# IMMUNE DESIGN CORP.

## FORM 8-K
(Current report filing)

Filed 08/31/17 for the Period Ending 08/30/17

| | |
|---|---|
| Address | 1616 EASTLAKE AVE. E<br>SUITE 310<br>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 30, 2017**

# IMMUNE DESIGN CORP.

(Exact name of registrant as specified in its charter)

| **Delaware** | **001-36561** | **26-2007174** |
|---|---|---|
| (state or other jurisdiction of incorporation) | (Commission File Number) | (I.R.S. Employer Identification No.) |

| **1616 Eastlake Ave. E., Suite 310**<br>**Seattle, Washington** | **98102** |
|---|---|
| (Address of principal executive offices) | (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 8.01. Other Events.**

On August 30, 2017, Immune Design Corp. (the "Company") issued a press release announcing new topline data from an interim analysis of the Company's ongoing, randomized Phase 2 clinical trial of CMB305 in combination with atezolizumab (Tecentriq®) versus atezolizumab alone in patients with soft tissue sarcoma, which data will be presented in a poster discussion session at the European Society of Medical Oncology (ESMO) 2017 Congress in September.

A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

| Exhibit Number | Description |
|---|---|
| 99.1 | Press Release, dated August 30, 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 30, 2017

**EXHIBIT INDEX**

| Exhibit Number | Description |
|---|---|
| 99.1 | Press Release, dated August 30, 2017. |

# Immune Design Announces New CMB305 + Checkpoint Inhibitor Topline Data from an Upcoming Presentation at the ESMO 2017 Congress

- Interim data analysis shows greater clinical benefit and immune response with CMB305+atezolizumab than with atezolizumab alone

**SEATTLE and SOUTH SAN FRANCISCO, August 30, 2017 --** Immune Design (Nasdaq: IMDZ), a clinical-stage immunotherapy company focused on oncology, today announced positive topline data from its interim analysis of the ongoing, randomized Phase 2 trial evaluating CMB305 in combination with atezolizumab (TECENTRIQ ®) or atezolizumab alone in 88 soft tissue sarcoma patients. The data will be presented in a poster discussion session at the European Society of Medical Oncology (ESMO) 2017 Congress, September 8-12, 2017 in Madrid, Spain.

"The two main goals of this study are (1) to determine whether combining a next-generation vaccine like CMB305 with a checkpoint inhibitor (such as an anti-PD-L1 antibody) provides improved clinical benefit compared to that of the checkpoint inhibitor alone, particularly in a PD-L1-low or -negative tumor, and (2) in a randomized setting, to determine the biological activity of CMB305," said Carlos Paya, M.D., Ph.D., President and Chief Executive Officer of Immune Design. "We believe these interim data constitute the first steps towards answering both questions in a favorable manner."

Data to be presented at ESMO build upon those data on the first 36 patients summarized in the abstract, and include a greater number of patients enrolled.

- **Clinical Benefit:** Data from the larger patient population show that patients receiving CMB305 and atezolizumab experienced greater clinical benefit in the form of Disease Control Rate (including objective responses), Progression Free Survival and Time to Next Treatment than those receiving atezolizumab alone.
- **Immune Response:** Patients who received the combination of CMB305 and atezolizumab demonstrated an increased frequency of induced immune responses to NY-ESO-1, including NY-ESO-1-specific T cells, NY-ESO-1 antibodies, and antigen spreading, in comparison to patients who received atezolizumab alone.
- **Biomarkers:** In an exploratory analysis, a trend towards improved overall survival was observed in patients in the CMB305 and atezolizumab combination arm who had pre-existing and treatment-induced anti-NY-ESO-1 immunity, compared to the atezolizumab alone arm. Pre-treatment tumor biopsy analysis showed negligible levels of PD-L1 expression.
- **Safety:** No new safety signals have been observed in either arm.

The fully enrolled trial is evaluating the safety, immunogenicity and efficacy of CMB305 in combination with atezolizumab, or atezolizumab alone, in a total of 88 patients with locally advanced, relapsed, or metastatic NY-ESO-1 $^{+}$ synovial sarcoma or myxoid/round-cell liposarcoma. Atezolizumab is a monoclonal antibody designed to target and bind to a protein called PD-L1 (programmed death ligand-1) and is being developed by Genentech, a member of the Roche Group. The trial is being conducted pursuant to a clinical collaboration with Genentech. Immune Design intends to present survival data in 2018 once all patients have at least one year of follow up (current data are preliminary: median duration of observation <six months).

The ESMO Poster Discussion session presentation details are as follows:

**A Phase 2 Study of CMB305 and Atezolizumab in NY-ESO-1+ Soft Tissue Sarcoma: Interim Analysis of Immunogenicity, Tumor Control and Survival**

Abstract # 1480PD
Session Title: Sarcoma Poster Discussion Session
Date: Monday, Sept. 11, 2017
Time: 11 a.m. - 12:30 p.m.
Location: Bilbao Auditorium

Poster Presenter: Dr. Sant Chawla
Poster Discussant: Dr. Robert Maki

**About CMB305**

CMB305 is a prime-boost vaccine approach against NY-ESO-1-expressing tumors, designed to generate an integrated, anti-NY-ESO-1 immune response *in vivo* via a targeted, specific interaction with dendritic cells, a mechanism of action Immune Design believes differs from traditional cancer vaccines. CMB305 is being evaluated in soft tissue sarcoma patients in ongoing Phase 1 monotherapy and 2 combination studies. Immune Design has received Orphan Drug Designation for CMB305 from the U.S. Food and Drug Administration (FDA) for the treatment of soft tissue sarcoma, as well as from the FDA and European Medicines Agency for each of the components of CMB305 for the treatment of soft tissue sarcoma.

**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 disease. 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 primary foci of Immune Design's ongoing immuno-oncology clinical programs, are products of its two synergistic discovery platforms, ZVex and GLAAS, the fundamental technologies of which were licensed from the California Institute of Technology and the Infectious Disease Research Institute (IDRI), respectively. Immune Design has offices in Seattle and South San Francisco. For more information, please 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, and the timing and likelihood of obtaining regulatory approval of Immune Design's product candidates. 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.*

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

**Investor Contact**
Shari Annes
Annes Associates
Shari.Annes@immunedesign.com
650-888-0902