dennis Saadeh, who pled guilty and was convicted of two felonies and two misdemeanors. The felonies were for (1) Unlawful Possession of Hydrocodone, and (2) Possession of Methylphenidate, while the misdemeanors were for (1) Possession of Alprazolam, and (2) Driving While Under the Influence of Drugs. The crux of the complaint (elaborated below) recognized that Saadeh stole protected drugs from his own pharmacy and got into an auto accident while under the influence of those drugs. Saadeh's experience just prior to joining Harrow was as Founder of the "Integrative Therapies Institute" (ITI), which appears to offer training modules such as "NeuroMeditation" aimed at alternative medicine practitioners. Despite this history, Saadeh was not only brought onto the Company in January 2015 with the acquisition of Park, he was promoted to the C-suite as "Chief of Formulation Strategy" in June 2019.

In the same press release announcing Saadeh's promotion, the Company announced the appointment of Larry Dillaha as CMO. Dillaha was previously at Insys Therapeutics as CMO, Nutriband as CMO, and Repros Therapeutics as CEO and CMO. Insys filed for bankruptcy in June 2019 as its former executives now face jail time. Nutriband

generated no revenue in 2017 or 2018, and the SEC filed an administrative proceeding / cease and desist in December 2018 due to material misstatements. Repros once traded close to \$30 per share, but was acquired by Allergan for just \$0.67 per share. We might excuse Baum's prior public market history, Saadeh's felonies, or Dillaha's resume as one-offs, but all three of these executives in the C-Suite ought to be highly concerning to HROW investors.

We uncovered what we believe are undisclosed or misleading disclosures regarding the Company's relationship with previously mentioned Integrative Therapies Institute (ITI). The last time that we found ITI mentioned in the Company's filings, conference calls, or other public materials was Q2 2017, yet it appears that Harrow is still involved as of at least February 2019. We found that an ImprimisRx employee displayed promotional materials for an ITI conference on their LinkedIn profile as the creator of such materials, suggesting at the least that HROW continues to sponsor the conference. We question why Harrow employees are working on behalf of ITI, and believe investors deserve full disclosure regarding the nature of the relationship between the two entities, especially given that ITI appears to promote questionable medical practices.

While investors may argue that Harrow has "cleaned up" its operations through the sale of Park, we recognize that through 2017 and 2018, the Company transferred much of the Park business – which included adulterated drugs – from Park to its New Jersey facilities. We believe this opens the Company's New Jersey facilities up to liabilities that led Park to surrender its license. Notwithstanding this transferred business, the New Jersey facilities have operated similarly to Park in many ways which mirror the issues leading to the Park license surrender.

First, in July 2017, the Company's New Jersey Outsourcing Facility (NJOF) was issued a form 483 (which "notifies the Company's management of objectionable conditions"). The form contained 12 observations, such as deficient environmental monitoring, inadequate validation of the sterilization process, inadequate lab testing, and many more. Moreover, the form noted customer complaints of "the presence of black/grey particles" and "unknown particles" in their vials. While this form was issued almost two years ago, as of the most recent confirmation available (June 7, 2019), the [FDA indicates](#) that the issues are still open, meaning corrective action can still be taken. We believe – given the amount of time that has passed – that investors ought to expect it.

Second, in December 2017, the Company was issued a warning letter related to improper promotional materials for its entire ophthalmology portfolio, including false and misleading claims regarding safety and efficacy. Given that ophthalmology sales were 83% of 2018 revenues and 91% in Q1 2019, the risk is significant, should the FDA decide to act, which could mean "legal action without further notice, including, without limitation, seizure and injunction."

Third, the FDA issued a warning letter to the Company's NJ Compounding ("RxNJ") facility in September 2018, stating that the Company violated the FDCA due to compounding drug products using ingredients ineligible for compounding, as well as misbranded and adulterated drug products.

Outside of the NJ pharmacies' issues, we find that investors would be well-served with a better understanding of Harrow's actual business operations. First, Harrow is not a pharmaceutical company: it is merely a collection of low-quality pharmacy assets that sells ophthalmology products. These products are licensed from their respective owners, chiefly Novel Drug Solutions (NDS). The Company pivoted at least twice before reaching the current ophthalmology strategy, including bankrolling a failed phase 3 drug and selling urology products. In urology, the flagship product was URG101, which the Company was forced to stop selling after its licensor alleged unpaid commissions – a fact pattern eerily similar to the current situation, as the Company is now embroiled in a legal battle with NDS for its core Tri-Moxi product. We estimate that Tri-Moxi alone comprised 22% of the Company's

revenues, yet we believe investors have put little effort into understanding the potential implications of the lawsuit.

We also found evidence to suggest that the Company has grown its business in an aggressive manner, including through practices that we don't believe are sustainable.

These practices have already led [to the deaths](#) of a 30-year-old female and a 71-year-old male in March 2017 and May 2017. These patients were administered a curcumin emulsion product that was compounded by the Company. Jade Erick – the 30-year-old who died – merely had eczema, while Imprimis sold her Naturopathic Doctor (ND) the emulsion without a prescription. While investors may argue that these events are isolated and well in the Company's past, our checks of recent (issued April 2018 and May 2019) New Jersey Pharmacy Board inspection reports show that:

“Pharmacists do not perform drug utilization review upon receipt of a new or refill prescription ... there was also no documentation to indicate that the patient's complete medication profile was obtained. The pharmacists present in the dispensing area admitted that drug utilization review was not performed upon receipt of a new or refill prescription” and “Patient allergies are not recorded in the electronic patient profile record.”

Failure to maintain complete medication profile, including patient allergies, was a core reason for these 2017 patient deaths, yet the Company's failure to properly address these deficiencies years later ought to be significant cause for concern. With respect to the Company's more recent focus on ophthalmology products, June 2019 lawsuit alleges that Harrow's eye injections caused the patient, now plaintiff, to go blind, which isn't the first time that such allegations have been made. Additional concerns we have include the facts that:

In April 2017, [Harrow hired](#) “Precision Lens” as its exclusive distributor in the Midwest, covering 13 states. Just 8 months later, in February 2018 [the DOJ accused](#) Precision Lens of illegal kickbacks and bribing physicians for the sale of ophthalmology products.

Harrow's board includes Richard Lindstrom, who, per the proxy, is a practicing physician, owns 1.1% of shares, and [licenses his technology](#) to Harrow. At the same time, Lindstrom can be seen promoting the Company's products here in [November 2017](#), [June 2018](#), and [January 2019](#).

In May 2019, the Company [settled a TCPA lawsuit](#), wherein a doctor alleged that Imprimis / Harrow sent unsolicited faxes advertising its products.

Even in a best-case scenario in which management's 2021 goal of \$100 million in revenues is realized, the pharmacy assets are worth just \$2.31 per share. However, given (1) Park was sold, (2) the New Jersey facilities carry tremendous ongoing risks, and (3) the Company's flagship product remains embroiled in litigation, we believe this \$100 million target is a pipe dream. Thus, we believe intrinsic value of the pharmacy assets at a generous multiple of pro-forma revenue is just \$0.72 per share. After adjusting for the Company's net debt and investments (ETON and private stakes), shares are worth a total of just \$2.64, or 63% downside. Given that the Company continues to burn cash and is a serial equity issuer, having increased its share count at a 24% CAGR since 2013, each day that goes by lowers this intrinsic value.

In summary, Harrow Health trades at an order of magnitude greater than intrinsic value as Mark Baum, who we believe is a serial stock promotor, has convinced investors that the Harrow is a high-growth pharmaceutical company rather than a collection of low-quality pharmacy assets that are rife with safety, quality, and regulatory

issues. These issues have already led to regulatory intervention and sale of its California facility, while substantial risks remain in the Company's other two facilities and ophthalmology sales at large. As investors recognize the true cause for the Park sale, management's track record, and the risks in the Company's remaining business, we see the "high growth pharma company" narrative unraveling as shares reach intrinsic value of \$2.64 in short order.

Business and Management Overview

Harrow Health ("Harrow", "ImprimisRx", "HROW", "the Company") is in the business of pharmaceutical compounding. It conducts its business through ImprimisRx ("Imprimis") located in New Jersey. The Company changed its name from Imprimis Pharmaceuticals (IMMY) to Harrow Health (HROW) in December 2018. Harrow holds three pharmacies:

- (1) The New Jersey compounding facility ("RxNJ") operates under section 503A (i.e. licensed) and is the Company's primary compounding facility, focused on ophthalmology-based formulations. These are solutions for ocular surgery, glaucoma, and dry eye disease. The primary products here are LessDrops®, Simple Drops®, and Total Tears®. 503A facilities compound drugs as needed, on a "one-off" which are prescribed to specific patients by their doctors. These facilities are regulated only by the state pharmacy boards. Harrow's facility was acquired in February 2014 as [Pharmacy Creations LLC](#). Pharmacy Creations was run by Scott Karolchyk, MS, RPh, DNM, FIACP and Bernard Covalesky, MS, RPh., who are also responsible for much of the Company's ophthalmic IP, as will be discussed further on. The Company's Q1 2014 [Form 10-Q states](#) that the initial purchase price was just \$600,000, and subsequent filings indicate that contingent considerations took the total purchase price to \$1.0 million, per our calculations.
- (2) The New Jersey outsourcing facility ("NJOF") operates under Section 503B, meaning that it is permitted to compound large quantities of drugs prior to the receipt of prescriptions for such drugs, which it then distributes out of state. As such, the facility is subject to both state pharmacy boards and the FDA, which has more stringent requirements. Drugs that can be compounded are restricted to what the FDA has deemed to be a "clinical need" or those on a shortage list, while the facility must adhere to cGMP (current good manufacturing practices) and are subject to regular FDA inspection. NJOF's primary compounds are eye drops and eye injectables, [including](#) the "flagship Dropless Therapy injectable and LessDrops topical formulations."
- (3) Park Compounding, Inc. ("Park") was primarily focused on health and wellness-related compounding for sterile and non-sterile medications. Park also produced and dispensed ophthalmology-based formulations. Park is located in Irvine, California.

The Company also has stakes in [three deconsolidated companies](#): Eton Pharmaceuticals, Inc. (ETON), Surface Pharmaceuticals, Inc., and Melt Pharmaceuticals, Inc. Collectively, these stakes are worth \$56 million, per the Company's [most recent presentation](#) (note that ETON stock has also fallen since then, thus the true figure is ~\$50 million).

CEO Mark Baum is the Company's architect, and as such we believe investors ought to be aware of his history. We found that Baum has been involved in various stock promotions throughout the years. The Company's 2012 [Form S-1](#) originally referenced several of these, shown below:

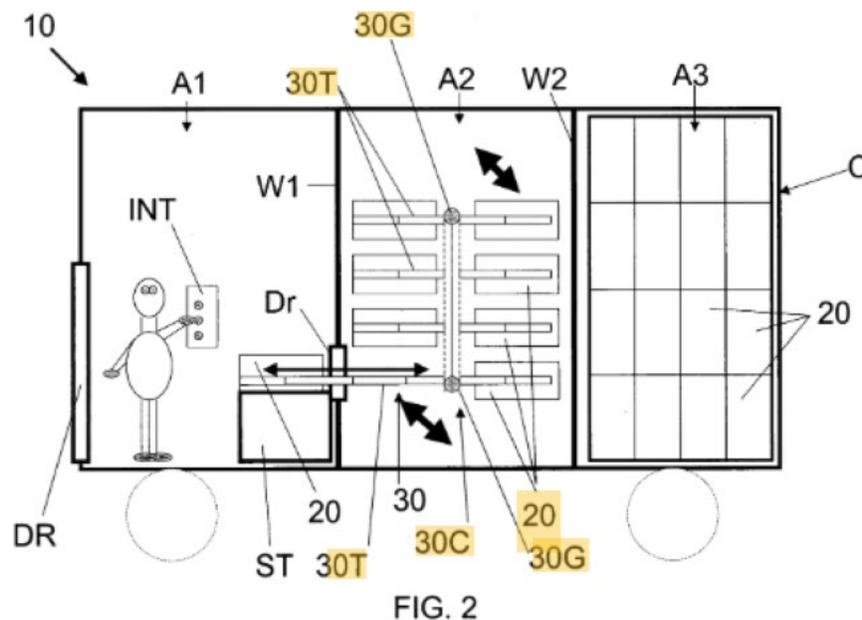
Mr. Baum has served on numerous boards of directors, including Chembio Diagnostic Systems, Inc. (CEMI.OB), Applied Natural Gas Fuels, Inc. (formerly AGAS.OB), Shrink Nanotechnologies, Inc. (INKN.PK),

You on Demand, Inc. (CBBDOB) and CoConnect, Inc. (CCONOB), as well as boards of advisors for domestic and international private and public companies.

We also found connections between Baum and companies such as [Kaire Holdings](#) Incorporated all the way back in 1999. Baum also [received shares](#) for consulting for eConnect in February and March 2002. Additional former company involvement includes Audiostocks Inc., YesRx, China Media Networks International, Inc. and PNG Venture Inc. (now Applied LNG). He was on the board of Ideal Power from November 2012 to December 2017, during which shares fell from a high of over \$11 per share to just \$1.60 at the time of resignation and \$0.34 today. Baum appears to remain involved in Curology, Inc. and BuglessBeds.com, Inc., the latter of which stems from his time selling mattresses in his father's store in Houston, which explains why one former employee [characterized](#) Baum as a "mattress discounter salesman reject." It also appears that in 2007, Baum registered a [patent](#) for "Home Furnishing and the Like Mobile Selling Systems and Methods" which in layman's terms means "selling mattresses out of a truck." Per Baum's press release issued at the time,

My patent and the execution of our related SleepTruck.com business model will create a revolution in the way in which mattresses are ultimately sold to consumers.

Baum's patent [filing](#) was generous enough to include a picture of the interior of the trucks:



BuglessBeds.com doesn't have a functioning website, but its [Facebook](#) page appears to be last updated in September 2018, and describes itself as:

Flight Attendants who decided after an outbreak of bedbugs in our Crew Hotel, [who] needed to create tools to help keep our fellow Flight Attendants from becoming a meal for bedbugs that may be lingering in our hotel beds.

As for the product:

This is a combination of Diatomaceous Earth and Essential Oils to kill bed bugs over time as they come in contact with the product. We suggest sprinkling the powder on the mattress under the sheets and at the headboard and legs or base of the bed at the carpet edge. This has a long-lasting effect and will kill any bugs that come in contact with it up to a week later or longer.

Bug Dead NOW! – come in a plastic spray bottle This is rubbing alcohol and an Essential Oil blend to kill any bugs you come in direct contact. Just spray the bug and he/she is toast. You can also spray the sheets at the corners and if there are any hiding, they will be killed on contact.

Most importantly, per our review of public filings, we believe that Mark Baum has acted as the “architect” or otherwise been heavily involved in at least 7 public entities that have effectively gone to zero. See the table below:

Ticker	Current Market Cap (millions)	Company Name	Role(s)
OTC:MSMT	\$0.0	Medical Solutions Management Inc.	CEO, CFO
OTC:CBBD	\$0.0	China Broadband, Inc.	CFO, President
OTC:QOIL	\$0.9	Luna Medical Technologies, Inc. (Quest Oil)	General Counsel
OTC:VTDI	\$0.0	VisiTrade Inc. (Blackbox SemiConductor Inc)	CEO, CFO, President, etc.
OTC:INKN	\$0.0	Shrink Nanotechnologies, Inc.	Founder, CEO, CAO, etc.
OTC:CCON	\$0.0	CoConnect Inc.	Chairman, CEO
OTC:ACCR	\$0.0	Access Power Inc	CEO, President, Director

Notably, the [current proxy statement](#) omits all references to these companies in favor of stating that,

Prior to Mr. Baum’s involvement with the Company, from 2001 to 2011, he was the founder and managing director of TBLF, LLC, a consulting firm and fund manager, where he managed a series of three funds and acted as a principal investor in financing publicly traded companies or bridge-to-public equity transactions. Before his fund management experience, Mr. Baum founded and served as the president of YesRx, and practiced as a U.S. securities lawyer focused on public company reporting requirements and finance-related matters.

As an additional note, Baum has commented both against [restrictions placed on shell companies](#) and for increased [short seller position reporting](#) while at Chembio Diagnostics, Inc. (CEMI), which [Baum also took public](#) with H.C. Wainwright through a reverse merger. Baum came to Harrow / Imprimis in 2011 and became CEO in April 2012.

We believe that investors also ought to be aware of the Company’s original ties to notorious fraudster Barry Honig through its reverse merger process. For the uninitiated, Honig has been tied to [numerous stock frauds](#), [market manipulation schemes](#), and SEC [investigations and allegations](#). While there are no mentions of him in Imprimis’s / Harrow’s SEC filings, we found that he played a role in the Company’s reverse merger, as Honig loaned greater-than-5% shareholder Michael Corwin capital, while Corwin pledged his shares as collateral. Details can [be found here](#), as Corwin’s widow, Merlyn Corwin, filed suit against the Company for then “plotting to restrict Merlyn’s sales of Imprimis stock and to acquire her stock at below-market prices.”

In February 2013, [the Company uplisted](#) to NASDAQ, while “continu[ing] to be focused on pursuing the Impracor clinical development program and monetizing its portfolio of PCCA development assets.” Impracor was a cream

(Ketoprofen 10%) to treat acute pain. However, these assets didn't pan out as expected, and in November 2013, [Imprimis shifted focus](#) from Impracor, deciding to instead "develop and commercialize its proprietary formulations in the ophthalmic, wound management, urology and pain therapeutic areas utilizing multiple commercialization pathways ..."

This strategic shift began with urology. In October 2014, the Company licensed certain patents and applications for Urigen's URG101 product, "a heparin and alkalinized lidocaine compounded formulation for the prevention or treatment of disorders of the lower urinary tract." However, Urigen sued for breach of contract asserting unpaid royalties. Per the Company's disclosures,

In June 2016, the Company received notice from Urigen of their election to terminate the Urigen License. In November 2016, the Company and Urigen entered into a settlement and mutual release agreement whereby all parties agreed to settle all disputes related to the Urigen License and associated litigation matters, the Company agreed to make a one-time payment to Urigen related to past sales of Urigen's URG101 product and to cease selling the URG101 product over a certain period of time.

The Company's ceasing its URG101 sales is especially pertinent, as its ophthalmology IP is now embroiled in litigation for very similar reasons, which we will discuss below.

June 2019: Appointments of Larry Dillaha and Dennis Saadeh Ought to Give Pause

In June 2019, the Company announced that Larry Dillaha and Dennis Saadeh would both be joining the C-Suite in the Company's new Nashville headquarters. While investors may view these appointments as signs of growth, we see them as highly concerning.

Dennis Saadeh: Convicted Felon is now Chief of Formulation Strategy

Harrow [acquired South Coast Specialty Compounding](#), Inc., DBA Park Compounding (Park) in January 2015 for \$3.0 million. Park's original State of California [filings](#) indicate that Dennis Saadeh formed the company.

ARTICLE FOUR: The name of the corporation's initial agent for service of process is Dennis Saadeh, who may be served at: 250 East Yale Loop, Irvine, Calif. 92604-4697.

Source: Articles of Incorporation

The Company's June 2019 press release indicates that "Dr. Saadeh, who is a 30-year veteran of pharmaceutical development, has worked with Harrow since January of 2015 ..." indicating that Saadeh joined the Company upon Park's acquisition. Per his [LinkedIn profile](#), Saadeh also founded the "Integrative Therapies Institute" prior to joining the Company.

**Dennis Saadeh**

VP Product Strategy at Imprimis Pharmaceuticals, Inc.

**Founder****Integrative Therapies Institute**

Mar 2012 – Dec 2014 · 2 yrs 10 mos

Irvine, CA

During his tenure at Park Compounding, Dr. Saadeh identified the need to better educate his fellow healthcare professionals, and in 2012 he founded Integrative Therapies Institute (ITI) as the educational arm of his company. Since then, ITI has grown significantly, bringing together a multitude of highly specialized lecturers covering numerous medical conditions at annual conferences, and this has now expanded to several regionalized conferences across the nation.

[See less](#)

ITI_Logo-002-300x203

Source: LinkedIn

The Integrative Therapies Institute [website](#) indicates that it offers a \$375, 20-hour program that includes instruction on “a group of diverse medical, healing and health care systems, practices, and products that are not presently considered a part of conventional therapy or medicine.” [YouTube videos](#) indicate that these modules include topics such as “NeuroMeditation.” We also found marketing materials via LinkedIn for the Integrative Therapies Institute conferences, shown below.

Interestingly, we found these materials were not listed under an employee of “Integrative Therapies Institute” but of ImprimisRx. The employee’s listed occupation is “Creative Marketing Associate” at ImprimisRx (an HROW subsidiary):



ImprimisRx

Graphic Designer

Greater San Diego Area · 36 connections · [Contact info](#)

About

I have BA in Graphic Design. I currently work as a Creative Marketing Associate at Imprimis Rx.



Experience



Creative Marketing Associate

ImprimisRx

Dec 2018 – Present · 8 mos

San Diego



Source: LinkedIn



WWW.events.syncopatemeetings.com/cit

Topics include: Feb 8-9, 2019

- ▶ Estrogen Dominance Phenomenon
- ▶ Stemcells: Educate Yourself On True Applications
- ▶ Testosterone therapy controversy: an update on the evidence
- ▶ Low Dose Immunotherapy As A Novel Therapy in Modulating Immune Function
- ▶ Menopause Management with HRT: Benefits vs Risk
- ▶ Controversies in Women's Health
- ▶ Controversies in Lyme Disease
- ▶ Seeds, Soil and Solar - Mold, Mitochondria, and Melatonin

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Guest Speakers include:

 Brenden Cochran, ND	 Ron Hunninghake, MD	 Tori Hudson, ND	 Darin Ingels, ND
 Sunny Raleigh, DO	 Melinda Silva, MD	 Michael Traub, ND, FABNO	



Source: LinkedIn

Note the topics include “estrogen dominance phenomenon, stem cells, testosterone therapy, immunotherapy,” and more. The first listed speaker for the February 2019 conference states expertise in “intravenous therapies” in addition to a slew of questionable medical practices.

SPEAKERS



Brenden Cochran, ND

Dr. Cochran strives for innovation and success in clients. He has a passion for education, guidance and outside the box thoughts to create and engage clients to reach peak performance. Dr. Cochran received his Doctorate in Naturopathic Medicine from Bastyr University. He founded Interactive Health Clinic, with specialty focuses in functional/biological medicine, regenerative medicine, integrative oncology, and healthy aging. He is an expert in his field on regenerative injections and intravenous therapies. He has served as the medical fellow/director of intravenous therapy at the Bastyr Integrative Oncology Research Center (BIORC), Bastyr University's cancer research center. Dr. Cochran is well known worldwide as a lecturer with International IV Therapy for Professionals a group that specializes in educating physicians on intravenous nutrient therapy. He is also a lead instructor of Regenerative Therapies (Neural Therapy, Neural Prolotherapy (Perineural Injections), Ozone injections, PRP, and Biological Allograft). He has an active consulting business with inFORMS and H.E.R.O.E.S where he coaches physicians and professionals. As a keynote speaker and content creator. Dr. Cochran is dedicated to empowering doctors to build

In our review of the Company's public filings, we found only 3 mentions of the Integrative Therapies Institute. The first is in the Company's year-end 2016 form 10-K. The second is in the Company's [Q1 2017 Form 10-Q](#), where the language is the same as the previous 10-K and stated:

We sponsor the Integrative Therapies Institute (ITI) conferences that cover a multitude of integrative topics and feature speakers considered thought leaders in their respective fields.

However, the Company's [Q2 2017 Form 10-Q](#) stated that,

In the past, we have sponsored the Integrative Therapies Institute (ITI) conferences that cover a multitude of integrative topics and feature speakers considered thought leaders in their respective fields.

This is [the last time](#) that the Integrative Therapies Institute is mentioned in any of the Company's public filings, yet as noted in the promotional materials above, the Company appears to still have employees working on materials for the February 2019 conference. It remains unclear to us the exact nature of the relationship between ITI and Harrow, but we believe that investors deserve improved disclosures on this topic.

What is altogether more concerning is the fact that Saadeh pled guilty on two felony charges and was publicly reproved (i.e. admitted guilt) as recently as May 2015 – well after he was with the Company. The 2015 reproval was due to errors in formulas which led to recalls of various products.

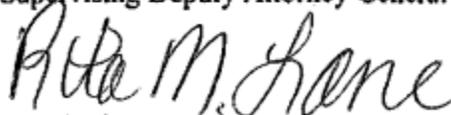
ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: 5-28-15

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
GREGORY J. SALUTE
Supervising Deputy Attorney General


RITA M. LANE
Deputy Attorney General
Attorneys for Complainant

Re: LETTER OF PUBLIC REPROVAL

In the Matter of the Accusation Against: Park Compounding; Dennis Elias Saadeh; and Tina Marie Sulic Saadeh

Pharmacy License No. PHY 41748, Sterile Compounding License No. LSC 99026, and Pharmacist License No. RPH 41232

Dear Mr. and Ms. Saadeh:

On or about May 20, 2015, the Board of Pharmacy, Department of Consumer Affairs, State of California, filed a First Amended Accusation against South Coast Specialty Compounding Corporation, dba Park Compounding, with Dennis Elias Saadeh, President and Tina Marie Sulic Saadeh as Secretary and Treasurer (Respondent Park Compounding). The First Amended Accusation was also filed against Pharmacist Tina Marie Sulic Saadeh. The First Amended Accusation alleged that you engaged in unprofessional conduct for variation from prescription under Business and Professions Code section 4301(o). On August 2, 2013, you violated regulations regarding pharmacy law when you deviated from the requirements of a prescription when an error was made entering data into Park Pharmacy's computer that resulted in an incorrect salt conversion into the master formula for Multitrace-4 concentrate and Multitrace-5 concentrate.

You admit that the charges and allegations in First Amended Accusation No. 5055, if proven at a hearing, constitute cause for imposing discipline upon your Original Pharmacy Permit No. PHY 41748 and your Sterile Compounding License No. LSC 99026. It also would constitute cause to impose discipline upon Ms. Saadeh's Original Pharmacist License Number RPH 41234. The Board has decided that the charges warrant a public reproof.

Accordingly, in resolution of this matter under the authority provided under Business and Professions Code section 495, the Board of Pharmacy, Department of Consumer Affairs issues this letter of public reproof.

Source: [California Pharmacy Board Enforcement Actions](#)

In December 2017, the board filed complaint against Saadeh with a remarkable 16 causes for discipline. The crux of these causes lies in the fact that Saadeh: (1) Stole controlled substances from the pharmacy while he was pharmacist-in-charge, and (2) consumed these substances without a prescription.

25

FACTS

26

29. Complainant is informed and believes, and thereon alleges, that,

27

Respondent Saadeh, while the pharmacist-in-charge (PIC) and owner of Park Pharmacy, illegally

28

took controlled substances and dangerous drugs from Park Pharmacy from the time period of

7

1

2003 through 2005. On or about October 13, 2005, an inspector for the Board inspected Park

2

Pharmacy and confirmed that Respondent Saadeh was missing controlled substances and

3

dangerous drugs from his inventory. Respondent Saadeh had not completed a DEA 106 form

4

and did not know the exact quantity of the medications that he had taken from Park Pharmacy for

5

his own personal use. During the inspection, the inspector found the following controlled

6

substances and dangerous drugs had been diverted or there was a discrepancy in the inventory

7

amount by Respondent Saadeh from Park Pharmacy during the time period of 2003 through

8

2005:

9

Drug**Amount**

10

Hydrocodone

Loss of 651 tablets

11

Alprazolam

Showed discrepancy of an excess of 1698 tablets

12

Methylphenidate

Showed discrepancy of an excess of 149 tablets

13

To date, Respondent Saadeh has not filed any loss report with the Board, Federal Drug

14

Enforcement or Department of Justice as required by law.

Source: [California Enforcement Actions](#)

Moreover, Saadeh drove under the influence of these substances, leading to an auto accident wherein both airbags were deployed. Various drugs were found in his vehicle and opiates were found in his system. He pled guilty on 2 felony counts and 2 misdemeanors.

15 30. On or about May 12, 2004, while Respondent Saadeh was the owner and
16 PIC at Park Pharmacy, Respondent Saadeh was involved in a single car accident wherein his
17 vehicle hit the center divide and his car sustained major front-end damage and both airbags were
18 deployed. Respondent Saadeh told the responding officer that he was sleepy and had taken
19 Vicodin, Valium and Elavil. Respondent Saadeh told the officer that he did not have
20 prescriptions for the drugs. Respondent Saadeh failed a field sobriety test and was arrested for
21 being under the influence of drugs. A search of Respondent Saadeh's car revealed 3.56 grams of
22 Methylphenidate, two tablets of Alprazolam and 2 capsules of Hydrocodone. Respondent
23 Saadeh's subsequent drug screen revealed the presence of opiates in Respondent Saadeh's
24 system.

25 31. On or about September 17, 2004, in the Superior Court of California,
26 County of Orange, in a case entitled *People v. Dennis Saadeh*, Case No. 04HF0870, Respondent
27 Saadeh was convicted on his plea of guilty of violating Health and Safety Code section 11350(a)
28 (Unlawful Possession of Hydrocodone), a felony; Health and Safety Code section 11377(a)

8

1 (Possession of Methylphenidate), a felony; Health and Safety Code section 11375(b)(2)
2 (Possession of Alprazolam), a misdemeanor; and Vehicle Code section 23152(a) (Driving While
3 Under the Influence of Drugs), a misdemeanor. Respondent Saadeh was sentenced as follows:
4 a. Respondent Saadeh was placed on three years formal probation on the
5 terms and conditions that he serve 90 days in the Orange County Jail with credit for time served
6 of 2 days; his 90 days jail to be served as 90 days in a residential drug program; he attend and
7 complete a 3 month Level 1 First Offender Alcohol Program; pay a fine of \$390; pay a restitution
8 fee of \$200; pay a \$50 controlled substance lab fee; pay a \$50 Alcohol abuse education fee; pay a
9 \$37 DUI Lab/Blood Alcohol fee; pay a \$20 Security fee; register pursuant to Health and Safety
10 Code section 11590; use no unauthorized drugs; and submit to drug testing.

Source: [California Enforcement Actions](#)

In June 2019, Harrow [announced](#) that it promoted Saadeh to its Chief of Formulation Strategy, stating that “He will be responsible for Harrow’s existing portfolio of drug candidate formulations and will continue to develop additional drug candidates for its portfolio of businesses.” We question what Saadeh did to deserve this role, let alone any role at the Company, but believe his connections to the “alternative medicine” community may be explanatory.

Larry Dillaha Adds an Additional Concerning Track Record

In the same press release announcing Saadeh’s promotion, the Company also [announced](#) that Larry Dillaha joined as Chief Medical Officer (CMO). Dillaha was formerly the CMO at Insys Therapeutics since April 2010, which filed for bankruptcy in June 2019 after being sued for various fraud charges, chiefly the illegal marketing of its opioid painkillers and defrauding of government healthcare programs. Executives were found guilty by a Boston jury, and racketeering charges carry up to 20 years in prison. Executives included Founder and CEO John Kapoor, Richard Simon (National Director of Sales), Sunrise Lee (Regional Sales Director), Joseph Rowan (Regional Sales Director), and Michael Gurry (VP of Managed Markets).

Dillaha then [joined](#) Nutriband (NTRB) as Chief Medical Officer in August 2018. NTRB generated no revenue in 2017 or 2018, but purports to develop and sell “transdermal patches that provide nutritional supplements.” In December 2018, the SEC [filed](#) an administrative proceeding / cease and desist to Nutriband due to material misstatements. NTRB has a \$39 million market cap and trades \$1,073 per day.

Dillaha was also formerly CMO, [then CEO](#) of Repros Therapeutics (RPRX). Repros “focuses on the development of small molecule drugs for major unmet medical needs that treat male and female reproductive disorders.” Repros was eventually [acquired](#) by Allergan for just \$0.67 per share.



Source: Barchart.com

In summary, we believe investors ought to be highly concerned that Harrow’s C-Suite is now occupied by this trio which has been responsible for so much prior value destruction.

Park Compounding: One Man's License Surrender and Forced Sale is Another Man's Strategic Alternatives Process

In May 2019, the California Pharmacy Board filed a [complaint](#) against the Company on a stunning 21 causes for discipline. We strongly recommend that Harrow Health investors read the complaint in full.

These causes for discipline include: manufacture and sale of adulterated drugs, compounding adulterated drugs, sale of misbranded drugs, compounding misbranded drugs, dispensing prescriptions with errors, failing to support assigned beyond use dates, gross negligence, failing to maintain records, transferring dangerous drugs to unlicensed entity, subverting a board investigation, failing to report adverse events, false public statements and advertising, failing to complete non-sterile to sterile end product testing, failing to correctly label, and failing to document process and procedures.

Though the Company does not explicitly disclose every revenue stream, we back into the following revenue streams of each of the Company's three facilities for the past two years given publicly available data. We assume a 50/50 split of Park ophthalmology sales and New Jersey compounding sales for simplicity. Per this methodology, the Park facility constituted 31% of 2018 revenues. However, even were Park to have sold no ophthalmology products, it would still have constituted 17% of 2018 revenues. These figures are important, since Park voluntarily surrendered its pharmacy license.

Revenue Breakdown	2017	2018	Source
New Jersey outsourcing	9.4	22.5	<i>publicly disclosed</i>
New Jersey compounding	4.9	5.8	<i>author assumptions</i>
All other sales (Park Health & Wellness)	7.5	7.2	<i>publicly disclosed</i>
Park ophthalmology sales	4.9	5.8	<i>author assumptions</i>
Sales, net	26.7	41.3	<i>publicly disclosed</i>
Park total sales	12.4	13.0	
Park as % of sales, net	47%	31%	

Notably, a read of the California Pharmacy Board complaint indicates that the California facility (i.e. Park) is not alone in its liability. First, the complaint consistently refers to Park as “ImprimisRx” rather than “Park.” While minor, the Board clearly has its eyes on the entire Company. Moreover, the compounds in question were not only sold out of California, but were transferred to the Company’s New Jersey facilities.

9 **FACTUAL ALLEGATIONS**

10 37. From January 23, 2017 through May 29, 2017, Mariam ElGawly was the Pharmacist-
11 in-Charge of ImprimisRx (collectively Respondents). From July 24, 2017 through December 5,
12 2017, Ronak Amit Desai was the Pharmacist-in-Charge of ImprimisRx. From December 6, 2017
13 to the present, Nadia Mohamed Elsayed Ibrahim was the Pharmacist-in-Charge of ImprimisRx.
14 ImprimisRx compounded and dispensed sterile injectable drug preparations and other human drug
15 products. ImprimisRx is not registered as a “503A outsourcer” with the Federal Drug
16 Administration (FDA) nor does it hold a valid license with the California State Department of
17 Public Health.

18 38. ImprimisRx possessed written policies and procedures for recalling a dispensed
19 compounded drug preparation where subsequent information demonstrated the potential for
20 adverse effects with continued use. Specifically, ImprimisRx’s policies and procedures entitled
21 “Handling Products Recalls” stated that a recall will be initiated if “a determination subsequent to
22 the dispensing of a prescription that the medication may not have met specifications for
23 preparation, content, sterility and/or quality or may present a risk to patients.”

24 39. On January 16, 2017, Respondents transferred dangerous drugs to a facility which
25 was not licensed by the Board and located in New Jersey.

26 **Compounding and Dispensing Human Drug Products made with Curcumin.**

27 40. From January 13, 2017 through June 15, 2017, Respondents compounded a sterile
28 injectable drug preparation, curcumin emulsion. Respondents compounded that drug preparation

By transferring drugs to New Jersey, the Company mitigated its California / Park exposure, hence explaining, at least partially, why revenues in the New Jersey outsourcing facility grew so rapidly vs. the rest of the Company from 2017 to 2018. Further, in March 2017, a 30-year-old patient died due to anaphylactic shock after being treated with "higher than allowable levels of DEG."

22 44. On February 8, 2017, Respondents dispensed curcumin emulsion to the wife of a
23 naturopathic physician, K.K.

24 45. On March 10, 2017, Dr. K.K. administered that curcumin emulsion compounded by
25 Respondents to a 30-year old patient, J.E., via an infusion for the treatment of a skin disorder.

26 Patient J.E., had an anaphylactic reaction, was taken to the emergency room of a hospital and
27 subsequently died.
28

15

FIRST AMENDED ACCUSATION

1 46. The vial of curcumin emulsion compounded by ImprimisRx and administered to
2 patient J.E., and the lots from which that vial was derived, contained higher than allowable levels
3 (i.e., greater than 0.1%) of DEG.

4 47. On March 16, 2017, Respondents dispensed curcumin emulsion to a naturopathic
5 nurse practitioner, S.G.

6 48. On March 17, 2017, ImprimisRx reported J.E.'s adverse effects to the curcumin
7 emulsion to the Board even though it learned of those adverse effects on March 13, 2017.
8 ImprimisRx did not voluntarily recall its curcumin emulsion within expiry nor suspend the
9 compounding of curcumin emulsion.

From there, the FDA was on the Company's tail for the next several months, issuing deficiency forms in March 2017 and noting numerous adverse events and product quality complaints in Q1 2017. Thus, the Company again transferred drugs from California to its unlicensed facility in New Jersey.

- 1 51. On March 31, 2017, the FDA issued another Form FDA 483 to ImprimisRx,
2 observing, among other things, that ImprimisRx's "aseptic processing areas [were] deficient
3 regarding air supply that is filtered through high-efficiency particulate air filters under positive
4 pressure" and that ImprimisRx had 69 Quality Related Events (QRE), including ADEs [adverse
5 drug events] and product quality complaints" in 2016 and the first quarter of 2017.
- 6 52. On April 10-12, 2017, Respondents transferred dangerous drugs to a facility which
7 was not licensed by the Board and located in New Jersey.
- 8 53. On or about May 4, 2017, Nurse Practitioner S.G. administered curcumin emulsion
9 compounded by Respondents to a patient, W.K. who was subsequently admitted to an emergency
10 room of a hospital with an anaphylactic reaction.
- 11 54. On May 8, 2017, ImprimisRx reported W.K.'s adverse effects to the curcumin
12 emulsion to the Board even though it learned of W.K.'s adverse effects on May 4, 2017.
13 ImprimisRx did not voluntarily recall its curcumin emulsion within expiry or suspend the
14 compounding or dispensing of curcumin emulsion.

We estimate that 47% of the business was Park in 2017 at \$12.4 million in revenues, yet this grew to just \$13.0 million in revenues in 2018, while New Jersey outsourcing grew from \$9.4 million to \$22.5 million in revenues.

In May 2017, another patient went into anaphylactic shock due to the curcumin emulsion compounded by ImprimisRx. Again, the Company failed to voluntarily recall the emulsion or suspend the compounding. In fact, the Company incorrectly denied responsibility for the events.

15 60. On August 7, 2017, ImprimisRx denied responsibility for improperly compounding
16 the unsafe curcumin emulsion, issuing a press release in which it blamed the victim, physician
17 and supplier for the events at issue and contending that its compounding and dispensing of
18 curcumin emulsion were in compliance with all applicable laws.

19 61. On August 22, 2017, and in response to the Board's inquiry, ImprimisRx represented
20 that preliminary results showed that DEG levels in the curcumin emulsion compounded by it
21 were at or below required amounts even though the FDA informed them on June 1, 2017, that the
22 FDA had preliminarily tested ImprimisRx's curcumin emulsion and determined that the DEG
23 levels in the excipient, PEG 40 castor oil (No. P2404) were actually above the allowable 0.1%
24 limit.

25 62. Despite receiving five requests from the Board, ImprimisRx failed to produce all
26 records requested by the Board, including prescriptions. ImprimisRx's dispensing records were
27 incomplete including prescriptions which did not list the pharmacist who dispensed curcumin
28 emulsion.

In a less than two-year period and through at least August 2018, the Company continued to illegally compound over 50,000 vials of medication.

1 **Compounding and Dispensing Human Drug Products made with Artesunate.**

2 63. From November 26, 2016 to August 22, 2018, ImprimisRx compounded at least
3 50,475 vials of human drug products with the bulk drug substance, artesunate, in the form of
4 lyophilized powder, 60mg injectable and other forms, including capsules and suppositories.

5 ImprimisRx then dispensed and sold at least 4,194 orders (1 to 123 vials per order) of human drug
6 products made with the bulk drug substance, artesunate to patients, including those diagnosed
7 with cancer.

8 64. When it compounded the human drug products described in paragraph 63,
9 ImprimisRx did not comply with the requirements of sections 501(a)(2)(b), 502(f)(1) and 505 of
10 the Federal Food, Drug and Cosmetic Act (21 U.S.C. §353a) (Act). Namely, it did not receive
11 approval for these human drug products from the FDA under new or abbreviated new drug
12 applications, label these human drug products with adequate directions for use or follow current
13 good manufacturing practices when compounding these human drug products.

Notwithstanding the California Pharmacy Board's involvement, the FDA also sent warning letters to the California facility in [March 2017](#) and [March 2019](#). The former letter noted that,

During the FDA inspection, the investigators observed that your firm does not receive valid prescriptions for individually-identified patients for a portion of the drug products you produce. Accordingly, the drugs you compound without valid prescriptions for individually identified patients do not qualify for the exemptions in section 503A of the FDCA.

There were also adulterated drug products.

FDA investigators observed that drug products in your facility that were intended or expected to be sterile were prepared, packed, or held under insanitary conditions, whereby they may have become contaminated with filth or may have been rendered injurious to health, causing the drug products to be adulterated under section 501(a)(2)(A) of the FDCA.

In the latter letter, the FDA recognized that the Company (1) sold adulterated drug products, (2) marketed unapproved new drug products, and (3) misbranded drug products by both (a) labeling "so that a layman can use these products" which is "not amenable to self-diagnosis and treatment" and by (b) failing to include "material facts regarding the potential for serious adverse reactions."

The California Pharmacy Board ultimately acted. Per April and May 2019 [enforcement](#) actions,

Park Compounding Inc., LSC 100771, Administrative Case AC 6271
Irvine, CA

Through a disciplinary action of the Board, the license is voluntarily surrendered. The effective date shall be stayed until August 27, 2019, at which time the pharmacy shall be sold or closed.
Decision effective 05/29/2019.

The Company characterized the situation in its Q1 2019 conference call as such (author emphasis):

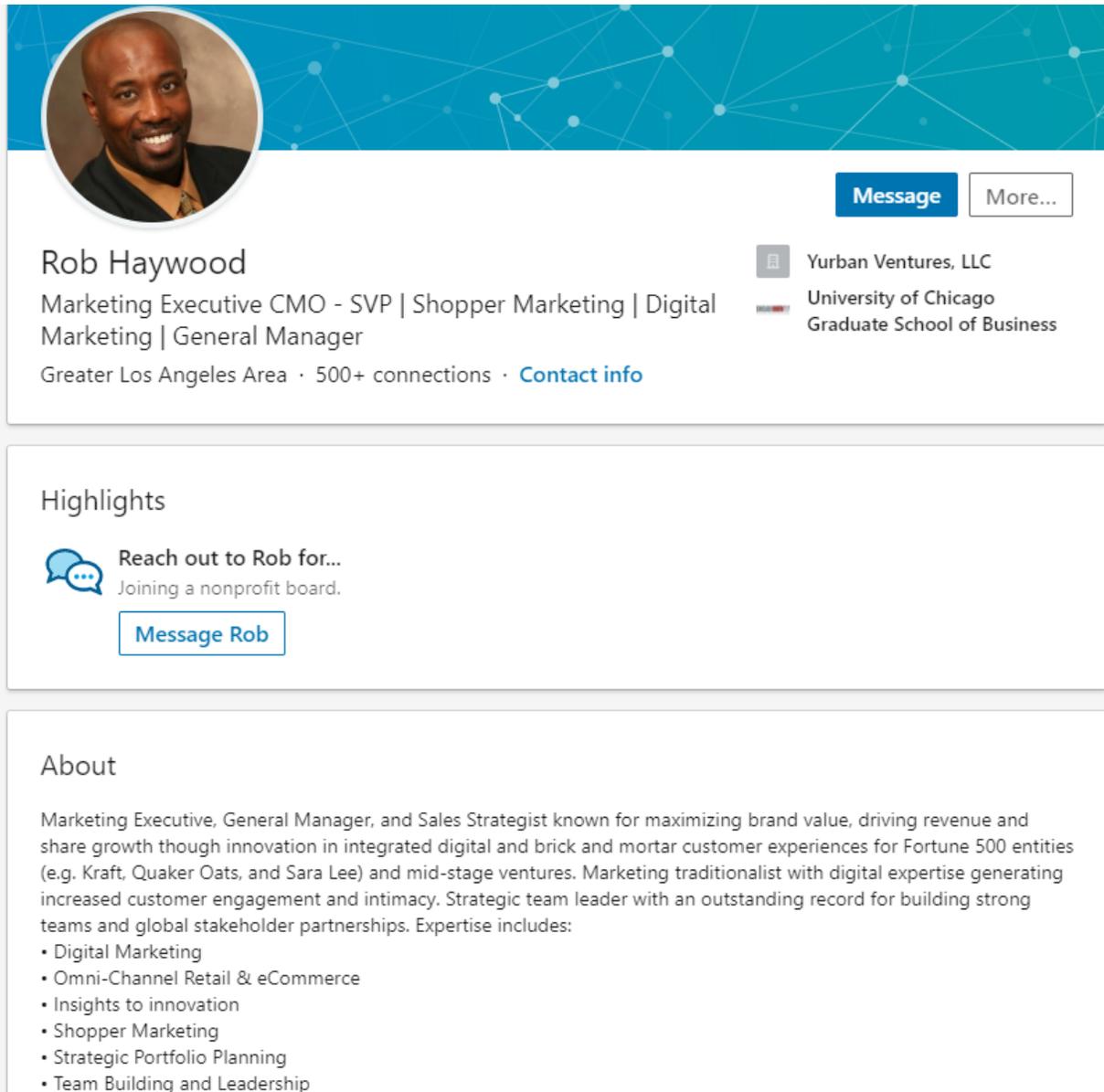
We're also making progress reducing temporary costs associated with legal matters including **recently reaching an agreement with the California Board of Pharmacy to resolve a long running matter** against our Park compounding subsidiary. We are pleased that the matter and the costs related to it are now behind us and we **can now enter a process to consider strategic alternatives related to our Park business.**

We'd hardly consider the license surrender and resulting forced closure or sale of an entire business segment to be a traditional "strategic alternatives" process, but to each his own. On July 26, 2019, this process concluded with the sale of Park for \$8.0 million via a seller's note. The Company's [form 8-K](#) on the matter named the buyer as Noice Rx, LLC. [Texas public records](#) show that Robert Haywood is the registered agent of Noice, with a street address listed at 1105 Central Expressway N, Allen, TX 75013:

View Details	Name
 Details	NOICE RX LLC

NOICE RX LLC	
Texas Taxpayer Number	32068192288
Mailing Address	1105 CENTRAL EXPY N STE 2110 ALLEN, TX 75013-6122
 Right to Transact Business in Texas	ACTIVE
State of Formation	TX
Effective SOS Registration Date	08/27/2018
Texas SOS File Number	0803102018
Registered Agent Name	ROBERT HAYWOOD
Registered Office Street Address	1105 CENTRAL EXPWY N, SUITE 2110 ALLEN, TX 75013

Interestingly, Haywood was the buyer on Harrow's Texas facility as well; this 1105 address is the original Imprimis TX address. Imprimis registered the Texas facility as an outsourcing facility [in April 2016](#). However, the Company then decided to take this business to New Jersey, so its Texas facility [was sold](#) in February 2017 for just \$10,000. The Company took a \$303,000 write-down. The buyer was Livernois & London, LLC, which lists Robert Haywood as its registered agent. We found the Robert Haywood in question, whose [LinkedIn](#) is below:



The image shows a LinkedIn profile for Rob Haywood. At the top left is a circular profile picture of a man with a beard and short hair, wearing a dark suit and a patterned tie. To the right of the picture are two buttons: a blue 'Message' button and a white 'More...' button with a grey border. Below the picture, the name 'Rob Haywood' is displayed in a large, bold font. Underneath the name is his title: 'Marketing Executive CMO - SVP | Shopper Marketing | Digital Marketing | General Manager'. To the right of the title are two icons: a grey building icon for 'Yurban Ventures, LLC' and a red and white flag icon for 'University of Chicago Graduate School of Business'. Below the title and icons, it says 'Greater Los Angeles Area · 500+ connections · [Contact info](#)'. Below this is a 'Highlights' section with a blue speech bubble icon and the text 'Reach out to Rob for...' followed by 'Joining a nonprofit board.' and a blue 'Message Rob' button. At the bottom is an 'About' section with a paragraph of text and a bulleted list of skills.

Rob Haywood
Marketing Executive CMO - SVP | Shopper Marketing | Digital Marketing | General Manager
Greater Los Angeles Area · 500+ connections · [Contact info](#)

Yurban Ventures, LLC
University of Chicago Graduate School of Business

Highlights

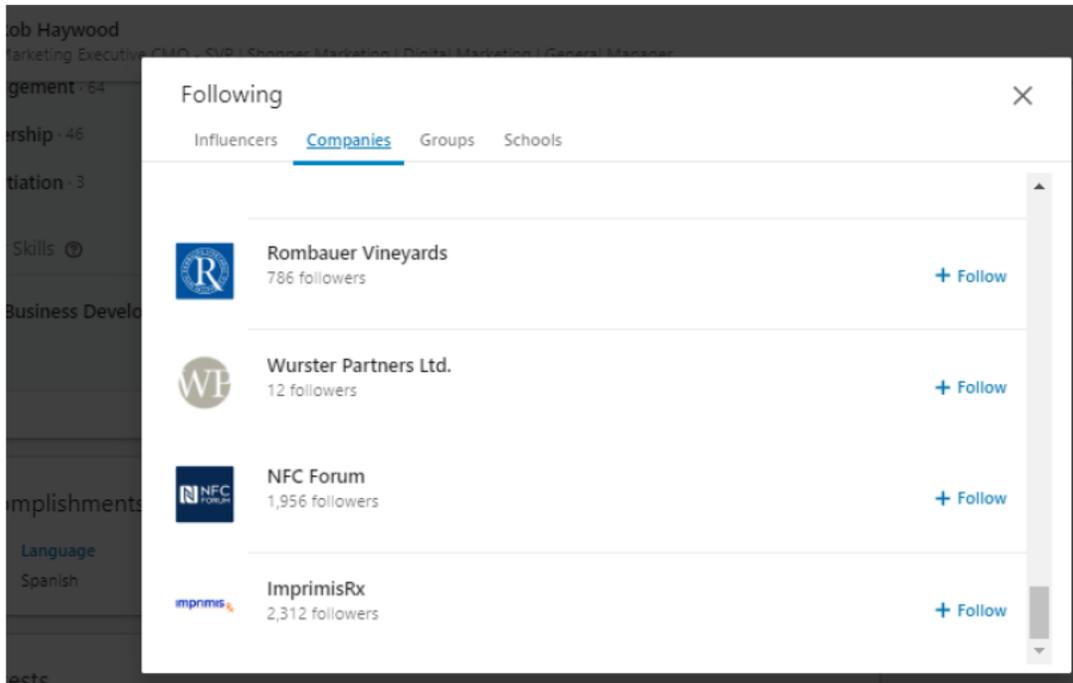
 **Reach out to Rob for...**
Joining a nonprofit board.
[Message Rob](#)

About

Marketing Executive, General Manager, and Sales Strategist known for maximizing brand value, driving revenue and share growth through innovation in integrated digital and brick and mortar customer experiences for Fortune 500 entities (e.g. Kraft, Quaker Oats, and Sara Lee) and mid-stage ventures. Marketing traditionalist with digital expertise generating increased customer engagement and intimacy. Strategic team leader with an outstanding record for building strong teams and global stakeholder partnerships. Expertise includes:

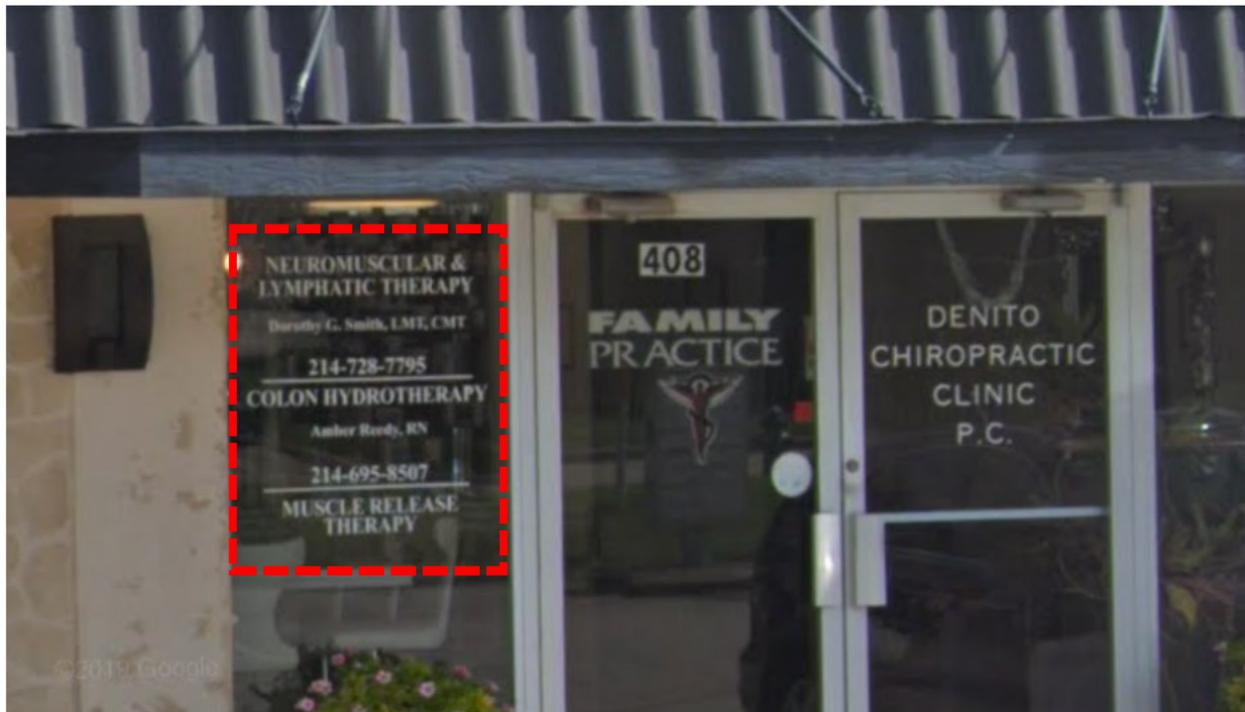
- Digital Marketing
- Omni-Channel Retail & eCommerce
- Insights to innovation
- Shopper Marketing
- Strategic Portfolio Planning
- Team Building and Leadership

As shown, there is no evidence that Haywood is even involved in the pharmacy business. The only piece of evidence we found to confirm was that Haywood followed ImprimisRx on LinkedIn.



Imprimis’s Texas facility became Livernois Rx, located at 1105 Central Expwy N, Suite 2110, Allen, TX. At this location, we found an Arizona Pharmacy Board [document](#) that listed Julio Amorin as the Pharmacist in Charge (PIC). However, on Mr. Amorin’s LinkedIn, we found no mention of Livernois Rx, only that he is a “Pharmacy Business Consultant” at “Excel Rx Consulting.” Excel’s listed provider practice location is at 408 N Allen Dr, Allen, TX. Google [street view](#) directs us to a small office plaza which shows it offers services including “SlimGENERation Weight Loss Management”, “Neuromuscular & Lymphatic Therapy”, “Colon Hydrotherapy”, and “Muscle Release Therapy.”





Julio Amorin also runs a business called Pharmex Trading Company, LLC, which also does business as RxPro Medical Supply – a medical supply distributor. The listed address is 1105 Central Expwy N, Suite 228, Allen TX, which is the same building as Livernois Rx (Harrow’s former Texas facility).

We find many aspects of this information to be highly perplexing, including Haywood’s involvement in the pharmacy business at all, given his career in consumer products, the recurring presence of alternative therapy providers, even as Harrow sells two of its facilities to a seemingly unrelated party, and the multiple business interests of each of the officers and pharmacists at these pharmacies.

Notwithstanding the issues related to Park, what is altogether more concerning for Harrow’s remaining business is the historical fact pattern leading up to the closure of the California facility that is now remarkably similar to what we observe in the Company’s New Jersey facilities, as we describe below.

New Jersey Facilities Subject to Same Risks that Caused Park License Surrender

We believe that these issues referenced in the above complaint are representative of the Company’s entire business model, even without considering the business transferred from California to New Jersey. The New Jersey facilities carry the same risks of closure that we believe have been ignored by the market. The Company calls these two facilities the (1) New Jersey Outsourcing facility (“NJOF”) and the (2) New Jersey compounding facility (“RxNJ”), and each of them carries their own set of risks.

New Jersey Outsourcing Facility (NJOF)

The Company discloses (see table above) that NJOF produced \$22.5 million of revenues (54% of total) in 2018, and \$7.4 million in Q1 2019 (60.2% of total). The FDA inspected NJOF and issued it a [form 483](#) (which “[notifies](#) the

company's management of objectionable conditions) on July 10, 2017. While this was almost two years ago, as of June 7, 2019, the [FDA indicates](#) that the issues are still "Open".

Imprimis NJOF, LLC, Ledgewood, NJ	Brad M. Bingham 858-704-4625	11/12/2016	12/21/2018	7/10/2017	Yes	Open	Yes
--------------------------------------	------------------------------------	------------	------------	-----------	-----	------	-----

Per the FDA,

"Open" means that FDA has not made a determination as to whether further action will be taken. If an action has been taken, it will be listed. Possible FDA actions include: warning letter; seizure; or injunction.

Given the amount of time that has passed and the fact that the issue is still present, we see risks to the facility here as underappreciated by the market.

New Jersey Compounding (RxNJ)

More recently, the Company was [issued a warning letter](#) on December 21, 2017 related to improper promotional materials that encompasses what appears to be **the Company's entire ophthalmology product portfolio**,

This is to advise your firm that the U.S. Food and Drug Administration (FDA) has reviewed promotional materials disseminated by your firm, including the website at www.imprimisrx.com  1 where you take orders for the following compounded drug products:

- "Droplless" products

- o Tri-Moxi (triamcinolone acetonide, moxifloxacin hydrochloride), 15/1mg/ml
- o Tri-Moxi-Vanc (triamcinolone acetonide, moxifloxacin, vancomycin), 15/1mg/10mg/mL
- o Moxi (moxifloxacin hydrochloride), 5mg/mL

- "LessDrops" products

- o Pred-Gati-Nepaf (prednisolone acetate, gatifloxacin, nepafenac), 1/0.5/0.1%/mL
- o Pred-Gati (prednisolone acetate, gatifloxacin), 1/0.5%/mL
- o Pred-Nepaf (prednisolone acetate, nepafenac), 1/0.1%/mL

- "Simple Drops" products

- o Tim-Brim-Dor PF **2** (timolol/brimonidine/dorzolamide), 0.5/0.15/2%
- o Tim-Brim-Dor-Lat PF (timolol/brimonidine/dorzolamide/latanoprost), 0.5/0.15/2/0.005%
- o Tim-Dor-Lat PF (timolol/dorzolamide/latanoprost), 0.5/2/0.005%
- o Tim-Lat PF (timolol/latanoprost), 0.5%/0.005%

- "Klarity C-Drops" product (cyclosporine 0.1%/chondroitin sulfate)

Source: FDA Warning Letter

We'd encourage investors to read the letter in its entirety. Nevertheless, we attempt to summarize the core argument of the letter as (1) the Company's ophthalmology products are drugs under 201(g)(1) of the FD&C act, (2) the Company has made numerous false and misleading claims about these drugs over time, including regarding their safety and efficacy, thus (3) the Company is distributing these drugs illegally.

Gross ophthalmology sales were 83% of revenues in 2018 and 91% in Q1 2019. The risk is significant, should the FDA decide to act, which could mean "legal action without further notice, including, without limitation, seizure and injunction."

Finally, the FDA [issued a letter](#) to the Company on September 25, 2018 related to its inspection of RxNJ. The letter stated that the Company produced drugs that violated the FDCA Act and failed to meet conditions of Section 503A. This included compounding drug products using artesunate, which is not eligible for exemption, as well as misbranded drug products and adulterated drug products. These are some of the same issues that led to the California closure.

However, as noted above, drug products compounded using artesunate are not eligible for the exemptions provided by section 503A of the FDCA because artesunate is not the subject of an applicable USP or NF monograph, is not a component of an FDA-approved human drug and does not appear on the 503A bulks list. ⁴ Should you continue to compound and distribute drug products that do not meet the conditions of section 503A, the compounding and distribution of such drugs would be subject to the new drug approval requirement, the requirement to label drug products with adequate directions for use, and the drug CGMP regulations.

E. Conclusion

The violations cited in this letter are not intended to be an all-inclusive statement of violations at your facility. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.

Within thirty (30) working days of receipt of this letter, please notify this office in writing if you have taken any steps to correct the violations. Please include an explanation of each step being taken to prevent the recurrence of the violations, as well as copies of related documentation. If you do not believe that the products discussed above are in violation of the FDCA, include your reasoning and any supporting information for our consideration. If you cannot complete the corrective actions within 30 working days, state the reason for the delay and the time within which you will complete the correction.

Given that the FDA issued a warning letter to the Company in September 2018, we don't believe that the earlier incidents were as isolated in nature as investors believe, but are rather more indicative of the Company's poor quality control processes and disregard for patient safety.

We also obtained documents from the New Jersey Board of Pharmacy's last 2 inspections of the Company's RxNJ facility, which also extended to the outsourcing facility, as both facilities share the same address (with different suite numbers). However, as shown, the facilities are merely separated "by doors" while "sections share the same employee entrance ... same employee locker room ... the break room ... and shipping and receiving" and "there is no true physical separation of each section."

The reports also illustrate that the Board also took issues with various aspects of Harrow's business, issues which we have also noted, such as inadequate patient records, improper handling of rejected product, and improperly assigned beyond use dates.

	<p>Both the 503A and 503B sections share the same employee entrance in the rear of the facility. They also share the same employee locker room for changing into scrubs upon arrival for a work shift. The locker rooms are located on the 503B section of the facility. Additionally, the employee break room, located in the 503A permitted pharmacy, is shared by employees of both the 503A and 503B sections of the facility.</p> <p>The 503A permitted pharmacy is separated from the 503B outsourcing facility by doors. Employees can easily access both sections with the swipe of a badge. There is no true physical separation of each section.</p>	
	Dead insects were observed on shelving at the employee's entrance and in both warehouse areas in the 503B outsourcing facility.	
	Restrooms in both the 503A permitted pharmacy and 503B outsourcing facility did not contain signage reading "Employees must wash hands before returning to work".	
	Shipping and receiving are also shared between the 503A and 503B sections. The shipping and receiving areas are located in the warehouse of the 503B outsourcing facility. Although there are separate FedEx accounts for each 503A and 503B shipping facility, they share the same shipping and receiving logs. Warehouse employees report directly to the Pharmacist-in-Charge, Suja Alum.	
	It should also be noted that "rejected" products were found in an unlabeled container comingled with other, non-rejected products in the smaller warehouse.	

Moreover, Pharmacist-in-Charge Suja Alum splits time between the two facilities, and "warehouse employees report directly to the Pharmacist-in-Charge, Suja Alum."

Details

CITE	DESCRIPTION	FINE
N.J.A.C.13:39-6.2(f)	The Pharmacist-In-Charge, Suja Alum, does not work a minimum of thirty-five (35) hours a week in the pharmacy. Ms. Alum verbalized that she spends approximately half of her forty (40) hours worked per week on Operations on the 503B side of the organization.	\$500.00 to RPIC
N.J.A.C.13:39-7.20(a)	Pharmacists do not perform drug utilization review upon receipt of a new or refill prescription. Two (2) electronic patient profiles were surveyed for compliance. No documentation was found to indicate drug utilization review was performed. There was also no documentation to indicate that the patient's complete medication profile was obtained. The pharmacists present in the dispensing area admitted that drug utilization review was not performed upon receipt of a new or refill prescription.	\$250.00
N.J.A.C.13:39-7.19(b)9i	Patient allergies are not recorded in the electronic patient profile record. Two (2) electronic patient profiles were surveyed for compliance. The allergy tab in the electronic patient profile is not complete. Pharmacists verbalized that patient allergies were checked upon dispensing when a quality control checklist is completed. Any patient allergies are recorded by a customer service representative on the quality control check list at the time the order is placed. It should be noted that the pharmacy's policy is to include known drug sensitivities and drug allergies in the medication record.	\$200.00

N.J.A.C.13:39-11.19(b)	The pharmacy assigns a beyond-use date of one hundred twenty (120) days to a high risk level preparation, Prednisolone-Gatifloxacin-Nepafenac ophthalmic drops, without supporting stability information on the preparation.	\$2,500.00
N.J.A.C.13:39-11.19(b)	The pharmacy assigns a beyond-use date of one hundred twenty (120) days to a high risk level preparation, Prednisolone-Gatifloxacin-Nepafenac ophthalmic drops, without supporting stability information on the preparation.	\$2,500.00
	Sterility and endotoxin testing are performed for each product. Ms. Alum was asked to produce stability studies for Prednisolone-Gatifloxacin-Nepafenac ophthalmic drops. The assay report is marked and attached as Exhibit #22. The potency results indicate that at one hundred twenty four (124) days, Nepafenac is below potency requirements. All ingredients in the preparation have their expected potency at ninety-seven (97) days. The stability of Nepafenac appears to decline after ninety-seven (97) days per the assay results.	

Source: New Jersey Pharmacy Board Inspection Records

We would not be surprised to see a similar fate for Harrow's New Jersey pharmacies, given the numerous warning letters and seemingly recurring issues that have occurred even in recent months.

Additional Red Flags: Product Safety and Promotional Strategy

As Harrow is merely a pharmaceutical compounding business and not a producer of drugs, its formulations are not subject to traditional FDA review and approval. Moreover, we were unable to find traditional FDA adverse event reporting for the Company. We believe this has created a void where investors do not realize the true nature of what Harrow sells, and to whom it caters its business. We present numerous pieces of evidence below that suggest Harrow caters to "alternative medicine" providers, while marketing / promoting its product in an aggressive manner. We believe this fact pattern presents additional risks that the FDA and state pharmacy boards are unlikely to look favorably upon.

In [March 2017 and May 2017](#), two patients – a 30 year old female and a 71 year old male – died from administration of a curcumin emulsion product compounded by the Company. Imprimis incorrectly claimed it held no liability, and also [stated](#) that it received no prescriptions for the emulsions, which ought to be altogether more concerning. The FDA found "the absence of a warning label ... the use of an ungraded inactive ingredient that is not suitable for human consumption or therapeutic use and may contain impurities such as DEG; and the IV administration of curcumin, despite the fact that its safety profile by this route of administration has not been established, nor has its effectiveness in treating eczema or thrombocytopenia." Importantly, Jade Erick – the 30-year-old who died – merely had Eczema, which is far from a life-threatening condition – and the doctor who treated Jade was a naturopathic doctor (ND). Industry insiders joke that ND stands for "Not-a-Doctor."

The Company was [sued](#) on June 18, 2019 by Sue Gaukel. Gaukel alleges that the Company compounded Triamcinolone/Moxifloxacin (“TriMoxi”), which was injected into her after surgery on both eyes.

16. Upon information and belief, the drug Triamcinolone/Moxifloxacin compounded by Imprimis and given as an intravitreal injection has caused Plaintiff Anna Sue Gaukel’s vision damage and loss.

17. Upon further information and belief, vision loss and/or damage has also been sustained by other patients who received the drug Triamcinolone/Moxifloxacin compounded by Imprimis and given as an intravitreal injection.

A few months after the surgery and injection during follow-up, Gaukel “was experiencing blurry eyesight, light sensitivity, inability to see pale colors, and difficulty in seeing letters and numbers.” The problem worsened to the point that (paragraph 18) “she can no longer drive.” Gaukel is now the lead on a class action which we believe will lead to more former patients coming forward. Again, we could find no adverse event reporting for the Company, as it is merely a pharmacy, so we are unclear as to the scope of potential outcomes.

In May 2019, the Company [settled a TCPA lawsuit](#) for \$1.45 million, wherein a doctor alleged that Imprimis / Harrow sent unsolicited faxes advertising its products.

In April 2017, the [Company announced](#) that it had signed an agreement with Cameron Ehlen Group, d/b/a Precision Lens, for a three-year exclusive sales representation agreement.

Under the agreement, Precision Lens will deploy a dedicated sales team to introduce Imprimis’ ophthalmic portfolio into select geographies in the U.S., primarily focused in 13 states in the U.S. Midwest. Precision Lens, which sells and distributes more than 60 percent of the intraocular lens (IOLs) for cataract surgery in its markets, will add resources to exclusively sell Imprimis’ pharmaceutical products, including Dropleess Therapy®, LessDrops® combination eye drops, Simple Drops™ preservative-free glaucoma drops, MKO Melt™ conscious sedation, and medications typically used for dilation, general inflammation and infection. Imprimis will continue to focus its sales efforts in all 50 states and provide support to new accounts procured by Precision Lens.

In February 2018, the Department of Justice [filed complaint](#) against Precision Lens for an alleged kickback scheme. The full complaint can be [viewed here](#).

The United States’ Complaint against Precision Lens and EHLEN alleges that Precision Lens provided kickbacks to physicians in various forms, including travel and entertainment. The Complaint identifies multiple examples of trips, including luxury skiing vacations, and high-end fishing, golfing and hunting vacations. For many of the trips, Precision Lens and EHLEN transported physicians to exclusive luxury vacation destinations on private jets. Precision Lens and EHLEN also sold frequent flyer miles to their physician customers at a steep discount, enabling the physicians to take trips at well below fair market value.

The Complaint-in-Intervention alleges that Precision Lens maintained a slush fund, also referred to internally at Precision Lens as a secret fund. Precision Lens used money from the slush fund to finance trips with key physician customers and sales targets.

As of [October 2018](#), a judge ruled that “the claims were detailed enough to allege a systematic fraudulent practice.” We have seen zero coverage of this issue from investors in Imprimis / Harrow, which is concerning given that (1) the DOJ accusations suggest that Harrow’s revenue growth could have also been fueled by illegal kickbacks, and (2) as the exclusive distributor of the Company’s product, any DOJ action against Precision Lens could also affect Harrow.

Finally, Harrow’s board includes Richard Lindstrom, MD, who per the proxy is a practicing physician, owns 1.1% of shares, and [licenses his technology](#) to Harrow. At the same time, Lindstrom can be seen promoting the Company’s products here in [November 2017](#), [June 2018](#), and [January 2019](#). Lindstrom’s status as both a (1) shareholder and board member, (2) practicing physician, and (3) promotor of the Company’s products is one we view with a skeptical eye.

Ongoing Lawsuit, May 2019 Cease & Desist Could Create Revenue Cliff

Finally, we believe that investors are ignoring a lawsuit filed against the Company by Novel Drug Solutions, LLC (NDS) that could adversely affect 22% of revenues.

The Company’s relationship with NDS began in [August 2013](#), when Imprimis acquired the rights “related to an ophthalmic compound for intraoperative ocular injection of anti-inflammatory and anti-bacterial agents.” The press release appears to indicate that this IP formed the base of the Company’s Moxifloxacin/Triamcinolone (“TriMoxi”) products:

The target compound, referred to as IPI-140, is **based on a novel combination of moxifloxacin and triamcinolone**. IPI-140 was co-invented by Novel Drug Solutions of Randolph, New Jersey and Dr. Jeffrey T. Liegner of Sparta, New Jersey. IPI-140 has been successfully administered by Dr. Liegner in more than 1,500 patients in his surgical practice.

Harrow then took this IP and created injectables named “DropLess” and “LessDrops.”



Droplless® Injectable Formulation*

- [Tri-Moxi®](#) (triamcinolone and moxifloxacin hydrochloride)

Source: company website

DroplLess injections are used to reduce the use of topical eye drops after ocular surgery. LessDrops [are used](#) around the time of ocular surgery and save costs by reducing the number of (high-cost) drops administered daily. There are 11 variations, which investors can [view here](#) per the Company as of April 2019. Imprimis's own [marketing materials](#) even reference that it was "invented by ophthalmologists and pharmacists," a nod to NDS.

Proprietary Sterile Injectable Compounded Formulations*

DroplLess® Formulations from ImprimisRx®

- Quality sterile injectable compounded medications* from an FDA-Registered facility
- Invented by ophthalmologists and pharmacists for unmet medical needs
- Surfactant Solubilizing Process (SSP) technology® that uniquely allow for the combination of drugs



ORDER TODAY

Available from our FDA-registered 503B outsourcing facility

Prednisolone Acetate*
Preservative-Free 1% Eye Drops

As low as \$33 per 5mL Bottle
(ships in boxes of 10)

Order Now **imprimisRx**
844.446.6979

*The professional-only, injectable eye drops in our sterile formulations formulated for ophthalmologists and practitioners needs. ImprimisRx dispenses only to healthcare providers with valid prescriptions. No compounded medications prepared for the FDA for safety or efficacy. ImprimisRx does not compound copies of commercially available products. References available upon request. ImprimisRx is a trademark of Harrow Health, Inc. ©2019 ImprimisRx. All Rights Reserved. 88P02029 02/19

Order Now

Order from 503B Outsourcing Facility today. No patient information required.

ORDER >

The purchase agreement can be [viewed here](#), and notes the relevant patent:

EPINEPHRINE COMPOSITIONS FOR INTRAOCULAR ADMINISTRATION AND METHODS FOR FABRICATING THEREOF

U.S. Serial No.: 61/886,269, filed October 3, 2013

The patent regarding the above serial number [indicates](#) that it includes injection applications as "using them for intraocular injections are also described." Simply put, NDS alleges that Harrow never paid for the use of this IP. Thus, our understanding is that per the lawsuit, (1) the Company formed an agreement for the right to use NDS's IP for injectables, (2) the Company then sold a lot of these injectables and subsequently, (3) the Company failed to pay NDS its share of revenues per the licensing agreement. Thus, NDS sued.

Moreover, on May 30, 2019, [NDS delivered](#) a Notice of Termination and Cease and Desist directive to Harrow Health,

Based on Harrow Health's failure to pay, Novel Drug Solutions, LLC and Eye Care Northwest, PA contends that it has an absolute right to terminate the relationship and, most importantly, to repossess all of its Technology and Assets from Harrow Health.

We believe this is a sign that NDS does not intend to settle; rather, NDS intends to partner with a different company, leaving Harrow / Imprimis in the dust. As of August 2018, the [Company stated](#) with respect to Tri-Moxi that "American ophthalmologists have administered over seven hundred thousand doses of this formulation to

cataract surgery patients over the past four years.” At present, the [Company states](#) (see below) that “More than 800,000 Droplless formulations have been dispensed.”



Tri-Moxi™ Injectable
(Triamcinolone acetate 15mg and moxifloxacin hydrochloride 1mg/mL)

- Unit Size: 0.6 ML
- Package Size: 20 per Box
- Package Price: \$440.00

More than 800,000 Droplless formulations have been dispensed.

Free ground shipping. Single-use vials.

[Click here for the full package insert.](#)

Add Povidone Iodine* for \$5 per Bottle

SKU: **10000004550684**

Manufacturer part number: **DL001**

Box(es) of 20

Add To Cart 

This appears to be HROW’s best-selling product, as (1) there is no such commentary related to number of formulations dispensed that we could find for any other product listing, again suggesting its importance to the Company as the “flagship” injection. Moreover, (2) At \$440 per 20 units in each box, this \$22 times 800,000 equates to \$17.6 million in total revenues. From 2015 through Q1 2019, the Company has generated \$78.3 million in ophthalmology revenues, suggesting that TriMoxi was ~22.5% of ophthalmology revenues. The pendency of this lawsuit presents another major gut punch to Harrow’s business. To illustrate, even if Harrow is able to grow its remaining business by 30% each year, a Tri-Moxi sales cliff would result in a 2020 pro forma revenue figure lower than 2018 revenues.

Pro Forma Revenue Analysis	\$ millions
2018 Revenues	41.3
Less: Park closure	(13.0)
Less: TriMoxi revenues	(7.7)
Remaining Business	20.7
2-year Growth CAGR	30%
2020 Revenues	34.9

We believe these factors will make it extremely difficult for Harrow to generate management’s goal of \$100 million in 2021 revenues. Importantly, this \$34.9 million figure doesn’t consider any regulatory risks to the New Jersey facilities, which we view as high, given our earlier commentary regarding the transfer of Park business to New Jersey and additional FDA and Pharmacy Board involvement in the New Jersey facilities.

Promotor Involvement

Our diligence suggests the Company is connected to multiple promoters. In the case shown below, Tailwinds Research literally “pumps” the Company’s prospects.

The screenshot shows the Streetwise Reports website header with navigation tabs for 'STREETWISE REPORTS', 'THE GOLD REPORT', 'THE ENERGY REPORT', and 'THE LIFE SCIENCES REPORT'. Below the header is a subscription banner that reads 'Get the Latest Investment Ideas Delivered Straight to Your Inbox.' with an email input field and a 'Subscribe' button. The main article title is 'IMPRIMIS: PRIMING THE PUMPS FOR A BIG 2019' and it is labeled as a 'CONTRIBUTED OPINION'. Social media sharing icons for Facebook, Twitter, LinkedIn, Pinterest, Email, and Print are visible, along with the source attribution: 'Source: Daniel Carlson for Streetwise Reports (11/15/18)'. A profile picture of Daniel Carlson is shown next to the text: 'Daniel Carlson of Tailwinds Research profiles a biotech company he is bullish on.'

Source: [StreetWise Reports / Tailwinds Research](#)

Adamis, Diplomat, and True Nature: Historical Compounding Pharmacy Value Destruction Present Cautionary Tales

The compounding pharmacy business is rife with examples of massive shareholder losses, including Adamis Pharmaceuticals, Diplomat Pharmacy, and True Nature Holding.

Adamis Pharmaceuticals (ADMP) [acquired US Compounding](#) – a 503B facility – in March 2016, for 1.62 million shares, or ~\$9.5 million, and the [assumption of \\$5.7 million](#) in debt (10-K page F-13), for a total implied purchase price of \$15.6 million. Adamis commented,

“the combination of revenues of \$20 million or greater in each of the last two years, a large sales and marketing team and robust manufacturing capabilities, will be both synergistic with and accretive to Adamis’ overall value. We expect the new division will generate at least \$5 million in operating income over the first 12 months and achieve an annualized run rate of \$50 million per year within 24 months after closing.”

Thus, the implied purchase price was just a 0.78x revenue multiple, which was anticipated to be a 0.31x “pro forma” revenue multiple “within 24 months” given \$50 million of run rate revenues. The reality was far different. Just months later, Adamis shares fell precipitously as it [received a complete response](#) letter from the FDA for its

epinephrine pre-filled syringe NDA, which precluded its approval. Moreover, the Company produced just \$15.1 million in total revenues in 2018.

Adamis shares now trade at \$1.29, vs. \$6.14 when the US Compounding acquisition was announced. We believe that investors in Harrow ought to be familiar with the Adamis saga, as the history is similar to what is being witnessed at Harrow today. Adamis also received multiple FDA letters, form 483s, and warnings prior to the equity's collapse.

Second, we found it puzzling that in a September 2015 [interview](#), Mark Baum characterized Diplomat Pharmacy as a “fabulously successful stock.”

Of course Diplomat has been a fabulously successful stock. DPLL is their symbol. And they do a lot of compounding. And I think there are a couple of private equity backed companies that will likely go public that are very large compounding and specialty pharmacy companies that you'll see do IPOs maybe this year, if not early next year. So a lot of positive light being shined on the industry, what it's capable of, and I think the financial community is going to get a better idea of what the opportunity is here real soon.

At the time of the interview, Diplo shares closed the day at \$38.85 per share. Today, shares trade at just \$5.72 per share. Moreover, investors ought to take note that Baum himself is comparing the Company to Diplomat, which now trades at an enterprise value of just \$1.0 billion, even as the Company generated \$5.5 billion in revenues in 2018, implying an EV to Revenue multiple of just 0.18x. The same multiple on Harrow's LTM Q1 2019 revenues implies a value of just \$0.30 per share.

Finally, investors ought to look to [True Nature Holding, Inc](#) (OTC:TNTY). Earlier in its history, True Nature [intended to be a roll-up](#) of compounding pharmacies, but has [since pivoted](#) to “building healthcare applications and IT-enabled services that focus on patient engagement, care coordination, remote monitoring, data analytics, and may include Blockchain RX(TM) to provide applications for market participants in healthcare through the encryption of sensitive data.” Stock performance is shown below.

0.060 USD **-0.000100 (0.17%)** ↓

Closed: Aug 9, 4:22 PM EDT · Disclaimer
After hours 0.060 +0.000050 (0.083%)

1 day 5 days 1 month 6 months YTD 1 year **5 years** Max



Source: Google Finance

Harrow Health is Worth \$2.64, for 63% Downside

We estimate that from 2013 through 2018, this entire business has been constructed with ~\$5.45 million in acquisitions and ~\$11.7 million in capex and IP investments, or \$17.9 million in total. For that, investors are now paying \$189 million in Pro Forma EV, or \$139 million excluding the value of public investments. We believe given the quality of the assets, cash burn, and the fact that these assets have been assembled for so little, this \$144 million implied value is an absurd premium.

Typical pharmacy margins are minimal, even at scale. Thus, revenue and EBITDA valuation multiples are also low. Recall that the Company was able to purchase Park for \$3.0 million in 2013, or just 0.75x its anticipated \$4.0 million in revenues for 2014.

In 2016, Diplomat Pharmacy acquired TNH Advanced Specialty Pharmacy for \$75 million in cash and stock, while TNH had annual revenues “of about \$400 million,” implying a 0.19x revenue multiple. In 2017, Diplomat pharmacy [paid](#) \$9.8 million in cash and stock for Accurate Rx Pharmacy Consulting, which generated revenues of \$17 million – for a 0.58x revenue multiple – and was one of 2015’s “fastest-growing, private specialty pharmacies.” Diplomat later paid \$16 million in cash and up to \$10 million in contingent consideration for Affinity Biotech, which had \$27 million of revenues – an implied 0.59x to 0.96x revenue multiple, or 0.77x at the midpoint.

In February 2016, McKesson announced the acquisition of Vantage Oncology and Biologics for a collective \$1.2 billion. Barclays [estimated](#) that Biologics generated \$900 million in revenues. Though we don’t know the breakdown, Vantage Oncology owned and operated more than 50 cancer treatment facilities in 14 states. Thus, we believe a 50/50 split of the purchase price is fair, rendering the effective multiple for Biologics at 0.67x revenues.

Finally, we note that McKesson’s online Pharmacy [Valuation calculator](#) uses a 0.20x sales multiple to value potential acquisitions of private / specialty pharmacies. We summarize the above in the table below.

Acquirer	Target	Price	Revenues	EV to Revenues
Diplomat Pharmacy	TNH Advanced Specialty	\$75	\$400	0.19x
Diplomat Pharmacy	Accurate Rx Pharm	\$10	\$17	0.58x
Diplomat Pharmacy	Affinity Biotech	\$21	\$27	0.78x
McKesson	Biologics	\$600	\$900	0.67x
Adamis Pharmaceuticals	US Compounding	\$16	\$20	0.78x
Imprimis / Harrow	Park Compounding	\$3	\$4	0.75x
			Mean	0.62x
			Median	0.71x

Source: public filings and press releases, author analysis

Note that Harrow also owned a facility in Pennsylvania, which was sold [in July 2017](#) for just \$450,000 after Imprimis [purchased it](#) in October 2015 for \$524,000. This came after the FDA inspected the facility from June to August 2016 [and found](#) “serious deficiencies in your practices for producing drug products, which put patients at risk ...” Thus, “Based on this inspection, it appears that you produced drug products that violate the Federal Food, Drug, and Cosmetic Act (FDCA).”

This is all to say that we believe Harrow's compounding business is hardly worth the \$144 million implied by the current share price. Recall that the Company sold its Texas facility for just \$10,000, sold its Pennsylvania facility for just \$450,000, and purchased the New Jersey compounding facility for just \$1.0 million. As Park has been sold, the Company left with just its two New Jersey facilities, which the market implies are worth orders of magnitude greater than their purchase prices and historical M&A precedent. We simply don't believe it.

The only sell-side analyst we found that covers the Company states that HROW is worth 4x revenues with the justification that this "is at the low end of multiples commonly seen for growing pharmaceutical companies."

Valuation

We base our \$12.75 price target through an SOTP, whereby we utilize an EV/sales valuation methodology on our 2020 projections, applying a 4x multiple to our sales estimate of \$65.1M, which is almost completely tied to the company's compounding revenue. We then apply our 2020 diluted share count of 26.7M, to arrive at ~\$10.00 per share. We believe our 4x multiple is justified, as it is at the low end of multiples commonly seen for growing pharmaceutical companies. We then add \$2.75/share for spinout equity ownership, which gets us our \$12.75 PT.

Source: June 2019 sell-side note

However, this is not a pharmaceutical company. It's a compounding pharmacy business that carries a vastly different financial profile and set of risks, as we've described thoroughly above. Given the slate of comparable M&A transactions and a generous 0.6x revenue multiple, we put the value of the Compounding business at \$19.1 million, or just \$0.72 per share. Moreover, we demonstrate that even if everything goes perfectly right for the Company and management hits their ambitious 2021 revenue goal of \$100 million, the Compounding business (excluding net debt and equity stakes) is only worth \$2.31 per share.

Harrow Health EV to Revenue Valuation	\$ in millions
LTM Revenue Excl. Park	38.1
Multiple	0.5x
Value at 0.5x LTM PF Revenues	19.1
Shares	26.6
Present Value per Share	\$0.72
2021 Revenue Goal	100.0
Multiple	0.8x
Value at 0.8x 2021 Revenue Goal	80.0
Shares	26.6
2021 Value per Share	\$3.01
Present Value per Share	\$2.31

Given that (1) Park is now sold, (2) the Company's New Jersey facilities remain under FDA and NJ Pharmacy Board review, and (3) the Company remains embroiled in a lawsuit regarding its core product at estimated 22% of ophthalmology revenues, we believe this \$100 million in 2021 revenues is a pipe dream. Thus, we place intrinsic value of the Compounding business at \$19.1 million, or \$0.72 per share.

We also have concerns around the Company's investment stake in Eton Pharmaceuticals (ETON). The Company owns 3.5 million shares, putting its value at \$20.9 million. However, we believe that three of ETON's top products have already been failures:

EM-100 is Eton's flagship product, which is an ophthalmic solution for treatment of allergic conjunctivitis. The FDA issued a CRL in 2018,

Our development partner previously submitted an ANDA for EM-100 and in response to a complete response letter, or CRL, from the FDA we ran a bioequivalence trial in April 2018. The 65-patient clinical trial successfully showed statistically significant non-inferiority to ZADITOR (ketotifen fumarate ophthalmic solution 0.035%) and statistically significant superiority to the placebo with no adverse events reported. We responded to the CRL in September 2018. We are utilizing the 505(j) pathway for FDA approval of EM-100. The 505(j) pathway is typically utilized for generic drug candidates. We do not anticipate utilizing the 505(j) pathway for any other of our current product candidates.

EM-100 was expected to be approved in 2019, but the FDA issued an additional Complete Response Letter (CRL) to Eton's partner, Bausch Health in July 2019, indicating that more steps needed to be taken prior to approval. On average, the issuance of a CRL adds anywhere from 6 months to 2 years to the commercialization path. For many companies, this is a death blow given the race against others for similar or competing technology. ETON stock was down from ~\$8.31 to ~\$6.98 over the following trading sessions and now trades at ~\$6.00 as of the time of this writing.

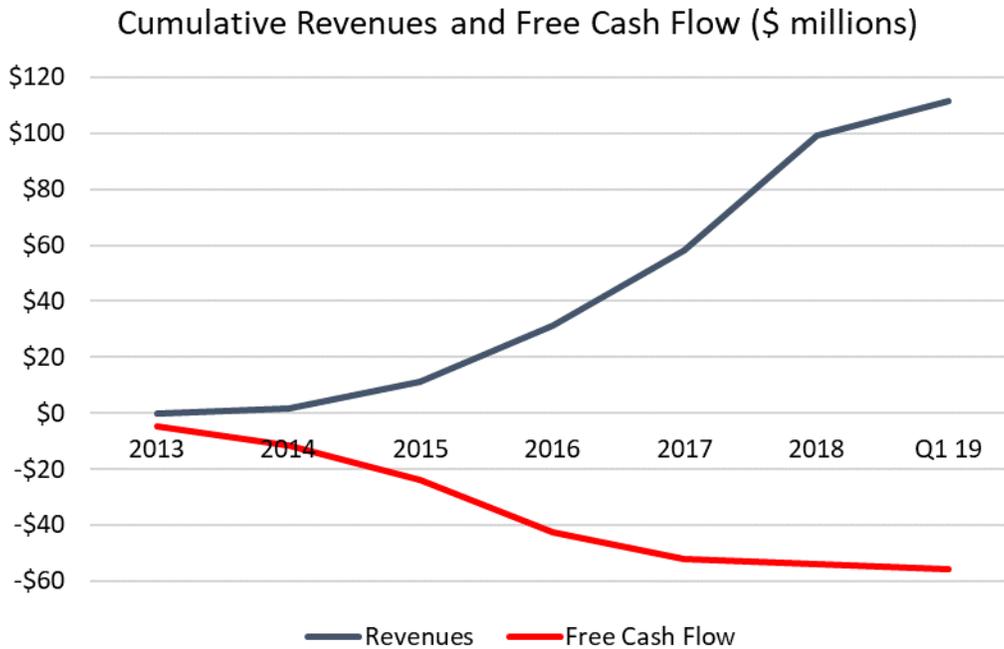
ETON also seemed to hold promising products in DS-200 and DS-300, but neither was successful, in our view. DS-300 was intended to be the second key product, which would be approved via the FDA's NDA (accelerated) regulatory pathway, but the FDA ruled against this in June 2019 as a competitor had their product approved, which utilized DS-300's active ingredient. The Company is now appealing but will be required to follow the ANDA pathway, again extending potential time to market. DS-200 was also a failure, as a competitor received approval for an NDA product which contained DS-200's active ingredient and was granted New Chemical Entity (NCE) exclusivity. We view this as a death blow to the product, as the FDA now granted the competitor 5 years of exclusivity.

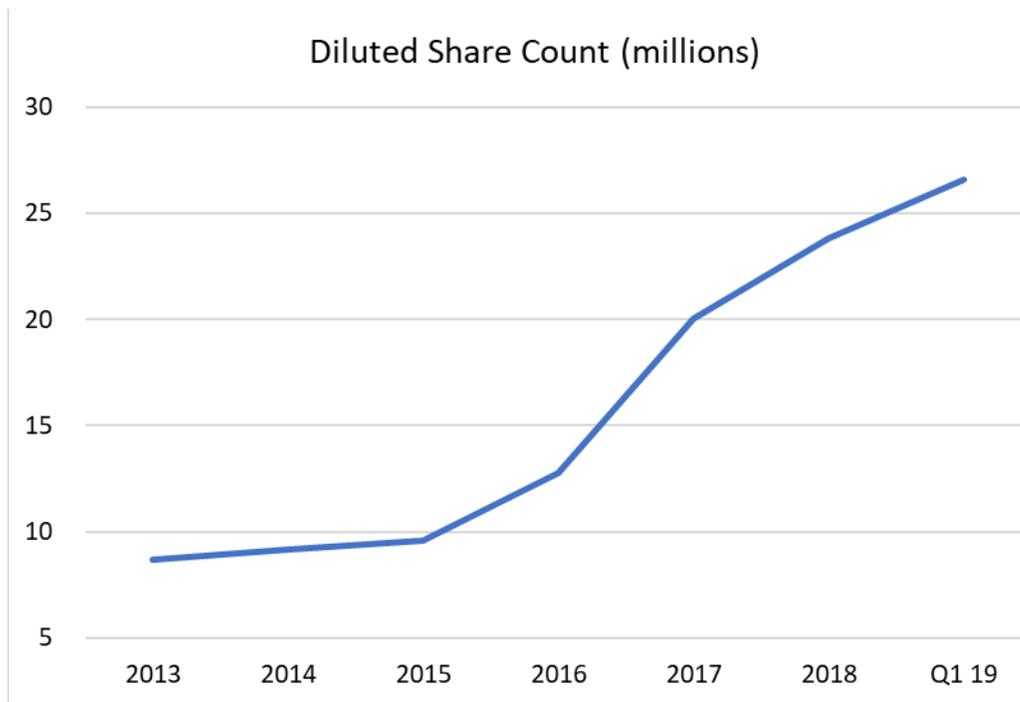
ETON is only 42.7%-owned by institutions and insiders, with Harrow consisting of 19.8% of this total. At 3.5 million shares and \$5.98 per share, ETON contributes \$20.9 million or \$0.79 per share to our \$2.64 fair value of HROW shares. Although ETON is not the focus of this report, we believe, given our view of Harrow's architects and their co-involvement, as well as the multiple failures already experienced, that ETON shares also hold significant downside.

Nevertheless, even if we award full market value of the ETON shares, as well as other investments and net debt, we come to a fair value of just \$2.64 per share, or 63% downside. Note that we include the full \$8.0 million Park sale price in the cash figure below, yet investors ought to recognize that this "sale" has come via an 8-year seller's note. Thus, the Company doesn't even have this cash on the balance sheet.

Harrow Health Valuation	\$ in millions
Value of Compounding Business	19.1
Investment Stakes (incl. ETON)	50.1
Cash (incl. \$8 mil Seller's Note)	12.3
Debt	11.4
Equity Value	70.1
Fully diluted shares (millions)	26.6
Equity Value per Share	\$2.64
Downside	-63%

As the Company continues to burn cash and issue equity, this value decreases day by day.





We expect that as investors come to realize management's history, the true nature of the strategic alternatives process related to Park, and the risks that remain in Harrow's New Jersey facilities, this downside ought to be realized in short order.

Conclusion

In summary, we believe Harrow Health was a reverse merger brought to market by serial stock promotor Mark Baum with the aid of notorious fraudster Barry Honig. Harrow has convinced the market, with the aid of paid promoters, that 2 subpar pharmacy facilities in New Jersey are worth \$139 million, even as the Company only paid just \$1 million for these same assets. As another one of the Company's recently sold pharmacies surrendered its license in the face of a multitude of disciplinary actions, these two remaining facilities remain subject to the very same risks. Regulators have already demonstrated a willingness to act, and we don't believe that the Company's aggressive sales and marketing practices are sustainable. Peer M&A multiples suggest that even were the Company not to be employing a convicted felon in the C-Suite, it would be worth just \$2.64 per share after accounting for net debt and investments and the sale of Park. Given the risks we have laid out above, we believe HROW equity is uninvestible.