IMMUNOMEDICS INC
Form DEFA14A
February 09, 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 ý

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

ý 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):

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**IMMUNOMEDICS ANNOUNCES SECOND QUARTER FISCAL 2017 RESULTS AND CLINICAL PROGRAM DEVELOPMENTS**

**Morris Plains, NJ, February 9, 2017 --- Immunomedics, Inc. (NASDAQ: IMMU**) ("Immunomedics" or "the Company") today reported financial results for the second quarter ended December 31, 2016. The Company also highlighted recent key developments and planned activities for its clinical pipeline.

**Second Quarter Fiscal 2017 Results**

Total revenues for the second quarter of fiscal 2017, which ended on December 31, 2016, were $0.4 million, compared to $0.7 million for the same quarter last fiscal year, a decrease of $0.3 million, or approximately 43%. The decrease was due primarily to a $0.3 million decrease in LeukoScan® product sales, primarily from a delay in obtaining regulatory approval for new LeukoScan® inventory.

Total costs and expenses for the quarter ended December 31, 2016 were $15.7 million, compared to $16.4 million for the same quarter in fiscal 2016, a decrease of $0.7 million or approximately 4%. This decrease was due primarily to $1.5 million reduction in research and development expenses resulting from a $4.6 million reduction in expenses related to the Phase 3 PANCRIT-1 clinical trial, which was terminated during the third quarter of fiscal 2016, and a $0.6 million reduction in manufacturing material purchases compared to the same period in the prior year. These reductions were partially offset by a $3.7 million increase in product development expense related to manufacturing the antibody drug-conjugate sacituzumab govitecan (IMMU-132). The decrease in research and development expenses was also partially offset by a $1.1 million increase in general and administrative expenses, due primarily to a $0.5 million increase in legal fees and a $0.9 million increase in professional fees associated with the proxy contest commenced by venBio Select Advisor LLC ("venBio"), partially offset by a reduction in employee related costs.

The Company recognized a $7.2 million non-cash expense during the three-month period ended December 31, 2016 reflecting the corresponding increase in the fair value of the warrant liability at December 31, 2016 resulting from the increase of the common stock price from the issuance date of October 11, 2016. Interest expense related to the 4.75% Convertible Senior Notes due 2020 was $1.4 million for both quarters ended December 31, 2016, and December 31, 2015, including amortization of $0.2 million debt issuance costs in each quarter.

There was no income tax benefit for the quarter ended December 31, 2016, compared to $3.2 million income tax benefit for the same quarter in fiscal 2016, which is related to the sale of a portion of our New Jersey State tax net operating losses (NOL) and research and development (R&D) tax credits.

Net loss attributable to stockholders was $24.4 million, or $0.23 per basic and diluted share, for the second quarter of fiscal year 2017, compared to net loss attributable to stockholders of $13.7 million, or $0.15 per basic and diluted share, for the same quarter in fiscal 2016, an increase of $10.7 million, or approximately 78%. The increase was due primarily to the increase in the fair value of the warrant liability of $7.2 million, the receipt of proceeds from the non-recurring $3.2 million NOL and R&D tax credit sale in 2015, and the $1.1 million increase in general and administrative expenses primarily attributable to the proxy contest commenced by venBio, partially offset by a $1.5 million decrease in research and development expenses.

**First Half Fiscal 2017 Results**

Total revenues for the first half of fiscal 2017 were $1.1 million, compared to $1.4 million for the same period last fiscal year, a decrease of $0.3 million, or approximately 21%. The decrease was due primarily to $0.3 million decrease in LeukoScan® product sales, primarily from a delay in obtaining regulatory approval for new LeukoScan® inventory.

Total costs and expenses for the six-month period ended December 31, 2016 were $31.4 million, compared to $31.2 million for the same period in fiscal 2016, an increase of $0.2 million or approximately 0.6%. Research and development expenses increased $0.1 million over the prior year due primarily to a $8.4 million increase in product development expense from manufacturing the antibody drug-conjugate sacituzumab govitecan (IMMU-132), which was partially offset by a $7.7 million decrease in expenses related to the early termination of the Phase 3 PANCRIT-1 clinical trial. General and administrative expenses increased $0.1 million compared to the previous year, reflecting an $0.8 million increase in legal fees and a $0.9 million increase in professional fees associated with the proxy contest commenced by venBio, offset by approximately $1.5 million in adjustments for deferred unearned executive bonuses compared to the same period in the prior year.

The Company recognized a $7.2 million non-cash expense during the six-month period ended December 31, 2016 reflecting the corresponding increase in the fair value of the warrant liability at December 31, 2016 resulting from the increase of the common stock price from the issuance date of October 11, 2016. Interest expense related to the 4.75% Convertible Senior Notes due 2020 was $2.7 million for both periods ended December 31, 2016 and December 31, 2015, including amortization of $0.4 million debt issuance costs in each quarter.

There was no income tax benefit for the six-month period ended December 31, 2016, compared to $3.2 million income tax benefit for the same period in fiscal 2016, which is related to the sale of a portion of our New Jersey State tax NOL’s or R&D tax credits.

Net loss attributable to stockholders was $40.7 million, or $0.41 per basic and diluted share, for this period, compared to net loss attributable to stockholders of $29.1 million, or $0.31 per basic and diluted share, for the same period last fiscal year, an increase of $11.6 million, or approximately 40%. The increase was due primarily to the increase in the fair value of the warrant liability of $7.2 million and the receipt of proceeds from the non-recurring $3.2 million NOL and R&D tax credit sale in fiscal 2016.

Cash, cash equivalents, and marketable securities were $46.6 million as of December 31, 2016.

Michael R. Garone, Vice President Finance and Chief Financial Officer, said, “We continue to make significant progress in our efforts to initiate a Phase 3 trial and file a Biologics License Application (BLA) to the U.S. Food and

Drug Administration (FDA) for accelerated approval of IMMU-132 in patients with metastatic triple-negative breast cancer (TNBC) in mid-2017. As always, we are committed to taking all actions to realize the full potential of our pipeline, including a robust strategic process, and delivering on the significant promise it holds for cancer patients."

Additionally, during the quarter Immunomedics achieved and planned for critical milestones, including:

Sacituzumab Govitecan (IMMU-132)

- Updated Phase 2 clinical results in patients with metastatic TNBC were presented at the 2016 San Antonio Breast Cancer Symposium
- The Company achieved its target enrollment of 100 assessable TNBC patients with at least two prior therapies required for a BLA submission to the FDA, which is on track for mid-2017
- As part of the preparation for the BLA filing, the Company has retained an outside consultant to conduct an independent audit of commercial manufacturing facilities, processes, and other relevant Chemistry, Manufacturing, and Controls matters
- New data in metastatic TNBC, urothelial cancer (UC) , non-small-cell lung cancer (NSCLC) and small-cell lung cancer (SCLC) were presented at the Company's Investor R&D Day in January 2017
- Results in patients with metastatic UC will be updated at the 2017 Genitourinary Cancers Symposium in Orlando, Florida

**Conference Call**

The Company will host a conference call and live audio webcast tomorrow at 8:00 a.m. Eastern Time to discuss financial results for the second quarter of fiscal year 2017, and review key clinical developments and planned activities. To access the conference call, please dial (877) 303-2523 or (253) 237-1755 using the Conference ID 58226264. The conference call will be webcast via the Investors page on the Company's 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.

**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 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, 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

**Media**

Dan Katcher / Ed Trissel / Nick Lamplough

Joele Frank, Wilkinson Brimmer Katcher

(212) 355-4449

**Investors**

Dan Burch/Bob Marese

MacKenzie Partners, Inc.

dburch@mackenziepartners.com / bmarese@mackenziepartners.com

(212) 929-5500