

IMMUNOMEDICS INC
Form DEFA14A
February 23, 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

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Immunomedics, Inc.

(Name of Registrant as Specified In Its Charter)

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

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☒ No fee required.

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IMMUNOMEDICS ANNOUNCES COMPANY'S IMMUNE CHECKPOINT INHIBITOR ENHANCES ANTI-TUMOR POTENCY OF T-CELL-REDIRECTING BISPECIFIC ANTIBODIES

Orlando, FL., February 23, 2017 --- Immunomedics, Inc., (NASDAQ: IMMU) ("Immunomedics" or "the Company") today reported a notable increase in potency when its novel bispecific antibodies (bsAbs) that can redirect T cells, a type of immunoactive white blood cells, to kill cancer cells were combined with its proprietary immune checkpoint inhibitor. This preclinical study was selected to be included in a Poster Walk at the inaugural ASCO-SITC Clinical Immuno-Oncology Symposium in Orlando, Florida, that is focused on clinical and translational research in immuno-oncology and the implications for clinical care.

"These results emphasize the potential of combining T-cell-redirecting bsAbs with antagonists or agonists that mitigate T-cell inhibition within the tumor microenvironment to improve the immunotherapy of solid cancers in patients, which has been elusive to date," stated the lead author, Dr. Chien-Hsing Chang, Vice President, Research and Development. Other Immunomedics scientists involved in this study are Dr. Yang Wang, Diane L. Rossi, Rongxiu Li, and Drs. Donglin Liu, Edmund A. Rossi, Thomas M. Cardillo, and David M. Goldenberg.

BsAbs are genetically-engineered antibodies capable of binding to two different targets simultaneously. In this preclinical study, two bsAbs were created using the Company's proprietary Dock-and-Lock® (DNL®) protein conjugation platform technology. In addition to targeting the CD3 receptor on T cells, these bsAbs can also bind bivalently to the tumor antigens, Trop-2 or CEACAM5, which are expressed by many solid cancers. As a result, they can capture T cells in a patient and redirect them to kill a variety of cancer cells that express these target antigens. The two bsAbs killed Trop-2- or CEACAM5-expressing cancer cells grown in monolayer cultures at low picomolar concentrations, with similar potency observed for target cells that are resistant to a topoisomerase-I-inhibiting antibody-drug conjugate.

The antitumor efficacy of these T-cell-redirecting bsAbs was also evaluated in a humanized mouse model of human triple-negative breast cancer (TNBC), and in 3D spheroids generated with cells from TNBC and human colonic cancers in order to mimic the *in vivo* behavior and microenvironment of these tumors. Moreover, the benefit of adding an immune checkpoint inhibitor was also examined.

In a mouse model of human TNBC that expresses the immune checkpoint PD-1, the Trop-2-targeting bsAb, (E1)-3s, in combination with the Company's anti-PD-1 antibody, significantly reduced tumor volume and improved median survival time, when compared to an untreated control group. In addition, increased cell death in 3D spheroids was

seen with both T-cell-redirecting bsAbs, supporting the use of 3D spheroids as a predictive alternative to *in vivo* models for evaluating T-cell functions.

“These preclinical studies are critical to our understanding of how to best apply these new bispecific antibodies as well as our own anti-PD-1 antibody for a combination immunotherapy, as we prepare these novel constructs for clinical testing,” remarked Cynthia L. Sullivan, President and Chief Executive Officer.

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About Immunomedics

Immunomedics (the “Company”) 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 IntreALL 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. 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 will be 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 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. Copies will also be available at no charge at the Company’s website at www.immunomedics.com, by writing to Immunomedics, Inc. at 300 The American Road, Morris Plains, New Jersey 07950, or by calling the Company’s proxy solicitor, or by calling Dr. Chau Cheng, Senior Director, Investor Relations & Corporate Secretary, (973) 605-8200, extension 123.

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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 under the license and development agreement with Seattle Genetics), 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:

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