IMMUNOCELLULAR THERAPEUTICS, LTD.

FORM 8-K
(Current report filing)

Filed 03/09/17 for the Period Ending 03/09/17

Address	23622 CALABASAS ROAD SUITE 300 CALABASAS, CA 91302
Telephone	818-264-2300
CIK	0000822411
Symbol	IMUC
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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): March 9, 2017

IMMUNOCELLULAR THERAPEUTICS, LTD.

(Exact name of registrant as specified in its charter)

Delaware	**001-35560**	**93-1301885**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

23622 Calabasas Road
Suite 300
Calabasas, California 91302
(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: (818) 264-2300

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 (see General Instruction A.2. below):

☐ 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))

Item 2.02. Results of Operations and Financial Condition.

On March 9, 2017, ImmunoCellular Therapeutics, Ltd. (the "Company") issued a press release announcing financial results for the fourth quarter and year ended December 31, 2016. A copy of this press release is attached as Exhibit 99.1.

This information, including exhibits attached hereto and the information under item 9.01 below, shall not be deemed "filed" for the 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. This information shall not be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	Description
99.1	Press Release, dated March 9, 2017

SIGNATURES

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.

Date: March 9, 2017

IMMUNOCELLULAR THERAPEUTICS, LTD.

By: /s/ David Fractor

David Fractor
Principal Accounting Officer

EXHIBIT INDEX

Exhibit	Description
99.1	Press Release, dated March 9, 2017

Exhibit 99.1

Contact:

ImmunoCellular Therapeutics, Ltd.
Investor Relations
Jane Green
415.348.0010 direct
415.652.4819 mobile
jane@jmgcomm.com

ImmunoCellular Therapeutics Announces Fourth Quarter and Full Year 2016 Financial Results and Provides Corporate Update

Los Angeles, CA – March 9, 2017 – ImmunoCellular Therapeutics, Ltd. ("ImmunoCellular") (NYSE MKT: IMUC) today announced financial results for the fourth quarter and full year 2016 and provided a corporate update.

Anthony Gringeri, PhD, ImmunoCellular's President and Chief Executive Officer, commented: "During 2016, we continued to implement our ICT-107 registration trial in patients with newly diagnosed glioblastoma, and conduct our phase 1 trial of ICT-121 in patients with recurrent glioblastoma.Today, in our ICT-107 phase 3 trial, 376 patients have been screened, 21 have been randomized, and clinical site activation is continuing, with a total of 68 sites activated to date. We are pleased to report that the protocol amendment we submitted to the US FDA for the ICT-107 trial, designed to modify some elements of the patient screening process and accelerate the pace and efficiency of randomization, is currently being implemented at US clinical sites, and amended protocol submissions are underway in Europe and Canada. As a result of the protocol change, the Special Protocol Assessment (SPA) is no longer applicable. We plan to engage in further discussions with the FDA concerning a SPA for the amended protocol in the future. We do not expect the change in the status of the SPA to materially impact the execution of the phase 3 trial, and data generated from a successful phase 3 study can still be used as primary evidence to support a marketing application."

Continued Dr. Gringeri: "The phase 1 open-label trial of ICT-121 being conducted at six sites in the US, completed enrollment of 20 patients. We are now in the process of analyzing the results, and have submitted an abstract to present the data at the American Society of Clinical Oncology (ASCO) annual meeting in June. As previously noted, the preliminary results, while unvalidated, were encouraging. We were also pleased to announce the achievement of a significant milestone in our Stem-to-T-cell program: the successful sequencing of a target T cell receptor gene, which is a key step toward identification of a potential clinical candidate. We are excited that our stem cell program is advancing, and look forward to working with our collaborators to develop antigen-specific killer T cell therapies."

Achievements, Upcoming Goals and Milestones:

- ICT-107:
  - Continue to bring US, Canadian and European clinical sites online. A total of 68 sites have been activated to date.
  - Implementation of the protocol amendment, which will modify some elements of how patients qualify for the trial. We plan to randomize a total of 542 patients, and anticipate randomization of all patients to be completed by mid-2019, and an additional 2-3 years from then to achieve the number of required events.
  - Plan to conduct a futility interim analysis at 30% of events, or at about the time of full randomization, and an efficacy interim analysis at 67% of events, about six months later.
- ICT-121:
  - Complete analysis of the data from the phase 1 trial. An abstract to ASCO has been submitted, with the goal of presenting preliminary results at the annual conference in June 2017.
- Research:
  - Having achieved identification of a T cell receptor identified for a Stem-to-T-cell clinical candidate, the next research phase will focus on packaging the T cell receptor sequence into a lentivirus vector, the vehicle that will be used to transfect human hematopoietic cells.
  - Continue to progress in collaboration with University of Maryland on projects that have application to existing dendritic cell immunotherapy and Stem-to-T-cell technology platforms.

Fourth Quarter and Full Year 2016 Financial Results

For the year ended December 31, 2016, the Company incurred a net loss of $22.1 million, or $7.89 per basic and diluted share, compared to a net loss of $12.8 million, or $5.87 per basic and diluted share, for the year ended December 31, 2015. During 2016, the Company incurred $19.1 million of research and development expenses compared to $10.9 million in 2015. The $8.2 million increase reflects the additional expenses associated with the implementation of the phase 3 trial of ICT-107. During 2016, the Company accrued $1.3 million of interest expense related to the California Institute of Regenerative Medicine (CIRM) award compared to $134,000 in 2015. For the quarter ended December 31, 2016, the Company incurred a net loss of $6.3 million, or $1.36 per basic and diluted share, compared to a net loss of $4.8 million, or $2.13 per basic and diluted share, for the quarter ended December 31, 2015.

The Company also reported that cash used in operations in 2016 was $19.9 million compared to $19.0 million in 2015. During 2015, the Company purchased $2.2 million in supplies and incurred $3.7 million in vendor deposits. During 2016, the Company utilized $2.2 million of vendor deposits, and the amount of supplies on-hand remained relatively constant with the prior year. As of December 31, 2016, the Company had $11.4 million in cash and cash equivalents.

In August 2016, the Company entered into an underwriting agreement with Maxim Group LLC, pursuant to which the Company received net proceeds of approximately $6.6 million (after deducting the underwriting discount and offering expenses) from the initial sale of 863,750 shares of the Company's common stock, base warrants to purchase 881,250 shares of common stock at an exercise price of $7.68 per share, and pre-funded warrants to purchase 311,250 shares of common stock at an exercise price of $0.40 per share. The aforementioned securities were sold at an offering price of $6.40 per unit. The underwriters partially exercised their option to purchase additional shares and base warrants and purchased an additional 37,500 shares of the Company's common stock at a public offering price of $6.00 per share and base warrants to purchase 111,965 shares. The pre-funded warrants were substantially paid for at the time of the offering and have an exercise price of $0.40 per share. As of December 31, 2016, the Company had 3,444,859 shares of common stock issued and outstanding.

Additionally, the CIRM award was modified such that ImmunoCellular received an additional $1.5 million in August 2016 as part of the initial award received from CIRM. The total amount of the award and other award conditions remain unchanged.

Conference Call and Webcast Today

ImmunoCellular plans to hold a conference call and webcast today at 5:00 pm ET to discuss the year-end and fourth quarter 2016 financial results and business update. The call will be hosted by Anthony Gringeri, PhD, President and Chief Executive Officer.

LIVE CALL:	(877) 853-5636 (toll-free); international dial-in: (631) 291-4544; conference code 73761073.
WEBCAST:	Interested parties who wish to listen to the webcast should visit the Investor Relations section of ImmunoCellular's website at www.imuc.com, under the Events and Presentations tab. A replay of the webcast will be available one hour after the conclusion of the event.

The conference call will contain forward-looking statements. The information provided on the teleconference is accurate only at the time of the conference call, and ImmunoCellular will take no responsibility for providing updated information except as required by law.

About ImmunoCellular Therapeutics, Ltd.

ImmunoCellular Therapeutics, Ltd. is a Los Angeles-based clinical-stage company that is developing immune-based therapies for the treatment of brain and other cancers. The Company's lead product candidate, ICT-107, is a patient-specific, dendritic cell-based immunotherapy targeting glioblastoma and is currently being studied in an international phase 3 trial. ImmunoCellular's pipeline also includes: ICT-121, a patient-specific, dendritic cell-based immunotherapy targeting CD133 found in recurrent glioblastoma; ICT-140, a patient-specific, dendritic cell-based immunotherapy targeting ovarian cancer; and the Stem-to-T-cell research program which engineers hematopoietic stem cells to generate cytotoxic T cells. To learn more about ImmunoCellular, please visit www.imuc.com .

Forward-Looking Statements for ImmunoCellular Therapeutics

This press release contains certain forward-looking statements, including statements regarding ImmunoCellular's intentions and current expectations concerning, among other things, timing for enrollment and randomization of patients, the activation of clinical sites, the receipt and announcement of clinical data; ImmunoCellular's ability to obtain a SPA for the amended protocol of its phase 3 clinical trial of ICT-107; the development and commercialization of ICT-107; the development of its preclinical Stem-to-T-cell program and ImmunoCellular's ability to achieve its other clinical, operational and financial goals. Forward-looking statements are not guarantees of future performance and are subject to a number of risks and uncertainties, including the availability of resources to continue to develop ImmunoCellular's product candidates, the uncertain timing of completion and success of clinical trials, and the risk that ICT-107 can be further successfully developed or commercialized. Additional risks and uncertainties are described under the heading "Risk Factors" in ImmunoCellular's most recently filed quarterly report on Form 10-Q for the period ended September 30, 2016. Except as required by law, ImmunoCellular undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

Consolidated Condensed Balance Sheets

	12/31/2016	12/31/2015
Cash	$11,437,118	$22,604,481
Other current assets	1,977,671	1,956,057
Non current assets	3,475,201	5,521,836
Total assets	$16,889,990	$30,082,374
Current liabilities	$ 3,238,943	$ 2,269,398
CIRM liability	6,945,741	$ 4,133,905
Warrant liability	573,560	1,958,775
Shareholders' equity	6,131,746	21,720,296
	$16,889,990	$30,082,374

Consolidated Condensed Statements of Operations

	Year ended 12/31/2016	Year ended 12/31/2015	Year ended 12/31/2014
Revenue	$ 0	$ 0	$ 0
Research and development	19,105,727	10,896,591	5,969,182
General and administrative	5,006,398	4,616,500	3,889,359
Loss before other income (expenses)	(24,112,125)	(15,513,091)	(9,858,541)
Interest income	24,381	19,863	13,917
Interest expense	(1,311,836)	(133,905)	—
Financing expense	(498,520)	(88,939)	(62,683)
Change in fair value of warrant liability	3,812,398	2,925,258	529,774
Net loss	($ 22,085,702)	($ 12,790,814)	($ 9,377,533)
Net loss per share, basic and diluted:	$ (7.89)	$ (5.87)	$ (6.26)