
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 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): October 29, 2018

IMPRIMIS PHARMACEUTICALS, 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)

Registrant's telephone number, including area code: **(858) 704-4040**

N/A

(Former name or former address if changed since last report.)

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:

- 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))
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Item 7.01. Regulation FD Disclosure

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

The information contained in Item 7.01 of this report and in Exhibit 99.1 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 [Melt Pharmaceuticals, Inc. Corporate Presentation dated October 2018](#)

SIGNATURES

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.

Imprimis Pharmaceuticals, Inc.

Date: October 29, 2018

By: /s/ Andrew R. Boll

Name: Andrew R. Boll

Title: Chief Financial Officer

MELT

PHARMACEUTICALS



CORPORATE PRESENTATION

OCTOBER 2018



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 Imprimis Pharmaceuticals, Inc.'s ("Imprimis") and Melt Pharmaceuticals, Inc.'s ("Melt", and collectively with Imprimis the "Company") 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; 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. 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. 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. Imprimis' compounded formulations are not FDA approved.

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.

ABSTRACT



Our vision is to be the leading provider of non-opioid, non-intravenous pharmaceuticals used for conscious sedation and analgesia during medical procedures in a variety of healthcare settings

Melt is led by an experienced management and clinical advisory team

Melt Pharmaceuticals is a subsidiary of Imprimis Pharmaceuticals (NASDAQ: IMMY)

Since 2017, Imprimis has successfully spun-out two separately financed and managed companies to develop 505(b)(2) drug candidates:



Spun-out of Imprimis (June 2017)
after closing a \$20M Series A
financing; NASDAQ IPO expected 2018



Spun-out of Imprimis (May 2018)
after closing a \$21M Series A
financing

Imprimis intends to execute a strategy to fund, separately manage and spin-out Melt

OPPORTUNITY

- Our core IP is a patented series of combination non-opioid sedation drug formulations
- We intend to seek regulatory approval through the FDA's 505(b)(2) regulatory pathway for our proprietary drug candidates
- We believe there are in excess of 100M procedures in the US where our formulations may be used to replace IV sedation, and an equal number in developed countries OUS, creating a multi-billion dollar market opportunity for Melt
- Our lead drug candidate is MELT-100, a dissolving tablet containing midazolam + ketamine, administered sublingually for conscious sedation for surgical (HOPD and in-office) procedures
- A cGMP compounded version of our lead drug candidate has been dispensed over 100,000 times
- When used for cataract surgery, in a 611 patient study, the compounded drug demonstrated that it is a superior ($P = 0.01$) alternative to diazepam in reduction of anxiety and need for additional IV medications



LEAD DRUG CANDIDATE

MELT-100: FOR CONSCIOUS SEDATION
sublingual midazolam + ketamine drug candidate

Key competitive advantages:

- Non-opioid
- Institutional use only; drug will never be prescribed to patients (lowering abuse deterrence need)
- Patient preference for sublingual delivery over standard of care which typically includes IV sedation medications such as propofol, ketamine, midazolam, diazepam
- Clinical data from 611 patient randomized study and nearly 100,000 other units sold as a compounded drug validate advantages

It is widely believed that the sublingual route of administration delivers drugs directly to the central circulation, bypassing first-pass metabolism, providing high bioavailability and rapid sedation while also avoiding complications associated with IV drug delivery



MARKET OPPORTUNITY



Near Term: Cataract Surgery Sedation

- Compounded drug experience is primarily during cataract surgery and “conscious sedation during cataract surgery” label may provide lowest development risk with immediate commercial upside
- Attain Medicare Part B temporary pass-through code and fund label expansion studies
 - 4.4 million cataract surgeries equates to a \$1B opportunity
- Melt intends to leverage Imprimis’s existing commercial footprint in cataract surgery to commercially launch with minimal capital outlay

Long Term: Conscious Sedation Portfolio

- In the U.S. alone, there are an estimated 100M procedures with durations from 10 minutes to 2 hours where MELT-100 may be appropriate as a pre-sedation or procedural-sedation drug
- We intend to pursue broader labels and new applications for our IP for procedures such as colonoscopies, and application in dentistry, podiatry, dermatology, ER settings and others (see next slide)
- US patent issued March 20, 2018 (expiration in: 2036); in addition to 4 pending-patent applications (formulation and methods of use)

TARGETED PROCEDURES	Annual Procedures (US)
Ocular Surgeries ¹	4,500,000
Vasectomies ²	500,000
Endoscopic ³	18,500,000
Dental ⁴	20,000,000
Women's Health ⁵	1,100,000
Biopsies ⁶	3,200,000
Emergency Room ⁷	19,000,000
Cosmetic/Dermatology ⁸	500,000
Minor surgeries (e.g. skin, bone breaks) ⁹	1,000,000
MRI ¹⁰	34,000,000
Foot Surgeries ¹¹	150,000
Total	102,450,000

1. Market Scope, LLC, Comprehensive Report on the Global IOL Market (2013, May).

2. Allen, A. (2007). Vasectomy Risks and Benefits. Retrieved November 08, 2016, from <http://www.webmd.com/men/features/vasectomy-erisks-benefits>

3. US Market Report Suite for Gastrointestinal Endoscopic Devices 2017 - MedSuite. (2016, August 01). Retrieved January 08, 2017, from <https://www.databaserearch.com/product/us-market-report-suite-for-gastrointestinal-endoscopic-devices-2017-medsuite/>

4. Endodontic Facts by the American Association of Endodontists. (n.d.). Retrieved January 07, 2017, from <http://www.aae.org/about-aae/newsroom/endodontic-facts-aae>

5. Sklavos, M. M., Spracklen, C. N., Safflas, A. F., & Pirto, L. A. (2014, February 23). Does Loop Electrosurgical Excision Procedure of the Uterine Cervix Affect Anti-Mullerian Hormone Levels Retrieved January 08, 2017, from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3953513/> 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/65512a1.htm>

6. Voigt, J., & Mosier, 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/>

7. Internal estimate based on data from National Hospital Ambulatory Medical Care Survey: 2015 Emergency Department Summary Tables https://www.cdc.gov/nchs/data/nhamcs/web_tables/2015_ed_web_tables.pdf

8. ASPS 2015 Plastic Surgery Statistics Report - American Society of Plastic Surgeons. (2015). Retrieved January 8, 2017, from <https://dzwerz3b6wgn.cloudfront.net/News/Statistics/2015/plastic-surgery-statistics-full-report-2015.pdf>

9. 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/PMC3929546/>

10. I.M.V. Medical Information Division, Inc. Benchmark Report MR2013 (2013, July). Retrieved December 15, 2015.

11. LaPointe, Bunion Surgery: A Prospective Clinical Outcomes Study http://www.podiatryinstitute.com/pdfs/Update_2001/2001_11.pdf

MELT PIPELINE



MELT 101

sublingual combination of ketamine + midazolam

- Expanded label of MELT-100 for dental and other short duration surgeries (biopsies, vasectomies, etc.)

MELT 102

sublingual combination of ketamine + midazolam

- Expanded label of MELT-100 for acute claustrophobia and emergency room applications

MELT 130

sublingual combination of ketamine + midazolam

- Extended release formulation, for colonoscopies and other longer duration procedures

MELT 150

sublingual combination of ketamine + midazolam

- Lower concentration and more prevalent flavor masking for pediatric use

COMPETITION BACKGROUND

- Most widely used products in procedural sedation are IV propofol, fentanyl and midazolam. Common oral medications used for sedation in minor procedures include diazepam and lorazepam
- We believe IV midazolam alone and in many instances in combination with other medications, such as fentanyl, ketamine and propofol are the most commonly used medications for sedation during cataract surgeries and colonoscopies
- The propofol label mandates the presence of an anesthesia or other certified medical professionals throughout the procedure due to propofol's risk of respiratory and cardio depressive side effects, which results in additional cost
- For midazolam, these respiratory and other side effects are less pronounced and have a different relevance, because an undesirably deep sedation can be reversed with flumazenil
- There are known costs associated with administering IV sedation, which in addition to supply and personnel costs, include patient anxiety leading to procedure cancellations





REAL WORLD EXPERIENCE

MELT PHARMACEUTICALS



REAL WORLD

EXPERIENCE WITH MELT TECHNOLOGIES



- Nearly 100,000 units of MELT-100 (with ondansetron) have been produced and dispensed by Imprimis as a compounded drug (the “MKO Melt”), primarily used during cataract surgery
- MKO Melt is currently dispensed from Imprimis’ FDA-registered outsourcing facility
- MKO Melt is made to cGMP specifications (21 CFR Parts 210 and 211)
- 400+ US ophthalmologists, anesthesiologists and other medical doctors use the MKO Melt in dental, urology, dermatology/cosmetic and pediatric procedures

HUMAN CLINICAL EXPERIENCE

The Jeffries Study - Cataract Surgery

A board certified anesthesiologist conducted a 611 patient IRB approved prospective, controlled, randomized, 3 arm comparator study for conscious sedation during cataract surgery.

- PRECIS: When used for cataract surgery, the MKO Melt offered an opioid-sparing alternative to conscious sedation that is safe, effective and superior to diazepam in reduction of anxiety and need for IV medications
- Data showed statistical significance and/or equivalent results of safety, efficacy and patient anxiety favoring the MKO Melt vs. (i) diazepam and (ii) diazepam/tramadol/ondansetron combo
- No significant difference in surgical or discharge times, surgeon or patient satisfaction, or side effect profile

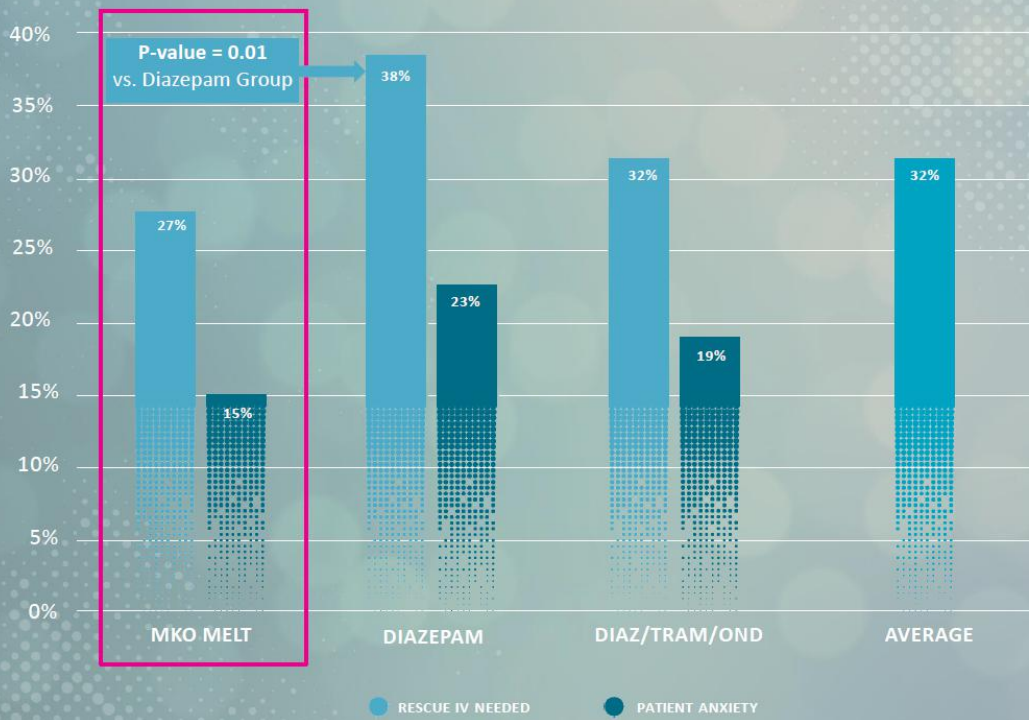


MELT JEFFRIES STUDY OUTCOMES

PHARMACEUTICALS

WITH MELT TECHNOLOGIES

Jeffries Study: Indicated MKO Melts provide an opioid-sparing, safe, and effective conscious sedation profile, and provided the lowest incidence/need for additional IV medications out of the three arms studied





CLINICAL PROGRAM

MELT PHARMACEUTICALS



MELT ¹⁰⁰ CLINICAL PROGRAM *

Expected Development Program Requirements:

- One pharmacological toxicity study before IND filing
- PK Study to establish bioavailability vs. reference drugs
- Single factorial designed study (Phase III), with multiple study arms:
 - Comparator against midazolam alone
 - Comparator against ketamine alone
 - Comparator against placebo alone
- Open label safety study to fully establish safety profile
- FDA may require a Phase II/Dose ranging study; however there may be enough data provided (Jefferies study and compounding experience) to establish dosing requirements
- PIND meeting with FDA in Q1 2019

*Plans and studies are dependent upon FDA review, recommendations, and determinations. The scenario described here is what we believe is probable, however other scenarios – for better or worse – are likely and may require additional capital and time to complete.



MELT 100 CLINICAL PROGRAM *

Key Points:

- Establish endpoints via proceduralist and patient satisfaction, which we believe includes the need for additional/rescue medication (similar to Jeffries endpoints)
- Exclude ondansetron in MELT-100 drug candidate to lower trial risk, cost and complexity
- Utilize KOLs and ex-FDA leaders to maximize chances of success with program
- Continue to invest in investigator-led studies to help further inform our clinical trial designs and program
- Pre-IND meeting scheduled in Q1 2019, if accurate with assumptions, we believe we could complete our Phase II study (if needed) near the end of 2020
- Preliminary estimate of program costs (PIND through PDUFA): \$15M - \$18M

*Plans and studies are dependent upon FDA review, recommendations, and determinations. The description above is what we believe is probable, however other scenarios – for better or worse – are likely and may require additional capital and time to complete



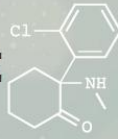


FORMULATION CHARACTERISTICS

MELT PHARMACEUTICALS

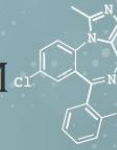


KETAMINE



- Ketamine is an FDA approved anesthetic, and was first introduced in the U.S. market in 1970
- Described as: “rapidly acting, nonbarbiturate general anesthetic” and a suggestion that ketamine, a unique intravenous anesthetic, would be useful for short procedures
- 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
- It also preserves the airway reflexes and has minimal effect on the respiratory drive
- 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

MIDAZOLAM



- 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

BIOAVAILABILITY ANALYSIS

A 2016 pharmacokinetics and pharmacodynamics analysis of midazolam, ketamine and ondansetron in a conscious sedation troche reported:

- Significantly lower peak plasma concentrations of midazolam and ketamine for sublingual delivery as compared to IV
- Peak plasma concentrations of midazolam and ketamine are achieved with only a modest delay as compared to IV administration; however, the elimination half times are similar via the two routes
- The onset of sedation following sublingual delivery of midazolam and ketamine is rapid, occurring within approximately 20 minutes of drug administration, and recovery from sedation is similar when drugs are given sublingually and IV
- There is an additive effect of midazolam and ketamine given IV, as such if the concentration of one drug is increased, the concentration of the other should be incrementally reduced



SUMMARY

- Our vision is to be the leading provider of non-opioid, non-IV conscious sedation and analgesia pharmaceuticals used in hospital, outpatient, and in-office settings
- Our IP is based on a patented series of sedation drug formulations that have been dispensed - as a compounded drug – nearly 100,000 times
- We believe the key competitive advantages of our drug candidates include: (i) non-opioid; (ii) institutional-use only of the drug candidates; and (iii) preference for sublingual delivery over standard-of-care IV sedation medications
- Based on a 600+ patient study, our technology indicated that it provides a safe and effective conscious sedation profile, and provided the lowest incidence/need for additional IV medications compared to the control groups
- If approved, we believe there are multi-billion dollar market opportunities for our drug candidates





APPENDIX

MELT PHARMACEUTICALS



I P S U M M A R Y

- US Patent 9,918,993 B2 entitled “Pharmaceutical compositions for anesthesiological applications” was issued on March 20, 2018 (filed date: June 16, 2016)
- 4 filed divisionals and CIPs for additional composition of matter and methods of use claims; additional routes of administration claims pending (nasal, buccal, suppository, etc.)

Key Claims Summary:

- A pharmaceutical composition, comprising a benzodiazepine-based compound, a NMDA antagonist and a pharmaceutically suitable binder therefor. Methods for fabricating the compositions and using them for anesthesiological applications are also described. More specifically, compositions described in claim 1 include:
 - (a) a therapeutically effective quantity of a first pharmaceutically active compound selected from the group consisting of midazolam, diazepam, lorazepam, flunitrazepam, alprazolam, chlordiazepoxide, clonazepam and clorazepate, and pharmaceutically acceptable salts, hydrates, solvates or N-oxides thereof;
 - (b) a therapeutically effective quantity of a second pharmaceutically active compound selected from the group consisting of ketamine, dextrorphan, etomidate, methadone, memantine, amantadine, dextromethorphan, and pharmaceutically acceptable salts, hydrates, solvates or N-oxides thereof;
 - (c) a pharmaceutically suitable binder therefor; and
 - (d) optionally, a pharmaceutically acceptable excipient,
- Wherein the pharmaceutical composition is formulated as a solid item adapted for sublingual or buccal administration, the solid item being selected from the group consisting of a troche, a lozenge, a capsule, a pill, a cap and a bolus.



MELT PHARMACEUTICALS

THANK YOU
