Immune Design Corp.

Form 8-K
(Current report filing)

Filed 05/17/17 for the Period Ending 05/17/17

Address 1616 Eastlake Avenue E.
          Suite 310
          Seattle, WA, 98102
Telephone (650) 392-8350
CIK 0001437786
SIC Code 2834 - Pharmaceutical Preparations
Industry Biotechnology & Medical Research
Sector Healthcare
Fiscal Year 12/31
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):
May 17, 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.


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 8.01.  Other Events.

On May 17, 2017, the Company also issued a press release reporting new clinical and biomarker data from the Company’s CMB305 and G100 monotherapy studies, which data will be presented at the 2017 Annual Meeting of the American Society of Clinical Oncology (ASCO) in June.

A copy of the press release is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01.  Financial Statements and Exhibits.

(d) Exhibits.

<table>
<thead>
<tr>
<th>Exhibit Number</th>
<th>Description</th>
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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: May 17, 2017
<table>
<thead>
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Immune Design Reports First Quarter 2017 Financial Results
and Provides Corporate Update

Company conference call at 2:00 p.m. PT today

SEATTLE and SOUTH SAN FRANCISCO, May 17, 2017 - Immune Design (Nasdaq: IMDZ), a clinical-stage immunotherapy company focused on oncology, today reported financial results and a corporate update for the first quarter ended March 31, 2017.

“During the first quarter of the year, we were pleased to complete enrollment in the first randomized studies for each of CMB305 and G100, an important milestone for Immune Design,” said Carlos Paya, M.D., Ph.D., President and Chief Executive Officer of Immune Design. “We hope that the emerging biomarker and clinical data that we intend to present starting at ASCO and continuing throughout 2017, may form the initial foundation to support commercialization of novel and safe immunotherapies for selected cancer patients.”

Recent Highlights

Product Development: Two Phase 2 randomized studies fully enrolled; multiple ASCO presentations; Orphan Drug status for G100 in follicular NHL

Antigen Specific Immunotherapy: CMB305 Program

- CMB305, the novel, prime-boost NY-ESO-1 targeted immunotherapy, 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
    - Follow-up continues on the two enrolled monotherapy Phase 1 trials (25 CMB305 STS patients, and 23 STS patients treated with CMB305’s vector-only component, LV305).
    - Data from the CMB305 trial will be presented in two separate presentations at the American Society of Clinical Oncology annual meeting in 2017 (ASCO 2017):
      - Both clinical and translational data from at least 25 STS patients will be presented in an oral presentation entitled “Immune response, safety, and survival impact from CMB305 in NY-ESO-1+ recurrent soft tissue sarcomas (STS)”;
      - An analysis of translational data indicating an association of baseline and immunotherapy (LV305 and CMB305)-induced NY-ESO-1 immune response with survival in patients with multiple tumor types, will be presented in a poster presentation entitled “Association of CMB305 or LV305-induced and baseline anti-NY-ESO-1 immunity with survival in recurrent cancer patients.”
  - CMB305 combination therapy with Tecentriq *
    - Enrollment was completed by the end of Q1 in the randomized, 80-patient, Phase 2 study comparing CMB305 plus Tecentriq (atezolizumab) vs. atezolizumab alone, pursuant to a collaboration with Genentech.
    - Immune Design intends to submit early data from a pre-specified analysis of this Phase 2 study for presentation at the European Society for Medical Oncology 2017 Congress to be held in September 2017.

Antigen Agnostic Intratumoral Immunotherapy: G100 Program

- G100, the novel, synthetic TLR4 agonist injected intratumorally, is being evaluated in an ongoing Phase 1 dose escalation and in a randomized Phase 2 trial in patients with low grade follicular non-Hodgkin lymphoma (FL).
G100 monotherapy (with low dose radiation (XRT)). Data from the fully enrolled Phase 1 dose escalation monotherapy portion of the trial (n=9) evaluating G100 with XRT will be presented at ASCO 2017 in a poster presentation entitled “Intratumoral G100 induces systemic immune responses and abscopal tumor regression in patients with follicular lymphoma.”

G100 and XRT combination therapy with Keytruda ®:

- Patient enrollment was completed by the end of Q1 in the randomized, 24-patient, Phase 2 study comparing 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 follow-up data from all patients in both the Phase 1 dose escalation and Phase 2 randomized portions of the study for presentation at the American Society of Hematology Annual Meeting in December 2017.

The U.S. Food and Drug Administration recently granted Orphan Drug Designation for G100 for the treatment of FL. Orphan Drug Designation provides the sponsor certain benefits and incentives, including a period of marketing exclusivity for the first marketing application, if regulatory approval is received for the designated indication, potential tax credits for certain activities and waiver of certain administrative fees.

Financial Results

First Quarter

- Immune Design ended the first quarter of 2017 with $90.1 million in cash and 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 three months ended March 31, 2017 was $17.4 million.
- Net loss and net loss per share for the first quarter of 2017 were $12.6 million and $0.50, respectively, compared to $12.3 million and $0.61, respectively, for the first quarter of 2016.
- Revenue for the first quarter of 2017 was $5.5 million and was primarily attributable to $5.2 million in collaboration revenue associated with the Sanofi G103 (HSV2 therapeutic vaccine) collaboration and $0.3 million in product sales to other third parties. Revenue for the first quarter of 2016 was $1.9 million and was primarily attributable to the Sanofi G103 collaboration.
- Research and development expenses for the first quarter of 2017 were $14.0 million compared to $10.6 million for the same period in 2016. The $3.4 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 first quarter of 2017 were $4.1 million, relatively consistent with general and administrative expenses of $3.9 million recorded in the first quarter of 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 2:00 p.m. Pacific time / 5:00 p.m. Eastern time to discuss the first 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: 20090178.
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. Actual results may differ materially from these 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 for Immune Design’s product candidates and the reporting of clinical data regarding 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 enrolment rates that are lower than expected, changes in expected or existing competition, changes in the regulatory environment, failure of Immune Design’s collaborators to support or advance collaborations or product candidates 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)

<table>
<thead>
<tr>
<th></th>
<th>March 31, 2017 (unaudited)</th>
<th>December 31, 2016</th>
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<tbody>
<tr>
<td>Cash and cash equivalents</td>
<td>$27,918</td>
<td>$45,214</td>
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<td>Short-term investments</td>
<td>61,991</td>
<td>62,041</td>
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<td>Other receivables</td>
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<td>3,156</td>
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<tr>
<td>Total assets</td>
<td>99,882</td>
<td>114,495</td>
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<td>Total current liabilities</td>
<td>14,753</td>
<td>19,263</td>
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<tr>
<td>Total stockholders' equity</td>
<td>85,066</td>
<td>95,176</td>
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## Condensed Consolidated Statements of Operation and Comprehensive Loss Data

(\textit{In Thousands Except Per Share Amounts})

<table>
<thead>
<tr>
<th></th>
<th>Three Months Ended</th>
<th></th>
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<tbody>
<tr>
<td></td>
<td>March 31,</td>
<td>2017</td>
<td>2016</td>
</tr>
<tr>
<td></td>
<td>( unaudited)</td>
<td></td>
<td></td>
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<tr>
<td>Revenues:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product sales</td>
<td>$ 261</td>
<td>$ 7</td>
<td></td>
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<tr>
<td>Collaborative revenue</td>
<td>5,204</td>
<td>1,856</td>
<td></td>
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<tr>
<td>Total revenues</td>
<td>5,465</td>
<td>1,863</td>
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<tr>
<td>Operating expenses:</td>
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<td></td>
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</tr>
<tr>
<td>Cost of product sales</td>
<td>37</td>
<td>22</td>
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<tr>
<td>Research and development</td>
<td>14,038</td>
<td>10,570</td>
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<td>General and administrative</td>
<td>4,135</td>
<td>3,914</td>
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<tr>
<td>Total operating expenses</td>
<td>18,210</td>
<td>14,506</td>
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<tr>
<td>Loss from operations</td>
<td>(12,745)</td>
<td>(12,643)</td>
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<tr>
<td>Interest and other income</td>
<td>125</td>
<td>349</td>
<td></td>
</tr>
<tr>
<td>Net loss</td>
<td>$ (12,620)</td>
<td>$ (12,294)</td>
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</tr>
<tr>
<td>Other comprehensive income (loss):</td>
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<td></td>
<td></td>
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<tr>
<td>Unrealized (loss) gain on investments</td>
<td>(23)</td>
<td>20</td>
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<tr>
<td>Comprehensive loss</td>
<td>$ (12,643)</td>
<td>$ (12,274)</td>
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<tr>
<td>Basic and diluted net loss per share</td>
<td>$ (0.50)</td>
<td>$ (0.61)</td>
<td></td>
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<tr>
<td>Weighted-average shares used to compute basic</td>
<td>25,463,202</td>
<td>20,153,202</td>
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<tr>
<td>and diluted net loss per share</td>
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### Media Contact
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New Clinical and Biomarker Data Validate Immune Design’s Lead Programs and Discovery Platforms

Data from CMB305 and G100 to be Presented at ASCO Annual Meeting in June 2017

SEATTLE and SOUTH SAN FRANCISCO, May 17, 2017 - Immune Design (Nasdaq: IMDZ), a clinical-stage immunotherapy company focused on oncology, reported new clinical and biomarker data today from CMB305 and G100 monotherapy studies. The American Society of Clinical Oncology (ASCO) is publishing three abstracts today relating to these new data. A broader set of data will be presented at the ASCO 2017 Annual Meeting, providing further clinical validation of the company’s lead product candidates and discovery platforms.

CMB305 Monotherapy in Patients with Soft Tissue Sarcoma

- Most recent patient survival data meaningfully exceed published survival outcomes for standard of care therapy in comparable soft tissue sarcoma (STS) patients with recurrent metastatic disease.
  - With a median follow up exceeding 18 and 11 months for LV305 and CMB305, respectively, median overall survival (mOS) has not yet been reached in recurrent metastatic STS patients.
- Durable disease control was observed in more than half of STS patients, including durable tumor growth arrest in patients who had evidence of disease progression prior to CMB305 therapy.
- CMB305’s safety profile consisted mostly of mild to moderate adverse events, with therapy being well tolerated by patients.
- Anti-NY-ESO-1 immune biomarkers identify cancer patients who may be more likely to have prolonged survival following therapy with CMB305.
  - Anti-NY-ESO-1 immune responses were observed in more than half of the patients who received CMB305 therapy.
  - Induction of anti-NY-ESO-1 immunity in patients treated with CMB305 or LV305 was associated with better clinical outcomes, including survival.
  - Immune biomarkers pre-treatment may guide regulatory strategy via the selection of patients more likely to respond to CMB305 therapy.

G100 Intratumoral Monotherapy with Radiation in Patients with Low-grade Follicular NHL (FL)

- More than 40% of the FL patients experienced objective responses based on WHO criteria (at least a 50% tumor reduction), including substantial tumor shrinkage in untreated, unirradiated distal (abscopal) lesions.
- Safety profile remains favorable at higher doses than those previously reported in Merkel cell carcinoma patients.
- G100 resulted in favorable tumor microenvironment changes.
  - An increased intratumoral expression of inflammatory cytokines/chemokines, T cell infiltration, and an increased frequency of clonal tumor infiltrating lymphocytes, were observed.

“The ability to identify patients who are likely to benefit from antigen-targeted immunotherapy has been an elusive goal. We believe the results highlighted here should be considered as we aim to maximize the chance of success of these novel modalities, including CMB305 and future product candidates from our ZVex platform.” said Carlos Paya, M.D., Ph.D., President and Chief Executive Officer of Immune Design. “During the second half of the year, we hope to have the opportunity to build on these positive clinical and biomarker data for CMB305 and G100 monotherapy with the results from ongoing trials evaluating each agent in combination with anti-PD-1/PD-L1 inhibitors.”

Presentations at American Society of Clinical Oncology Annual Meeting

Data underlying the topline releases above were published online today by the American Society of Clinical Oncology (ASCO) in abstracts accepted for presentation at ASCO’s 2017 Annual Meeting in June (presentation information set forth below). The abstracts reflect an analysis performed on or before February 2017; additional data will be presented at the Annual Meeting.
ORAL PRESENTATION

Immune response, safety, and survival impact from CMB305 in NY-ESO-1+ recurrent soft tissue sarcomas (STS)

Abstract # 11006
Session Title: Sarcoma
Date: Friday, June 2, 2017
Time: 3 p.m. - 6 p.m. CT (oral session)
Location: S100bc
Presenter: Neeta Somaiah, M.D., Department of Sarcoma Medical Oncology, The University of Texas MD Anderson Cancer Center

POSTER PRESENTATIONS

The Association of CMB305 or LV305-induced and baseline anti-NY-ESO-1 immunity with survival in recurrent cancer patients

Abstract # 3090
Session Title: Developmental Therapeutics-Immunotherapy
Date: Monday, June 5, 2017
Time: 8 a.m. - 11:30 a.m. CT
Location: Hall A
Presenter: Seth M. Pollack, M.D., Fred Hutchinson Cancer Research Center

Intratumoral G100 to induce systemic immune responses and abscopal tumor regression in patients with follicular lymphoma

Abstract # 7537
Session Title: Hematologic Malignancies - Lymphoma and Chronic Lymphocytic Leukemia
Date: Monday, June 5, 2017
Time: 8 a.m. - 11:30 a.m. CT
Location: Hall A
Presenter: Christopher Flowers, M.D., Department of Hematology and Medical Oncology, Emory University School of Medicine

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 STS patients in ongoing Phase 1 monotherapy and 2 combination studies with the anti-PD-L1 antibody, Tecentriq ® (atezolizumab), pursuant to a collaboration with Genentech. 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 G100

G100 contains a potent synthetic small molecule toll-like receptor-4 (TLR-4) agonist, Glucopyranosyl Lipid A (GLA), and is the lead product candidate in Immune Design's Antigen Agnostic approach. It leverages the activation of both innate and adaptive immunity, including dendritic cells, in the tumor microenvironment to create an immune response against the tumor's preexisting diverse set of antigens. G100 is being evaluated as both a monotherapy (with XRT) and in combination with Merck's anti-PD-1 agent, Keytruda ® (pembrolizumab), pursuant to a clinical collaboration with Merck, in a randomized Phase 1/2 trial in patients with follicular non-Hodgkin's lymphoma. The FDA has granted Orphan Drug Designation for G100 for the treatment of follicular non-Hodgkin's lymphoma.
About Immune Design

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