## 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): February 16, 2017

### **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))

#### Item 2.02 Results of Operations and Financial Condition

On February 16, 2017, Imprimis Pharmaceuticals, Inc. (the "Company") issued a press release which contained certain preliminary unaudited sales estimates of the company's ophthalmology business for the fourth quarter ended December 31, 2016. The press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information furnished under this Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section. The information in this Item 2.02, including Exhibit 99.1, shall not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent it is specifically incorporated by reference but regardless of any general incorporation language in such filing.

The information furnished under this Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed to constitute an admission that such information or exhibit is required to be furnished pursuant to Regulation FD or that such information or exhibit contains material information that is not otherwise publicly available. In addition, the Company does not assume any obligation to update such information or exhibit in the future.

#### Item 7.01. Regulation FD Disclosure

Attached as Exhibit 99.2 to this Item 7.01 is a presentation that is being used by the management of Imprimis Pharmaceuticals, Inc. (the "Company") at investor conferences and at meetings describing the Company.

The information contained in Item 7.01 of this report and in Exhibit 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 Press release dated February 16, 2017 issued by Imprimis Pharmaceuticals, Inc.

99.2 Imprimis Pharmaceuticals, Inc. presentation dated February 2017

#### 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.

By: /s/ Andrew R. Boll

Name: Andrew R. Boll Title: Chief Financial Officer

Dated: February 16, 2017

#### EXHIBIT INDEX

- 99.1 Press release dated February 16, 2017 issued by Imprimis Pharmaceuticals, Inc.
- 99.2 Imprimis Pharmaceuticals, Inc. presentation dated February 2017



#### Imprimis Pharmaceuticals Begins Dispensing from FDA-Registered 503B Outsourcing Facility

Improved efficiencies and additional revenue opportunities expected for Imprimis' ophthalmic portfolio

San Diego, Calif. – February 16, 2017 — Imprimis Pharmaceuticals, Inc. (NASDAQ: IMMY), an ophthalmology-focused pharmaceutical company, today announced that it has begun shipping its core sterile ophthalmic medications to select customers from its FDA-registered outsourcing facility without the need for a patient-specific prescription. Over the next few weeks Imprimis' flagship <u>Dropless Therapy</u><sup>®</sup> injectable and <u>LessDrops</u><sup>®</sup> topical formulations will become available to all customers. New and existing customers can register for an ImprimisRx 503B account at <u>http://www.imprimisrx.com/503b-prereg/</u>.

Imprimis' New Jersey-based outsourcing facility, which is equipped with robotics for automated filling and labeling of products, will initially produce and dispense Imprimis' core sterile ophthalmic medications in compliance with current good manufacturing practice (cGMP) requirements for outsourcing facilities. Imprimis customers are now able to purchase Dropless and LessDrops medications in convenient 20-unit boxes without the need for patient-specific prescriptions. To facilitate expected growth, the company is introducing a new integrated order and fulfillment system that provides "online shopping cart-type" functionality that bypasses customer service and moves orders directly to the facility's fulfillment center. Increased production, labor and ordering efficiencies are expected to result in improved customer satisfaction and increased margins.

Mark L. Baum, CEO of Imprimis, stated, "This is a significant milestone for our company. We believe sales and adoption of our core ophthalmic formulations will increase considerably as a result of simplifying the ordering process for physicians, hospitals, group purchasing organizations and surgery centers. The new facility will accommodate those customers who prefer, or in some cases, require medications purchased from an FDA-registered outsourcing facility compliant with the highest quality standards. We are confident the investments we have made in infrastructure, improvements in operating efficiencies and our senior leadership team have positioned us to meet the current and anticipated increase in demand in our core ophthalmic business."

"Through our commitment to quality and innovation, Imprimis is making strong inroads into the ophthalmic pharmaceutical business. We expect our market capture trends to continue and increase as we move more business through our New Jersey outsourcing facility. We also believe the New Jersey outsourcing facility will be instrumental in realizing an increase in margins from the current low 50 percent range to greater than 60 percent in 2017. Our ophthalmology business growth was 20% in the fourth quarter 2016 versus the third quarter 2016, with preliminary unaudited ophthalmology sales of \$3.6 million in the fourth quarter of 2016. Over 1,450 customers have adopted our Dropless and LessDrops medications and we have serviced over 600,000 cataract and refractive surgeries since mid-2014. A growing number of high-volume ophthalmic surgery practices, hospitals and ambulatory surgery centers throughout the U.S. have become customers and we expect this number to significantly increase with the opening of our new FDA-registered cGMP outsourcing facility."

"Based on our successes in ophthalmology, we plan to expand our ophthalmology program and introduce additional innovative medications in 2017 for glaucoma, wet age-related macular degeneration and diabetic macular edema, dry eye disease and ocular infection and inflammation. Our ophthalmology business currently represents 60 percent of total revenues and we expect this to increase to 80 percent in 2017 and beyond. The efficiency of our model allows us to quickly innovate and safely deliver high-quality novel and clinically-relevant products to the market with less complications and at lower costs for our customers than our traditional pharmaceutical company competitors."

#### **About Imprimis Pharmaceuticals**

Imprimis Pharmaceuticals, Inc. (NASDAQ: IMMY) is a pharmaceutical company dedicated to producing and dispensing high quality innovative medications in all 50 states. The company's unique business model increases patient access and affordability to many critical medicines. Headquartered in San Diego, California, Imprimis owns and operates three production and dispensing facilities located in California, New Jersey and Pennsylvania. For more information about Imprimis, please visit the corporate website at www.ImprimisRx.com.

#### **Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Any statements in this release that are not historical facts may be considered such "forward looking statements." Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties which may cause results to differ materially and adversely from the statements contained herein. Some of the potential risks and uncertainties that could cause actual results to differ from those predicted include our ability to make commercially available our compounded formulations and technologies in a timely manner or at all; physician interest in prescribing our formulations; risks related to our compounding pharmacy operations; our ability to enter into other strategic alliances, including arrangements with pharmacies, physicians and healthcare organizations for the development and distribution of our formulations; our ability to obtain intellectual property protection for our assets; our ability to accurately estimate our expenses and cash burn, and raise additional funds when necessary; risks related to research and development aimpacting compounding pharmacies, outsourcing facilities and the pharmaceutical industry; competition; and market conditions. These and additional risks and uncertainties are more fully described in Imprimis' filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K and its Quarterly Reports on Form 10-Q. Such documents may be read free of charge on the SEC's web site at www.sec.gov. Undue reliance should not be placed on forward looking statements, which speak only as of the date they are made, or to reflect the occurrence of unanticipated events.

Other than drugs compounded at a registered outsourcing facility, all Imprimis compounded formulations may only be prescribed pursuant to a physician prescription for an individually identified patient consistent with federal and state laws.

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Source: Imprimis Pharmaceuticals, Inc.

#### Media Contact

Deb Holliday <u>deb@pascalecommunications.com</u> 412-877-4519

#### **Investor Contact**

Bonnie Ortega <u>bortega@imprimispharma.com</u> 858-704-4587



## NASDAQ: IMMY

Mark L. Baum, CEO February 2017

# 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 (the "Company" or "Imprimis") 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 forwardlooking 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 forwardlooking 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. Imprimis expressly disclaims any intent or obligation to update these forward-looking statements except as required by law.

Imprimis



Ophthalmology focused

pharmaceutical company

1,450+ ophthalmologist

Shifting treatment paradigms

Cash-based 90% of revenues

in cataract, glaucoma and

Not reliant on "middlemen"

(PBMs, insurance, rebates

27+ patents and pending

Committed to lower-cost

innovative medications

customers & growing

conscious sedation

wholesalers)

patents

.

## Rerformance/Value

- 8 quarters of consecutive quarterly growth
- 245% revenue CAGR since launch (2014 - 2016)
- Ranked 12<sup>th</sup> on Deloitte's 2016 Technology Fast 500 and 4<sup>th</sup> fastest growing U.S. pharmaceutical/biotech
- Estimated >10% share in post-cataract and refractive surgery care markets
- Balance sheet to execute
- 2017 Expectations:
  - Increase margins from low 50% to 60%
  - Realize operating profit

 2017 planned ophthalmology launches into:

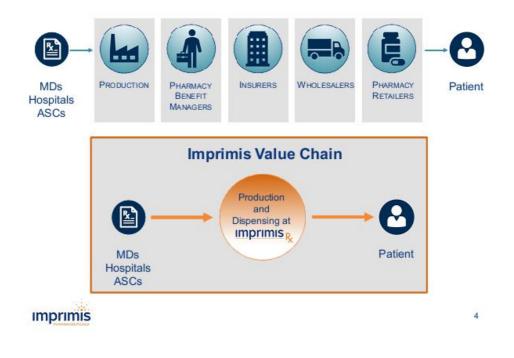
**Planned Growth** 

- Glaucoma
- Wet AMD & DME
- Dry Eye Disease (DED)
- Infection and Inflammation
- Expand ophthalmology segment to 80% of revenues
- Narrow product portfolio
- Lower unit costs with larger batch sizes and labor savings
- Utilize paid-for production & distribution infrastructure to increase operating efficiency
- Expand relationships with existing and new payor networks

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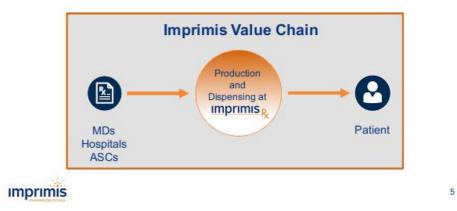
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# **Traditional Pharmaceutical Value Chain**



## 100% Transparency

- No insurance company, pharmacy benefit manager (PBM), wholesaler or distributor middlemen
- No formulary rejections, discount cards or rebates
- No payment submittals, investigations or PBM clawbacks
- No need for "Patient Assistance Programs" with affordable pricing



## 2017 Expected Margin Expansion

#### **Production Efficiency**



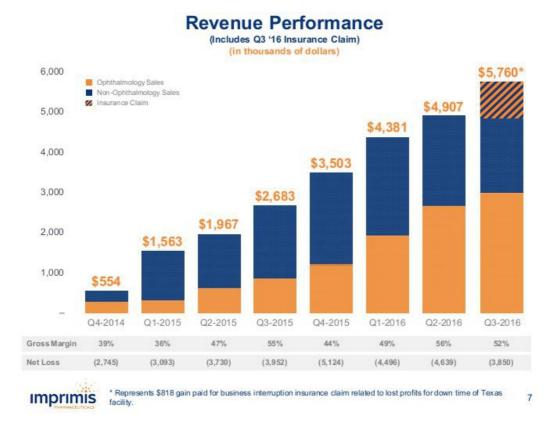
- New state-of-the-art cGMP production facility
- \$5M+ investment in robotics and automation
- Increased batch sizes and unit yields per batch
- Lower labor costs (fewer FTEs; lower-cost personnel)
- cGMP standards open new account opportunities



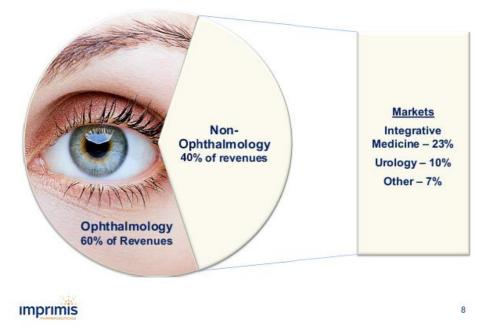
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Integrated order and fulfillment software system

- "Amazon-type" online ordering portal bypasses customer service directly to fulfillment
- Automated invoice generation and labeling
- Minimum order requirement of 20 units increases average sales per order
- Improved customer convenience and satisfaction
- Reduced customer service costs per order



## 2016 Revenue Mix

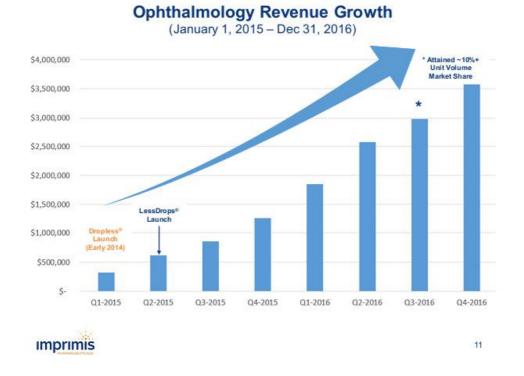




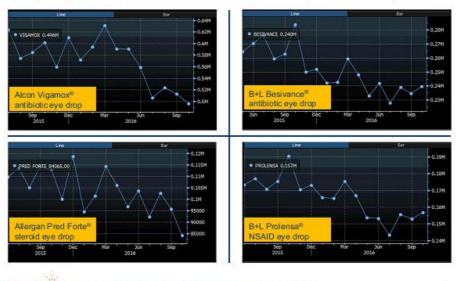
Post-Cataract Post-LASIK Surgery Antibiotics Stenids NSAIDS		Ophthalmic Sedation	Wet AMD DME	Glaucoma	Ophthalmic Surgery	Uveitis	Dry Eye	Infection Inflammation
		Conscious Sedation	Anti-VEGF Bevacizumab Ranibizumab Aflibercept	Prostaglandins Beta Blockers Alpha Agonists Carbonic Anhydrase Inhibitors	Epinephrine Pherrylephrine Shurgcaine Ketorolac	Carticasteroids	Cyclosporine Lifitegrast Artificial Teans Devices Nutraceuticals	Combination Steroid & Antibiotic
Dropless Therapy® Injectable	LessDrops® Combination Drops	MKO Melt™ Sublingual Sedation*	Repackaged Avastin	Combination Eye Drops	Mydriatics Anesthetics	Corticotropin*	Combination Eye Drops	Combination Gati-Dex
VIGAMOX <sup>®</sup> (antibiotic) Besivance <sup>®</sup> (antibiotic) DUREZCL <sup>®</sup> (stencic) PROLENSA <sup>®</sup> (NSAID) Predrisidone Acetatie (stencid)- Ketorolec (NSAID)			Eylea <sup>e</sup> Lucentis <sup>®</sup> Repackaged Avastin	Lunigan <sup>e</sup> Combigan <sup>e</sup> Alphagan <sup>e</sup> P Latanoprost Dorzdamide/ Timdd	OMIDRIA® Phenylephrine and ketorolac	Lotemaxi <sup>®</sup> Durezol <sup>®</sup> Acthar <sup>®</sup> H.P. Gel	Restasis® Xidra® Cyclosporine	TcbraDex® Zylet® Lotemax® Tobramydin / Dexamethasone
\$100m	\$360m	\$100M	\$130m	\$500m	\$100m	\$100m	\$100m	\$100m
APR 2014	JAN 2015	MAY 2016	1H 2017	1H 2017	1H 2017	2H 2017	2H 2017	1H 2017

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\*Other large non-ophthalmology market opportunities MKO Melt: MRI procedures, dental procedures, colonoscopies, vasectomies, biopsies, women's health, and cosmetic surgery procedures. Corticotropin: Infantile spasms, multiple sclerosis, nephrotic syndrome, systemic lupus enythematosus

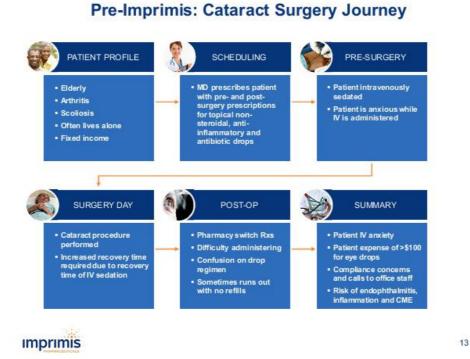


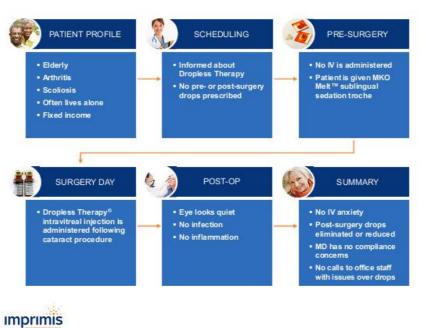
# **Competitive Analysis of Market Leaders**



Eye drop market leaders unit volumes since LessDrops® launch - May 2015

IMPLIMIS Symphony Health Solutions (IMS Health Inc. data) retrieved February 7, 2017 2





# Imprimis' Dropless<sup>®</sup> and IV Free<sup>™</sup> Experience

# **Dropless Cataract Surgery®**

### **Dropless Therapy®**



### **Standard of Care**



## What is it?

 Patent-pending one-time steroid/antibiotic combination injection at the end of cataract procedure

## Why is it important?

- Substantially reduces or eliminates the need for post-operative eye drops
- Lower-cost compared to standard of care eye drops costing an estimated \$323<sup>3</sup>
- Patients and MDs prefer Dropless<sup>®4</sup>
- Over 325,000 units sold since mid-2014
- Strong body of supportive clinical research<sup>4-6</sup>

## What is the opportunity?

- Imprimis est. TAM = \$100M
- Growing market with aging population, 3.8M cataract annually U.S.<sup>7</sup>



\* Published clinical data (Appendix)

## **Combination Eye Drops**



#### Standard of Care



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### What is it?

- Patent-pending combination eye drops used following cataract and refractive procedures:
  - Antibiotic + Steroid
    NSAID + Steroid
  - · NOAD + Steron
  - Triple Drop<sup>®</sup>

### Why is it important?

- Lower-cost compared to standard of care eye drops - \$60 vs. \$323<sup>3</sup>
- 50% fewer eye drop applications
- Growing business with over 235,000 units sold since launch in early 2015

#### What is the opportunity?

- Imprimis est. TAM = \$360M
- 3.8M cataract and 600,000 LASIK surgeries annually U.S.<sup>7,8</sup>

What is it?
<ul> <li>Patent-pending MKO Melt<sup>™</sup> sublingual sedation</li> </ul>
<ul> <li>Combination midazolam, ketamine &amp; ondansetror</li> </ul>
\$15 per Melt; sold in 1, 2 or 3 Melt packs
Why is it important?
<ul> <li>Conscious sedation instead of intravenous sedation</li> </ul>
<ul> <li>Growing customer base with over 120 prescribing</li> </ul>
MDs since launch in mid-2016
What is the opportunity?
Imprimis est. ophthalmology TAM = \$100M
<ul> <li>4.4M ocular surgeries performed annually in U.S.<sup>7,8</sup></li> </ul>
Imprimis est. non-ophthalmology TAM = \$1.9B
<ul> <li>70M+ procedures<sup>*1,9-19</sup></li> </ul>

IV Free<sup>™</sup> Conscious Sedation



### **Glaucoma Eye Drops**

#### Glaucoma Combination Drop



#### Standard of Care is 2+ Bottles



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#### What is it?

- Portfolio of combination eye drops for glaucoma expected to be launched in 1H 2017
- Preservative-free to reduce burning and stinging common in current drops
- Proprietary technology increases corneal penetration and length of residence on the eye

### Why is it important?

- Glaucoma is chronic, incurable and if not treated can lead to blindness
- Lower-cost; more convenient than multiple drops

#### What is the opportunity?

- Imprimis est. TAM = \$500M
- 4 million glaucoma patients in the U.S.<sup>20</sup>



### **Integrative Medicines**

#### Ascorbic Acid, Curcumin & Artesunate

23% of total 2016 revenues



### What is it?

- Integrative medicines for oncology, autoimmune diseases and chronic infectious diseases
- Leading medications include ascorbic acid (non-corn source), curcumin emulsion (patent pending) and artesunate (lyophilized)

### Why is it important?

- Integrative medicines represented 23% of total 2016 revenues
- Customers are thought leaders in their fields
- Imprimis' leadership demonstrated by Integrative Therapies Institute (ITI) educational conferences (running since 2012)

What is the opportunity?

Imprimis est. TAM = \$100M

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## Injectable For Erectile Dysfunction

#### Tri-Mix Injectable

### What is it?

### Recommended by AUA



imprimis

 Tri-Mix (phentolamine, papaverine and prostaglandin) injectable for erectile dysfunction (ED)

### Why is it important?

- Recommended treatment by the American Urology Association (AUA)
- Lower-cost vs. standard of care oral medications
- Growing business with over 600 patients
- Key customer is a leading national managed healthcare company

#### What is the opportunity?

- Imprimis est. TAM = \$500M+
- 30M U.S. males have ED<sup>21</sup>

## Lower-Cost Alternative to Elmiron for IC



#### What is it?

 PPS DR<sup>®</sup> (pentosan polysulfate sodium) for interstitial cystitis (IC)

### Why is it important?

- Recommended treatment by the American Urology Association
- Delayed-release
- Lower-cost alternative to Elmiron<sup>®</sup>
- \$99 vs. \$800 per month<sup>22</sup>

### What is the opportunity?

- Imprimis est. TAM = \$100M
- Up to 12M patients in the U.S.<sup>23</sup>



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### **Cost and Simplicity**

- ~90% cash pay
- 50-75% consumer cost savings
- No middlemen, rebates, discount cards



# **Company Profile**

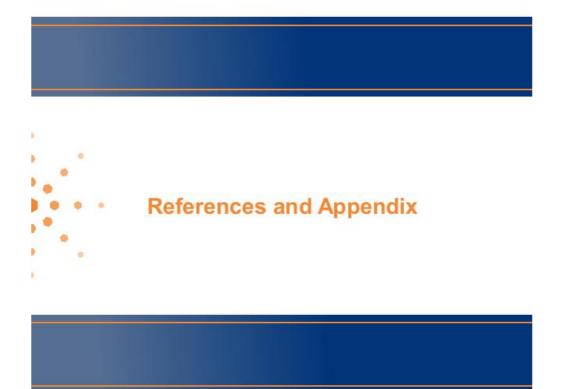


Trading symbol: NASDAQ: IMMY Price per share (2-10-2017): \$2.62 Stock price range (52-week): \$1.65 - \$4.90 Average daily trading volume: 116,000 shares Market cap: \$43 million Shares Outstanding: 18.6 million



Corporate headquarters: San Diego, CA Facilities: Irvine, CA, Ledgewood, NJ, Folcroft, PA Website: www.ImprimisRx.com

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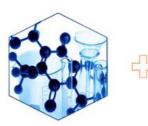


#### Imprimis Pharmaceuticals (NASDAQ: IMMY)

12264 El Camino Real, #350 San Diego, CA 92130 (858) 704-4040 www.imprimispharma.com

## **Disruptive Business Model**

We use 7,800+ FDA-approved generic drugs to create *new* lower-cost, high-quality, customizable and often patentable compounded formulations



FDA-approved APIs made in FDA registered facilities according to USP monographs



Strict quality standards mandated by the Drug Quality & Security Act of 2013



Lower cost novel compounded medications

imprimis

# **Drug Combination IP**



imprimis

### **Published Clinical Data**

Tyson, S. L., et al. (2017, January). Clinical outcomes after injection of a compounded pharmaceutical for prophylaxis after cataract surgery: a large-scale review. *Current Opinion in Ophthalmology*.

No major intraoperative complications associated with the transzonular injection technique. There were no cases of postoperative endophthalmitis. Rates of infection and inflammation reported in this retrospective review of 1,541 cases from 922 patients receiving a transzonular injection of Tri-Moxi-Vanc for prophylaxis after cataract surgery appear similar to reported rates with alternative prophylactic therapies such as topical drops.<sup>5</sup>

Fisher, B. L., & Potvin, R, (2016, July 18). Transzonular vitreous injection vs a single drop compounded topical pharmaceutical regimen after cataract surgery. *Current Pharmaceutical Design*.

Review of the rationale for reducing topical therapy in cataract surgery prophylaxis, and what is known to date about the efficacy and safety of the Dropless<sup>®</sup> approach. Both groups expressed similar satisfaction with surgery, but patients who received Dropless<sup>®</sup> preferred the overall experience (*P*=0.01).<sup>4</sup>

Lindstrom, R.L., et al. (2017). Dropless Cataract Surgery: An Overview. *Current Pharmaceutical Design*. (E-pub ahead of print – Volume 22).

Cataract surgery completed with Tri-Moxi-Vanc intraocular solution injected transzonularly into the vitreous vs. topical formulation of Pred-Moxi-Ketor, followed by Pred-Ketor was similar in outcome. Significantly more subjects preferred the injection, presumably as a function of the greater convenience with no apparent difference in the therapeutic effect.<sup>6</sup>

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