IMMUNOMEDICS INC
Form DEFA14A
February 10, 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.

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

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(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):

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

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Immunomedics Enters into Exclusive Global Licensing Agreement with Seattle Genetics for Sacituzumab Govitecan (IMMU-132) with Potential Payments of up to

Approximately $2 Billion, Plus Royalties

Immunomedics to Receive $250 Million in Upfront Cash Payment; Plus Among Other Milestone Payments, an Additional $50 Million or Negotiated Economic Splits Relating to Rights Outside US, Canada and EU

Agreement Provides for Seattle Genetics to Develop, Manufacture and Commercialize IMMU-132 in Multiple Indications; Immunomedics Retains Rights to Co-Promote in the United States

Seattle Genetics to Make up to $57 Million Equity Investment for up to 9.9% Stake in Immunomedics Via an Immediate Purchase of Common Stock and a Three-Year Warrant, Each Priced at a 10% Premium to the Company's 15-Day VWAP

Agreement Follows Months-Long Robust, Strategic Process Led by Independent Transaction Committee of the Board and Outside Financial Advisor, Greenhill & Co.

IMMU-132 Represents Potential for First-Ever Approved Therapy Specifically for

Advanced Metastatic Triple-Negative Breast Cancer (TNBC)

Company to Host Conference Call at 8:00 AM Eastern Time to Discuss Transaction

Morris Plains, N.J., February 10, 2017 – Immunomedics, Inc. (NASDAQ: IMMU) ("Immunomedics") today announced that it has entered into an exclusive global licensing agreement with Seattle Genetics, Inc. (NASDAQ: SGEN), an innovative global biotechnology company that develops and commercializes novel antibody-drug conjugates (ADCs) for the treatment of cancer. Under the agreement, Seattle Genetics will develop, fund, manufacture and commercialize IMMU-132, Immunomedics' proprietary solid tumor therapy candidate.

The agreement also provides that Seattle Genetics will be responsible for initiating the Phase 3 clinical trial of IMMU-132 in patients with metastatic triple-negative breast cancer (TNBC) and submitting the initial Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for accelerated approval. The agreement includes the development of additional indications for IMMU-132, including urothelial cancer (UC), small-cell lung cancer (SCLC) and non-small-cell lung cancer (NSCLC), which are currently in Phase 2 clinical studies, along with other solid tumor indications being studied in ongoing clinical trials.

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Cynthia L. Sullivan, President and Chief Executive Officer of Immunomedics, said, “We are pleased to enter into this exclusive worldwide licensing agreement with Seattle Genetics to further advance IMMU-132 on behalf of patients with late-stage cancers, who have limited therapeutic options, while delivering significant and compelling near- and long-term value to stockholders. Since its founding, Immunomedics has been dedicated to creating and advancing novel therapies in challenging diseases with unmet therapeutic needs. Seattle Genetics’ reputation, development portfolio and track record make them an ideal partner to advance IMMU-132. Additionally, this agreement validates the dedication and effort by our entire internal teams in research and development, manufacturing, clinical, regulatory and general administration. In just over three years, we have brought IMMU-132 through clinical developments in multiple indications, and have advanced the TNBC indication to a potential accelerated approval and launch by late 2017 or early 2018, which could make IMMU-132 available to patients dealing with a highly malignant form of breast cancer. We are proud to have achieved this critical milestone and thank our entire team for their hard work. Immunomedics looks forward to appropriately supporting Seattle Genetics as it seeks to bring IMMU-132 to commercialization.”

Clay Siegall, Ph.D., President and Chief Executive Officer of Seattle Genetics, said, “As the global leader in ADCs, we are excited to enter into this licensing agreement with Immunomedics for sacituzumab govitecan. This program would complement our rich pipeline of late- and early-stage programs, potentially allowing us to bring a new therapy for triple-negative breast cancer to patients in need. We have successfully demonstrated our expertise in the development, manufacturing and commercialization of ADCs in oncology, and we look forward to working with Immunomedics to advance this program.”

Dr. David M. Goldenberg, Chairman and Chief Scientific Officer of Immunomedics, commented, “After extensive preclinical research conducted by our scientists, and about three years of clinical development by our clinicians and our collaborating external investigators studying over 400 patients, we have decided that this is the right time to out-license IMMU-132. Although we have had partnerships in the past, I am extremely enthusiastic about entering into this collaboration with Seattle Genetics, a company that has achieved a leadership role in antibody-drug conjugates. Both companies are committed to bringing important products to cancer patients. This common goal is sincere and will be the basis of making IMMU-132 fulfill its full potential.”

Dr. Goldenberg further remarked, “After a long period of interactions with many interested partnering candidates, and a considerable period of discussion with Seattle Genetics, we concluded that working with this group of successful business and marketing executives, clinicians and scientists would allow us to contribute our own scientific and clinical knowledge to them as they further develop IMMU-132 and bring it to commercialization. We are particularly pleased with their enthusiasm, and that this arrangement allows us to continue our ongoing Phase 2 studies in a number of additional cancer types while we transition this product candidate to them.”

Terms of the Agreement

The agreement provides for potential payments of approximately $2 billion across multiple indications, plus double-digit tiered royalties on global net sales. Under the terms of the agreement, Immunomedics will receive $250 million in upfront cash payment, plus, among other milestone payments, an additional $50 million (or negotiated economic splits) relating to rights outside the U.S., Canada and the EU. The remainder of the consideration comprises approximately $1.7 billion that is contingent upon achieving certain clinical, development, regulatory and sales milestones, including an anticipated near-term milestone for acceptance of the Biologics License Application (BLA) by the U.S. Food and Drug Administration for TNBC, additional milestones based on regulatory approval of IMMU-132 for TNBC in the U.S. and other territories, and future development and regulatory milestones for additional indications beyond TNBC. Future royalty payments are tiered double-digit royalties based on global net sales. In addition, Immunomedics will retain the right to elect to co-promote IMMU-132 in the United States by participating in 50% of the sales effort, subject to certain parameters set forth in the agreement.

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Joint Steering Committee

Upon completion of the transaction, Immunomedics and Seattle Genetics will each appoint representatives to serve on a Joint Steering Committee (JSC) that will be chaired by a Seattle Genetics representative. The JSC will be responsible for, among other things, determining the overall development, commercialization, manufacturing and intellectual property strategy for IMMU-132.

Timing and Approvals

The companies expect the transaction to close in the first quarter of 2017, subject to expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act, as well as other customary closing conditions.

Modified Go-Shop Period

Under the terms of the agreement, for a limited period, through February 19, 2017, Immunomedics has the right to continue negotiating with a select number of parties still in the strategic process, and accept a superior proposal. Seattle Genetics has the right to match any superior proposal and if it decides not to match, Immunomedics has the right to accept the superior proposal and terminate the proposed development and license agreement upon payment of a termination fee to Seattle Genetics.

Equity Investment

Concurrent with the transaction, Seattle Genetics is purchasing 3,000,000 shares of common stock, representing an approximately 2.8% stake in Immunomedics, at a per share price of $4.90, which represents a 10% premium to Immunomedics' 15-day trading volume weighted average stock price of $4.45 for the period ending at the close of trading February 9, 2017, the last trading day prior to entering into the global licensing agreement. Seattle Genetics will also be issued a three-year warrant to purchase 8,655,804 shares of common stock at the same price, which shall be exercisable when the Company has sufficient authorized shares of common stock to enable the exercise of the warrant. Seattle Genetics will not be eligible to vote its stake at the upcoming 2016 Annual Meeting of Stockholders.

"We are delighted to welcome Seattle Genetics to our stockholder base and appreciate their commitment to Immunomedics. Our promising clinical results and this partnership validating the promise of our novel antibody-drug conjugation technology stimulates us to advance our other product candidates using this platform technology," added Ms. Sullivan.

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Strategic Process

The agreement with Seattle Genetics follows a 13 months-long competitive strategic process led over the past several months by outside financial advisor, Greenhill & Co. ("Greenhill"), which was retained for their global capabilities and their significant experience in biopharma M&A and licensing transactions. Greenhill & Co. reports directly to the Transaction Committee of the Board, composed exclusively of the Company's five independent directors.

Jason Aryeh, independent Vice Chairman of the Immunomedics Board, stated, "We are pleased to offer Immunomedics stockholders the compelling and significant value provided by this agreement with Seattle Genetics. This agreement is the culmination of a robust strategic process, led by Greenhill and the Transaction Committee. Greenhill's outreach was to more than 45 parties and involved more than half of those parties entering into confidentiality agreements and participating in diligence. In addition to the highly competitive financial terms of the transaction, we believe that Seattle Genetics is the ideal partner for IMMU-132."

Future Financial Plans

Upon closing of the transaction, the Immunomedics Board and management will evaluate and prioritize the Company's remaining clinical programs, long- and short-term funding requirements and tax-efficient ways to return capital to stockholders, including share buybacks. The Company will announce the outcome of this review once a decision has been reached.

Immunomedics expects that the transaction will fulfill its liquidity needs such that the Company can fund itself without additional equity raises for the foreseeable future.

Advisors

Greenhill & Co., LLC, is serving as financial advisor to Immunomedics and DLA Piper LLP (US) is serving as legal advisor on the transaction.

Conference Call to Discuss Transaction and Second Quarter 2017 Financial Results

Immunomedics will host a conference call and live audio webcast today at 8:00 AM Eastern Time to discuss this announcement and will also discuss the Company's second quarter 2017 financial results announced separately yesterday, February 9, 2017. The Company will post a presentation for analysts and investors to its website, www.immunomedics.com, at least 15 minutes prior to the beginning of the conference call.

To access the conference call, please dial (877) 303-2523 or (253) 237-1755 using the Conference ID 58226264. The conference call will be also webcast via the Investors page on Immunomedics' website at www.immunomedics.com.

Approximately two hours following the live event, a webcast replay of the conference call will be available on the Company's website for 30 days through March 11, 2017.

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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 301 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:

Dr. Chau Cheng

Senior Director, Investor Relations & Corporate Secretary

(973) 605-8200, extension 123

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

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