

IMMUNOMEDICS INC  
Form DEFA14A  
January 18, 2017

---

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

SCHEDULE 14A

Proxy Statement Pursuant to Section 14(a) of  
the Securities Exchange Act of 1934 (Amendment No. )

Filed by the Registrant

Filed by a Party other than the Registrant

Check the appropriate box:

Preliminary Proxy Statement

**Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))**

Definitive Proxy Statement

Definitive Additional Materials

Soliciting Material under §240.14a-12

**Immunomedics, Inc.**

(Name of Registrant as Specified In Its Charter)

(Name of Person(s) Filing Proxy Statement, if other than the Registrant)

Payment of Filing Fee (Check the appropriate box):

No fee required.

Fee computed on table below per Exchange Act Rules 14a-6(i)(1) and 0-11.

(1) Title of each class of securities to which transaction applies:

(2) Aggregate number of securities to which transaction applies:

(3) Per unit price or other underlying value of transaction computed pursuant to Exchange Act Rule 0-11 (set forth the amount on which the filing fee is calculated and state how it was determined):

(4) Proposed maximum aggregate value of transaction:

(5) Total fee paid:

Fee paid previously with preliminary materials.

Edgar Filing: IMMUNOMEDICS INC - Form DEFA14A

.. Check box if any part of the fee is offset as provided by Exchange Act Rule 0-11(a)(2) and identify the filing for which the offsetting fee was paid previously. Identify the previous filing by registration statement number, or the Form or Schedule and the date of its filing.

(1) Amount Previously Paid:

(2) Form, Schedule or Registration Statement No.:

(3) Filing Party:

(4) Date Filed:

**Immunomedics Highlights Expanded Pipeline Positioning Company for Sustained Value Creation**

**— Details Preclinical and Clinical Progress in Advancing IMMU-114, IMMU-130, IMMU-140, and Immuno-Oncology Program —**

**— Expresses Confidence in Near- and Long-Term Growth Prospects for Stockholders —**

**MORRIS PLAINS, N.J., January 18, 2017 — Immunomedics, Inc. (NASDAQ: IMMU)** (“Immunomedics” or “the Company”) today highlighted additional value-creation inflection points in its robust pipeline in connection with the Company’s Investor R&D Day held at The Roosevelt Hotel in New York City. In addition to announcing new data for sacituzumab govitecan (IMMU-132), Immunomedics detailed the preclinical and clinical progress it has achieved in advancing IMMU-114, IMMU130, IMMU-140 and its immune-oncology program, which the Company believes will result in near- and long-term value creation for stockholders.

“While IMMU-132 is the key near-term driver of value creation for Immunomedics stockholders, we are making significant progress in advancing the rest of our robust pipeline with the goal of sustained value creation,” said Cynthia L. Sullivan, President and Chief Executive Officer. “We are on track to achieve numerous other milestones to position these assets for future monetization in parallel with our efforts to achieve the value potential of IMMU-132.”

To date, the Company has:

Advanced IMMU-114 in clinical trials and presented results at peer-reviewed clinical meetings (2015 Annual Meeting of the American Society of Hematology and 2016 Pan Pacific Lymphoma Conference);

Completed the Phase 2 trial of its solid cancer ADC, labetuzumab govitecan (IMMU-130), in patients with advanced, metastatic, colorectal cancer;

Consulted with the FDA on the Phase 3 registration trial for IMMU-130 in patients with advanced, refractory, colorectal cancer;

Advanced the Company's development of IMMU-140, an antibody-drug conjugate (ADC) using the Company's proprietary SN-38 conjugation technology together with the IMMU-114 humanized antibody, presenting first preclinical results at the 2016 Annual Meeting of the American Society of Hematology; and

Continued to establish, expand and explore our robust pipeline of potential treatments, including a novel, proprietary methodology to harness the patient's own immune system to treat cancer with bispecific antibodies retargeting T cells (immuno-oncology program).

## **CLINICAL PROGRAMS:**

### **IMMU-130**

This ADC contains the exact same linker + drug as IMMU-132, but employs a different antibody, labetuzumab. The antibody recognizes carcinoembryonic antigen (CEA, or CEACAM5), which is elevated in over 85% of patients with metastatic colorectal cancer (mCRC). Enrollment into a Phase 2, single-arm study in about 91 patients with mCRC has been completed. Promising activity in heavily-pretreated patients (median five prior therapies and all treated with irinotecan) were reported. In patients receiving the 10 mg/kg dose on days 1 and 8 of 21-day cycles, the median progression-free survival (PFS) was 4.6 months, and the median overall survival (OS) was 9.2 months. This compares favorably to results with regorafenib, which had a 3<sup>rd</sup> line median PFS of 1.9 months and an OS of 6.4 months. Although there were no partial responses (PRs) with IMMU-130 at this dose level/schedule, 87% of these patients had stable disease (SD). Immunomedics states that it will continue to follow patients in this Phase 2 study and will continue discussions with the regulatory authorities on the design of a future Phase 3 clinical trial.

### **Epratuzumab**

To date, epratuzumab (humanized anti-CD22 antibody) has been administered to more than 2,000 patients with non-Hodgkin lymphoma (NHL), acute lymphoblastic lymphoma (ALL), and lupus. Clinical studies showed that it could be combined with rituximab, an anti-CD20 antibody, resulting in improved efficacy, which is the rationale leading to the Company developing bispecific antibodies against both CD22 and CD20 (discussed below). Currently, epratuzumab is being evaluated in a Phase 3 clinical trial in pediatric patients with ALL. This long-term, randomized study will enroll 612 patients, with the primary endpoint of PFS at four years. The IntReALL consortium, based in Berlin, Germany, is sponsoring this study, supported by a program grant from the European Union. The Company provides epratuzumab under a reimbursement program for the manufacturing costs.

### **Veltuzumab**

The Company's 2<sup>d</sup> generation (humanized) anti-CD20 antibody, veltuzumab, was constructed with one amino acid difference in the binding site compared to rituximab, and has different framework regions due to humanization. Because of this structural change, functional difference compared to rituximab were observed during development, including veltuzumab's binding to CD20 3-times longer, increased complement-dependent cytotoxicity (CDC), and improved survival in lymphoma xenograft models when compared to rituximab. This CD20 antibody has been formulated in subcutaneous (sc) dosing and has been evaluated in patients with NHL and immune thrombocytopenia (ITP), and has been administered under compassionate use in patients with lupus and pemphigus. Promising clinical results in over 200 patients receiving active and convenient sc dosing positions this program for advancement into controlled trials, alone and in combination with other agents. The indications would be patients with hematological malignancies and autoimmune diseases. The Company's unique sc formulation has been patented.



## **Milatuzumab**

Milatuzumab is a humanized anti-CD74 antibody targeting CD74 present on antigen-presenting cells, including B cells and dendritic cells. The Company is studying milatuzumab (sc formulation) in patients with lupus, under a U.S. Department of Defense grant. Previously, milatuzumab was studied as a monotherapy and in combination with veltezumab, in patients with relapsed, refractory NHL, as well as a monotherapy in patients with advanced and refractory multiple myeloma; it showed activity in both disease settings. In a Phase 1b open-label study, patients with lupus received a dose per week for four weeks of milatuzumab, and were then assessed for disease activity using BILAG and SELENA-SLEDAI scoring systems. Results presented at EULAR in 2016 included all 10 patients enrolled showed a decrease in disease activity in at least one body system. Suppression of disease activity extended for 24 weeks in most patients. Injection reactions were mild-moderate. This has now moved into a double-blind, placebo-controlled, expansion phase, to confirm the activity of sc milatuzumab in this population, and continues to be supported by the U.S. Department of Defense.

## **IMMU-114**

This 2<sup>nd</sup> generation anti-HLA-DR humanized antibody is an IgG4 immunoglobulin, administered by sc injection, and designed to reduce toxicities (severe infusion reactions) seen with prior IgG1 antibodies administered intravenously. Initial clinical studies in NHL and chronic lymphocytic leukemia (CLL) patients are continuing, with activity reported after patients had failed therapy with rituximab. Treatment cycles are now given repeatedly in a dose-determining clinical trial.

## **PRECLINICAL PROGRAMS:**

### **IMMU-132 Preclinical Development (PARP Inhibitors/Chemotherapy Combinations)**

Based on a preclinical study, the encouraging efficacy observed with IMMU-132 in animal models were presented, demonstrating the potential for improved therapeutic results when combined with agents that inhibit DNA repair pathways, both in mutated and wild-type *BRCA1/2*. Results from this preclinical study were published online in *Clinical Cancer Research*, a major peer-reviewed journal in cancer research and one of the official publications of the American Association for Cancer Research (AACR). Company scientists are also studying why cancer cells that express Trop-2 respond differentially to IMMU-132, in an effort to enhance the therapeutic effects clinically. Results suggest that different degrees of tumor resistance may be overcome, which could have a major impact on future clinical results.

### **IMMU-140 Preclinical Development**

IMMU-140 is an ADC comprising SN-38 conjugated to IMMU-114 (anti-HLA-DR humanized antibody). It has been shown that the ADC possesses both the functional activities of the unconjugated antibody, IMMU-114, and the toxic

effects of selective delivery of SN-38 to tumors, thus having a dual function. At the recent 2016 annual meeting of the American Society of Hematology (ASH), the Company's scientists showed that this dual activity resulted in more potent antitumor effects compared to IMMU-114, and that IMMU-140 had potent activity against five hematological neoplasms grown in cell culture and in suitable mice: NHL, CLL, ALL, multiple myeloma, and acute myeloid leukemia. IMMU-140 also targets some solid cancers not under investigation by the Company's other two ADCs; namely, malignant melanoma and glioblastoma multiforme. This ADC is completing studies necessary to transfer it to clinical trials.

### **Bispecific Antibody Technology**

The Company reported on the Dock-N-Lock® (DNL®) technology for making multi-valent antibody constructs, including CD22-CD20 bispecific antibodies, and the potential therapeutic indications in NHL, CLL, ALL, and multiple autoimmune diseases. By targeting two different receptors on circulating malignant B cells or B cells implicated in autoimmunity, the Company has shown enhanced potency compared to the parental antibodies targeting either CD22 or CD20. Moreover, these new constructs appear to have less destruction of normal B cells needed for immunity than the parental anti-CD20 antibody or other anti-CD20 antibodies currently available.

### **T-cell Retargeting**

The Company presented preclinical data on a DNL®-derived bispecific antibody for T-cell redirected killing of various hematological and solid tumors. This construct comprises the bivalent binding of CD19 or Trop-2 and monovalent CD3 recruitment of T cells on many different types of hematological and epithelial cancers, respectively.

Vinson & Elkins L.L.P. and DLA Piper LLP (US) are serving as legal advisors, and Greenhill & Co., LLC, is serving as financial advisor to Immunomedics.

### **About Immunomedics**

Immunomedics is a clinical-stage biopharmaceutical company developing monoclonal antibody-based products for the targeted treatment of cancer, autoimmune disorders and other serious diseases. Immunomedics' advanced proprietary technologies allow the Company to create humanized antibodies that can be used either alone in unlabeled or "naked" form, or conjugated with radioactive isotopes, chemotherapeutics, cytokines or toxins. Using these technologies, Immunomedics has built a pipeline of eight clinical-stage product candidates. Immunomedics' portfolio of investigational products includes antibody-drug conjugates (ADCs) that are designed to deliver a specific payload of a chemotherapeutic directly to the tumor while reducing overall toxic effects that are usually found with conventional administration of these chemotherapeutic agents. Immunomedics' most advanced ADCs are sacituzumab govitecan (**IMMU-132**) and labetuzumab govitecan (**IMMU-130**), which are in Phase 2 trials for a number of solid tumors and metastatic colorectal cancer, respectively. **IMMU-132** has received Breakthrough Therapy Designation from the FDA for the treatment of patients with triple-negative breast cancer who have failed at least two prior therapies for metastatic disease. Immunomedics has a research collaboration with Bayer to study epratuzumab as a thorium-227-labeled antibody. Immunomedics has other ongoing collaborations in oncology with independent cancer study groups. The IntraALL Inter-European study group is conducting a large, randomized Phase 3 trial combining epratuzumab with chemotherapy in children with relapsed acute lymphoblastic leukemia at clinical sites in Australia, Europe, and Israel. Immunomedics also has a number of other product candidates that target solid tumors and hematologic malignancies, as well as other diseases, in various stages of clinical and preclinical development. These include combination therapies involving its antibody-drug conjugates, bispecific antibodies targeting cancers and infectious diseases as T-cell redirecting immunotherapies, as well as bispecific antibodies for next-generation cancer and autoimmune disease therapies, created using its patented DOCK-AND-LOCK® protein conjugation technology. The Company believes that its portfolio of intellectual property, which includes approximately 306 active patents in

the United States and more than 400 foreign patents, protects its product candidates and technologies. For additional information on the Company, please visit its website at [www.immunomedics.com](http://www.immunomedics.com). The information on its website does not, however, form a part of this press release.

### **Important Additional Information**

Immunomedics, Inc. (the “Company”), its directors and certain of its executive officers are deemed to be participants in the solicitation of proxies from Company stockholders in connection with the matters to be considered at the Company’s 2016 Annual Meeting. The Company has filed a definitive proxy statement and form of WHITE proxy card with the U.S. Securities and Exchange Commission (the “SEC”) in connection with any such solicitation of proxies from Company stockholders. **COMPANY STOCKHOLDERS ARE STRONGLY ENCOURAGED TO READ THE DEFINITIVE PROXY STATEMENT (INCLUDING ANY AMENDMENTS AND SUPPLEMENTS), THE ACCOMPANYING WHITE PROXY CARD AND ANY OTHER RELEVANT DOCUMENTS THAT THE COMPANY FILES WITH THE SEC WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION.** Information regarding the identity of the participants, and their direct or indirect interests, by security holdings or otherwise, is set forth in the proxy statement and other materials filed by the Company with the SEC. Stockholders will be able to obtain the proxy statement, any amendments or supplements to the proxy statement and other documents filed by the Company with the SEC for no charge at the SEC’s website at [www.sec.gov](http://www.sec.gov). Copies will also be available at no charge at the Company’s website at [www.immunomedics.com](http://www.immunomedics.com), by writing to Immunomedics, Inc. at 300 The American Road, Morris Plains, New Jersey 07950, by calling the Company’s proxy solicitor, MacKenzie Partners, Inc. at (212) 929-5500, or by calling Dr. Chau Cheng, Senior Director, Investor Relations & Corporate Secretary, (973) 605-8200, extension 123.

### **Forward-Looking Statements**

This release, in addition to historical information, may contain forward-looking statements made pursuant to the Private Securities Litigation Reform Act of 1995. Such statements, including statements regarding clinical trials (including the funding therefor, anticipated patient enrollment, trial outcomes, timing or associated costs), regulatory applications and related timelines, out-licensing arrangements (including the timing and amount of contingent payments), forecasts of future operating results, potential collaborations, and capital raising activities, involve significant risks and uncertainties and actual results could differ materially from those expressed or implied herein. Factors that could cause such differences include, but are not limited to, the Company’s dependence on business collaborations or availability of required financing from capital markets, or other sources on acceptable terms, if at all, in order to further develop our products and finance our operations, new product development (including clinical trials outcome and regulatory requirements/actions), the risk that we or any of our collaborators may be unable to secure regulatory approval of and market our drug candidates, risks associated with the outcome of pending litigation and competitive risks to marketed products, and the Company’s ability to repay its outstanding indebtedness, if and when required, as well as the risks discussed in the Company’s filings with the Securities and Exchange Commission. The Company is not under any obligation, and the Company expressly disclaims any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise.

### **For More Information:**

Dr. Chau Cheng

Senior Director, Investor Relations & Corporate Secretary

(973) 605-8200, extension 123

[ccheng@immunomedics.com](mailto:ccheng@immunomedics.com)

**Media**

Dan Katcher / Ed Trissel / Nick Lamplough

Joele Frank, Wilkinson Brimmer Katcher

(212) 355-4449

**Investors**

Dan Burch/Bob Marese

MacKenzie Partners, Inc.

(212) 929-5500

###

5