

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.

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:
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Fee paid previously with preliminary materials.

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.:
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IMMUNOMEDICS, INC. Advanced Antibody - Based Therapeutics Oncology Autoimmune Diseases February 10, 2017 Immunomedics Announces Exclusive Global Licensing Agreement with Seattle Genetics for Sacituzumab Govitecan (IMMU - 132) in Multiple Indications Worldwide

Important Additional Information / Forward Looking Statements 2 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 AND THE SUPPLEMENT FILED ON JANUARY 10, 2017 (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. Forward - Looking Statements This presentation, 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 thereof, 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 Company’s License and Development Agent with Seattle Genetics, Inc.), 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.

3 Overview

Overview of Terms 4 Transaction Summary • Seattle Genetics will develop, fund, manufacture and commercialize IMMU - 132, Immunomedics' proprietary solid tumor therapy candidate, in multiple indications worldwide Total Consideration • The agreement provides for potential payments of approximately \$2 billion across multiple indications, plus double - digit tiered royalties on global net sales • Risk - adjusted pre - tax net present value (rNPV) of more than \$1.4 billion 1 Upfront Cash Consideration • \$250 million to Immunomedics for U.S., Canada and EU rights ROW Consideration • Additional \$50 million or designated economic split on rights relating to territories outside the U.S., Canada and EU Potential Milestone Payments • Approximately \$1.65 billion contingent upon achieving certain clinical, development, regulatory and sales milestones 2 , including: • Anticipated near - term milestone for acceptance of the initial Biologics License Application (BLA) for TNBC by the U.S. Food and Drug Administration (FDA) • Future development regulatory and sales milestones for each additional indication beyond TNBC Rights to Co - Promote • Immunomedics will retain the right to co - promote IMMU - 132 in the U.S. by participating in 50% of the sales effort in that territory Royalty Payments • Tiered double - digit royalties based on global net sales Development Costs • Seattle Genetics assumes responsibility for all development and commercialization costs for IMMU - 132 • Relieves Immunomedics of approximately \$80 - \$100 million of near - term clinical, manufacturing and other development costs 1 Based on only initial four indications of triple - negative breast cancer TNBC, urothelial cancer UC , non - small - cell lung cancer NSCLC and small - cell lung cancer SCLC; risk - adjustments to revenues, milestones and royalties based on phase and indication per the Hay Study (Michael Hay et al. Clinical development success rates for investigational drugs. Nature Biotechnology. 2014. Volume 32 Number 1.) that analyzes clinical success rates across the drug industry for clinical drugs at various stages of development; NPV figure based on present value date of 12/31/16 assuming pre - tax risk - adjusted cash flows, calculated based on base case revenues to Immunomedics at 11% discount rate utilizing mid - year discounting 2 To clarify confusion related to statements made by venBio Select Advisor LLC and pursuant to his existing contract, no 20% partnership royalty payment due to Dr. Goldenberg from licensing this asset

Overview of Terms (cont.) 5 Equity Investment • Up to a 9.9 % stake • 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 trading day VWAP of \$4.45 • Three - year warrant to purchase 8,655,804 shares of common stock at the same price, which will be exercisable when the Company has sufficient authorized shares of common stock to enable the full exercise of the warrant • Seattle Genetics will not be permitted to vote its stake at the upcoming 2016 annual meeting of stockholders Approvals & Closing • Expected closing in Q1 2017 • Subject to expiration or termination of the applicable waiting period under the Hart - Scott - Rodino Antitrust Improvements Act and customary closing conditions Modified Go - Shop • Through February 19, 2017, Immunomedics has right to continue negotiating with a select number of parties still in the strategic process and accept a superior financial proposal • Seattle Genetics has right to match any superior financial proposal • If Seattle Genetics decides not to match, Immunomedics has right to terminate proposed development and license agreement upon payment of termination fee to Seattle Genetics

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Seattle Genetics Assuming Rights to Develop, Fund, Manufacture & Commercialize IMMU - 132 • Agreement provides for Seattle Genetics to develop, fund, manufacture & commercialize IMMU - 132 in multiple indications • Immunomedics will retain the right to elect to co - promote IMMU - 132 in the United States by participating in 50% of the sales effort • 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 • JSC will be responsible for determining overall development, commercialization, manufacturing and intellectual property strategy for IMMU - 132 6 The agreement with Seattle Genetics will further advance IMMU - 132 on behalf of patients with late stage cancers, who have limited therapeutic options, while delivering significant and compelling near - , medium - and long - term value to stockholders

• Seattle Genetics is an industry leader in developing and commercializing antibody - drug conjugates (ADCs) • Agreement with Seattle Genetics includes multiple indications for IMMU - 132, including: – Triple - negative breast cancer (TNBC) – Urothelial cancer (UC) – Small - cell lung cancer (SCLC) – Non - small - cell lung cancer (NSCLC) – Other solid tumor indications being studied in ongoing clinical trials • For TNBC patients: – Seattle Genetics will initiate the Phase 3 clinical trial and is assuming the duties of submitting the initial Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for accelerated approval (AA) – Anticipate FDA approval of IMMU - 132 and commercial launch by late 2017 or early 2018 • Expect IMMU - 132 will become a high priority program for Seattle Genetics – Seattle Genetics assuming obligation to develop and commercialize IMMU - 132 globally in multiple indications beyond TNBC and multiple regions beyond the United States 7 Seattle Genetics and IMMU - 132 We Expect IMMU - 132 Will Become a Key Development Program for Seattle Genetics

8 Seattle Genetics

• Global headquarters in Bothell, Washington • Traded on Nasdaq Stock Market under the symbol SGEN • More than 900 employees • Industry leader in ADCs — technology designed to harness the targeting ability of antibodies to deliver cell - killing agents directly to cancer cells • Has one marketed liquid tumor product — ADCETRIS® — in collaboration with Takeda Pharmaceutical Company Limited – Commercially available in more than 65 countries, including the United States, Canada, Japan and members of the European Union – ADC that targets CD30, which is expressed in classical Hodgkin lymphoma (HL) and in systemic anaplastic large cell lymphoma (sALCL), an aggressive type of T - cell non - Hodgkin lymphoma – Currently in more than 70 clinical trials • Expanded global footprint in 2016 by establishing international office in Switzerland, providing base to develop and commercialize products globally • Advancing robust pipeline of more than 10 early - and late - stage clinical programs to address significant unmet medical needs 9 Who is Seattle Genetics?

- Seattle Genetics has a reputation as one of the most successful and financially strong standalone ADC companies – Expertise in clinical development, regulatory activities, manufacturing and commercialization of ADCs makes Seattle Genetics ideally suited to advance IMMU - 132 program globally
- Agreement with Seattle Genetics provides substantial upfront cash, and Seattle Genetics was unique among the numerous interested parties in that they are committed to commercializing IMMU - 132 for the broadest possible range of indications
- IMMU - 132 will become a high priority development program for Seattle Genetics
- Seattle Genetics has strong clinical development capabilities in hematologic oncology as well as regulatory accomplishments in expanding indications for current ADC – Strong basis for expanding into solid cancers with IMMU - 132
- Seattle Genetics has marketing and sales organization and infrastructure established in the United States for current ADC to serve as foundation for expansion to solid cancer indications – EU marketing and sales organization targeted to scale quickly to support IMMU - 132 launch
- Seattle Genetics’ international office in Switzerland provides base for regulatory, medical affairs, clinical development, supply chain, market operations and commercial operations for IMMU - 132 and potential future products outside the U.S.

10 Seattle Genetics is the Right Partner for IMMU - 132

11 Implications for Immunomedics

What Does This Deal Mean for Immunomedics? 1. Per share value of the \$250 million upfront cash payment is \$ 2.12 per share 3,4 2. Risk - adjusted pre - tax NPV (base case) of contingent payments: \$9.40 per share 3,4 – Successful combinations with checkpoint and PARP inhibitors could make IMMU - 132 a first - line option for most patients and drive significantly higher peak annual revenues and per share NPV 3. Plus value of Immunomedics pipeline 12 E nhances financial profile, transferring responsibility for IMMU - 132 program to reduce cash burn and providing substantial upfront capital along with rights to future milestone and royalty payments Post - Deal Financial Position Cash balance as of 12/31/16 \$47 Upfront proceeds \$250 Equity investment (1) \$15 Pro Forma Cash Balance \$311 Proceeds from potential warrant exercise (2) \$42 Adj. Pro Forma Cash Balance \$354 Per basic share (3) \$3.00 Non - upfront NPV of deal (4) \$1,107 Per basic share (3) \$9.40 (1) Based on 3.000 million shares issued at \$ 4.90 (2) Based on 8.656 million warrants issued, subject to shareholder authorization, at \$4.90; including equity investment implied total inve stm ent value of \$57 million for a 9.9% stake (3) Based on 117.735 million basic shares (current basic shares of 106.080 million pro forma for SGEN equity investment and warra nts issued) (4) Based on Health Advances revenue forecasts assuming Base Case scenario; pre - tax NPV assuming 12/31/16 valuation date, mid - year discounting at 11% and 44% tax rate for Immunomedics with utilization of existing federal and state NOLs Source: Immunomedics management, Health Advances (\$ in millions, except per share values)

Our Development Pipeline is Advanced, Robust & Promising 13 Therapy Treatment Purpose Phase 3 Epratuzumab (humanized anti - CD22) Pediatric acute lymphoblastic leukemia* Phase 2 Labetuzumab govitecan/ IMMU - 130 (anti - CEACAM5 - SN - 38 antibody - drug conjugate) Metastatic colorectal cancer Veltuzumab (anti - CD20) Cancer and autoimmune diseases Phase 1 Milatuzumab (anti - CD74) Autoimmune diseases (Lupus) IMMU - 114 (anti - HLA - DR) Hematologic malignancies Pre - Clinical IMMU - 140 Hematopoietic tumors Bispecific CD20/CD22 Acute lymphoclastic leukemia (ALL) Bispecific CEACAM5/CD3 Head and neck cancer, colorectal cancer & ER+ breast cancer * The International clinical trial on childhood relapsed acute lymphoblastic leukemia (IntReALL) is funded by the European Commission

14 Strategic Process

Original Strategic Process • A financial advisor was retained in December 2015 – Mandate to explore an out - licensing deal only – Board and financial advisor conducted outreach to 30 parties, 22 signed NDAs and were in different levels of due diligence – Made progress and received non - binding term sheets, but process didn't move meaningfully forward beyond these steps • Immunomedics decided to allow engagement with financial advisor to expire, according to agreement terms • However, the gap in time while the engagement expired led to speculation in the market about challenges to the clinical and CMC development 15

Greenhill & Co. Process • Greenhill & Co. was retained in September 2016 on the basis of its reputation and global capabilities in biopharma M&A and licensing transactions – Given a broader mandate by the Board to explore a range of strategic and business opportunities, including licensing or sale of IMMU - 132, as well as sale of the entire Company – Prepared Company & management for months • Undertook extensive preparation work for the process, including the creation of non - confidential and confidential summaries, marketing materials on recent developments and clinical updates • Assisted the Company on the creation of a confidential data room and in the preparation for dialogue on clinical, CMC, regulatory and IP functional areas • Assisted the Company on the selection of an independent commercial consultant and on the engagement of our independent CMC audit – Greenhill started reaching out to companies (including those that had previously expressed interest in IMMU - 132) post - Thanksgiving and gave guidance that it was looking for non - binding bids in late January or early February 2017 – Contacted 45 parties, and moved forward into advanced diligence with 18 parties 16

Depth of Diligence Clinical CMC Regulatory IP Commercial • 110+ page detailed clinical deck • Detailed data was made available in data room • Access to the Company's raw clinical data/database was made available • Multiple rounds of Q&A (both written responses & calls) • On - site visits for review of CRFs, patient binders, source documents, data files • 80+ page detailed CMC deck • Detailed data was made available in data room • Full comparability document (Phase 2 vs Phase 3/commercial product) • Multiple rounds of Q&A (both written responses & calls) • On - site CMC document review • Review facility audit results • All correspondence with FDA and EMA made available • Review of all minutes from FDA/EMA meetings • Review of regulatory filings for type B/C meetings • All granted and pending applications were made available • Opportunity for follow - up calls with IP experts • Independent Health Advances report made available • Opportunity for follow - up calls with Health Advances team 17 Reverse due diligence • Companies asked to present to IMMUNOMEDICS on their development and commercialization capabilities

Overall Process • Immunomedics' process and intent were very public over 13 months – Investor R&D Day on January 18, 2017 made public the latest clinical data for IMMU - 132 and detailed CMC and regulatory updates • Over 45 parties contacted with 33 parties receiving detailed diligence information under a confidentiality agreement • All appropriate parties contacted • Importantly, no parties cited management as a reason to refrain from engaging and moving forward toward a transaction • Exhaustive, competitive, complete process – Some expressed preference for only doing an asset deal or whole company acquisition and they were allowed to proceed and progress in the process • Several parties completed advanced diligence (including CMC, regulatory and clinical and commercial deep dives) & submitted term sheets • Seattle Genetics was involved in the first process, but re - engaged seriously in late 2016 and moved aggressively – Agreed to give modified go - shop 18

19 Transaction Committee Process

Transaction Committee Process • Greenhill & Co. reported to the Transaction Committee of the Board – Transaction Committee consists of the five independent Board members • Transaction Committee kept apprised of outreach program and approach – Involved in negotiating term sheets and contracts • On timing: – Transaction Committee members were, and continue to be, aware of their fiduciary responsibilities to the Company and all its stockholders (regardless of the proxy fight) – Transaction Committee was unanimous in its decision not to rush a transaction simply to consummate a transaction prior to the vote at the Annual Meeting of Stockholders – Transaction Committee was also unanimous in its view that it would evaluate all potential offers presented to it regardless of timing to determine whether such a transaction was in the best interest of all stockholders – Transaction Committee demanded a modified go - shop for superior licensing proposals in the contract with Seattle Genetics, even though such provisions are uncommon in licensing transactions, as a way to ensure a good process and allow other parties additional time to put forward a superior proposal • As a result, the transaction agreement includes a modified go - shop period for certain parties and a matching period for the licensee 20

Out - licensing vs. Commercializing Internally • Research & development (R&D) is Immunomedics' core competency, not commercialization • Company has no commercial infrastructure in the United States – Immunomedics would need to build a commercial arm from scratch, including marketing, sales, logistics, and commercial manufacturing to commercialize IMMU - 132 on a global scale • Cost of capital – Company would have to raise significant additional capital at higher cost than established commercial companies • Time to market – If the Company developed a commercial infrastructure successfully, it would take the Company longer to bring IMMU - 132 to market itself, affecting the lives of cancer patients • Industry trends and risk management – Most successful companies transitioning from R&D to commercialization do so through a strategic partnership – Commercializing internally is generally accepted to be a high - risk approach • Weak competitive position – Company would have to compete with strong oncology companies with far more commercial resources at their disposal • Brand recognition – Immunomedics' products would have to overcome lack of Company/brand recognition compared to its competitors • Relatively high unit costs/inefficient operations – Company would have higher marketing and sales costs because it would start with a “one - product ” marketing and sales program and could not achieve marketing economies of scale from multiple products for many years • Competition for scarce resources – Company's commercial products and R&D performance could suffer from spreading itself too thin 21

Use of Proceeds • Upon closing of the transaction, the Company will evaluate: – Priority of clinical programs – Long - and short - term funding needs – A budget for the remainder of 2017 – Potential tax - efficient ways to return capital to stockholders • Overall, this transaction supports the Company's liquidity needs such that Immunomedics can fund itself for the foreseeable future, and removes any financing overhang on the stock 22

Transaction Summary • Agreement provides for potential payments of approximately \$2 billion, plus royalties – \$250 million upfront cash to Immunomedics for U.S., Canada and EU rights – Additional \$50 million or designated economic split on rights relating to territories outside the U.S., Canada and EU – Approximately \$ 1.65 billion contingent upon achieving certain clinical, development , regulatory and sales milestones – Additional tiered double - digit royalties based on global net sales • Seattle Genetics to purchase up to a 9.9% stake representing – Approximately 2.8% stake in Immunomedics common stock – Remainder through a three - year warrant, which shall be exercisable when the Company has sufficient authorized shares of common stock to enable the full exercise of the warrant • Immunomedics will retain the right to co - promote IMMU - 132 in the U.S. by participating in 50% of the sales effort in that territory • Supports liquidity needs such that Immunomedics can fund itself for the foreseeable future and removes a financing overhang and drives significant value for Immunomedics stockholders • Benefits patients in multiple indications of IMMU - 132, including TNBC, UC, SCLC, NSCLC and other solid tumor indications 23 The Immunomedics Board of Directors and outside financial and strategic advisor, Greenhill & Co., have been acutely focused on maximizing strategic value, and we are proud to have achieved this critical milestone