IMMUNE DESIGN CORP.

FORM 8-K
(Current report filing)

Filed 11/01/17 for the Period Ending 11/01/17

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):
November 1, 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 **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 2.02. Results of Operations and Financial Condition.

On November 1, 2017, Immune Design Corp. (the "Company") issued a press release announcing its financial results for the quarter ended September 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 November 1, 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: November 1, 2017

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

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

SEATTLE and SOUTH SAN FRANCISCO, Calif., Nov. 1, 2017 - Immune Design (Nasdaq: IMDZ), a clinical-stage immunotherapy company focused on oncology, today reported financial results and a corporate update for the third quarter ended September 30, 2017.

"During the third quarter, we made significant progress on our strategy to bring a novel cancer vaccine to market. Our discussions with the FDA resulted in positive feedback on a Phase 3 trial design and approval criteria for CMB305 as a monotherapy for synovial sarcoma patients in the maintenance setting - a significant milestone for the company," said Carlos Paya, M.D., Ph.D., President and Chief Executive Officer of Immune Design. "In addition, at ESMO we presented interim analysis data from our ongoing randomized Phase 2 study of CMB305 and atezolizumab showing that patients receiving the combination therapy experienced greater clinical benefit and immune response than those receiving atezolizumab alone."

Recent Highlights

- **CMB305 Monotherapy: progressing to pivotal Phase 3 in synovial sarcoma patients**
  - Based on productive discussions with the FDA, Immune Design announced plans to initiate a pivotal Phase 3 randomized trial to support a Biologics License Application for CMB305 in patients with synovial sarcoma.
    - The trial will compare CMB305 vs. placebo in NY-ESO-1 $^{+}$ locally advanced unresectable or metastatic synovial sarcoma patients without evidence of progression after first-line chemotherapy ("maintenance setting").
    - Immune Design intends to start the study in mid-2018 and enroll 248 patients aged 12 and older.
    - Progression free survival (PFS) and overall survival will be co-primary endpoints.
      - PFS analysis may occur as early as 24 months from the first patient dosed, depending on the number of events.
- **CMB305 Combination Therapy (CMB305+Atezolizumab vs Atezolizumab) Randomized Phase 2 Trial: interim analysis presented at ESMO 2017 shows greater benefit in sarcoma patients receiving the combination**
  - The **interim analysis (n=36 patients)** data showed that NY-ESO-1 $^{+}$ synovial sarcoma or mixoid round cell liposarcoma patients receiving the combination of CMB305 and Genentech's checkpoint inhibitor, Tecentriq ® (atezolizumab) experienced greater clinical benefit, in the form of Disease Control Rate (including partial responses), median Progression Free Survival and Time to Next Treatment, as well as immune response, than those receiving atezolizumab alone.
  - In the full study population (n=88), the trend of greater clinical benefit on the combination arm remains consistent.
- **G100 +/- pembrolizumab data in follicular NHL patients to be presented at ASH; receipt of EMA Orphan Drug designation**
  - The American Society of Hematology (ASH) has accepted an Immune Design presentation for its Annual Meeting in December 2017.
    - Data from a randomized, 26-patient, Phase 2 study evaluating G100, the novel, synthetic TLR4 agonist injected intratumorally, and low-dose radiation (XRT), versus G100 and XRT with the systemic administration of Merck's anti-PD-1 antibody, Keytruda ® (pembrolizumab) will be presented.
    - The data in the submitted abstract show:

        - a 31% ORR for patients receiving G100+XRT+pembrolizumab (G+P), as compared to a 15% ORR for patients receiving G100+XRT (G); and
        - shrinkage of untreated (abscopal) tumors in 62% of patients receiving G+P and 46% of patients receiving G.
        - These abstract data are earlier (June 2017) than the data that will be presented in the planned presentation. The updated data appear to demonstrate a stronger clinical response and biomarker profile for those patients receiving G100, XRT and pembrolizumab, as compared to those patients receiving G100 and XRT alone.
    - G100 received Orphan Drug Designation for the treatment of follicular non-Hodgkin's lymphoma from the EMA in October 2017.

Additional Upcoming Presentations

The Society for Immunotherapy of Cancer (SITC) has accepted five Immune Design abstracts for presentation at its 32 nd Annual Meeting, November 8-12, 2017 in National Harbor, Maryland. The oral and poster presentations are as follows:

- Novel Biomarkers in Next-generation Cancer Vaccines: Public NY-ESO-1 specific TCRs as novel biomarkers for immune monitoring of NY-ESO-1 positive cancer patients
- Combination Therapy (Cancer Vaccine + Intratumoral Immunization): G100 and ZVex-based combination immunotherapy induces near complete regression of established glioma tumors in mice
- Multi-Target Cancer Vaccines: Transduction of MAGE-A1, A3, A4, A10 and IL-12 by ZVex, a dendritic cell targeting platform induces robust multi-antigen T-cell immune responses without antigenic interference or immunodominance
- Next-Generation Intratumoral Vaccination Using ZVex: Intratumoral expression of IL12 using the ZVex dendritic cell-targeting lentiviral vector exerts potent anti-tumor effects via induction of multiple immune effectors, including CD8 T cell responses
- Anti-NY-ESO-1 Immune Response and Survival Benefit After LV305 Therapy in Patients With Advanced Sarcoma and Other Solid Tumors

In addition to an investigator-sponsored presentation, at the Connective Tissue Oncology Society (CTOS) Annual Meeting being held in Maui from November 8-11, Immune Design will be presenting data from the ASCO annual meeting in two presentations:

- A Phase 2 Study of CMB305 and Atezolizumab in NY-ESO-1+ Soft Tissue Sarcoma: Interim Analysis of Immunogenicity, tumor control and survival.
- Association of NY-ESO-1 Expression with Baseline Immunity and Clinical Outcomes in Soft Tissue Sarcoma Patients Treated with LV305 or CMB305.

Completion of Follow-On Financing

On October 27, 2017, Immune Design completed an underwritten follow-on public offering, which resulted in the sale of 22,425,000 shares of common stock, inclusive of the full exercise by the underwriters of the 30-day option to purchase 2,925,000 additional shares, at a public offering price of $4.10 per share. Estimated net proceeds from the offering were $86.6 million after deducting underwriting discounts and commissions and estimated offering expenses of $5.4 million. Both new and existing investors participated in the offering.

Financial Results

Third Quarter

- Immune Design ended the third quarter of 2017 with $67.5 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 nine months ended September 30, 2017 was $43.2 million.
- Net loss and net loss per share for the third quarter of 2017 were $13.4 million and $0.52, respectively, compared to $12.4 million and $0.60, respectively, for the third quarter of 2016.

- Revenue for the third quarter of 2017 was $0.5 million and was primarily attributable to collaboration revenue associated with the Sanofi G103 HSV therapeutic vaccine product collaboration. Revenue for the third quarter of 2016 was $8.2 million and was primarily attributable to $7.0 million in license revenue, $0.4 million in product sales associated with Immune Design's collaboration partner Sanofi and $0.8 million in collaboration revenue associated with the Sanofi G103 product collaboration.
- Research and development expenses for the third quarter of 2017 were $10.2 million compared to $11.2 million for the same period in 2016. The $1.0 million decrease was primarily attributable to a decrease in in-licensing royalties and fees to other third parties that the company licenses various technologies from and a decrease in contract manufacturing activities primarily driven by the timing of when services are performed. These decreases were offset by an increase in personnel-related expenses and facility costs to support the company's advancing research and clinical pipeline.
- General and administrative expenses for the third quarter of 2017 were $3.9 million compared to $9.6 million for the same period in 2016. The $5.7 million decrease was primarily attributable to the settlement and license agreements with TheraVectys SA (TVS) involving the acquisition of certain present and future intellectual property rights from TVS and resolving the litigation initiated by TVS in July 2014 against the company, as well as related claims and counterclaims.

Year-to-Date

- Net loss and net loss per share for the nine months ended September 30, 2017 were $39.9 million and $1.56, respectively, compared to $39.1 million and $1.92, respectively, for the same period in 2016.
- Revenue for the nine months ended September 30, 2017 was $6.7 million and was primarily attributable to $6.4 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 $11.2 million and was primarily attributable to $7.0 million in license revenue, $1.2 million in product sales associated with Immune Design's collaboration partner Sanofi and $3.0 million in collaboration revenue associated with the Sanofi G103 product collaboration.
- Research and development expenses for the nine months ended September 30, 2017 were $35.1 million compared to $33.1 million for the same period in 2016. The $2.0 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 for the nine months ended September 30, 2017 were $11.9 million compared to $17.4 million for the same period in 2016. The $5.5 million decrease was primarily attributable to the settlement and license agreements with TVS involving the acquisition of certain present and future intellectual property rights from TVS and resolving the litigation initiated by TVS in July 2014 against the company, as well as related claims and counterclaims.

Cash Guidance

Based on current expectations following Immune Design's recent follow-on offering, the company expects to have cash to fund operations into 2020.

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 third 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:4793869

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 Immune Design’s 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)

	September 30, 2017	December 31, 2016
	(unaudited)	
Cash and cash equivalents	$ 28,369	$ 45,214
Short-term investments	35,970	62,041
Other receivables	3,113	3,156
Total assets	78,069	114,495
Total current liabilities	15,390	19,263
Total stockholders' equity	62,588	95,176

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
			(unaudited)	
Revenues:				
Licensing revenue	$ 0	$ 7,000	$ 0	$ 7,000
Collaborative revenue	510	780	6,395	3,036
Product sales	6	426	315	1,166
Total revenues	516	8,206	6,710	11,202
Operating expenses:				
Cost of product sales	16	72	71	347
Research and development	10,246	11,173	35,147	33,129
General and administrative	3,909	9,554	11,932	17,416
Total operating expenses	14,171	20,799	47,150	50,892
Loss from operations	(13,655)	(12,593)	(40,440)	(39,690)
Interest and other income	239	150	558	606
Net loss	$ (13,416)	$ (12,443)	$ (39,882)	$ (39,084)
Other comprehensive income (loss):				
Unrealized gain (loss) on investments	29	(23)	10	7
Comprehensive loss:	$ (13,387)	$ (12,466)	$ (39,872)	$ (39,077)
Basic and diluted net loss per share	$ (0.52)	$ (0.60)	$ (1.56)	$ (1.92)
Weighted-average shares used to compute basic and diluted net loss per share	25,620,781	20,803,776	25,551,065	20,372,376

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

###