# Imprimis Pharmaceuticals, Inc.

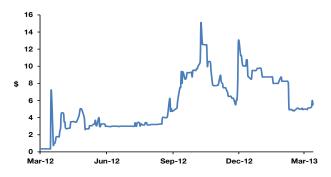
RESEARCH INITIATION | MARCH 14, 2013

### **Company Details**



Company	Imprimis Pharmaceuticals, Inc.
Headquarters	Solana Beach, CA
Employees	5
Fiscal Year End	December 31
Listing	IMMY (NASDAQ)

#### **Price Performance**



	YTD	3m	ı	6m	12m
Return	-37.03%	-37	.74%	-31.13%	1474.29%
Last Price			\$5.51		
Date of Price			3/13/13		
52-week Range			\$0.35 - \$30.00		
Shares Outstanding (mm)			8 89		

### **Analyst Information**

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Please read the disclosures beginning on page 25 for important required information, including analyst certification.

### **Investment Summary**

MDB Capital Group is initiating coverage of Imprimis Pharmaceuticals, Inc. ("Imprimis," or the "Company"). Imprimis has a unique clinical model that could disrupt the pharmaceutical industry.

### **Unique Clinical Strategy**

The FDA approval process for new drugs is notoriously expensive and lengthy. However, drugs that leverage data already approved by the FDA can use a streamlined approval process known as the 505(b)(2) alternative pathway. Imprimis intends to pursue this pathway, and then out-license these drugs before the most expensive and time-consuming phases of the FDA approval process. In combination, these tactics should serve to retire much of the risk traditional pharmaceutical companies face.

### Partnership with PCCA

The Company enhanced its drug pipeline by entering into an exclusive relationship with Professional Compounding Centers of America ("PCCA"), a trade organization that provides support functions to its 4,000 member compounding pharmacies. PCCA has developed a robust database of custom drug formulations. The relationship with PCCA enables Imprimis to take the strongest of these formulations down the 505(b)(2) pathway.

#### **Accudel Platform**

Accudel, the Company's proprietary, cream-based topical delivery system, transfers medicine directly to an affected area and is aesthetically pleasing. Imprimis' first drug, Impracor, leverages the Accudel system to relieve acute musculoskeletal pain. Phase 3 trials for Impracor should commence in the second quarter of 2013; the Company expects to achieve FDA approval as soon as late 2014.

#### **Strong Management**

Imprimis has a strong team in place to commercialize these opportunities. CEO Mark Baum is a seasoned health-care entrepreneur, and President Balbir Brar was instrumental in developing Botox and Latisse at Allergan.



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## **Background**



Imprimis was recently re-launched with a focus on licensing new, proprietary drugs.

The Company is taking its lead drug candidate, Impracor, through regulatory approval.

Imprimis Pharmaceuticals, formerly Transdel Pharmaceuticals, was founded in 1998. The Company has five employees, who work primarily from its headquarters in Solana Beach, California.

Imprimis' CEO, Mark L. Baum, brought the Company out of bankruptcy in 2011. He reformulated the Company's strategy and assembled a new management team to license new, proprietary drugs. Imprimis is now taking Impracor, its lead candidate drug, through the FDA approval process. The Company should begin Phase 3 trials for Impracor in the second quarter of 2013; it expects to achieve FDA approval for the drug as soon as late 2014.

## Imprimis Strategy



The FDA approval process for a new drug is complex and extensive, requiring significant preclinical work and three clinial trial phases.

The 505(b)(2) alternative pathway can enable Imprimis to save time and expense while also providing the benefit of new drug exclusivity and the credibility of FDA approval.

### The 505(b)(2) Approach

The traditional FDA approval process (undertaken under section 505(b)(1) of the Federal Food, Drug and Cosmetic Act) is famously long, expensive, and risky. However, for some drugs, the FDA allows for a streamlined clinical trial and approval process known as the 505(b)(2) alternative pathway. The 505(b)(2) pathway exists for drugs for which approval may rest on data previously accepted by the FDA, making expensive replication of the studies unnecessary.

Imprimis plans to pursue a drug development strategy around this 505(b)(2) alternative pathway, in which the Company will reformat or repurpose drugs that have already been approved by the FDA.

The 505(b)(2) approach has clear benefits over the 505(b)(1) approach. It also has certain key benefits over the 505(j) approach (which is used to approve generics that have not been reformatted) and the approach taken by compounding pharmacies today (which do not have their formulations approved by the FDA).

### Benefit over 505(b)(1): Time and Expense

The traditional FDA approval process is infamous for its length, expense and risk. (See Figure 1.) Indeed, 505(b)(1) filers must conduct extensive pre-clinical studies even before they reach Phase 1, including in vitro experiments, animal tests, and microdosing studies to obtain preliminary efficacy, toxicity, phamacodynamic and pharmacokinetic data.

Figure 1: 505(b)(1) Clinical Trial Process
FDA Trial Phase



Source: FDA, Manhattan Institute for Policy Research

According to FDA guidelines, in a 505(b)(2) application "at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference." Drugs filed under a 505(b)(2) therefore use a shortened version of the New Drug Application ("NDA") required under 505(b)(1). One of the key benefits of the 505(b)(2) NDA is that a filer can use preexisting published data, regardless of whether it was granted rights to that data by the originator. This can result in significant time savings. (See Figure 2.)

Figure 2: 505(b)(1) vs. 505(b)(2)
Drug Development Timeline

	Discovery	Preclinical Research	Clinical Studies
505(b)(1)	2-5 years	1-3 years	8-15 years
505(b)(2)	<1-3 years	<1-2 years	2-5 years

Source: Carmago Pharmaceutical Services

The Company estimates that a 505(b)(2) NDA costs on the order of \$2 to \$5 million to complete; by contrast, a 505(b)(1) NDA can cost over \$100 million.

### Benefit over 505(j): Exclusivity

The 505(b)(2) approach also has a key benefit over the 505(j) approach of approving generics that have not been reformatted. The 505(j) approach allows a filer to utilize an Abbreviated New Drug Application, which is even shorter than the 505(b)(2) NDA.

## Imprimis Strategy



However, the FDA recognizes that there is real innovation occurring when a pharmaceutical company reformats a drug (as it does in the 505(b)(2) approach), as opposed to simply copying it (as it does in the 505(j) approach). Consequently, the FDA grants the 505(b)(2) innovator between 3 and 7 years of new drug exclusivity. (Outside of certain narrow circumstances, a 505(j) generic receives no exclusivity period at all.)

In fact, even after this period of exclusivity ends, there still remain high barriers to entry for those reformulations attempting to make generic versions of topical drugs. To approve generics, the FDA asks that the manufacturer demonstrate bioequivalence, essentially to demonstrate that the generic is detectable in the blood at the same concentration as the branded drug it is copying. For pill-based generics, the easiest way to demonstrate bioequivalence is to use pharmacokinetic measurements (active drug and/or metabolite found in blood, urine, and/or plasma).

However, topical drugs traditionally do not provide strong pharmacokinetic data, often forcing an applicant to run clinical trials to gain FDA approval for a topical generic. Most generic drug manufacturers are low-margin businesses focused on operational efficiency, and therefore do not have the time, money or expertise to run a clinical trial. This should at least reduce the interest of most generics houses in making copies of Imprimis' products.

This benefit might allow Imprimis to explore a "branded generics" strategy, a best-of-both-worlds approach that has both the premium pricing enjoyed by patented drugs and the lower risk environment of generic drugs.

## Benefit over Traditional Compounding Approach: FDA Approval

Compounding pharmacies often produce reformatted drugs, just as Imprimis intends to do. The critical difference, however, is that Imprimis' drugs will be FDA-approved, unlike those the compounders produce. (In general, compounding pharmacies are exempt from FDA oversight because they typically make their compounded drugs in very small batches.)

We believe this difference might be material to doctors. In October 2012, 25 people died after a large Massachusetts compounding pharmacy broke from traditional compounding protocol by mass-producing and distributing steroid shots that were tainted due to poor sanitation. (A March 2013 episode of 60 Minutes revisited the story, indicating it remains in the spotlight.) We believe events such as this could cause doctors to prefer prescribing FDA-approved drugs to their patients.

The media attention surrounding this incident might also lead to increased regulation on compounding pharmacies. In November 2012, FDA Commissioner Margaret Hamburg testified before Congress on the issue, calling for compounding pharmacies to be returned to FDA oversight. This level of scrutiny further validates Imprimis' approach of gaining FDA approval for compounded formulations.

Finally, compounded products are exempt by law from having National Drug Code ID numbers. Because of this, some insurance companies will not directly reimburse compounding pharmacists. Though many insurance plans allow patients to send in claim forms for reimbursement, this friction likely causes many patients to prefer FDA-approved drugs.

## Imprimis Strategy



### **Out-Licensing Potential**

For each drug opportunity, Imprimis will decide how far it should take the trial process. Depending on the risk, expense and complexity of the trial, the Company may complete some of its drug trials in-house or out-license to an upstream partner (which might be a larger drug company).

Imprimis expects it will typically out-license its opportunities to larger companies that will ultimately take the drug to market. This business model should shorten the length of time before the Company starts to receive cash; in addition, it significantly mitigates the risk of developing and commercializing these drugs, as it should avoid the large costs associated with commercialization and late stage trials.

In some instances, Imprimis may find a development partner that has sufficient interest to work on and finance a pre-clinical development program with the Company. However, in general, we expect that Imprimis will outlicense its opportunities.

### **Successful Precedents**

Other drugs have successfully followed the 505(b) (2) blueprint in the past. Examples of successfully reformatted drugs include: Makena, Testim, Nuedexta, EstroGel, TestoPel, CaverJect, Crinone, Minoxidil, Preometrium, Testoderm, and Prascend. Therefore, the Company's strategy though innovative, is not unprecedented. This means Imprimis' success in pursuing this strategy should be governed by certain knowable factors. We discuss those success factors in the next section.

### **Success Factors**



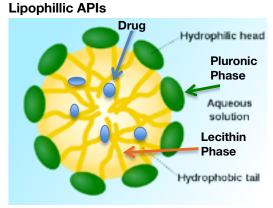
Three main factors enable the successful execution of Imprimis' strategy:

- Proprietary Accudel delivery platform.
- Large product pipeline, enabled by the relationship with PCCA.
- Management team's expertise in evaluating opportunities and designing clinical strategies.

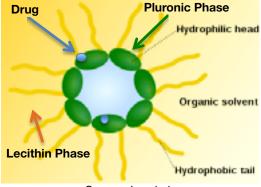
### **Delivery Platform**

The first critical success factor that enables the execution of a 505(b)(2) strategy is an expertise in reformatting drugs. Imprimis has this expertise in the form of Accudel, its cream-based, proprietary topical delivery system. Accudel can suspend many different active pharmaceutical ingredients in a stable cream format and efficiently transfer them directly to affected sites. Accudel is also aesthetically pleasing (i.e., it is not greasy or smelly), and is quickly

Figure 3: Accudel Delivery System



#### **Hydrophillic APIs**



Source: Imprimis

absorbed by the skin. The Accudel delivery system is thermodynamically stable, insensitive to moisture, and resistant to microbial contamination. (See Figure 3.)

We believe that Accudel is a very robust platform. The granted patent on Accudel (USPTO number 5,837,289) indicates that Accudel can work with over 500 generic drugs, running the gamut from vitamins and insulin to anesthetics, beta-blockers, and antibacterials.

Imprimis management also believes it has an opportunity to add to the Accudel system by incorporating certain PCCA delivery technologies, including intraoral (i.e., through the cheek or tongue through dissolving tablets), suppository, or other transdermal formats.

#### **Formulations and Market Data**

A second critical success factor for a company pursuing a 505(b)(2) strategy is a deep bench of formulations. In order to develop its drug pipeline, Imprimis entered into an exclusive relationship with PCCA. PCCA is the largest compounding pharmacy organization in North America, with some 4,000 members.

#### **Background: Compounding Pharmacies**

Compounding pharmacies reformat drugs to meet specific patient needs. They play a critical role in the marketplace by filling prescriptions for patients who are unable to take the FDA-approved drugs their doctor prescribes to them because of the format that drug is in. (For example, a patient may be allergic to inactive ingredients in the drug, or unable to swallow a pill.)

There are roughly 5,000 compounding pharmacies in the U.S.; combined, they account for approximately 1% of the \$300 billion U.S. pharmaceutical industry. Many of these are "mom and pop" businesses. Consequently, they need significant support.

### **Success Factors**



#### **PCCA**

PCCA helps provide that support. Founded in 1981, PCCA started out by repackaging chemicals and supplies into sizes more suitable for use by compounding pharmacies, which tend to have smaller inventory requirements. PCCA soon added training and consulting services to its offering.

Most relevantly, though, today PCCA develops drug formulations and teaches compounders how to make these formulations for patients who have requested them. To perform this function, PCCA has on staff more than 30 pharmacists, Ph.D.'s, and chemists. These professionals have developed a catalog of more than 8,000 proprietary formulations and delivery methods for use by PCCA members. PCCA runs a support center that receives 100,000+ calls a year from member pharmacies seeking information on how to make these formulations (among other requests).

PCCA has built database from its support center information that paints a clear picture of the market need for these 8,000 proprietary formulations. In other words, the PCCA database highlights gaps in the marketplace where an FDA-approved drug can fill a significant need.

The PCCA database also contains data that help to demonstrate the empirical success of its formulations. These empirical data provide information about which drugs are most likely to pass the FDA approval process.

### The PCCA-Imprimis Strategic Partnership

In an August 2012 strategic partnership between the parties, PCCA granted the Company exclusive access to the database, as well as the right of first refusal to create new, proprietary drugs from any of PCCA's formulations. PCCA also invested \$4 million into Imprimis.

Ultimately, the database enables PCCA to feed Imprimis with novel formulations that have proven empirical success; after that, Imprimis can use the 505(b)(2) process to significantly decrease the time, cost, approval risk, and commercialization uncertainty associated with traditional drug development. In a sense, then, we think of PCCA as being a kind of outsourced research and development arm for Imprimis.

Additionally, Imprimis and PCCA developed a business framework that allows innovative PCCA members to gain access to a commercialization pathway for novel formulations. The framework allows PCCA inventor-members to leverage the financial, legal, regulatory, drug development, and technical resources of Imprimis / PCCA. Imprimis / PCCA will accept novel formulations from PCCA members and then work to protect relevant IP, assess the market potential and the FDA "friendliness" of the formulation, optimize the formulation for the FDA process, design and fund the necessary clinical trials and studies, and finally, secure approval and/or negotiate licensing deals with other commercial entities. The inventor-member receives a share of the financial upside after the drug is commercialized.

#### **Evaluating Opportunities from the Partnership**

To review the currently actionable opportunities that could emerge from the PCCA-Imprimis relationship, PCCA and the Company have together created an Opportunity Development and Licensing Matrix, where each formulation is categorized into 5-7 health verticals (pediatrics, women's health, etc.). Imprimis and PCCA then review each opportunity in each category against observed market demand (including data on the current number of compounding pharmacy prescriptions filled, how often they are refilled, and the dollar size of the market). Imprimis can use that review, alongside other

### **Success Factors**



relevant factors (such as competition, IP considerations, and ease of trial design) to inform its go/no-go decisions on potential drug development opportunities.

Imprimis and PCCA have already identified some opportunities that look promising to pursue. The first of the 5-7 verticals the parties chose to focus on was women's health; in that vertical alone, the vetting process yielded four development opportunities. Imprimis has not yet made those development opportunities public, but we will monitor its progress on this front carefully.

### **Management Expertise**

Finally, a third critical success factor for a company pursuing a 505(b)(2) strategy is the strength of the management team. We like to see this strength manifest in two main ways: first, in evaluating the data to determine which drugs to pursue, and second, in designing a clinical strategy around both early and late stages of development.

### **Evaluate Opportunities**

Imprimis management has extensive experience in creating new drug markets, evaluating competition, and establishing IP.

Balbir Brar, D.V.M. and Ph.D., the Company's President, has 25 years of senior drug development experience (most recently with Allergan), including key roles in developing Botox, Latisse, Ketorolac, Restasis, Lumigam, and Alphagan. Imprimis' Chief Medical Officer, Joachim P.H. Schupp, M.D, has developed line extensions for Voltaren (the current leading topical NSAID, which we discuss in further detail below), as well as Apligraf, Femara, Exjade, and Sandoglobulin. We believe this team has both the broad pharmaceutical industry experience and the specific experience with topical drugs to intelligently lead the Company through the selection process.

### Design Clinical Strategy

The Company has a strong clinical team with significant experience. Imprimis has hired Lee S. Simon, M.D., as one of its Senior Regulatory Advisors. Dr. Simon served as the FDA Division Director of Analgesic, Anti-Inflammatory & Ophthalmologic Drug Products from 2001 to 2003, in additional to serving on multiple FDA advisory committees.

Imprimis also has advisors with critical skills in designing clinical strategies. Roy Altman, M.D., one of the Company's Senior Clinical Advisors, is a Professor of Medicine at UCLA with over 35 years of clinical experience. He is a founding member of the Osteoarthritis Research Society and has served as Chairman for the Design and Conduct of Clinical Trials in Osteoarthritis, as well as the Chairman on Clinical Trials in Osteoarthritis.

Finally, a drug developer will work with a Contract Research Organization ("CRO") to complete whatever trial work it cannot complete in-house. The applicant and CRO work together to develop a trial strategy that is likely to meet FDA regulatory data requirements. Imprimis has selected a very strong trial partner—Analgesic Solutions, led by Dr. Nathaniel Katz, is a CRO with a stellar reputation for designing pain trials.



Imprimis' Impracor Cream is a topical NSAID that offers considerable advantages over oral and other topical NSAIDs, and is well-equipped to take share in a growing, potentially multi-billion dollar market.

Impracor Cream is the Company's first drug. It is a non-steroidal anti-inflammatory drug ("NSAID") for acute musculoskeletal pain relief. Impracor uses Imprimis' proprietary Accudel delivery system to deliver the active agent (ketoprofen) through the skin.

### **NSAID Overview**

NSAIDs are among the most commonly prescribed pain relief medications in the world (aspirin and ibuprofen are both NSAIDs). Patients use NSAIDs to soothe mild to moderate pain such as osteoarthritis, muscle soreness, sprains, headaches, migraines, and menstrual cramps.

According to the *Nature Reviews Drug Discovery* journal, the global NSAIDs market was over \$9 billion in 2009. According to the *Archives of Internal Medicine*, more than 60 million people in the U.S., including over 70% of people over the age of 65, regularly use NSAIDs. We expect that this market will grow as the population ages.

### Alternatives to Impracor

NSAIDs are available in oral (tablet, capsule) and topical (gel, drop, patch, spray and cream) formats. We believe that Impracor compares favorably to both the existing oral and topical NSAIDs on the market.

### Oral NSAIDs

The FDA approved the first topical NSAIDs in 2007, so oral drugs still dominate the NSAID market. Oral NSAIDs based on ketoprofen include Actron, Orudis, and Oruvail.

That said, regular use of oral NSAIDs comes with serious health risks, since a swallowed pill can cause side effects beyond the pain site. According to the *American Journal of Medicine*, oral NSAIDs are responsible for over 100,000 gastrointestinal bleeding hospitalizations, \$2 billion in healthcare costs, and more than 16,000 deaths in the U.S. per year. (Indeed, Vioxx, which Merck withdrew from the market in 2004 because of concerns about increased risk of heart attack and stroke, was an oral NSAID.)

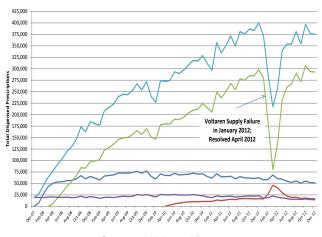
### **Topical NSAIDs**

Patients who cannot tolerate the side effects that oral NSAIDs can cause—especially patients who are either elderly, at-risk, and/or require pain relief medication on a regular basis—are therefore forced to find alternatives to these drugs.

#### Market

As a result, the topical NSAID market has been growing. According to Wolters Kluwer, the market for topical NSAIDs has grown to \$506 million in 2011 (at a five-year CAGR of 28%). (See Figure 4.)

Figure 4: U.S. Topical NSAID Prescription Volume (2007 – 2012)

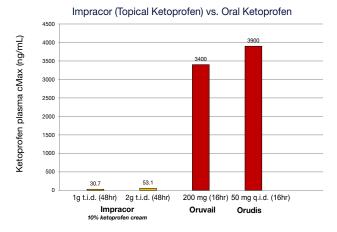


Source: Wolters-Kluwer



In theory, topical NSAIDs offer the same pain relief medication as oral NSAIDs, but are delivered directly to the pain site through the skin. Topical delivery results in lower levels of the active agent entering the blood stream, reducing gastrointestinal and other health risks, and minimizing potentially dangerous drug-to-drug interactions. (See Figure 5.) The Company's initial analysis indicates that Impracor exposes the patient to 98% less ketoprofen systemically than the oral alternatives.

Figure 5: Topical Ketoprofen Shows Less Residual Drug in the System



Source: Cannavino, C. et al. Efficacy of Transdermal Ketoprofen in delayed onset muscular soreness, Clinical Journal of Sports Medicine, 13: 200-208, 2003 and Clinical Study Report Project No. 990808, Phase 1/2 Study Report Aug 2007; Oruvail and Orudis Prescription Information

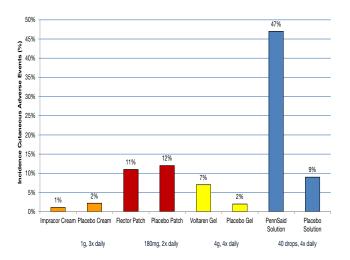
Because of these benefits, The American College of Rheumatology has approved and issued guidelines for the treatment of osteoarthritis, recommending topical NSAIDs as first-line treatment for certain osteoarthritis patient populations (such as patients aged 75 and over).

#### Diclofenac-Based Offerings

Several topical NSAIDs have sprung up to respond to this market need. All of these, however, use diclofenac as the active ingredient rather than ketoprofen, the active ingredient in Impracor. A University of Oxford study entitled "Topical NSAIDs for acute pain in adults" indicated that participants in trials using ketoprofen showed a 73% success rate, whereas those using diclofenac showed a success rate of only 52%.

Furthermore, a study conducted by the Company indicates that Impracor has lower incidence of cutaneous adverse effect than the diclofenac-based alternatives in the space. (See Figure 6.)

Figure 6: Impracor Has Fewer Adverse Effects Than Diclofenac-Based Alternatives



Source: Clinical Study Report: TDLP-110-001, September 2010; and Prescribing Information for Flector Patch, Voltaren Gel and Pennsaid Solution



In addition, each of the diclofenac-based topicals currently in the market presents its own idiosyncratic challenges:

- Voltaren (gel format): This is the largest player in the topical NSAID market, with approximately 80% of the market. (See Figure 4, above.) However, it is greasy, has a strong alcohol smell, and is very weak.
- Pennsaid (solution format): This requires a huge amount of patient compliance, requiring a precise count of around 40 drops on each of the four sides of the knee 4 times a day, for a total of 640 drops per day.
- Flector (patch format): This has issues with adhering to skin (especially in the shower), making it impractical for most people with chronic pain.
- Solaraze (cream format): This improves on Voltaren
  by reducing odor and greasy texture, but its high
  price limits its adoption by patients, doctors, and
  insurance companies; though prices for prescription
  drugs can vary significantly, a recent check of online
  prices for Solaraze yielded an average of around
  \$200 per 100g tube.

Impracor does not share these weaknesses. The Accudel delivery system is aesthetically pleasing, with no smell, and a smooth texture. It is also much easier to apply than a solution. Since Impracor absorbs into the skin quickly, it does not have the adhesion issues a patch might have. Finally, at under \$8 per 90g tube, it is significantly more affordable than Solaraze.

### **New Impracor Phase 3 Study**

In June 2008, the Company initiated a Phase 3 clinical study to test the efficacy of Impracor (then known as Ketotransdel). The study was designed as a randomized, double blind, placebo-controlled, multi-center Phase 3 study that enrolled 361 patients with acute soft tissue injuries of the upper or lower

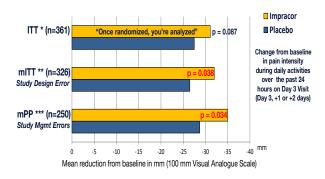
extremities in 26 centers across the U.S. Efficacy would be demonstrated by the difference in the change in pain intensity between the drug and the placebo as measured by the 100 mm Visual Analogue Scale on the Day 3 visit.

Unfortunately, the study failed to demonstrate statistical significance in pain relief. The Company conducted subsequent analysis that demonstrated that this failure was due to poor study design by Imprimis' previous management team, rather than a weakness in the drug itself. (Indeed, at the same time, compounders were selling an Impracor-like cream to patients; this market validation is partly what motivated the current management team to take over the Company and redo the study correctly.)

In further analysis, Imprimis found that, of the 361 patients in the population, 35 should have been deemed ineligible for entry due to other drug use, and 78 should have been eliminated for not complying with the study protocol (essentially, they used improper doses of the drug). Imprimis further found that, among the correct group of patients, use of Impracor did yield a statistically significant change from baseline in pain intensity. (See Figure 7.)

Figure 7: Retrospective Analysis of 1st Phase 3 Impracor Study

Design & Execution Optimization Lead to Statistical Significance (p = <0.05)



Source: Imprimis

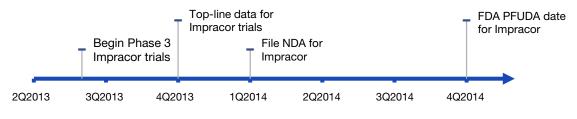


- ITT: the Intent-to-treat (ITT) population, which failed the statistical significance test (in which the p-value must be less than or equal to 0.05).
- mITT: the Modified ITT of ITT patients, which excludes the 35 patients who should have been excluded, largely because of other positive drug screens. This population already passes the p-value test described above.
- mPP: the Modified per protocol (mPP) analysis of mITT patients, which samples only the patients

who complied with the protocol. In this population, we see both an improved p-score and a more meaningful reduction of pain level overall.

The Company believes a new Phase 3 study, with improved design and management, will achieve statistical significance and enable FDA approval for Impracor under the 505(b)(2) NDA timeline described below. (See Figure 8.)

Figure 8: Impracor Phase 3 Trials Timeline



Source: Imprimis

## **Intellectual Property**



We believe Imprimis has both the core patents and IP strategy to protect its drug products.

The pharmaceutical industry does not easily lend itself to the type of IP analyses we have done in previous reports on companies in the clean-tech, consumer electronics or enterprise software spaces. Essentially, the pharmaceutical industry is one of monopolistic competition; each drug is strongly differentiated from each other drug, and there are often no real substitutes.

We typically do a multidimensional analysis on the strength of a subject company's IP. We measure corporate capability with respect to intellectual property goals on two dimensions: the ability to protect the Company's existing product portfolio, and the ability to generate future licensing revenues from related technologies. However, in the pharmaceutical industry, it is uncommon to generate licensing revenue from related drug technologies, so that multidimensional analysis would also have limited value. In addition, a patent landscape analysis for Imprimis (as we have done in the past for reports on other subject companies) would have limited value.

We focus this IP analysis, then, a bit differently than we have in our past reports. We ask, first, whether the Company has the core patents to protect its drugs. We believe that it does. As noted above, the foundational patent on Accudel (USPTO number 5,837,289) is very robust, protecting uses across over 500 generic drugs. The Company is also filing a number of new patent applications on the packaging and manufacturing of Impracor.

Second, we ask if the Company has a strategy to protect the drugs that will represent its future sales. Again, we believe that it does. We believe that

PCCA will pursue an active patent strategy to protect the core intellectual property that Imprimis will be commercializing.

Finally, we note that, even in an industry that does not typically license its intellectual property, the Company has found a way to monetize some of its portfolio. In March 2013, Imprimis announced it had entered into a licensing agreement to allow resolutionMD to use Accudel for anti-cellulite formulations (which is not a core focus of the Company). We are encouraged that Imprimis management is thinking of creative ways to generate value from its IP assets.

### Competitors



Imprimis could face competition from generic drug manufacturers, big pharma companies, and compounding pharmacies; however, the Company's drug development strategy provides significant advantage to mitigate these threats.

### **Generic Drug Manufacturers**

As a natural result of Imprimis' strategy, there will be generic drugs in different formats that compete with its product offerings (for example, several oral NSAIDs based on ketoprofen already exist in the market, including Actron, Orudis, and Oruvail). That said, Imprimis' products will be in an environment of monopolistic competition with these alternatives; the people who need the specific formats in which Imprimis offers its drugs will need to turn to the Company's product.

In addition, the producers of generic drugs are focused on mass-producing existing formats as efficiently as possible. This makes them unlikely to want to do clinical trials, as they would need to do (in many cases) to gain FDA approval for a topical drug. Therefore, we do not view them as a significant threat to copy Imprimis' formulations.

#### "Big Pharma"

Large pharmaceutical companies have incredible resources and long-term development strategies. Therefore, if any of these large companies wanted to expand into a market similar or adjacent to Imprimis' products, they would likely represent a significant competitive threat.

However, these companies tend to move slowly, and are focused on developing new drugs, not the repurposing of generics. Additionally, "Big Pharma" telegraphs its moves by filing patents and NDAs well in advance of

product release, providing Imprimis management with ample time and information on which of its prospects are likely to face competition.

### **Compounding Pharmacies**

These small "mom and pop" businesses are scattered throughout the country and decentralized; individually, we do not believe they represent a threat to Imprimis. Imprimis has taken the same perspective, allowing these compounders to produce Impracor without suing them for patent infringement. (As noted above, this patience is what led to the Company's discovery that there was market demand for Impracor, as it saw that compounders were making similar products.)

Ultimately, this collaborative approach is what enabled Imprimis to forge a non-contentious relationship with PCCA, and we expect that the Company will continue to take the same approach to these "mom and pop" businesses in that spirit. In any event, we do not view individual compounders as being a threat to Imprimis, as they do not have scale or credibility with physicians, and have limited ability to reimburse patients through insurance.

### **Financial Position**



After giving effect to its recent public stock offering, Imprimis had approximately \$20.5 million in cash *pro forma* at September 30, 2012.

The Company's stock price at this stage will be largely driven by the success of its Impracor trials and future out-licensing agreements.

### **Cash Position**

On February 7, 2013, Imprimis announced the pricing of an underwritten public offering of 1,840,000 shares of its common stock at a price to the public of \$5.25 per share; including proceeds resulting from the exercise of the overallotment option, the Company received net proceeds of approximately \$9.5 million from the offering. In connection with the offering, Imprimis completed a 1-for-5 reverse stock split.

In the Company's most recent 10-Q filing (for the quarter ended September 30, 2012), the Company had approximately \$11.0 million in cash and equivalents on hand. Therefore, after giving effect to the public offering, Imprimis had approximately \$20.5 million in cash *pro forma* at September 30, 2012.

The Company intends to spend approximately \$9.3 million in operating expenses over the next 12 months; most of that will be used on the Phase 3 Impracor trial, with the remainder earmarked for developing subsequent PCCA opportunities and paying general operating expenses. Imprimis management has indicated its does not expect to spend any cash on capital expenditures over the next 12 months.

### **Key Stock Price Drivers**

Imprimis will start generating revenue when it launches Impracor, which could be as early as the end of 2014. Before that time, we believe that certain key announcements could have a material positive impact on the Company's share price.

### Successful Impracor Trials

As discussed above, the Company is pursuing Phase 3 trials of Impracor. Positive news regarding the results of these trials should reduce the risk premium investors place on Imprimis.

### Additional Drug Trials

Besides Impracor, the Company has already identified other potential drugs they may take through the FDA approval process. Announcements or FDA filings associated with these new drugs will increase the potential market size available to Imprimis.

#### **Out-Licensing Partner Agreements**

Later stages of the FDA approval process can be time intensive and expensive. Out-licensing agreements could generate revenues for the Company and retire risk.

### **Risk Factors**



As a small company that has yet to deliver positive earnings, Imprimis carries certain risks of which investors should be aware.

### **Regulatory Risk**

The FDA approval process is very rigorous, so Impracor may still fail to pass FDA trials. Imprimis' near-term revenue stream depends on successfully completing Phase 3 trials of Impracor. We believe the qualifications of the Company's new management team mitigate this risk, but investors should continue to note it.

### **New Competitor Risk**

If Imprimis successfully validates its drug development platform, other pharmaceutical companies may attempt to copy its process. We believe the combination of the Company's patent protections on Accudel and its right of first refusal on the PCCA database mitigate this risk, but investors should continue to note it.

### Stock Risk

Because Imprimis is not yet a mature company, its stock price is very likely to be volatile. In addition, the Company's stock currently has very little market liquidity.

### **PCCA Risk**

The Company has entered into strategic agreements with PCCA, and is dependent on this relationship to maintain its pipeline of new development drugs. If this relationship were to deteriorate, Imprimis would need to find a new source of potential drugs. We do not anticipate this relationship will deteriorate, but investors should note this risk.

## **Executive Management**



Imprimis has a strong and experienced management team and board. (See Figures 9 and 10.)

### Figure 9: Biographies of Key Management

Mark L. Baum, Esq. Chief Executive Officer	<ul> <li>15 years' experience in financing, operating, and advising small capitalization publicly traded enterprises, with a particular focus on restructured or reorganized businesses.</li> <li>Completed more than 125 rounds of financing for 40+ publicly traded companies.</li> <li>Operational experience in the following industries: life science and diagnostics and closed door pharmacy industries.</li> <li>Significant boards of director service, including Chembio Diagnostic Systems, Inc., Applied Natural Gas Fuels, Inc., Shrink Nanotechnologies, Inc., You on Demand, Inc.</li> <li>Inactive member of both the State Bar of California and the State Bar of Texas.</li> </ul>
Balbir Brar, D.V.M., Ph.D. President	<ul> <li>Over 25 years of experience in drug and device development and worldwide registration of eight major drugs, including Botox.</li> <li>Significant experience in research and development, conducting clinical trials, implementation of product development plans, and working with U.S. and international regulators.</li> <li>Serves as a consultant to four biotechnology companies: AtheroNova, Aciont, Altheos, Aciex Therapeutics.</li> <li>Worked with major pharmaceutical companies, including Lederle Laboratories.</li> <li>Served as Senior Director of Drug Safety at SmithKline Beckman.</li> <li>Vice President Drug Safety, Research &amp; Development at Allergan, responsible for regulatory submission of 50 IND's/510K's and worldwide approval of six NDAs.</li> <li>Inventor of numerous patents.</li> <li>Ph.D. in Toxicology/Pathology from Rutgers University and D.V.M. from India, with finance training from Harvard Business School.</li> <li>Recipient of numerous achievement awards for excellence, belongs to a number of scientific organizations, and is author/coauthor of over 55 scientific publications.</li> </ul>
Joachim P.H. Schupp, M.D. Chief Medical Officer	<ul> <li>25 years of leadership experience in the pharmaceutical industry.</li> <li>Led international project teams that have brought several drugs through the development and the regulatory process and on to the market globally.</li> <li>Executive Consultant for pharmaceutical and biotechnology companies.</li> <li>Vice-President of Clinical Development at Apricus Biosciences, Vice President of Medical Affairs at Adventrx Pharmaceuticals, and Vice President of Clinical Data Services at ProSanos.</li> <li>19 years with Novartis Pharmaceuticals in Switzerland where he held various positions in clinical development and global project management.</li> <li>Began career at Ciba-Geigy, now Novartis, in 1985 where he was appointed to lead international clinical project teams to discover new non steroidal anti inflammatory drugs (NSAIDs) with improved gastrointestinal tolerability.</li> <li>Received several prestigious awards at Ciba-Geigy and Novartis for his team leadership contributions.</li> <li>M.D. from the Free University of Berlin in Germany and he served on the faculty at the University of Pretoria, South Africa, in Internal Medicine and Rheumatology.</li> </ul>
Andrew R. Boll Vice-President, Accounting & Public Reporting	<ul> <li>Over eight years of experience in financial reporting and accounting with a significant portion of that experience working with small capitalization companies, with a particular focus on restructured and reorganized businesses.</li> <li>Accountant for BCGU, LLC, a privately held fund manager that specializes in capital venture investment opportunities. Provided consulting services to public company clients, compiled numerous SEC financial reports, and accounted for several public company restructurings, financings, and private to public mergers.</li> <li>Held various accounting roles at Welsh Companies, LLC, a privately held commercial real estate company, its fund, and its other subsidiaries.</li> <li>B.S. degree in Corporate and Public Finance, summa cum laude, from Huron University, and is a member of the Institute of Management Accountants.</li> </ul>

# **Executive Management**



### Figure 10: Biographies of the Board of Directors

Robert Kammer, D.D.S. Chairman of the Board	Dental Surgery Degree from the University of Iowa in 1974.  Diplomat of The American Board of Orofacial Pain and a Founding Charter Member of The Academy for Sports Dentistry and Colorado Osseointegration Study Club.  Associate Professor and Course Director of Orofacial Pain Section in the Department of Restorative Dentistry at The University of Colorado Health Science Center.  Sports Medicine Advisory Committee at The University of Colorado Intercollegiate Athletics and was the Team Dentist for Football and Basketball.  Consultant to the Boulder-Denver Pain Control Center  Referee and Editorial Staff Consultant of the Journal of Orofacial Pain.  Consulting for Clear Choice Dental Implant Centers.
Jeff Abrams, M.D., M.P.H. Board Member	Served as a practicing primary care clinician for over twenty years.  B.A. from the State University of New York at Buffalo, an M.D. from the Albert Einstein College of Medicine and an M.P.H. from San Diego State University.  Co-founder and a co-developer of Imprimis' drug delivery technology.
Paul Finnegan, M.D., M.B.A. Board Member	Expertise involves development, commercialization, and product launches of multiple novel drugs, both blockbusters and ultra-orphan therapeutics, which encompassed various clinical indications.  Leadership roles in commercial, clinical, medical affairs, and business development functions of public and private companies.  Entrepreneur in residence with Avalon Ventures, serving as President, Chief Executive Officer and Board Director of Avelas BioSciences and InCode Pharmaceutics, as well as a member of the biotechnology investment team, leading the clinical, commercial, and regulatory due diligence efforts for over three years.  President and Chief Executive Officer of Cecoura Therapeutics, a private drug development company.  Vice President of Global Strategic Marketing and Development and other senior management positions at Alexion Pharmaceuticals.  Senior Director, Global Medical Marketing for Pharmacia Corporation and G.D. Searle & Co., providing medical affairs leadership for all therapeutic areas for the Asia-Pacific, Japan, Latin America, and Canadian business regions.  Board observer at Anaptys, member of the boards of directors of Avelas Biosciences and InCode Pharmaceuticals.  MBA with Honors, in Finance and Strategy, from the University of Chicago, Graduate School of Business, and the degrees of MD, CM from McGill University, Faculty of Medicine, in Montreal.

# **Executive Management**



### Figure 10: Biographies of the Board of Directors (continued)

Stephen G. Austin, C.P.A. Board Member	<ul> <li>CPA currently serving as the Audit Committee Chairman of several entities including private, public and not-for profit organizations and participates on over 12 boards and related board committees.</li> <li>Managing Partner at Swenson Advisors, LLP.</li> <li>At Swenson Advisors, manages audit, SEC, Sarbanes-Oxley and business consulting engagements with a focus on technology, manufacturing, service, real estate, social media, and non-profit organizations.</li> <li>22 years as an audit partner with Price Waterhouse LLP, and McGladrey &amp; Pullen, LLP, where he addressed complex accounting and reporting issues for publicly-traded companies and worked with various members of the FASB and EITF staffs.</li> <li>CPA in California and Georgia.</li> <li>Global board of directors of Integra International, an international association of accounting firms.</li> <li>Published a book on business ethics entitled "Rise of the New Ethics Class," articles in Asia discussing the Sarbanes-Oxley Act of 2002, and an article addressing audit committees and the COSO framework published in the Journal of Accountancy.</li> <li>B.S. degree in accounting from Bob Jones University and an M.B.A. degree from the University of Georgia.</li> </ul>
Gus S. Bassani, Pharm.D Board Member	, s ,

## **Exhibits**



Imprimis Pharmaceuticals, Inc.: Historical Balance Sheet

Imprimis Pharmaceuticals, Inc.: Historical Income Statement

Imprimis Pharmaceuticals, Inc.: Historical Statement of Cash Flows

Imprimis Pharmaceuticals, Inc.: Historical Balance Sheet

(\$ in thousands)	4Q11	1Q12	2Q12	3Q12
Assets				
Cash & Near Cash Items	146	147	7,717	10,991
Prepaid Expenses and Other Current Assets	15	64	46	76
Deferred Offering Costs	-	-	118	384
Total Current Assets	161	210	7,881	11,451
Net Fixed Assets	-	14	14	13
Total Long-Term Assets	-	14	14	13
Total Assets	161	225	7,895	11,464
Liabilities & Shareholders' Equity				
Accounts Payable and Accrued Expenses	219	257	424	595
Accounts Payable - Related Party	56	-	-	-
Accrued Phase 3 Expenses	56	56	56	56
Accrued Payroll	-	9	12	19
Deferred Revenue	100	-	-	-
Notes Payable and Accrued Interest - Related Party	300	609	-	-
Convertible Note Payable and Accrued Interest	1,130	-	-	-
Total Current Liabilities	1,861	930	491	670
Total Long-Term Liabilities	-	-	-	-
Total Liabilities	1,861	930	491	670
Share Capital & APIC	16,821	19,194	28,809	33,445
Retained Earnings & Other Equity	(18,521)	(19,900)	(21,405)	(22,651)
Total Equity	(1,700)	(706)	7,404	10,794
Total Liabilities & Equity	161	225	7,895	11,464

These financial statements are taken from the Company's most recent 10-Q, and therefore do not take into account its recent follow-on offering, which raised net proceeds of \$9.5 million, or the 1-for-5 reverse stock split. If these events had taken place in Q3 2012, Imprimis would have had cash & near cash items of approximately \$20.5 million and approximately 8.89 million shares outstanding at 30 September 2012.

Imprimis Pharmaceuticals, Inc.: Historical Income Statement

(\$ in thousands, except per share data)	4Q11	1Q12	2Q12	3Q12
Total Revenue	-	100	-	-
Cost of revenues	-	-	-	-
Gross Profit	-	100	-	-
Selling, general and administrative	283	309	985	946
Research and development	-	143	134	304
Total Operating Expenses	283	452	1,118	1,250
Operating Income (Loss)	(283)	(352)	(1,118)	(1,250)
Interest expense	(19)	(21)	(4)	-
Interest income	-	-	6	4
Loss on extinguishment of debt	-	(1,006)	(189)	-
Gain on forgiveness of liabilities	60	-	-	-
Income (Loss) before income taxes	(242)	(1,379)	(1,306)	(1,246)
Provision for (benefit from) income taxes	-	-	-	-
Net Income (Loss)	(242)	(1,379)	(1,306)	(1,246)
Deemed dividend to preferred stockholders	(100)	-	(200)	-
Net Income (Loss) attributable to common stockholders	(342)	(1,379)	(1,506)	(1,246)
EPS diluted	(\$0.17)	(\$0.26)	(\$0.08)	(\$0.04)
Weighted Average Shares fully diluted	1,989	5,316	19,373	31,099

These financial statements are taken from the Company's most recent 10-Q, and therefore do not take into account its recent follow-on offering, which raised net proceeds of \$9.5 million, or the 1-for-5 reverse stock split. If these events had taken place in Q3 2012, Imprimis would have had cash & near cash items of approximately \$20.5 million and approximately 8.89 million shares outstanding at 30 September 2012.

Imprimis Pharmaceuticals, Inc.: Historical Statement of Cash Flows

(\$ in thousands, except per share data)	4Q11	1Q12	2Q12	3Q12
Cash Flows From Operating Activities				
Net Income (Loss)	(272)	(1,379)	(1,306)	(1,246)
Gain on forgiveness of liabilities	(60)	-	-	-
Depreciation	-	0	1	1
Loss on extinguishment of debt	-	1,006	189	-
Non-cash interest on notes payable	19	21	4	-
Stock-based compensation	43	119	730	654
Payments by related party	254	-	-	-
Changes in non cash capital	42	(102)	100	(79)
Cash From Operations	26	(335)	(283)	(670)
Cash From Investing Activities				
Capital expenditures	-	(15)	(1)	-
Cash from Investing Activities	-	(15)	(1)	-
Cash from Financing Activities				
Proceeds from issuance of notes payable to related party	-	300	150	-
Proceeds received in connection with debt modification	-	50	-	-
Proceeds from issuance of notes payable to stockholders	300	-	-	-
Proceeds from issuance of preferred stock	100	-	-	-
Preferred stock deemed dividend paid at conversion	-	-	(200)	-
Repayment of advances from related party	(282)	-	-	-
Proceeds from issuance of common stock and warrants for cash, net of offering costs	-	-	7,934	3,982
Deferred offering costs	-	-	(30)	(39)
Cash from Financing Activities	118	350	7,854	3,943
Net Changes in Cash	144	1	7,571	3,274

These financial statements are taken from the Company's most recent 10-Q, and therefore do not take into account its recent follow-on offering, which raised net proceeds of \$9.5 million, or the 1-for-5 reverse stock split. If these events had taken place in Q3 2012, Imprimis would have had cash & near cash items of approximately \$20.5 million and approximately 8.89 million shares outstanding at 30 September 2012.

### **Disclosures**



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