
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 8-K

**CURRENT REPORT PURSUANT
TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934**

Date of report (Date of earliest event reported): September 12, 2019

Harrow Health, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-35814
(Commission
File Number)

45-0567010
(IRS Employer
Identification No.)

12264 El Camino Real, Suite 350
San Diego, CA
(Address of Principal Executive Offices)

92130
(Zip Code)

(858) 704-4040
(Registrant's Telephone Number, including Area Code)

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol | Name of each exchange on which registered |
|---|-----------------------|--|
| Common Stock, \$0.001 par value per share | HROW | The NASDAQ Capital Market |

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (See General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01. Regulation FD Disclosure.

Attached as Exhibit 99.1 to this Item 7.01 is a presentation of Harrow Health, Inc. (the “Company”), that is being used by the management of the Company at investor conferences and at meetings describing the Company.

Item 8.01. Other Events.

Attached as Exhibit 99.2 to this Item 8.01 is a presentation of Melt Pharmaceuticals, Inc. (“Melt”), that is being used by the management of Melt at investor conferences and at meetings describing Melt. The Company owns 3,500,000 shares of Melt common stock, which represents approximately 44% of the issued and outstanding equity interests of Melt.

The information contained in Items 7.01 and 8.01 of this report and in Exhibits 99.1 and 99.2 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits**(d) Exhibits**

99.1 [Harrow Health, Inc. Corporate Presentation dated September 2019](#)

99.2 [Melt Pharmaceuticals, Inc. Corporate Presentation dated September 2019](#)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

HARROW HEALTH, INC.

Date: September 12, 2019

By: /s/ Andrew R. Boll

Andrew R. Boll
Chief Financial Officer



NASDAQ: HROW
SEPTEMBER 2019

SAFE HARBOR

This presentation contains express "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. You are cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from Harrow Health, Inc.'s (the "Company" or "Harrow") expectations and projections. Some of these risks and uncertainties include, but are not limited to: the Company's ability to make commercially available its formulations and technologies in a timely manner or at all; market acceptance of the Company's formulations and challenges related to the marketing of the Company's formulations; its ability to obtain intellectual property protection for its assets; its ability to accurately estimate its expenses and cash burn and raise additional funds when necessary; its ability to generate profits from sales of its formulations; risks related to research and development activities; its estimates of the current and potential market size for its technologies and formulations; unexpected data, safety and technical issues; regulatory and market developments impacting compounding pharmacies, outsourcing facilities and the pharmaceutical industry; competition; and market conditions. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements is set forth in the Company's filings with the Securities and Exchange Commission, including its Annual Reports on Form 10-K and its Quarterly Reports on Form 10-Q filed with the SEC. Such documents may be read free of charge on the SEC's web site at www.sec.gov. This presentation may refer to non-GAAP financial metrics, specifically adjusted EBITDA and/or adjusted earnings. A reconciliation of any non-GAAP measures with the most directly comparable GAAP measures are included in the Company's press releases, available on its website. All forward-looking statements are qualified in their entirety by this cautionary statement. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Harrow expressly disclaims any intent or obligation to update these forward-looking statements except as required by law. Our compounded formulations are not FDA approved. All trademarks, service marks and trade names included in this presentation are the property of their respective owners.



TOPICS COVERED

Introduction to Harrow Health, Inc.

Financial Metrics

Harrow Health Equity Interests

- ImprimisRx Operating Business
- Other Subsidiaries
- Passive Equity Holdings

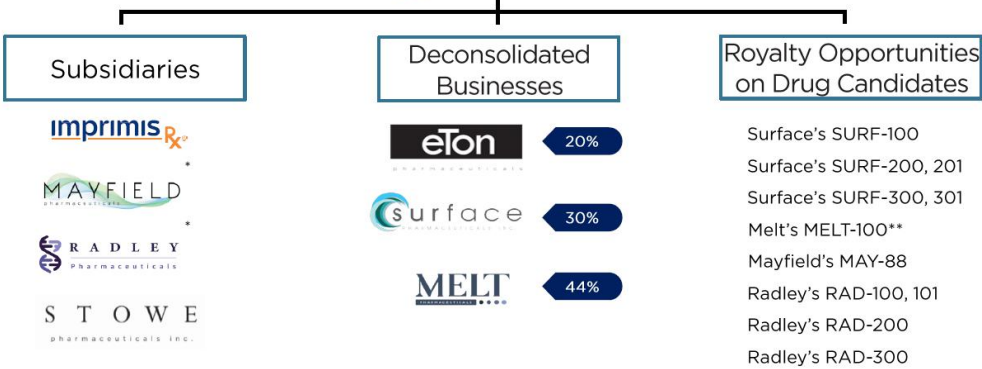
Defining Success in 2021



Harrow Health Introduction

- We found pharmaceutical companies.
- We own large equity stakes in these companies.
- We own royalties on many of the drug candidates they develop.

Harrow Health Introduction



* Pursuing a deconsolidating transaction
 ** Includes all future label extensions

HROW Equity Percentage

FINANCIAL METRICS



Consolidated Financials

Revenue Growth:

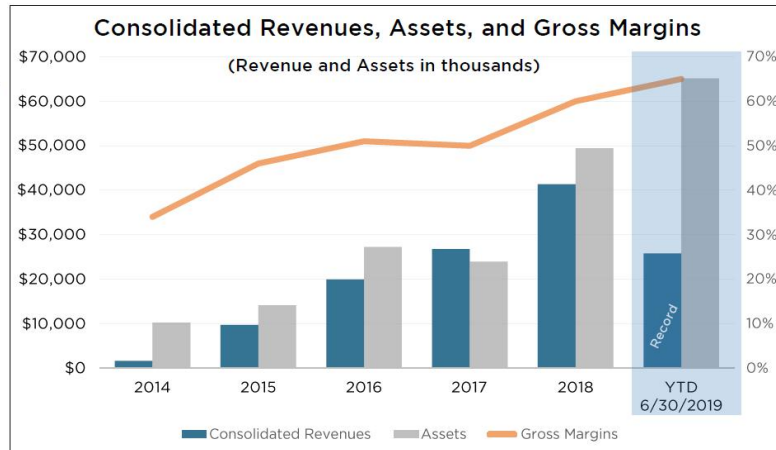
- Q2 2019 Revenue \$13.5M
- \$100M rev run rate goal in 2021
- 187% ophthalmology rev CAGR 2014-2018
- 46% ophthalmology year-over-year revenue growth (Q2 2019)
- 115% year-over-year revenue growth in chronic care ophthalmology drugs
- October CMS policy clarification may accelerate 2020 revenue growth

Gross & Operating Profit Margins:

- 65% gross margins (1H 2019)
- Medium-term (2020-21) gross margin target of $\geq 70\%$
- 25% adj. operating margin target in 2021

Earnings:

- ~\$2M Q2 2019 pharmaceutical compounding segment earnings
- Aggregate non-GAAP Adjusted EBITDA for 1H 2019 of ~\$1M



EQUITY INTERESTS

imprimis[®]

eTon
PHARMACEUTICALS

surface
PHARMACEUTICALS, INC.

MELT
PHARMACEUTICALS

MAYFIELD
PHARMACEUTICALS

 RADLEY
Pharmaceuticals

S T O W E
pharmaceuticals inc.



ImprimisRx Subsidiary

WHAT IS IT?

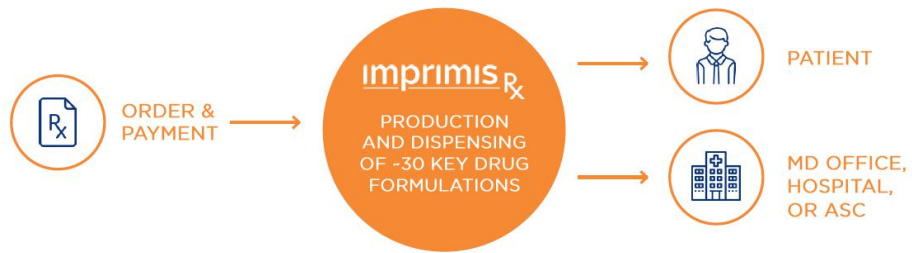
- Founded by Harrow in 2014
- 100% owned by Harrow
- Leading U.S. ophthalmology pharmaceutical compounder
- 100% cash pay business model
- Two facilities (30,000 ft²) producing ~30 SKUs
- IP focused; 60+ patents filed
- 3,000+ physician customers in all 50 states
- 187% revenue CAGR (2014 through 2018)
- \$10M+ CAPEX invested
- FDA-registered and inspected outsourcing facility

WHAT IS THE OPPORTUNITY?

- Growing, cash flowing and scalable
- Expectation to expand GMs to $\geq 70\%$
- Goal of \$100M revenue run rate in 2021
- Goal of 25% operating margins in 2021
- Ocular surgery, dry eye disease and glaucoma are each \$1B+ annual U.S. markets
- Developing a beachhead in dry eye disease
- ~30 new formulations in development



imprimis_{Rx} DECONSTRUCTING THE VALUE CHAIN



100% Affordable Cash Pay Eliminates:

Insurance Companies and the *dreaded* "Prior Authorization"
Pharmacy Benefit Managers (PBM)
Wholesalers, Distributors
Coupons, Discounts, Rebates

Other Subsidiaries



- Women's health-focused business
- Drug candidate pipeline:
 - MAY-44 for Dyspareunia symptoms
 - MAY-66 for Recurrent Bacterial Vaginosis
 - MAY-88 for Interstitial Cystitis
- Aggregate potential addressable market in U.S. of \$3B

Progress

- PIND meeting in June 2019; condensed FDA approval pathway for MAY-44
- Engaged experienced CEO
- In the process of capitalizing



- Patent-pending drug candidate for rare and orphan drug indications, anti-infective, and certain forms of cancer
- Additional drug development programs being reviewed for inclusion

Progress

- PIND request filed for RAD-100
- Investigator-IND and pre-clinical studies underway for lead drug candidate with established healthcare institutions



- First-in-class Zian™ anti-microbial molecule for ophthalmic / otic uses
- STE-006 drug candidate indication expected to be adenoviral conjunctivitis; secondary indications for mixed bacterial-viral infections, keratitis, and corneal ulcers

Progress

- Acquired asset in late July 2019
- Pre-clinical dataset (including rabbit and anti-biofilm models) showed elimination of broad spectra of bacteria and inactivated ranges of viruses within 15 seconds (MRSA and herpes simplex virus)





Subsidiaries



Deconsolidated businesses



Royalty opportunities

- Surface's SURF-100
- Surface's SURF-200, 201
- Surface's SURF-300, 301
- Melt's MELT-100**
- Mayfield's MAY-88
- Radley's RAD-100, 101
- Radley's RAD-200
- Radley's RAD-300

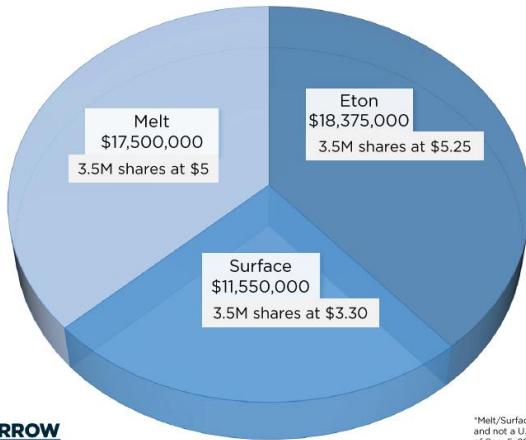


* Pursuing a deconsolidating transaction
** Includes all future label extensions



Passive Equity Holdings

HARROW'S DECONSOLIDATED EQUITY PORTFOLIO
ESTIMATED VALUE: \$47M*



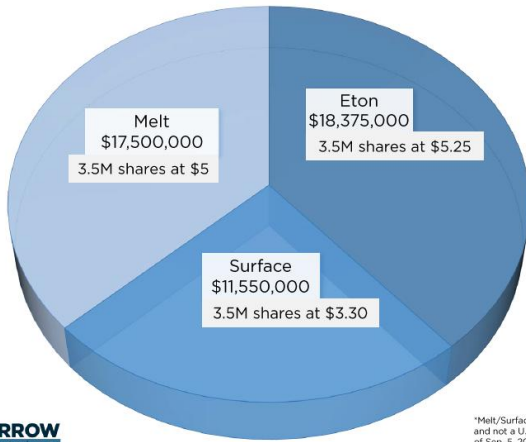
*Melt/Surface equity values estimated based on the conversion price of Series A preferred stock (the most recent financing, and not a U.S. GAAP measure); Eton value is calculated based on the closing stock market price of Eton's common stock as of Sep. 5, 2019.



- Eton was formed by Harrow in 2017
- Eton has:
 - 11 drug candidates in pipeline
 - 7 NDAs submitted or expected to be submitted by the end of 2019
 - Significant 2019-2020 value catalysts
- Eton is NASDAQ listed under "ETON"
- ~\$92M market capitalization*

Passive Equity Holdings

HARROW'S DECONSOLIDATED EQUITY PORTFOLIO
ESTIMATED VALUE: \$47M*



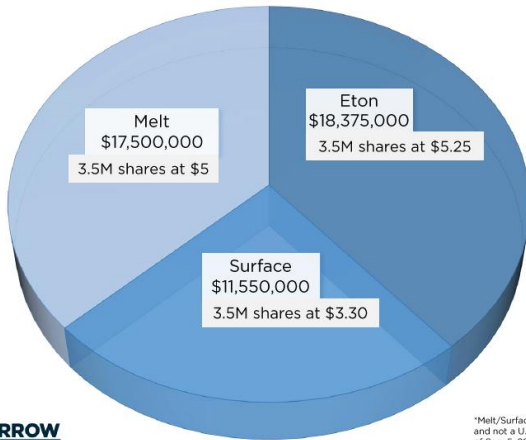
*Melt/Surface equity values estimated based on the conversion price of Series A preferred stock (the most recent financing, and not a U.S. GAAP measure); Eton value is calculated based on the closing stock market price of Eton's common stock as of Sep. 5, 2019.



- Surface was formed by Harrow in 2018
- Surface is:
 - Developing three ocular surface disease drug candidates for dry eye disease and blepharitis
 - Expecting Phase 2 clinical data in 2020
- \$21M Series A led by Flying L Partners
- 4-6% Net Sales royalties (on all programs)

Passive Equity Holdings

HARROW'S DECONSOLIDATED EQUITY PORTFOLIO
ESTIMATED VALUE: \$47M*



- Melt was formed by Harrow in 2018
- Melt is:
 - Developing non-opioid, non-IV, sedation and analgesia drug candidates
 - MELT-100 for conscious sedation and analgesia (cataract surgery)
 - MELT-200 for conscious procedural sedation
- \$11M Series A closed in Q1 2019
- 5% - 8% Net Sales royalties on MELT-100

*Melt/Surface equity values estimated based on the conversion price of Series A preferred stock (the most recent financing, and not a U.S. GAAP measure); Eton value is calculated based on the closing stock market price of Eton's common stock as of Sep. 5, 2019.

DEFINING SUCCESS IN 2021



Defining Success in 2021

Public company objectives:

- Drive substantial market capitalization and enterprise value growth
- Grow capital base to further operational strategic objectives and shareholders' returns

Operational objectives:

- Continue to found, fund and deconsolidate new pharmaceutical businesses
- Growth in value from our ImprimisRx ophthalmology business
- Management and monetization of our deconsolidated equity positions
- Positioning for the realization of royalties from drug development candidates

Company Profile*

TRADING SYMBOL:
NASDAQ: HROW

PRICE PER SHARE:
\$5.74

AVG. DAILY Q2-2019 TRADING VOLUME:
264,000 SHARES

OUTSTANDING COMMON STOCK:
25.2M SHARES

MARKET CAP:
\$145 MILLION

STRONG CEO/CFO INCENTIVE THRU
PERFORMANCE STOCK UNITS TO
ACHIEVE \$9 - \$15 SHARE PRICE



* As of Sep. 5, 2019

18



102 Woodmont Blvd. Ste 610
Nashville, Tennessee 37205
(858) 704-4040

IR@HARROWINC.COM
WWW.HARROWINC.COM



MELT PHARMACEUTICALS | CORPORATE PRESENTATION

Innovation and a New Paradigm in Conscious Sedation and Analgesia

JULY 2019

©2019 Melt Pharmaceuticals. CONFIDENTIAL.

Safe Harbor

This presentation contains express “forward-looking statements” as defined in the Private Securities Litigation Reform Act of 1995. You are cautioned not to rely on these forward-looking statements which involve substantial risks and uncertainties. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from Melt Pharmaceuticals, Inc.’s (the “Company”) expectations and projections. All statements other than statements of historical facts, including statements regarding our future financial condition, timing for and outcomes of clinical results, business strategy and plans and objectives for future operations, are forward looking statements. These forward looking statements include terminology such as ‘believe’, ‘will’, ‘may’, ‘estimate’, ‘continue’, ‘anticipate’, ‘contemplate’, ‘intend’, ‘target’, ‘project’, ‘should’, ‘plan’, ‘expect’, ‘predict’, ‘could’, ‘potentially’, or the negative of these terms. Some of these risks and uncertainties include, but are not limited to: the Company’s ability to make commercially available its formulations and technologies in a timely manner or at all; market acceptance of the Company’s formulations and challenges related to the marketing of the Company’s formulations; its ability to obtain intellectual property protection for its assets; its ability to accurately estimate its expenses and cash burn and raise additional funds when necessary; the Company’s ability to generate profits from sales of its formulations; risks related to research and development activities and any related regulatory approvals; the Company’s estimates of the current and potential market size for its technologies and formulations; unexpected data, safety and technical issues; regulatory and market developments impacting compounding pharmacies, outsourcing facilities and the pharmaceutical industry; competition; and market conditions. All forward-looking statements are qualified in their entirety by this cautionary statement. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The Company expressly disclaims any intent or obligation to update these forward-looking statements except as required by law. Harrow’ compounded formulations are not FDA approved and no representation is made as to their safety or effectiveness for the purposes for which they are being investigated.

All trademarks, service marks and trade names included in this presentation are the property of their respective owners.

This presentation shall not constitute an offer to sell or the solicitation of an offer to buy any securities described herein, nor shall there be any sale of any such securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such jurisdiction.

Vision

To create a new class of patient centric medications used in sedation and analgesia through the development on non-opioid, non intravenous therapeutics



Overview

Two programs: a sublingual formulation of midazolam for conscious sedation and a sublingual, non-opioid combination of midazolam and ketamine for conscious sedation and analgesia

- Large and growing initial market opportunity, currently 4.4 million cataract surgeries per year
- Numerous market expansion opportunities
- Accelerated launch potential with established user base of compounded version of drug in ophthalmology
- Accelerated clinical and regulatory timeline – plan to utilize FDA 505(b)(2)
- Our core IP is a patented series of combination non-opioid sedation drug formulations
- We were spun-out of Harrow Health, Inc. (NASDAQ: HROW) in Jan. 2019 upon close of our Series A financing

Leveraging our experience to advance clinical programs rapidly whilst attempting to minimize risk

Melt-200

Sublingual, rapidly dissolving tablet containing 3 mg of midazolam

- We utilize a patented fast dissolving technology, that allows the tablet to dissolve in the patients mouth in less than ten seconds

Likelihood of condensed clinical program leading to NDA filing in near-term

Significant Competitive Advantages:

- Established safety profile, new sublingual formulation of drug with long history of use
- Patient preference for sublingual delivery over standard of care IV sedation medicines
- Broad applicability - unique formulation allows for potential use across wide range of patients (pediatric to elderly, needle-phobic patients, etc.)
- Harrow's real-world experience and established base of sales provides potential for rapid conversion of cGMP compound to Melt-100 upon approval

Melt-100

Sublingual, rapidly dissolving tablet containing 3 mg of midazolam and 25 mg of ketamine

We utilize a patented fast dissolving technology, that allows the tablet to dissolve in the patients mouth in less than ten seconds

Significant Competitive Advantages:

- Established safety profile, non-opioid combination of two drugs with long history of use
- Patient preference for sublingual delivery over standard of care IV sedation medicines
- Broad applicability - unique formulation allows for potential use across wide range of patients (pediatric to elderly, needle-phobic patients, etc.)
- Patent profile includes formulation claims within variety of relevant drug classes and compositions, with method of use, expiration June 2036

Two well established and known medications

Midazolam

- Midazolam is an FDA approved benzodiazepine, and was first introduced in the U.S. market in 1997
- Midazolam is commonly utilized for conscious sedation, anxiolysis, amnesia as an IV, intramuscular, or as an orally administered agent
- Midazolam is typically also used as a premedicant for oral administration to pediatric patients (Versed® oral syrup)
- When used for anesthesia, midazolam can attenuate the hyperdynamic circulatory effects and unpleasant emergent reactions caused by ketamine
- Studies have demonstrated that midazolam and ketamine demonstrate additive effects on conscious sedation

Ketamine

- Ketamine is an FDA approved anesthetic, and was first introduced in the U.S. market in 1970
- Ketamine is a “rapidly acting, nonbarbiturate general anesthetic”
- Ketamine is known to produce a wide spectrum of pharmacological effects including sedation, catalepsy, somatic analgesia, bronchodilation, amnesia and sympathetic nervous system stimulation with a short recovery period
- In sedation using ketamine is associated with postoperative emergence phenomena and delirium in a proportion of subjects, these side effects can be minimized by administration of benzodiazepines such as midazolam
- Ketamine also preserves the airway reflexes and has minimal effect on the respiratory drive

Clinical and Regulatory Strategy

Melt-200

- Indication for conscious sedation during cataract and/or ocular surgery
- Condensed clinical program using 505(b)2 regulatory pathway allows for NDA filing in near-term.
- Advisory and expert feedback indicate likely clinical pathway includes
 - Phase 1 PK/Bioavailability study
 - Phase 3 Efficacy study to show superiority of Melt-200 versus placebo

Clinical and Regulatory Strategy

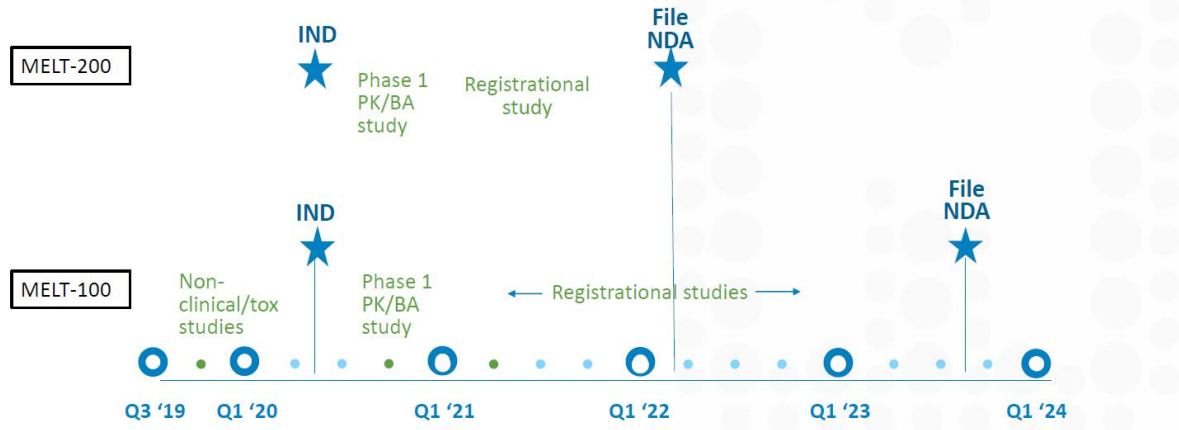
Melt-100

- Lifecycle Management as next generation advancement of Melt-200

Two pathways:

1. Indication for conscious sedation and analgesia during cataract and/or ocular surgery
 2. Indication for analgesia only during cataract and/or ocular surgeries
- Successful pre-IND meeting held with agency in January 2019
 - Agreement on non-clinical/toxicology studies required to open IND
 - Agreement on utilization of 505(b)2 regulatory pathway
 - Agreement on single PK/Bioavailability study vs midazolam and ketamine to establish safety bridge for MK Melt (relative bioavailability)

Clinical and Regulatory Timelines



Opportunity for accelerated commercial launch and revenues

- Upon approval, opportunity to rapidly transition clinicians using MKO Melt over to new FDA approved Melt 200 providing accelerated launch and near-term revenues
- Nearly 100,000 units of MKO Melt (with ondansetron) have been produced and dispensed by Harrow as a compounded drug (the “MKO Melt”), primarily used during cataract surgery
- 400+ US ophthalmologists, anesthesiologists and other medical doctors use the MKO Melt in cataract, dental, urology, dermatology/cosmetic and pediatric procedures
- Believe Melt 100 and Melt 200 would qualify for transitional pass-through status under Medicare Part B upon approval
- Believe Melt 100 also has opportunity to qualify for permanent pass-through status as a non-opioid alternative for conscious sedation and analgesia

Favorable Reimbursement Environment

Opportunity to be granted transitional pass-through reimbursement under Medicare Part B

Eligibility for separate payment from Centers for Medicare & Medicaid Services (“CMS”)

- designed to promote innovation and allows for separate payment (i.e., outside the packaged procedural payment) under Medicare Part B for certain new drugs and other medical technologies when used in hospital outpatient or ambulatory surgery centers and that meet well-established criteria specified by federal law and regulations governing Medicare spending.

Product reimbursed at ASP+6% when granted pass through status

Pass through reimbursement status generally lasts for three years after which it gets incorporated into the bundled payment rate; however, we expect new rules announced in 2019 may allow for a more permanent separate payment

2019 Policy Support from CMS...

Combating the Opioid Crisis

In response to recommendations from the *President's Commission on Combating Drug Addiction and the Opioid Crisis*, out of an abundance of caution and to avoid any potential unintended consequences of possible opioid overprescribing

In addition, the *President's Commission on Combating Drug Addiction and the Opioid Crisis* also recommended that "CMS review its payment policies for certain drugs that function as a supply, specifically non-opioid pain management treatments." Drugs that function as a supply in surgical procedures or diagnostic tests are packaged under the OPPI and ASC payment systems. In response to this recommendation as well as stakeholder requests, for CY 2019, CMS is proposing to "**pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as a supply when used in a covered surgical procedure** performed in an ASC."

Believe there is significant opportunity for Melt-100, as a non-opioid solution providing analgesia via the ketamine component to be eligible for separate reimbursement (ie outside packaged rate) beyond the three years granted for transitional pass through status.

Competition Background

Most common classes of medications for conscious sedation in cataract surgery:

- Benzodiazepines/Sedatives
- Opioids and Analgesic agents
- Combinations

Most widely used products in conscious sedation for cataract surgery are IV midazolam alone or in combinations with other IV medications like opioids (such as IV fentanyl)

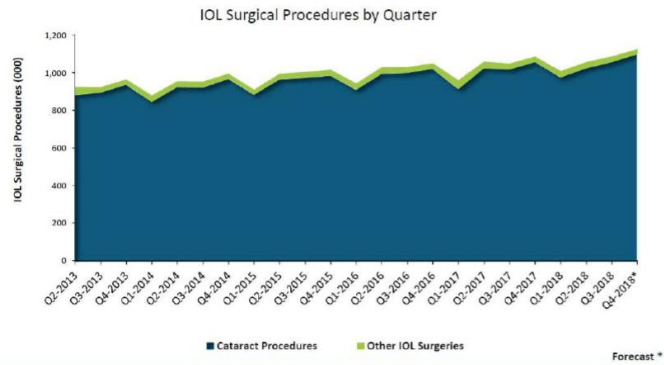
Oral medications utilized minimally due to first pass effect, bioavailability, and longer onset of action

Our objective with Melt 100/200 is to provide innovation and ultimately create a better experience for patients and caregivers with an oral, rapidly dissolving tablet that is both non-IV and non-opioid, yet highly effective and safe.



Cataract Surgery market is large and growing

Initial indication: Cataract surgery is one of the most common procedures performed in the US
4.4 million cataract surgeries performed in 2017, growing at rate of ~3% per year



Numerous Market Expansion Opportunities

*Short duration medical procedures requiring conscious sedation and/or analgesia

| TARGETED PROCEDURES | Annual Procedures (US) |
|---|------------------------|
| Endoscopic ¹ | 18,500,000 |
| Dental | 20,000,000 |
| Women's Health ² | 1,100,000 |
| Biopsies ³ | 3,200,000 |
| Emergency Room ⁴ | 19,000,000 |
| Cosmetic/Dermatology ⁵ | 500,000 |
| Minor surgeries (e.g. skin, bone breaks) ⁶ | 1,000,000 |
| MRI ⁷ | 34,000,000 |
| Foot Surgeries ⁸ | 150,000 |
| Total | 97,450,000 |

1. US Market Report Suite for Gastrointestinal Endoscopic Devices 2017 - MedSuite. (2016, August 01). Retrieved January 08, 2017, from <https://www.idataresearch.com/product/us-market-report-suite-for-gastrointestinal-endoscopic-devices-2017-medsuite/>
2. Slavov, M. M., Sraekhen, C. N., Saftoa, A. F., & Pinto, L. A. (2014, February 23). Does Loop Electrosurgical Excision Procedure of the Uterine Cervix Affect Anti-Müllerian Hormone Levels Retrieved January 08, 2017, from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3895513/> and Centers for Disease Control and Prevention - United States, 2013. (2016, November 24). Retrieved January 07, 2017, from <https://www.cdc.gov/mmwr/volumes/65/ss/6503a3a1.htm>
3. Voigt, J., & Mosler, M. (2013, September). A powered bone marrow biopsy system versus manual methods: a systematic review and meta-analysis of randomised trials. Retrieved January 08, 2017, from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3756462/>
4. Internal estimate based on data from National Hospital Ambulatory Medical Care Survey: 2015 Emergency Department Summary Tables https://www.cdc.gov/nchs/data/nhanca/web_tables/2015_ed_web_tables.pdf
5. ASPS 2015 Plastic Surgery Statistics Report - American Society of Plastic Surgeons. (2015). Retrieved January 8, 2017, from <https://ic2.wicct336wjm.cloudfront.net/News/Statistics/2015/plastic-surgery-statistics-full-report-2015.pdf>
6. Internal estimate based on data from S. Amin (2015). Trends in Fracture Incidence: A Population-Based Study over 20 Years <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3898546/>
7. MVI Medical Information Division, Inc. Benchmark Report MR2013 (2013, July). Retrieved December 15, 2016.
8. LaPointe. Bunion Surgery: A Prospective Clinical Outcomes Study; http://www.podiatryinstitute.com/pdf/Update_2001/2001_11.pdf

Experienced Leadership



Greg Madison, Chief Executive Officer: is a 30 year pharmaceutical industry veteran, most recently as CEO of Keryx Biopharmaceuticals, a commercial stage company where he oversaw the buildout of the company in preparation for their first product approval. Prior to this, he was the Chief Commercial Officer at AMAG pharmaceuticals. Greg spent 12 years at Genzyme Corporation where he served as VP and GM of the nephrology where he led a global organization with combined revenues exceeding \$1 billion. Earlier in his career, he served in leadership roles in sales management, training, managed markets and reimbursement for other multi-national pharmaceutical companies.



Mark Hazard, Chief Technical Officer: brings over 25 years of experience in the pharmaceutical sector to Melt Pharmaceuticals which he joins from Akebia Therapeutics where he served as the Vice President of CMC and Head of Quality Operations. Prior to that Mr. Hazard served as the Vice President of Manufacturing for Sinagua Biopharma. Before joining Sinagua, Mr. Hazard held positions of increasing responsibility in quality operations and manufacturing for Pfizer.

Summary

Significant opportunity to leverage platform of novel sub-lingual formulations providing a non-opioid and non-IV solution for conscious sedation and analgesia

- Unique drugs with potential competitive advantages (sublingual, non-opioid, IV free)
- Cataract/ocular surgery Initial indication is a \$1 billion market opportunity alone
- Positive payor momentum sentiment for non-opioid drugs, should allow for sustained revenue growth and value creation
- Multitude of market expansion opportunities for other short duration medical procedures
- Ability to leverage existing user base and sales to accelerate commercial uptake and revenues
- Positive pre-IND meeting provides momentum on development pathway

