

IMMUNE DESIGN CORP.

FORM 8-K (Current report filing)

Filed 08/02/17 for the Period Ending 08/02/17

Address	1616 EASTLAKE AVE. E SUITE 310 SEATTLE, WA 98102
Telephone	(206) 682-0645
CIK	0001437786
Symbol	IMDZ
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported):
August 2, 2017

IMMUNE DESIGN CORP.

(Exact name of registrant as specified in its charter)

Delaware

(state or other jurisdiction of incorporation)

001-36561

(Commission File Number)

26-2007174

(I.R.S. Employer Identification No.)

**1616 Eastlake Ave. E., Suite 310
Seattle, Washington**

(Address of principal executive offices)

98102

(Zip Code)

Registrant's telephone number, including area code: **(206) 682-0645**

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Condition.

On August 2, 2017, Immune Design Corp. (the “Company”) issued a press release announcing its financial results for the quarter ended June 30, 2017. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information provided in this Item 2.02, including Exhibit 99.1 hereto, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release, dated August 2, 2017

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

IMMUNE DESIGN CORP.

By: /s/ Carlos Paya, M.D., Ph.D.
Carlos Paya, M.D., Ph.D.
President and Chief Executive Officer

Dated: August 2, 2017

EXHIBIT INDEX

**Exhibit
Number**

Description

99.1

Press Release, dated August 2, 2017.



Immune Design Reports Second Quarter 2017 Financial Results and Provides Corporate Update

Company conference call at 1:30 p.m. PT today

SEATTLE and SOUTH SAN FRANCISCO, August 2, 2017 - Immune Design (Nasdaq: IMDZ), a clinical-stage immunotherapy company focused on oncology, today reported financial results and a corporate update for the second quarter ended June 30, 2017.

“During the second quarter, based on the positive data to date, Immune Design made the decision to move forward both of our lead product candidates, CMB305 and G100, and discuss regulatory paths for approval with the FDA,” said Carlos Paya, M.D., Ph.D., President and Chief Executive Officer of Immune Design.

Recent Highlights

Product Development: Data presented at the American Society of Clinical Oncology 2017 Annual Meeting (ASCO) Support Monotherapy Proof of Concept for both CMB305 and G100

Antigen Specific Immunotherapy: CMB305 Program

- CMB305 is being evaluated primarily in soft tissue sarcoma (STS) patients both as a monotherapy and in combination with an anti-PD-L1 antibody.
 - CMB305 monotherapy data presented at ASCO from 25 STS patients with recurrent disease indicated an impact on patient survival associated with biomarkers measuring induced anti-NY-ESO-1 immune response and pre-existing immunity:
 - Observed median overall survival (mOS) had still not yet been reached in these patients, with an overall survival rate at 12 and 18 months of 83% and 76%, respectively. These data compare favorably to mOS for approved agents for second line and beyond sarcoma treatment, as well as new anti-PD-1 antibody data presented at ASCO for nivolumab and pembrolizumab.
 - As of the data collection date for ASCO, the STS patients who received LV305, the priming component of CMB305, had still not yet reached a mOS.
 - Over 60% of the patients had an NY-ESO-1-specific immune response induced by CMB305, with a subset of patients showing evidence of antigen spreading.
 - In a pool of 64 patients treated with CMB305 or LV305, it was observed that:
 - The induction of an anti-NY-ESO-1 immune response by these agents was associated with improved patient survival in certain patients.
 - Immune Design believes conventional and novel biomarkers measuring NY-ESO-1 immunity may be used to guide regulatory strategy via the selection of patients more likely to have survival benefit on CMB305 therapy.
 - **Combination therapy with Tecentriq[®]**
 - In an upcoming presentation at the European Society for Medical Oncology 2017 Congress (ESMO) to be held in September 2017, Immune Design will present early data on at least 36 randomized patients (following a safety run-in) with a follow-up period of approximately six months. This 80 patient Phase 2 study, evaluating two separate arms consisting of CMB305 plus Tecentriq (atezolizumab) versus atezolizumab alone pursuant to a collaboration with Genentech, is fully enrolled.

- The data will focus on biomarker analysis and early clinical readouts, but not mOS due to the insufficient follow-up period in both treatment arms.

Antigen Agnostic/Intratumoral Immunotherapy: G100 Program

- **G100**, the novel, synthetic TLR4 agonist injected intratumorally, is being evaluated in a Phase 1 single arm and a Phase 2 randomized trial in patients with low-grade follicular non-Hodgkin lymphoma (NHL).
 - **Monotherapy (with low dose radiation (XRT)) data presented at ASCO** from the Phase 1 dose escalation in nine patients with naïve and refractory follicular NHL demonstrated:
 - 100% disease control rate (DCR), with over a third of patients achieving a partial response (PR) using WHO criteria (at least a 50% tumor reduction), with PRs at all three dose levels tested.
 - 50% of evaluable patients experienced shrinkage of untreated distal (abscopal) lesions in association with presence of T cell infiltrates.
 - **G100 and XRT combination therapy with Keytruda[®]**
 - Patient enrollment was completed in the first quarter in the randomized, 24-patient, Phase 2 study evaluating G100 and XRT versus G100 and XRT with the systemic administration of the anti-PD-1 antibody, Keytruda (pembrolizumab), pursuant to a collaboration with Merck.
 - Immune Design intends to submit for presentation at the American Society of Hematology (ASH) Annual Meeting in December 2017:
 - Data from all 24 patients in the randomized Phase 2 study comparing G100 and XRT versus G100 and XRT with pembrolizumab.
 - Follow-up data from all patients treated with G100 monotherapy in the Phase 1 dose escalation portion of this study.

Expansion of Senior Leadership Team

Heidi Petersen and Melanie Morrison joined the Immune Design team as Vice President of Regulatory Affairs, and Vice President, Oncology Platform Leader, respectively. Ms. Petersen and Ms. Morrison each bring approximately 20 years of experience to Immune Design, which the management team and company will leverage in interactions with regulatory agencies and in the execution of future registrational trials.

Financial Results

Second Quarter

- Immune Design ended the second quarter of 2017 with \$81.4 million in cash, cash equivalents, short-term investments and other receivables, compared to \$110.4 million as of December 31, 2016. Net cash used in operations for the six months ended June 30, 2017 was \$26.0 million.
 - Net loss and net loss per share for the second quarter of 2017 were \$13.9 million and \$0.54, respectively, compared to \$14.3 million and \$0.71, respectively, for the second quarter of 2016.
 - Revenue for the second quarter of 2017 was \$0.7 million and was primarily attributable to \$0.7 million in collaboration revenue associated with the Sanofi Pasteur G103 (HSV therapeutic vaccine) product collaboration. Revenue for the second quarter of 2016 was \$1.1 million and was primarily attributable to \$0.7 million in GLA product sales to collaboration partners Medimmune/Astra Zeneca and Sanofi and \$0.4 million in collaboration revenue associated with the Sanofi G103 product collaboration.
 - Research and development expenses for the second quarter of 2017 were \$10.9 million compared to \$11.4 million for the same period in 2016. The modest decrease is primarily driven by timing differences of manufacturing activities, which were offset by increased clinical costs attributable to continued advancement of Immune Design's Phase 1 and Phase 2 clinical trials and an increase in personnel-related expenses to support the company's advancing research and clinical pipeline.
-

- General and administrative expenses did not materially differ over the comparative periods. For the second quarter of 2017 general and administrative expenses were \$3.9 million, compared to \$3.9 million for the second quarter of 2016.

Year-to-Date

- Net loss and net loss per share for the six months ended June 30, 2017 were \$26.5 million and \$1.04, respectively, compared to \$26.6 million and \$1.32, respectively, for the same period in 2016.
- Revenue for the six months ended June 30, 2017 was \$6.2 million and was primarily attributable to \$5.9 million in collaboration revenue associated with the Sanofi G103 product collaboration and \$0.3 million in product sales to other third parties. Revenue for the same period in 2016 was \$3.0 million and was primarily attributable to \$2.3 million in collaboration revenue associated with the Sanofi G103 product collaboration and \$0.7 million in GLA product sales to collaboration partners Medimmune/Astra Zeneca and Sanofi.
- Research and development expenses for the six months ended June 30, 2017 were \$24.9 million compared to \$22.0 million for the same period in 2016. The \$2.9 million increase was primarily attributable to continued advancement of Immune Design's ongoing research and development programs, including ongoing Phase 1 and Phase 2 clinical trials and an increase in personnel-related expenses to support the company's advancing research and clinical pipeline.
- General and administrative expenses did not materially differ over the comparative periods. For the six months ended June 30, 2017 general and administrative expenses were \$8.0 million, compared to \$7.9 million for the same period in 2016.

Cash Guidance

Based on current expectations, Immune Design continues to expect to have cash to fund operations into the second half of 2018.

Conference Call Information

Immune Design will host a conference call and live audio webcast this afternoon at 1:30 p.m. Pacific time / 4:30 p.m. Eastern time to discuss the second quarter 2017 financial results and provide a corporate update.

The live call may be accessed by dialing 844-266-9538 for domestic callers and 216-562-0391 for international callers. A live webcast of the call will be available online from the investor relations section of the company website at <http://ir.immunedesign.com/events.cfm>. A telephone replay of the call will be available for five days by dialing 855-859-2056 for domestic callers or 404-537-3406 for international callers and entering the conference code: 58230231.

An archived copy of the webcast will be available on Immune Design's website beginning approximately two hours after the conference call. Immune Design will maintain an archived replay of the webcast on its website for at least 30 days after the conference call.

About Immune Design

Immune Design is a clinical-stage immunotherapy company employing next-generation *in vivo* approaches to enable the body's immune system to fight chronic diseases. The company's technologies are engineered to activate the immune system's natural ability to generate and/or expand antigen-specific cytotoxic T cells, while also enhancing other immune effectors, to fight cancer and other chronic diseases. CMB305 and G100, the two leading product candidates focused in cancer immunotherapy, are the first products from its two separate discovery platforms targeting dendritic cells *in vivo*, ZVex[®] and GLAAS[®]. Both ZVex and GLAAS also have potential applications in infectious disease and allergy as demonstrated by ongoing pharmaceutical collaborations. Immune Design has offices in Seattle and South San Francisco. For more information, visit www.immunedesign.com.

Cautionary Note on Forward-looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as “may,” “will,” “expect,” “plan,” “anticipate,” “estimate,” “intend” and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on Immune Design’s expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties that could cause our clinical development programs, future results or performance to differ significantly from those expressed or implied by the forward-looking statements. Forward-looking statements contained in this press release include, but are not limited to, statements about the progress, timing, scope and results of clinical trials, the association of data with treatment outcomes, the timing and likelihood of obtaining regulatory approval of Immune Design’s product candidates and timing estimates of cash remaining to fund operations. Many factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data observed during preclinical or clinical studies, clinical trial site activation or enrollment rates that are lower than expected, changes in expected or existing competition, changes in the regulatory environment, the uncertainties and timing of the regulatory approval process, and unexpected litigation or other disputes. Other factors that may cause Immune Design’s actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in Immune Design’s filings with the U.S. Securities and Exchange Commission, including the “Risk Factors” sections contained therein. Except as required by law, Immune Design assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

Immune Design Corp.

Selected Condensed Consolidated Balance Sheet Data

(In Thousands)

	June 30, 2017		December 31, 2016
	(unaudited)		
Cash and cash equivalents	\$ 35,311	\$	45,214
Short-term investments	45,964		62,041
Other receivables	123		3,156
Total assets	90,871		114,495
Total current liabilities	17,252		19,263
Total stockholders' equity	73,540		95,176

Condensed Consolidated Statements of Operation and Comprehensive Loss Data*(In Thousands Except Per Share Amounts)*

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2017	2016	2017	2016
	(unaudited)			
Revenues:				
Product sales	\$ 48	\$ 733	\$ 309	\$ 740
Collaborative revenue	681	400	5,885	2,256
Total revenues	729	1,133	6,194	2,996
Operating expenses:				
Cost of product sales	18	253	55	275
Research and development	10,863	11,386	24,901	21,956
General and administrative	3,888	3,948	8,023	7,862
Total operating expenses	14,769	15,587	32,979	30,093
Loss from operations	(14,040)	(14,454)	(26,785)	(27,097)
Interest and other income	194	107	319	456
Net loss	\$ (13,846)	\$ (14,347)	\$ (26,466)	\$ (26,641)
Other comprehensive income (loss):				
Unrealized (loss) gain on investments	4	10	(19)	30
Comprehensive loss:	\$ (13,842)	\$ (14,337)	\$ (26,485)	\$ (26,611)
Basic and diluted net loss per share	\$ (0.54)	\$ (0.71)	\$ (1.04)	\$ (1.32)
Weighted-average shares used to compute basic and diluted net loss per share	25,567,482	20,155,410	25,515,630	20,154,306

Media Contact

Julie Rathbun
Rathbun Communications
julie@rathbuncomm.com
206-769-9219

Investor Contact

Shari Annes
Annes Associates
sannes@annesassociates.com
650-888-0902

###