

**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): May 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 7.01. Regulation FD Disclosure

Attached as Exhibit 99.1 to this Item 7.01 is a presentation of Eton Pharmaceuticals, Inc. (“Eton”), 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 Eton 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 Eton Pharmaceuticals, Inc. presentation dated May 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.

Dated: May 16, 2017

By: /s/ Andrew R. Boll

Name: Andrew R. Boll

Title: Chief Financial Officer

EXHIBIT INDEX

99.1 Eton Pharmaceuticals, Inc. presentation dated May 2017



pharmaceuticals

CORPORATE PRESENTATION

MAY 2017





p h a r m a c e u t i c a l s

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 Eton Pharmaceuticals, Inc.'s (the "Eton", 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; 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 Imprimis' 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. Imprimis expressly disclaims any intent or obligation to update these forward-looking statements except as required by law.



pharmaceuticals

ABSTRACT

Eton is a subsidiary of Imprimis Pharmaceuticals, Inc. (NASDAQ: IMMY)

Focus on 505(b)(2) patent-pending drug candidates with multiple potential indications in billion dollar markets with single incumbent competition

Eton will be funded and managed outside of Imprimis

Initial development assets are two patent-pending drug candidates:

SYNTHETIC CORTICOTROPIN (drug incumbent: H.P. Acthar® Gel)
MS relapse, Infantile Spasms – incumbent drug sales \$1.1B+¹

INJECTABLE PENTOXIFYLLINE (drug incumbent: Xiflex®)
Peyronie's disease – U.S. drug market potential \$1B+²

Two **DESI ASSETS** to provide near term revenue and cash flow streams

DESI Asset #1 (pain) estimated annual peak sales potential of \$50M

DESI Asset #2 (dialysis) estimated annual peak sales potential of \$20M+

FASTER PATH TO APPROVAL

505(B)(2)

- Potential for lower risk due to reference product approval
- Lower cost, accelerated development, fewer studies
- Can rely on already completed clinical trials, existing data
- May qualify for 3-5 years of exclusivity (extended with IP)
- Shorter path to approval yet still rewards innovation

DESI DRUGS

- Drugs on market prior to efficacy requirement from FDA (pre 1962)
- Access 505(b)(2), approvals often near term & with no trials, at lower cost, less uncertainty
- Market exclusivity: up to 3 years; (extend with IP)
- Upon approval, sponsor determines market price
- Opportunity for generic product risks & cost, with branded product rewards
- DESI conversions can multiply total product sales dramatically

The logo for eTon pharmaceuticals, featuring the word "eTon" in a lowercase, sans-serif font. The "e" is lowercase, while "Ton" is uppercase. The logo is white and set against a dark, semi-transparent square background.

eTon

pharmaceuticals

MS RELAPSE & INFANTILE SPASMS

SYNTHETIC CORTICOTROPIN (FOR INJECTION)

The logo for eTon pharmaceuticals, featuring the word "eTon" in a lowercase, sans-serif font. The "e" is lowercase, while "Ton" is uppercase. The logo is white and set against a dark, semi-transparent square background.

eTon

pharmaceuticals

MS RELAPSE & INFANTILE SPASMS

SYNTHETIC CORTICOTROPIN (FOR INJECTION)



pharmaceuticals

MARKET ANALYSIS:

HP ACTHAR® GEL

Adrenocorticotrophic hormone analogue used for various indications (see slide 9)

H.P. Acthar® Gel was acquired by Mallinckrodt in 2014 through \$5.8B Questcor acquisition³

Questcor's sole commercial asset was H.P. Acthar® Gel

2016 net annual sales for H.P. Acthar® Gel est. \$1.1B¹

H.P. Acthar® Gel is currently priced at \$38,000 per 5mL vial⁴

FDA approved in 1952; off-patent; no generics or similar type drug⁵

Barriers to entry:

- HIGHLY UNSTABLE
- ANIMAL DERIVED MOLECULE IS DIFFICULT TO MANUFACTURE API
- NO ESTABLISHED BIOEQUIVALENCE MODEL

CORTICOTROPIN FORMULATION

Eton synthetic formulation mimics amino acid chain of H.P. Acthar[®] Gel

Patent-pending technology stabilizes a known unstable molecule

Eton formulation description:

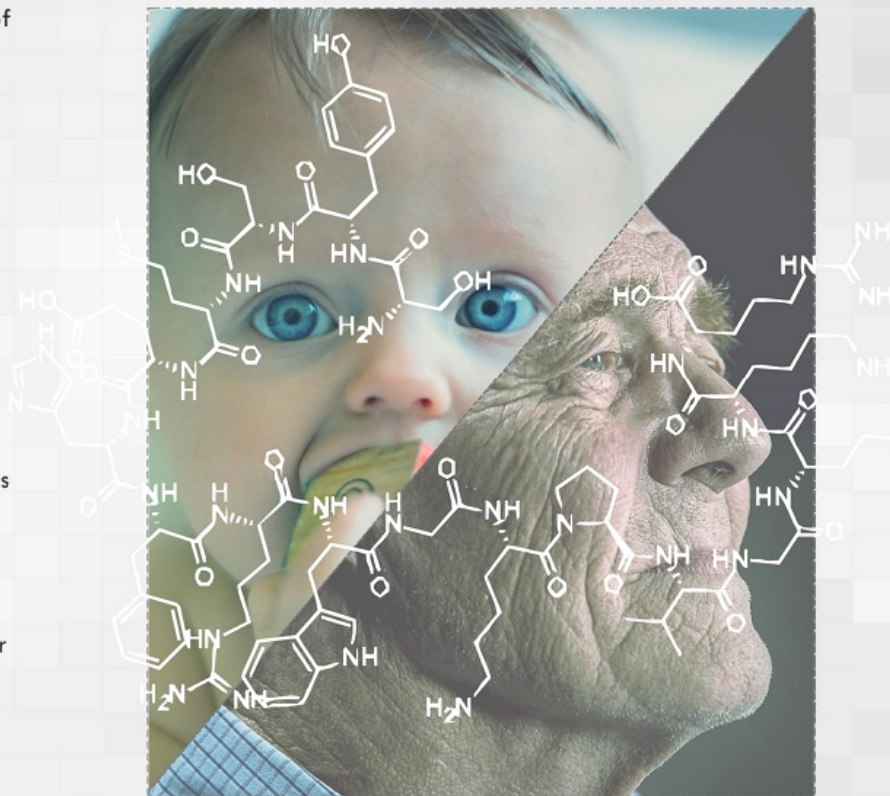
- 39-chain amino acid peptide synthetic adrenocorticotrophic hormone
- Preservative free and non-gelatin, extended release synthetic Corticotropin
- Demonstrated 180 days of stability – without significant deterioration over time

FDA has shown favorable bias for synthetic molecules

API sourcing/stability (porcine) may be overcome with Eton formulation


Formulation and dosage form (non-gelatin) allow for 505(b)(2) pathway

Payors are highly motivated to find alternatives to H.P. Acthar[®] Gel



COMPETITIVE ANALYSIS

	 Mallinckrodt ACTHAR GEL	 ani PHARMACEUTICALS, INC. CORTICOTROPIN (ZINC)	 MARATHON SYNACTHEN*
REGULATORY	FDA APPROVED (1952)	WORKING TOWARDS sNDA SUBMISSION	FTC FORCED LICENSE OF DRUG RIGHTS
API SOURCE	PORCINE PITUITARY GLANDS	PORCINE PITUITARY GLANDS	SYNTHETIC
AMINO ACID PEPTIDE	39 CHAIN	39 CHAIN	24 CHAIN
PATENTS	NONE	NONE	NONE



SYNTHETIC CORTICOTROPIN

505(B)(2)

SYNTHETIC

39 CHAIN

PATENT-PENDING

* Synacthen and Synacthen Depot:

- Synacthen Depot approved O.U.S.; excl. rights acquired by Questcor (2013) for up to \$300M from Novartis AG - WW controlled by Mallinckrodt⁶
- Mallinckrodt paid \$100M to settle anti-trust charges; agreed to grant a sublicense to develop Synacthen in US to Marathon (Jan. 2017)⁷

ESTIMATED TARGET MARKETS⁸

DIAGNOSIS	FISCAL 2016* ACTHAR ADDRESSABLE PATIENTS	FISCAL 2016* TREATED W/ ACTHAR	PATIENTS NOT TREATED W/ACTHAR	ACTHAR PENETRATION RATE
INFANTILE SPASMS	1,500	797	703	53%
MULTIPLE SCLEROSIS RELAPSE	26,456	4,829	21,627	18%
PROTEINURIA REMISSION IN IDIOPATHIC NEPHROTIC	12,156	1,494	10,662	12%
DERMATOMYOSITIS (POLYMYOSITIS)	20,000	849	19,151	4%
SYMPTOMATIC SARCOIDOSIS	22,000	506	21,494	2%
RHEUMATOID ARTHRITIS (ADJUVANT THERAPY)	84,332	1,492	82,840	2%
SLE (LUPUS)	76,170	1,043	75,127	1%
PSORIATIC ARTHRITIS	27,000	174	26,826	1%
ANKYLOSING SPONDYLITIS	49,080	43	49,037	0%
TOTAL	318,694	11,227	307,467	

*Estimate and based on Mallinckrodt Pharmaceuticals, Inc. fiscal year

SCENARIO 1

- FDA agrees that the product is the “same as” the naturally derived product
- Potential for significant CMC and possibly some immunogenicity work but not sophisticated analytical testing. Must demonstrate we meet current impurity and degradation limits under ICH
- No additional toxicology studies required; permits reliance on the DESI indications and the previous findings of safety and efficacy in the H.P. Acthar (Acthar) gel application
- FDA will likely require a bridging study to gauge reliance (e.g., AUC, partial AUCs and C_{max}, T_{max}) and are similar enough to permit such reliance
- Issues of endogenous material identified in any bridging studies
- FDA provides the full label as Acthar
- FDA agrees that the products are equivalent and gives an “AB” therapeutic equivalence evaluation (AB would permit substitution between the synthetic and naturally occurring product)

Estimated Cost/Duration of development:

- \$5M - \$12M
- 2 – 3 Years

SCENARIO 2

- FDA requires immunogenicity work and analytical work demonstrating not only that the sequence of the amino acids are the same, but that extraneous material in the naturally-derived material does not contribute to the effectiveness of the product (the conjugated estrogen example)
- Potential for bridging studies and perhaps some smaller clinical studies to demonstrate that the synthetic product performs the same clinically
- Issues of endogenous material must be identified in bridging studies
- Depending on the results of the bridging, small clinical, and immunogenicity testing and CMC work, FDA agrees to give the same label but does not give a therapeutic equivalence rating permitting substitution due to certain differences that FDA determines are clinically significant
- Must meet current impurity and degradation limits under ICH (International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use)

Estimated Cost/Duration of development:

- \$15M - \$30M
- 3 - 5 years

*Additional scenarios exist that include the possibility of longer durations, costs, efforts and/or even FDA denying use of 505(b)(2) application, although Eton has described the scenarios above it believes are most relevant and which are most preferred.

The logo for eTon, featuring the word "eTon" in a lowercase, sans-serif font. The "e" is lowercase, while "Ton" is uppercase. The logo is white and set against a dark, semi-transparent square background.

eTon

pharmaceuticals

PEYRONIE'S DISEASE

PENTOXIFYLLINE (FOR INJECTION)



pharmaceuticals

DISEASE PROFILE AND MARKET ANALYSIS:

PENTOXIFYLLINE

Peyronie's disease (PD) is the development of fibrous scar tissue (plaque) inside the penis that causes curved, painful erections

Symptoms can include: significant bend to and/or shortening of penis, penile pain with or without erection, and erectile dysfunction

~95,000 men in U.S. diagnosed annually⁹; experts believe disease may be underdiagnosed and prevalence of PD could be as high as 1 out of 11 men¹⁰
Some cases will not require treatment, most will remain or worsen without treatment

Xiaflex[®] (collagenase) is the only FDA approved, non-invasive treatment option for PD¹¹

- **"XIAFLEX[®] IS OUR FLAGSHIP BRANDED ASSET"** – ENDO Q4 and Full Year 2016 Presentation Feb. 28, 2017

Clinical study demonstrated avg. of 33%-35% improvement in curvature¹²

Course of treatment for Xiaflex[®]: \$26,000 - 8 injections total (2014)¹³

PD drug market estimated over \$1B U.S. market potential²

Xiaflex[®] also used to treat Dupuytren's Contracture and being developed for cellulite^{14,15}

ETON PHARMACEUTICALS:

PEYRONIE'S PROGRAM ADVANTAGES

Patent-pending formulation of pentoxifylline in solution as an injectable for the treatment of symptoms associated with PD

Generic, oral pentoxifylline is prescribed off-label as first-line treatment for certain patients suffering from PD for treatment of symptoms¹⁶

Pentoxifylline is a xanthine derivative, which improves blood flow and reduces blood viscosity and decreases the potential for platelet aggregation and thrombus¹⁷

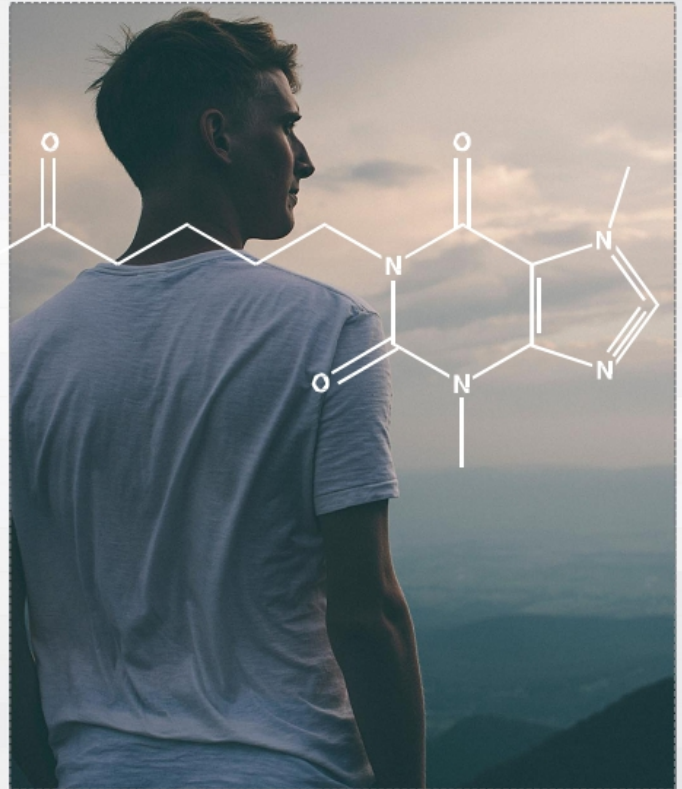
Certain reported side effects for oral pentoxifylline may be less severe when compared to Xiaflex/collagenase:

- **Xiaflex®**: penile fracture; swelling at injection site; bruising; hematoma; erectile dysfunction (ED); pain¹⁸
- **Oral pentoxifylline**: dizziness, headache, blurred vision; gas/upset stomach; nausea¹⁹

Compounded version of pentoxifylline injection prescribed by KOL: 5 treated; 2 finished treatment and reversed curvature; 3 completing treatment and "doing well"

Investigator initiated study (2014) showed improvement in pain, ED and curvature (described further in next slide)

Other indications covered under IP: Dupuytren's Contracture and Anti-Cellulite





pharmaceuticals

INITIAL STUDIES

OF ETON PENTOXIFYLLINE FORMULATION

Investigator-initiated study conducted at leading university to study up to 10 patients with PD

Goal was to determine:

- **Efficacy of injectable pentoxifylline for treatment of PD; identify ideal patient responders**
- **Gain experience with the formulation and treatment/dosing regimen**

Results:

- **6 patients completed full treatment regimen (12 injections)**
- **100% had improvement in pain and erectile dysfunction if either symptom was present**
- **2 patients indicated significant improvement in curve (approximately 50% improvement); 3 had arrested disease progression**
- **Outcome preliminarily revealed certain patients received better prognosis and response to treatment than others (presenting percent of curvature)**

Next Steps:

- **Identify proper patient profile for treatment (minimum amount of curvature, pain, etc.)**
- **Consider clinical pathway and Pre-IND* strategy: (a) extent of dosing studies and (b) safety studies; consider combination of existing data and literature with a small study for pain management (estimated \$5M to \$10M)**

*Additional scenarios exist that include the possibility of longer durations, costs, efforts and/or even FDA denying use of 505(b)(2) application, although Eton has described the scenarios above it believes are most relevant and which are most preferred.



pharmaceuticals



NEAR TERM OPPORTUNITIES

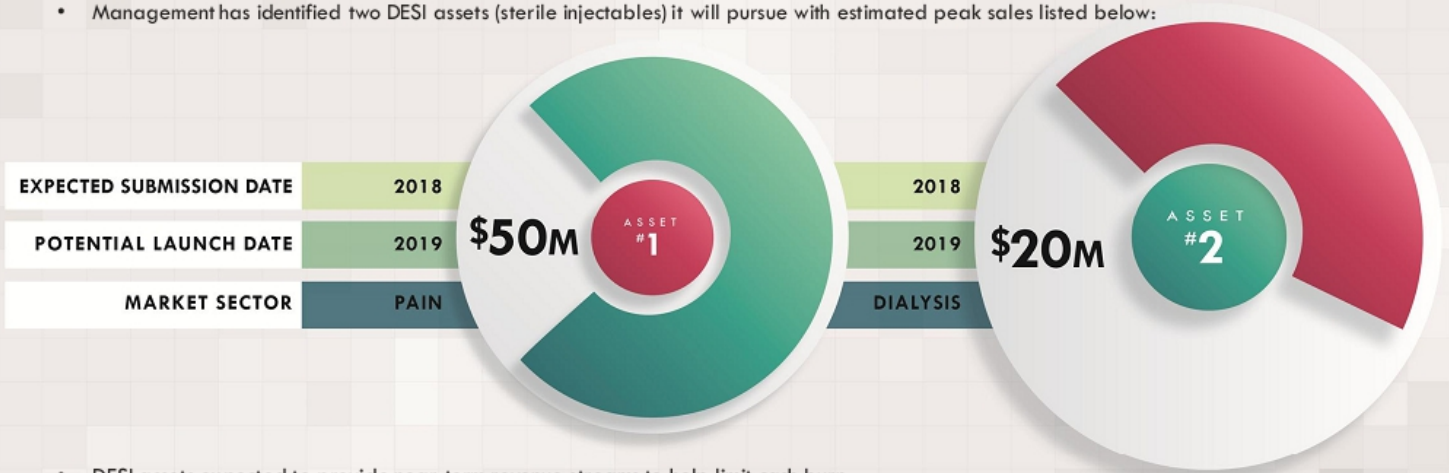
DESI DRUGS



DESI OPPORTUNITIES:

COMPETITIVE ANALYSIS

- FDA program Drug Efficacy Study Implementation (DESI) for drugs that came to market before 1962 prior to FDA approval for a drug requiring efficacy²⁰
- FDA can approve a new-drug application for a DESI drug and developer of the new drug may get a new period of market exclusivity for up to three years²⁰
- Management has identified two DESI assets (sterile injectables) it will pursue with estimated peak sales listed below:



- DESI assets expected to provide near-term revenue streams to help limit cash burn
- Management is aware of a number of additional DESI opportunities that exist and may be pursued as company's stage of development matures

DESI ASSET #1

Current product sales not captured by IMS, opportunity may be undervalued by the market

- Product is mostly sold direct to hospitals

Scarce API has been secured with long-term exclusive supply agreement

Development work is completed, registration batch production to be manufactured in August 2017

NDA submission with FDA anticipated in second half of 2018

Eton has signed an agreement to acquire DESI Asset #1, acquisition close upon Eton financing

Eton will pay a share of gross profits, less other certain expenses, generated from DESI Asset #1 to the seller



*Company internal estimates based on assumptions with respect to pricing, reimbursement, market penetration and other factors. Actual results and future Company estimates may differ materially.

DESI ASSET #2

Well known to physicians with decades long track record, providing immediate potential demand for product upon launch with no promotional spending

- There are no substitute prescription alternatives currently approved by the FDA

Finalizing development activities; registration batch production to be manufactured in Q4 2017

NDA submission with FDA anticipated in Q4 2018

Competing products have seen prices increase 15-40x over the last 5 years minimal impact on volumes – Asset 2 currently sold at discount to drug peers

Eton has signed an agreement to acquire DESI Asset #2, acquisition close upon Eton financing

Eton will pay a share of gross profits, less other certain expenses, generated from DESI Asset #2 to the seller



*Company internal estimates based on assumptions with respect to pricing, reimbursement, market penetration and other factors. Actual results and future Company estimates may differ materially.



pharmaceuticals



MANAGEMENT AND SUMMARY



pharmaceuticals

KEY TEAM MEMBERS

Chief Executive Officer*: Over 20 years of experience in the pharmaceutical industry. Mostly serving as senior executive in corporate development for multi-billion dollar pharma companies; has led over 100 transactions contributing hundreds of millions of dollars of annual revenue.

Director*: Charles Casamento former CEO of Questcor where he negotiated the purchase of H.P. Acthar Gel for \$100,000; Executive Director and Principal of The Sage Group, a health care advisory group; has led 5 startup companies, all of which were successfully taken public during his tenures. Has served on boards of 12 public companies.

Director: Mark L. Baum, J.D. is a founder, member of the board of directors and CEO of Imprimis Pharmaceuticals, Inc. He led the restructuring and reorganization of Imprimis, and has been its CEO since April 2012, and member of its board since December 2011.

Continued management, oversight and advisement from members of Imprimis Pharmaceuticals senior management team

*Appointment pending completion of financing.



pharmaceuticals

SUMMARY

505(b)(2) sterile injectable development focused Eton is a subsidiary of Imprimis Pharmaceuticals, Inc.

Eton will be funded and managed outside of Imprimis as a separate entity

Assembling experienced management and Board to carryout strategy

Two proprietary assets intended to treat diseases with significant unmet needs:

SYNTHETIC CORTICOTROPIN (drug incumbent: H.P. Acthar[®] Gel) -
Incumbent drug sales \$1.1B+

INJECTABLE PENTOXIFYLLINE (drug incumbent: Xiaflex[®]) -
U.S. drug market potential \$1B+

Two **DESI ASSETS** with potential to provide near term cash flow streams:

DESI Asset #1 estimated \$50M annual peak sales potential

DESI Asset #2 estimated \$20M+ annual peak sales potential

The logo for eTon, featuring the word "eTon" in a lowercase, sans-serif font. The "e" is lowercase, while "Ton" is uppercase. The logo is white and set against a dark, semi-transparent square background.

eTon

pharmaceuticals

APPENDIX



pharmaceuticals

REFERENCES

1. Mallinckrodt Pharmaceuticals: Jefferies London NDR Investor Presentation. (2017, March). Retrieved May 11, 2017.
2. Internal business data, 2017, based on assumptions with respect to pricing, reimbursement, market penetration and other factors. Actual results and future estimates may differ materially
3. Mallinckrodt Pharmaceuticals Press Release, PR Newswire. (2014, August 14). Mallinckrodt Completes Acquisition of Questcor Pharmaceuticals. Retrieved May 11, 2017, from <http://www.prnewswire.com/news-releases/mallinckrodt-completes-acquisition-of-questcor-pharmaceuticals-271292771.html>
4. GoodRx. (2017). H.P. Acthar Price. Retrieved May 11, 2017, from <https://www.goodrx.com/h.p.-acthar>
5. U.S. Food and Drug Administration. (2010, May 6). H.P. Acthar® Gel (repository corticotropin injection) for the Treatment of Infantile Spasms. Retrieved May 10, 2017, from <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PeripheralandCentralNervousSystemDrugsAdvisoryCommittee/UCM212954.pdf>
6. Questcor Pharmaceuticals, Inc. (2013, June 11). Current Report on Form 8-K filed with the Securities and Exchange Commission. Retrieved May 11, 2017, from <https://www.sec.gov/Archives/edgar/data/891288/000119312513254082/d552318d8k.htm>
7. Mangan, D. (2017, January 18). Mallinckrodt to pay \$100 million to settle FTC, state charges on antitrust violations. Retrieved May 11, 2017, from <http://www.cnbc.com/2017/01/18/mallinckrodt-reaches-settlement-with-ftc-on-probe-linked-to-martin-shkreli-backed-lawsuit.html>
8. Mallinckrodt Pharmaceuticals. (2015, December). H.P. Acthar® Gel Overview. Retrieved May 11, 2017, from <http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NjA0NzMwfENoaWxkSUQ9MzE1ODU2fFR5cGU9MQ==&t=1>
9. IMS Health, Inc. data (2014).
10. Johns Hopkins University (n.d.). Peyronie's Disease - The James Buchanan Brady Urological Institute. Retrieved May 11, 2017, from <http://urology.jhu.edu/peyronie/>
11. Talib, R. A., Ibrahim, M. A., & Cangüven, Ö. (2016, December). Nonsurgical treatment options in Peyronie's Disease: 2016 update. Retrieved May 11, 2017, from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5125733/>
12. Clinical data | XIAFLEX® (collagenase clostridium histolyticum). (n.d.). Retrieved May 11, 2017, from <https://peyronies-disease.xiaflex.com/hcp/clinical-data/>



p h a r m a c e u t i c a l s

REFERENCES

13. Pollack, A. (2013, December 6). Injections to Treat an Embarrassing Ailment Win U.S. Approval. Retrieved May 11, 2017, from <http://www.nytimes.com/2013/12/07/business/fda-approves-treatment-for-curved-penis.html>
14. XIAFLEX® Full Prescribing Information. (n.d.). Retrieved May 11, 2017, from http://www.endo.com/File%20Library/Products/Prescribing%20Information/Xiaflex_prescribing_information.html
15. Endo International plc Press Release, PR Newswire. (2016, November 17). Endo Announces Positive Data from Phase 2b Study of Collagenase Clostridium Histolyticum (CCH) in Patients with Cellulite. Retrieved May 11, 2017, from <http://www.prnewswire.com/news-releases/endo-announces-positive-data-from-phase-2b-study-of-collagenase-clostridium-histolyticum-cch-in-patients-with-cellulite-300364763.html>
16. Shamloul, R., & Bella, A. (2011). Management of Peyronie's Disease in the Aging Male. Retrieved May 11, 2017, from <http://www.medscape.com/viewarticle/740710>
17. RxList Inc. (n.d.). Trental (Pentoxifylline) Drug Information: Clinical Pharmacology - Prescribing Information at RxList. Retrieved May 11, 2017, from <http://www.rxlist.com/trental-drug/clinical-pharmacology.htm>
18. Important Safety Information for XIAFLEX®. (n.d.). Retrieved May 11, 2017, from <https://peyronies-disease.xiaflex.com/>
19. Pentoxifylline Oral: Uses, Side Effects, Interactions, Pictures, Warnings & Dosing. (n.d.). Retrieved May 11, 2017, from <http://www.webmd.com/drugs/2/drug-5022/pentoxifylline-oral/details#side-effects>
20. U.S. Food and Drug Administration. (2015, March 20). Marketed New Drugs Without Approved NDAs and ANDAs. Retrieved May 11, 2017, from <https://www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm074382.htm>



pharmaceuticals

180 DAY

OPERATIONAL PLAN

Assemble experienced management team and empanel Board of Directors

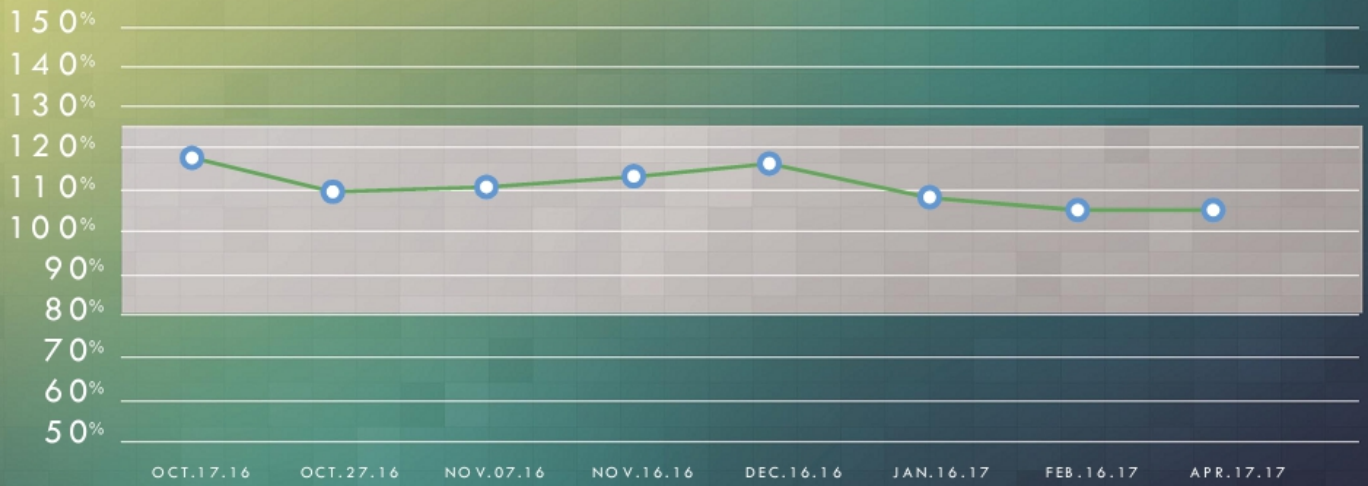
- Qualified candidates have 505(b)(2) and NDA submission experience

Request and prepare package for Pre-IND meeting with FDA regarding synthetic corticotropin asset

- Justification and support for 505(b)(2) application
- Objective is to define non-clinical/clinical development plan in meeting minutes

Execute on DESI assets program

CORTICOTROPIN CONCENTRATION 80U/ML
SIX MONTH STABILITY STUDY



U.S. Pharmacopeia monograph for corticotropin (injection): In a suitable diluent, of material containing the polypeptide chain hormone having the property of increasing the rate of secretion of adrenal corticosteroids. Its potency is not less than 80% and not more than 125% of the potency stated on the label of USP corticotropin units.



p h a r m a c e u t i c a l s

PRE-IND MEETING STRATEGY:

505(B)(2)

KEY QUESTIONS TO ANSWER:

- Toxicology studies requirements or other non-clinical studies to support the NDA
 - **Support with predicate data based on products used as Reference Listed Drug (RLD)**
- Define clinical or bridging studies requirements
 - **Bridging study will be rationalized with predicate data**
 - **Examples of bridging study designs will be proffered based on input from KOLs**

PRE-IND MEETING PACKAGE:

- CMC package to focus on similarity of synthetic vs. naturally-derived product
- Testing employed in development plan
- Bridging study protocol with supporting justification
- CMC issues relative to control of impurities and degradants
- Specifications used to monitor the manufacture and control of the drug product

INDICATIONS

- Treatment during an exacerbation or as maintenance therapy in selected cases of systemic lupus erythematosus
- Monotherapy for the treatment of infantile spasms in infants and children under 2 years of age
- The treatment of acute exacerbations of multiple sclerosis in adults. Controlled clinical trials have shown H.P. Acthar® Gel to be effective in speeding the resolution of acute exacerbations of multiple sclerosis. However, there is no evidence that it affects the ultimate outcome or natural history of the disease
- Inducing a diuresis or a remission of proteinuria in nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus
- Treatment during an exacerbation or as maintenance therapy in selected cases of systemic dermatomyositis (polymyositis)
- The treatment of symptomatic sarcoidosis
- Adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), ankylosing spondylitis
- Treatment of severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation
- Adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in psoriatic arthritis
- Adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy)



pharmaceuticals

THANK YOU



