Immune Pharmaceuticals Provides Business Update and Announces Fourth Quarter and Full Year 2015 Financial Results

NEW YORK, March 30, 2016 /PRNewswire/ -- Immune Pharmaceuticals Inc. (NASDAQ: IMNP) ("Immune" or the "Company") announced financial results for the fourth quarter and full year ended December 31, 2015. Immune filed its Annual Report on Form 10-K for fiscal year 2015 on March 30, 2016.

2015 Highlights

2015 was an important year for Immune as we formed a new leadership team based in New York City at the Alexandria Center for Life Science. Several key executives with successful track records at both large pharmaceutical and biotech companies have joined Immune, significantly improving our ability to execute our business plan:

- Monica Luchi, MD, MBA, Chief Medical Officer and EVP, Global Drug Development;
- Miri Ben-Ami, MD, President, Immune Oncology Pharmaceuticals Inc. and Immune Pharmaceuticals Ltd (Israel);
- Mark Levitt, MD, PhD, SVP Oncology Clinical Affairs;
- John Mohr, SVP, Business Development;
- John Militello, VP, Finance and Chief Accounting Officer; and
- Boris Shor, PhD, Executive Director R&D and Scientific Partnerships.

As a result, Immune achieved several notable milestones, including:

- First patient and ongoing enrollment into Phase II clinical trials with bertilimumab in ulcerative colitis;
- Clearance by the U.S. Food and Drug Administration of our Investigational New Drug application for bertilimumab for the treatment of bullous pemphigoid, an auto-immune orphan dermatological disease, allowing for expansion of the clinical trials to the United States;
- Acquisition of worldwide rights to NanoCyclo, a topical nano-formulated cyclosporine for the treatment of moderate atopic dermatitis and psoriasis; and
- In-licensing of a novel bispecific antibody technology and establishment of an R&D laboratory in NYC under the leadership of Dr. Shor, a former Pfizer executive, to focus on the development of bispecific antibodies targeting immune checkpoints and specific tumor targets.

Given the scope of Immune's development stage portfolio, we have initiated the establishment of a subsidiary with a focus on immuno-oncology therapeutic assets and technologies, allowing the Company to leverage the breadth of its new management team and to access financing opportunities in this vast area of unmet need. The newly established company, Immune Oncology Pharmaceuticals Inc., was created at the end of the first quarter of 2016, under the leadership of Dr. Miri Ben-Ami. Its portfolio includes Ceplene, a cancer immunotherapy for the treatment of Acute Myeloid Leukemia in combination with low dose IL-2; Azixa and crolibulin, Phase II vascular disrupting agents; and bispecific antibodies and NanomAbs (antibody nanoparticle conjugates), two innovative platforms to generate a pipeline of drug candidates. New European Phase IV data on Ceplene was published in two issues of Oncotarget (November 2015 and February 2016) and will be presented at the American Academy of Cancer Research on April 17, 2016. These data and additional analysis from previous trials with Ceplene may support design of an overall survival registrational trial in the U.S. Preclinical data in support of the bispecific antibody platform was published on February 26, 2016 in The Journal of Immunology.

"I am pleased, excited and gratified with the major clinical and organizational accomplishments during the year 2015." said Dr. Daniel Teper, CEO of Immune Pharmaceutical Inc. "We expect 2016 to be an important year for Immune, with several anticipated data milestones for the Company's product candidates, while we seek to unlock the potential value of our pipeline through financing and strategic partnering opportunities of specific asset groups."

4th Quarter and Full Year 2015 Financial Discussion

Immune reported a loss attributable to common stockholders of \$8.2 million, or \$0.27 per share, for the quarter ended December 31, 2015, compared to a loss attributable to common stockholders of \$7.0 million, or \$0.34 per share, for the quarter ended December 31, 2014. For the year ended December 31, 2015, Immune reported a loss attributable to common stockholders of \$24.1 million, or \$0.90 per share, compared to a loss attributable to common stockholders of \$24.4 million, or \$1.46 per share, for the year ended December 31, 2014.

R&D expenses increased by \$0.9 million during the quarter ended December 31, 2015 to \$2.5 million compared with \$1.6 million during the quarter ended December 31, 2014. For the year ended December 31, 2015, R&D expenses increased by \$0.3 million to \$5.9 million compared with \$5.6 million during the year ended December 31, 2014. The increase in R&D expenses for the fourth quarter and full year of 2015 was mainly due to an increase in outsourced consulting services related to the Phase II clinical trials of bertilimumab. Additionally, R&D related staff increased, positioning Immune to fully execute on its R&D programs in 2016.

General and administrative expense increased by approximately \$1.2 million during the quarter ended December 31, 2015 to \$3.6 million, compared with \$2.4 million during quarter ended December 31, 2014, due to higher payroll expense as a result of the move of the Company's headquarters from Israel to New York during fiscal 2015 and the hiring of additional U.S. employees. For the year ended December 31, 2015, general and administrative expense decreased by approximately \$0.9 million, or 9%, to \$9.8 million, compared with \$10.7 million during year ended December 31, 2014. The decrease was primarily due to a reduction in stock compensation expense of \$2.6 million due to the vesting of shares issued to consultants in 2014, partially offset by increased payroll expense due to the moving of the Company's headquarters from Israel to New York in fiscal 2015 and the hiring of additional U.S. based employees.

Non-operating expense decreased by \$2.6 million to \$0.4 million during quarter ended December 31, 2015 compared with non-operating expense of \$3.0 million during quarter ended December 31, 2014. For the year ended December 31, 2015, non-operating expense amounted to \$1.4 million compared with non-operating expense of \$7.2 million during year

ended December 31, 2014, a decrease of \$5.7 million. Non-operating expense for the year ended December 31, 2015 consisted of interest expense of \$0.8 million primarily relating to cash interest paid and amortization of the debt discount for the Company's loan and security agreement with Hercules. In addition, the Company recognized a loss on the extinguishment of debt of \$0.5 million due to early termination fees in conjunction with the repayment of the MidCap senior secured term loan during 2015. Non-operating expense for the year ended December 31, 2014 consisted of interest expense of \$3.4 million primarily due to a \$2.2 million charge for the accelerated vesting of restricted stock recorded as debt issuance costs and included \$3.1 million in warrant amendment expense in conjunction with the amendment of the March 2014 Warrants.

About Immune Pharmaceuticals Inc.:

Immune Pharmaceuticals Inc. (NASDAQ: IMNP) applies a personalized approach to treating and developing novel, highly targeted antibody therapeutics to improve the lives of patients with inflammatory diseases and cancer. Immune's lead product candidate, bertilimumab, is in Phase II clinical development for moderate-to-severe ulcerative colitis as well as for bullous pemphigoid, an orphan autoimmune dermatological condition. Other indications being considered for development include atopic dermatitis, Crohn's disease, severe asthma and NASH (an inflammatory liver disease). Immune recently expanded its portfolio in immunodermatology with topical nano-formulated cyclosporine-A for the treatment of psoriasis and atopic dermatitis. Immune's oncology pipeline includes Ceplene/IL-2 approved in Europe and Israel for maintenance remission in AML, Azixa and crolibulin, Phase II-ready vascular disrupting agents, and novel technology platforms; bispecific antibodies and targeted nanotherapeutics, NanomAbs. Immune's additional pipeline includes AmiKet Nano[™], a late clinical stage drug candidate for the treatment of neuropathic pain. For more information, visit Immune's website at <u>www.immunepharmaceuticals.com</u>, the content of which is not a part of this press release.

Forward-Looking Statements

This news release and any oral statements made with respect to the information contained in this news release contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. You are urged to consider statements that include the words "may," "will," "would," "could," "should," "believes," "estimates," "projects," "potential," "expects," "plans," "anticipates," "intends," "continues," "forecast," "designed," "goal" or the negative of those words or other comparable words to be uncertain and forwardlooking. Such forward-looking statements include statements that express plans, anticipation, intent, contingency, goals, targets, future development and are otherwise not statements of historical fact. These statements are based on our current expectations and are subject to risks and uncertainties that could cause actual results or developments to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. Factors that may cause actual results or developments to differ materially include, but not limited to: the risks associated with the adequacy of our existing cash resources and our ability to continue as a going concern; the risks associated with our ability to continue to meet our obligations under our existing debt agreements; the risk that clinical trials for bertilimumab or AmiKet will not be successful; the risk that bertilimumab, AmiKet or compounds arising from our NanomAbs program will not receive regulatory approval or achieve significant commercial success; the risk that we will not be able to find a partner to help conduct the Phase III trials for AmiKet on attractive terms, on a timely basis or

at all; the risk that our other product candidates that appeared promising in early research and clinical trials do not demonstrate safety and/or efficacy in larger-scale or later-stage clinical trials: the risk that we will not obtain approval to market any of our product candidates: the risks associated with dependence upon key personnel; the risks associated with reliance on collaborative partners and others for further clinical trials, development, manufacturing and commercialization of our product candidates; the cost, delays and uncertainties associated with our scientific research, product development, clinical trials and regulatory approval process; our history of operating losses since our inception; the highly competitive nature of our business; risks associated with litigation; and risks associated with our ability to protect our intellectual property. These factors and other material risks are more fully discussed in our periodic reports, including our reports on Forms 8-K, 10-Q and 10-K and other filings with the U.S. Securities and Exchange Commission. You are urged to carefully review and consider the disclosures found in our filings, which are available at www.sec.gov or at www.immunepharmaceuticals.com. You are cautioned not to place undue reliance on any forward-looking statements, any of which could turn out to be wrong due to inaccurate assumptions, unknown risks or uncertainties or other risk factors. We expressly disclaim any obligation to publicly update any forward looking statements contained herein, whether as a result of new information, future events or otherwise, except as required by law.

IMMUNE PHARMACEUTICALS INC AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(\$ in thousands, except share amounts)

December	31.Dec	cember	31.
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2014

2015

ASSETS	
Current assets	

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Cash and cash equivalents	\$ 4,543	\$ 6,767
Restricted cash	31	21
Other current assets	258	99

Total current assets	4,832	6,887		
Property and equipment, at cost, net of accumulated depreciation of \$77 and \$51	371	41		
In-process research and development acquired	27,500	27,500		
Intangible assets, net	3,111	3,415		
Other assets	370	21		
Total assets	\$ 36,184	\$ 37,864		
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities				
Accounts payable	\$ 2,439	\$ 1,243		
Accrued expenses	2,660	4,133		
Due to related parties	-	30		
Derivative financial instruments, warrants	84	-		
Notes and loans payable, current portion, net of debt discount	997	2,011		
Obligations under capital lease, current portion	106	-		
Total current liabilities	6,286	7,417		
Grants payable	-	469		
Notes and loans payable, net of current portion	2,886	1,564		
Obligations under capital lease, net of current portion and debt discount	91	-		

Series D Preferred Stock derivative liability	6,529	-
Deferred tax liability	10,870	10,870
Total liabilities	26,662	20,320
Series D Preferred Stock, net of discount, par value \$0.0001, 12,000 shares authorized, 1,263 shares issued and 963 shares outstanding as of December 31, 2015 and 0 shares issued and outstanding as of December 31, 2014	1,659	-
Commitments and contingencies		
Stockholders' Equity		
Series C Preferred Stock, par value \$0.0001; 15,000 shares authorized, 2,832 shares issued and 0 shares outstanding as of December 31, 2015, and 2,832 shares issued and outstanding, as of December 31, 2014	-	821
Common stock, \$0.0001 par value; authorized 225,000,000 shares; 32,434,942 and 23,975,358 shares issued and outstanding at December 31, 2015 and December 31, 2014, respectively	3	2
Additional paid-in capital	70,846	62,550
Accumulated deficit	(62,986)	(45,829)
Total stockholders' equity	7,863	17,544
Total liabilities and stockholders' equity	\$ 36,184	\$ 37,864

Condensed Consolidated Statements of Operations

(\$ in thousands, except share and per share amounts)

(Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2015	2014	2015	2014
Revenue	\$-	\$-	\$-	\$2
Costs and expenses:				
Research and development	2,532	1,626	5,935	5,640
General and administrative	3,577	2,431	9,789	10,725
Total costs and expenses	6,109	4,057	15,724	16,365
Loss from operations	(6,109)	(4,057)	(15,724)	(12,306)
Non-operating income (expense):				
Interest expense	(465)	(3,034)	(827)	(3,404)
Derivative liability instruments expense	13	(80)	(128)	(558)
Loss on extinguishment of debt	2	-	(463)	-
Warrant amendment expense	-	-	-	(3,145)
Other expense, net	(6)	81	(15)	(80)

Total non-operating expense	(456)	(3,033)	(1,433)	(7,187)
Net loss before income taxes	(6,565)	(7,090)	(17,157)	(23,550)
Net loss	\$(6,565)	\$(7,090)	(17,157)	(23,550)
Deemed dividend	(1,595)	-	(6,959)	(6,166)
Series C Preferred Stock dividend	-	58	-	(256)
Loss attributable to common stockholders	\$(8,160)	\$(7,032)	\$(24,116)	\$(24,422)
Basic and diluted loss per common sha	re\$(0.27)	\$(0.34)	\$(0.90)	\$(1.46)
Weighted average common shares outstanding –basic and diluted	30,542,32	25 20,916,54	5 26,741,39	2 16,742,550

To view the original version on PR Newswire, visit<u>http://www.prnewswire.com/news-</u> releases/immune-pharmaceuticals-provides-business-update-and-announces-fourth-quarterand-full-year-2015-financial-results-300243797.html

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