



# StockWatchIndex Research Report

### **DEVELOPING ANTIBODY THERAPEUTICS**

Immune Pharmaceuticals Inc. (IMNP) is a clinical stage development company researching and developing new and advanced therapies for the treatment of immune-inflammatory diseases and cancer. Immune Therapeutics applies a highly personalized approach to disease treatment, developing novel and carefully targeted antibody therapeutics to improve the lives of patients.

The Company's lead product candidate, Bertilimumab, is entering Phase II clinical studies for moderate-to-severe ulcerative colitis and bullous pemphigoid, with additional studies planned for Crohn's disease, severe asthma and liver diseases (NASH). The company recently expanded its portfolio in immuno-dermatology, topical Nano formulated Cyclosporine A (CsA) for the treatment of psoriasis and atopic dermatitis.

IMNP is currently evaluating the use of its NanomAb® platform, a second generation antibody drug conjugate technology with chemotherapeutics, in order to enhance their safety and efficacy profiles by delivering medicines directly to cancer cells. The Company's growing oncology pipeline also includes proprietary antibodies and clinical -stage small molecules that have been shown positive activity in a variety of solid tumors.



### FDA APPROVAL

Over the past few months Immune Pharmaceutical has made significant progress in the clinical development of its lead product candidate and first-in-class monoclonal antibody, Bertilimumab, which targets eotaxin-1, a key regulator of immune-inflammation. A recent application of an Investigational New Drug (IND) for bullus pemphigold (BP) has been approved by the U.S. FDA.

### **ADDING CLINICAL SITES**

The FDA approval will allow Immune Pharmaceuticals to add new U.S. clinical sites, including Mount Sinai for the company's Stage II clinical trial. Additional clinical sites in Europe will be added, once regulatory approval has been received there as well.

### **COMPLETING TWO TRIALS IN 2016**

Immune Pharmaceuticals plans to follow the same regulatory approach for its upcoming ulcerative colitis (UC) Clinical Trial. The company expects that the clearance by the FDA will allow to complete the BP Clinical Trial in the first half of 2016 and the UC clinical trial by the end of 2016. The company believes that it has sufficient working capital to complete both clinical trials during 2016. These studies represent significant and critical milestones for Bertilimumab.

NanomAb® Platform

Delivering Medicines

directly to Cancer Cells

Lead Product
Candidate entering
Phase II Clinical Studies

Investigational New Drug
Application approved
by the U.S. FDA

Adding Clinical Sites and completing Two Clinical Trials - in 2016

# In This Report

- Antibody Therapeutics
- Growing Oncology Pipeline
- Phase II
   Clinical Trials
- FDA Approval
- Market Size
- Capitalization
- Investment Opportunity

### **FDA APPROVAL**

The U.S. FDA has approved the Investigational New Drug
Application (IND) for Bullos Pemphigoid (BP)

### **NEW MANGEMENT TEAM**

Immune has appointed several new Members to its Leadership Team with extensive Experience in both Pharma and fast growing Biotech Companies

### INVESTMENT

Received \$16.5 Million with Access to additional \$5 Million subject to reaching certain clinical Milestones

### **SPIN OFFS & PARTNERSHIPS**

Immune is planning financing of a new Immune-Oncology
Business unit via Spin Offs and/or Strategic Partnerships

### **Price Development**



### THE COMPANY

Management has moved Immune's U.S. Headquarter, Clinical Development, Immunology R&D Lab and Translation R&D to the Alexandria Center for Life Science in New York, the heart of the Biotech industry. Its Bio-Process Development unit is located in Cambridge, MA. Clinical development, Translation R&D and Nanotechnology R&D located in Jerusalem, Israel.

### **MANAGEMENT TEAM**

**Daniel Teper, CEO** - formerly at Bionest Partners and Novartis.

**Boris Shor, PhD** - Executive Director of R&D and Scientific Partnership.

**G. John Mohr** - Senior Vice President of Business Development, formerly at Merck.

**Monica Luchi, M.D** - Chief Medical Officer, formerly at Novartis.

Miri Ben Ami, M.D.—President, Immune Pharmaceutical, Ltd., formerly at Teva and Aposense.

**John Militello** - Chief Accounting Officer, formerly at Retrophin, Inc.

The Company is also committed to further strengthen its Board of Directors with the addition of members with successful leadership experience at public Biotech or Pharma companies. The management team is supported buy a highly experienced Scientific Advisory Board from all sectors of the biotech, pharma and financial industries.

### CAPITALIZATION

SYMBOL	IMNP		
EXCHANGE	NASDAQ CM		
CURRENT PRICE	\$0.78		
52 WEEK range	\$0.61 - 2.32		
AVERAGE VOLUME	242,000		
SHARES AUTHORIZED	225 Million		
SHARES OUTSTANDING	24 Million		
MARKET CAP	41 Million		
FLOAT	15 Million		

# Global Market Size Estimated at \$62 Billion by 2019

The Global cancer immunotherapy market is expected to produce lucrative growth over the next few years, based on the increasing prevalence of cancer during the last two decades.

Technological enhancements and advanced R&D in genomic studies, Immuno-Inflammatory diseases and specifically bi-specific antibodies have propelled the growth of this market for the last decade.

The US/EU Market size is currently estimated at 60,000 patients and expected to reach 1,000,000 patients by 2025 due to population aging and improving diagnosis.

The addressable Global market for Bertilimumab in BP alone could reach \$1.6 billion. The market for Immune's Bertilimumab could reach over \$3 Billion in Dermatology (BP and AD Gastro)

Initial target price for Bertilimumab in BP is projected to be \$45,000/year/patient, the US/EU market size is currently estimated at 60,000 patients. The BP Opportunity in US/EU is \$1 Billion with additional Severe Atopic Dermatitis potential over \$500 MM.

# Market Estimated to Grow by 67 %

The worldwide market for Immune Therapy is expected to grow by 67% and exceed \$14Billion by 2019. The combined market for Immunology, including Rheumatology, Gastroenterology and Dermatology generated \$45.5 Billion in 2014 and is estimated to grow to \$62.Billion in 2019.

### TWO PROPRIETARY TECHNOLOGY PLATFORMS

Immune Pharmaceuticals has developed two leading edge proprietary platforms, NanomAbs - Antibody Nanoparticle Conjugates with Bi-Specific Antibodies

The companies Small Molecules (Azixa and Croliubulin will be out-licensed. Planned Spin Offs into the Immune-Oncology biotech sector are planned to be financed by institutional investors and corporate partners, with a buy-back option for Immune, or a full spin-off via new IPOs, or appropriate mergers and/or acquisitions.

### LEAD PRODUCT CANDIDATE - BERTILIMUMAB

The company's lead product candidate in the Immune Therapy field, Bertilimumab, is in an FDA approved Phase II clinical development for moderate to severe ulcerative colitis as well as for bullous pemphigoid. Other indications considered for Bertilimumab development include atopic dermatitis, Crohn's disease, severe asthma and inflammatory liver diseases (NASH).

### **BERTILIMUMAB - FIRST IN CLASS**

BP is a rare autoimmune blistering skin disease that typically affects individuals older than 65 years. Currently, there is no cure for BP. Immune's Bertilimumab is the First-in-Class Human Monoclonal Antibody, targeting and neutralizing Eotaxin-1. The US/EU market size is currently estimated at 60,000 patients, expected to grow to 1 Million patients by 2025.

Bertilimumab was originally developed by Cambridge Antibody Technology (now part of MedImmune, the biologics division of AstraZeneca). CAT licensed Bertilimumab to iCo Therapeutics, who retains the rights to develop ophthalmic indications (Kerato-conjunctivitis, wet Age-related Macular Degeneration). Immune Pharmaceuticals owns the rights and took responsibility for product supply and all non-ophthalmic indications in June 2011.

### **PRODUCT PORTFOLIO**

The company recently expanded its portfolio into immune-dermatology, topical nano formulated Cyclosporine A (CsA) for the treatment of psoriasis and atopic dermatitis. Immune's pipeline also includes NanomAbs®, antibody nanoparticle conjugates, for the targeted delivery of chemotherapeutics. The company plans to file additional IND applications for several of its new products during 2016.

CORE PROGRAMS	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3
Inflammation				
Bertilimumab				
Bullous Pemphigold				
IBD (Crohns and Colitis)			<del></del>	
Severe Asthma				
NASH / PSC (Liver Desease)		$\longrightarrow$		
Atopic Dermatitis				
Topical Immune-Dermatology				
Topical nano-formulated Cylosporine A				
Anitbody nanoparticle conjugates				
NenomAbs <sup>®</sup>				

# **EARLY STAGE INVESTMENT OPPORTUNITY**

Immune Pharmaceutical's management has engaged a new leadership team with a proven track record of execution in both pharma and fast growth biotech companies with former positions at Teva, Aposense, CV Therapeutics, Novartis and Merck, among others. The Company has also committed to further strengthening its board of directors with the addition of new members with successful leadership experience at public biotech companies.

With the recent influx of a \$16.5 Million investment, allowing access to an additional \$5Mill subject to certain development milestones, the company believes to have sufficient working capital for the timely execution of both clinical trials and to reach the milestones it has set for itself for 2016. The recent approval by the FDA will accelerate these efforts.

To strengthen the stock, which as been trading near the 52 week low range of \$0.61 - 2.32, the CEO, Dr. Daniel Teper in December, initiated a stock buy-back program for up to \$250,000, demonstrating management's confidence in its product development and the progress of its clinical trials on the path to generating revenues and profitability.

### **Financial Discipline**

With cash and cash equivalents of approximately \$9Million as of September 30, 2015 and a drastic reductions in SG&A by approximately \$3Mill, the company has demonstrated a financial discipline that is crucial for the success of a company in the development stage. The company's balance sheet currently reports \$27.5 Million for in-process research and acquired development assets, in addition to \$3.2 Million in other net tangible assets. The company plans to establish a new oncology business unit and to further expand its immune-oncology pipeline of products.

Immune's U.S. headquarter, Clinical development, Immunology R@D lab and Translation R&D has recently been relocated to the Alexandria Center for Life Science in New York and its Bio-Process Development unit is located in Cambridge, MA. Clinical development, Translation R&D and Nanotechnology R&D is located in Jerusalem in Israel.

#### **SWI OPINION**

Based on the stock currently trading at the low end of the 52 week range, the aggressive expansion of the company's product development pipe line, the FDA approval for an Investigational New Drug (IDG) application for the clinical trial of its lead product Bertilimumab and a top-tier new management team recruited from large Biotech companies, we consider IMNP an unusual early stage investment opportunity with a low risk to reward ratio.

### **SENIOR MANAGEMENTTEAM**

Dr. Daniel Teper, Chief Executive Officer Monica Luchi, MD, Chief Medical Officer John Militello, Chief Accounting Officer



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### **BOARD OF DIRECTORS**

Daniel Kazado, Chairman Cameron Durrant, MD, Lead Independent Director Chair of the Compensation Committee Elliot Maza, Chair of the Audit Committee



## Immune Pharmaceutical, Inc.

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