

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

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**FORM 8-K**

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**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 13, 2018**

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**Bellicum Pharmaceuticals, Inc.**  
(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-36783**  
(Commission  
File Number)

**20-1450200**  
(IRS Employer  
Identification No.)

**2130 W. Holcombe Blvd., Ste. 800**  
**Houston, TX**  
(Address of principal executive offices)

**77030**  
(Zip Code)

**Registrant's telephone number, including area code: 832-384-1100**

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations 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.

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**Item 2.02 Results of Operations and Financial Condition.**

On March 13, 2018, Bellicum Pharmaceuticals, Inc. (the “Registrant”) issued a press release announcing its financial results for the fourth quarter ended December 31, 2017. A copy of this press release is attached hereto as Exhibit 99.1.

The information in this Item 2.02, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any of the Registrant’s filings under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing to this Current Report on Form 8-K.

**Item 8.01 Other Events**

On March 13, 2018, the Registrant issued a press release announcing interim clinical data regarding its product candidate, BPX-501, in pediatric patients with acute myeloid leukemia and primary immunodeficiencies. A copy of this press release is attached hereto as Exhibit 99.2.

**Item 9.01 Financial Statements and Exhibits.**

**(d) Exhibits**

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#"><u>Press Release dated March 13, 2018.</u></a>
99.2	<a href="#"><u>Press Release dated March 13, 2018.</u></a>

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## **Bellicum Pharmaceuticals Provides Operational Update and Reports Financial Results for the Fourth Quarter and Year Ended December 31, 2017**

*Recruitment completed in European BP-004 registration trial of BPX-501 and rimiducid*

*Positive BPX-501 interim results reported in AML and primary immunodeficiencies*

*GoCAR-T candidate BPX-601 targeting PSCA in pancreatic cancer shows early promise with robust cell expansion in first patient dosed*

*Management to host conference call and webcast today at 5 p.m. Eastern*

**HOUSTON, TX-March 13, 2018**-Bellicum Pharmaceuticals, Inc. (NASDAQ:BLCM), a leader in developing novel, controllable cellular immunotherapies for cancers and orphan inherited blood disorders, today reported financial results for the fourth quarter and full year ended December 31, 2017.

"In the past year, we made substantial progress toward our vision of delivering cures through controllable cell therapy," said Bellicum's President & CEO Rick Fair. "We completed enrollment in our first registrational trial of BPX-501 and remain on track for our first filing for product approval in Europe in 2019. We moved three new projects featuring our industry-leading cellular control technology into clinical trials, including the first-ever GoCAR-T with our iMC activation switch. We also made substantial preclinical progress on our next generation 'dual-switch' platform containing both activation and safety switches in the same CAR-T cell, and initiated plans to move two dual-switch CAR-T projects into clinical trials in 2019."

### **2017 HIGHLIGHTS AND CURRENT UPDATES**

#### **Bellicum Submits Response to FDA Clinical Hold on BPX-501 Trials**

Last week, the Company submitted a full response to the FDA clinical hold notification, including requested changes to study protocols to provide guidelines for comprehensive monitoring and management of neurologic adverse events associated with hematopoietic stem cell transplants. The Company expects the response to satisfy the conditions for removal of the clinical hold, which applies to BPX-501 clinical trials in the U.S.

#### **Recruitment Complete in BPX-501 E.U. Registration Trial**

The Company completed enrollment in the treatment arm of its BP-004 E.U. registration trial in pediatric patients undergoing haploidentical hematopoietic stem cell transplant (haplo-HSCT) and expects to report updated data from this trial at upcoming medical meetings. The Company remains on track to file European Marketing Authorization Applications for BPX-501 and rimiducid in 2019.

**Positive BPX-501 Interim Results Reported in AML and Primary Immunodeficiencies**

Earlier today, the Company announced interim survival results in pediatric patients with acute myeloid leukemia (AML) suggesting that the addition of BPX-501 T cells to a haplo-HSCT may improve the anti-leukemic effect of stem cell transplantation. The Company also reported interim data in pediatric patients with primary immunodeficiencies (PIDs) undergoing a curative haplo-HSCT with BPX-501 demonstrating favorable disease-free and overall survival rates at one year. These interim results have been submitted for presentation at an upcoming medical meeting.

**Robust BPX-601 GoCAR-T™ Cell Expansion Observed Following Rimiducid Administration**

The Phase 1 study of BPX-601-the first product featuring the Company's iMC activation switch-is enrolling patients with nonresectable pancreatic cancer who test positive for prostate stem cell antigen (PSCA). The first patient dosed with rimiducid-to activate iMC following infusion of BPX-601 cells-showed a robust expansion of circulating BPX-601 cells following a single dose of rimiducid, providing the first clinical proof of concept of iMC. The patient continues to be evaluated for safety and efficacy, and the clinical site is enrolling additional patients. Bellicum expects to report findings from the initial cohorts of pancreatic cancer patients at an upcoming medical meeting and to expand the trial to other PSCA-expressing cancers later this year.

**Collaborator CD19 CAR-T Trial Initiated**

The first patients have been treated in a Phase 1 pediatric ALL clinical trial of a CD19 CAR-T incorporating the CaspaCIDE® safety switch, which is being conducted in collaboration with Ospedale Pediatrico Bambino Gesù (OPBG), a leading European pediatric research center and hospital. The trial is designed to assess the impact of CaspaCIDE in managing the acute toxicities of CAR-T therapy.

**Completed Buildout of In-House Manufacturing and Vector Production Facility**

The Company recently completed the buildout and initial launch of a 30,400 square foot state-of-the-art cell manufacturing and vector production facility at its headquarters in Houston, Texas. This facility is designed and constructed to satisfy both U.S. and European regulatory standards, and the Company expects the facility will meet U.S. clinical trial and early commercialization requirements.

**Bellicum Continues to Strengthen its Management Team and Board of Directors**

Since August 2017, the Company has added Gregory Naeve, Ph.D. (Chief Business Officer), William Grossman, M.D., Ph.D. (Chief Medical Officer), and several key leadership appointments to strengthen its clinical and quality functions. Additionally, Edmund P. Harrigan, M.D. was recently appointed to Bellicum's Board of Directors, bringing 28 years of cross-functional pharmaceutical industry experience, most recently as Senior Vice President, Worldwide Safety and Regulatory at Pfizer.

**ANTICIPATED 2018 MILESTONES**

- Report updated data from the BP-004 study of BPX-501
- Initiate pivotal clinical trials of BPX-501 in adult AML and in either pediatric AML or PIDs, pending regulatory clearances
- Report initial results from the BPX-601 clinical trial, and expand the trial to include additional PSCA-expressing cancers
- Present initial findings from the BPX-701 clinical trial at upcoming medical meetings

## Fourth Quarter and Full Year 2017 Financial Results

**Cash Position and Guidance:** Bellicum ended the year on December 31, 2017 with cash, restricted cash and investments totaling \$106.5 million, compared to \$113.4 million at December 31, 2016. In the fourth quarter of 2017, the Company paid off its Hercules Capital debt facility with a \$35.0 million loan from Oxford Finance. The new loan provided approximately \$2.1 million in additional liquidity, interest-only payments until February 1, 2020 and a lower interest rate. Based on current operating plans, Bellicum expects that current cash resources will be sufficient to meet operating requirements through the first quarter of 2019.

**R&D Expenses:** Research and development expenses were \$14.3 million and \$65.7 million for the fourth quarter and year ended December 31, 2017, respectively, compared to \$15.1 million and \$51.3 million during the comparable periods in 2016. The higher expenses in 2017 were primarily due to increased clinical trial costs, particularly for BPX-501, start-up costs related to Bellicum's in-house manufacturing facility and contract manufacturers in Europe and increased personnel and consulting expenses. The higher R&D expenses in the fourth quarter of 2016 were attributable to costs associated with characterization studies of rimiducid.

**G&A Expenses:** General and administrative expenses were \$5.1 million and \$21.0 million for the fourth quarter and year ended December 31, 2017, respectively, compared to \$4.2 million and \$16.9 million during the comparable periods in 2016. The increased G&A expenses in 2017 were primarily due to Bellicum's overall growth, including an increase in personnel-related costs, facility costs, and other administrative costs.

**Net Loss:** Bellicum reported a net loss of \$21.9 million for the fourth quarter of 2017 and \$91.8 million for the year ended December 31, 2017, compared to a net loss of \$19.9 million and \$69.2 million for the comparable periods in 2016. The results included non-cash, share-based compensation charges of \$3.4 million and \$13.6 million for the fourth quarter and year ended December 31, 2017, respectively, and \$3.1 million and \$12.3 million for the comparable periods in 2016.

### Shares Outstanding:

At December 31, 2017, Bellicum had 33,285,177 shares of common stock outstanding.

### Conference Call and Webcast

Bellicum management will host a webcast and conference call at 5:00 p.m. Eastern today to discuss the financial results. To access the call, participants should dial 877-407-3103 (domestic) and 201-493-6791 (international) at least 10 minutes prior to the start of the call. The event will be webcast live and can also be accessed in the [Investors & Media](#) section of [bellicum.com](#). An archived version of the webcast will also be available for replay in the Investors & Media section of the Bellicum website for at least two weeks following the call.

### About BPX-501

BPX-501 is an adjunct T cell therapy administered after allogeneic HSCT, comprising genetically modified donor T cells incorporating Bellicum's CaspaCIDE® safety switch. It is designed to provide a safety net to eliminate alloreactive BPX-501 T cells (via administration of activator agent rimiducid) should uncontrollable GvHD or other T-cell mediated complications occur. This enables physicians to more safely perform stem cell transplants by administering BPX-501 engineered T cells to speed immune reconstitution, provide control over viral infections and enhance Graft-versus-leukemic effect without unacceptable GvHD risk. The ongoing BP-004 clinical study of BPX-501 is being conducted at transplant centers in the U.S. and Europe.

**About BPX-601**

BPX-601 is a GoCAR-T™ product candidate containing Bellicum's proprietary inducible MyD88/CD40, or iMC, activation switch, designed to treat solid tumors expressing prostate stem cell antigen, or PSCA. Preclinical data show enhanced T cell proliferation, persistence and *in vivo* anti-tumor activity compared to traditional CAR-T therapies. A Phase 1 clinical trial in patients with non-resectable pancreatic cancer is ongoing. In addition to pancreatic cancer, PSCA is expressed in several other solid tumor indications, including: gastric, esophageal, cholangiocarcinoma, glioblastoma, prostate and bladder cancers. The Company plans to expand the clinical development of BPX-601 to include additional PSCA expressing cancer types.

**About BPX-701**

BPX-701 is a high affinity T cell receptor product candidate designed with the CaspaCIDE® safety switch. It is currently being tested in a Phase 1 study of patients with refractory or relapsed acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS) who test positive for PRAME, or preferentially expressed antigen in melanoma. In preclinical studies, PRAME-specific clones showed high reactivity against a panel of PRAME positive tumor cell lines, metastatic melanoma, sarcomas and neuroblastoma tissues. *In vitro* study data showed that BPX-701 demonstrated strong affinity to panels of cancer cells presenting PRAME peptides and low affinity to non-tumor cells, as well as complete elimination of BPX-701 cells in response to rimiducid.

**About Bellicum Pharmaceuticals**

Bellicum is a clinical stage biopharmaceutical company focused on discovering and developing cellular immunotherapies for cancers and orphan inherited blood disorders. Bellicum is using its proprietary Chemical Induction of Dimerization (CID) technology platform to engineer and control components of the immune system. Bellicum is developing next-generation product candidates in some of the most important areas of cellular immunotherapy, including CAR-T, TCR, and hematopoietic stem cell transplantation (HSCT) therapies. More information can be found at [www.bellicum.com](http://www.bellicum.com).

**Forward-Looking Statement**

*This press release contains forward-looking statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Bellicum may, in some cases, use terms such as “predicts,” “believes,” “potential,” “proposed,” “continue,” “designed,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “will,” “should” or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Forward-looking statements include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: our research and development activities relating to BPX-501, BPX-601, BPX-701, rimiducid, CaspaCIDE, iMC, dual switch, CAR-T and TCR programs; the effectiveness of BPX-501, BPX-601 and BPX-701, their possible ranges of application and potential curative effects and safety in the treatment of diseases, including as compared to other treatment options and competitive therapies; the timing and success of our current and planned clinical trials, including the timing of receipt of data from such clinical trials and the timing of our reports of such data; the rate and progress of enrollment in our clinical trials for BPX-501, BPX-601 and BPX-701, including our planned registration trials for BPX-501 and rimiducid; the timing and success of regulatory filings for BPX-501 and rimiducid; our research and development activities relating to our GoCAR-T and GoTCR technologies, the presentation of our preclinical and clinical data at medical or scientific meetings; our cash uses and cash runway; and our response to the FDA and its satisfaction of the conditions for removal of the clinical hold. Various factors may cause differences between Bellicum's expectations and actual results as discussed in greater detail under the heading “Risk Factors” in Bellicum's filings with the Securities and Exchange Commission, including without limitation our annual report on Form 10-K for the year ended December 31, 2017. Any forward-looking statements that Bellicum makes in this press release speak only as of the date of this press release. Bellicum assumes no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.*

**BELLICUM PHARMACEUTICALS, INC.****Unaudited Condensed Consolidated Balance Sheets**

(in thousands)

	<u>December 31,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
Current Assets:		
Cash and cash equivalents	\$ 38,839	\$ 33,140
Investment securities, available-for-sale, short-term	60,057	70,632
Receivables and other current assets	2,754	1,838
Non-Current Assets:		
Investment securities, available-for-sale, long-term	1,368	—
Property and equipment, net	25,942	16,504
Restricted cash	6,190	9,640
Other assets, net	378	283
Total assets	<u>\$ 135,528</u>	<u>\$ 132,037</u>
Current Liabilities:		
Accounts payable and other accrued liabilities	9,679	12,986
Current maturities of long-term debt	—	1,787
Other current liabilities	2,477	340
Long-Term Liabilities:		
Other liabilities, net of current portion	38,724	20,350
Total Stockholders' Equity	84,648	96,574
Total liabilities and stockholders' equity	<u>\$ 135,528</u>	<u>\$ 132,037</u>

**BELLICUM PHARMACEUTICALS, INC.****Unaudited Condensed Consolidated Statements of Operations**

(in thousands, except share and per share amounts)

	<u>Three Months Ended</u> <u>December 31,</u>		<u>Year Ended</u> <u>December 31,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
Grant Revenues	\$ (69)	\$ 81	\$ 185	\$ 388
Operating Expenses:				
Research and development	14,308	15,084	65,663	51,263
License fees	15	300	864	580
General and administrative	5,053	4,210	21,045	16,925
Total operating expenses	<u>19,376</u>	<u>19,594</u>	<u>87,572</u>	<u>68,768</u>
Operating loss	(19,445)	(19,513)	(87,387)	(68,380)
Interest expense, net	(687)	(425)	(2,606)	(861)
Loss on extinguishment of debt	(1,786)	—	(1,786)	—
Net loss	<u>\$ (21,918)</u>	<u>\$ (19,938)</u>	<u>\$ (91,779)</u>	<u>\$ (69,241)</u>
Net loss per share attributable to common shareholders, basic and diluted	<u>\$ (0.66)</u>	<u>\$ (0.74)</u>	<u>\$ (2.89)</u>	<u>\$ (2.57)</u>



Weighted-average common shares outstanding, basic  
and diluted

33,226,475

27,043,002

31,714,164

26,950,906

Investors:

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Alan Musso, CFO

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Source: Bellicum Pharmaceuticals



**Bellicum Announces Interim Results Showing Low Rates of Cancer Recurrence in Pediatric AML Patients Treated with BPX-501**

*Company also reports encouraging disease-free survival and overall survival rates in pediatric patients with primary immunodeficiencies*

*A pediatric registration trial is being planned*

**HOUSTON, TX-March 13, 2018**-Bellicum Pharmaceuticals, Inc. (NASDAQ:BLCM), a leader in developing novel, controllable cellular immunotherapies for cancers and orphan inherited blood disorders, today reported interim clinical data of BPX-501 in pediatric patients with acute myeloid leukemia (AML) and primary immunodeficiencies (PIDs). BPX-501 is an adjunct T cell therapy incorporating CaspaCIDE<sup>®</sup> administered after haploidentical hematopoietic stem cell transplant (haplo-HSCT) for the treatment of hematologic cancers and inherited blood diseases.

Data from the ongoing BP-004 trial suggest that BPX-501 T cells may contribute to a durable anti-leukemic effect in patients with AML. In the study, 38 pediatric AML patients in their first (n=13) or second (n=25) complete response underwent a haplo-HSCT followed by treatment with BPX-501. With a median follow-up of one year, rates of relapse-free survival and overall survival were 91.5% and 97.3%, respectively. This compares to one-year rates reported in the literature in pediatric AML patients undergoing alternate-donor HSCT of 60% to 80%.

"The recurrence of cancer is one of the most serious risks to AML patients receiving a stem cell transplant. These impressive results in children with AML suggest that BPX-501 may be effectively reducing or eradicating residual cancer cells following a haplo-transplant procedure," commented Neena Kapoor, M.D., Director of the Blood and Marrow Transplantation Program at Children's Hospital of Los Angeles and an investigator in the BP-004 trial.

Also from the BP-004 study, the Company reported high rates of disease-free survival and overall survival in pediatric patients with PIDs, including Severe Combined Immunodeficiency ("bubble boy disease"), Wiskott-Aldrich syndrome, Chronic Granulomatous Disease, and other rare immune deficiencies. Of 59 pediatric PID patients undergoing a haplo-HSCT and treatment with BPX-501, disease-free survival was reported at 88.1% and overall survival was reported at 88.6% with a median follow-up of one year.

Continued Dr. Kapoor: "Delayed immune reconstitution can lead to severe infectious complications, a major cause of morbidity and mortality in PID patients who undergo a T-depleted haplo-HSCT. BPX-501 donor T cells administered after a transplant support immune recovery in these patients, and the CaspaCIDE safety switch engineered into BPX-501 may provide a critical safety net to address the risk of uncontrolled GvHD from donor T cells."

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Based on these clinical data, Bellicum is working with the investigators and the U.S. Food and Drug Administration to develop a protocol for a potential U.S. registration study in pediatric patients. Pending regulatory clearances, the Company expects to initiate the study by the end of 2018. These clinical data have been submitted for presentation at an upcoming medical meeting.

**About BPX-501**

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**About CaspaCIDE**

CaspaCIDE® (also known as inducible Caspase-9, or iC9) is the Company's safety switch, incorporated into certain Bellicum product candidates. The CaspaCIDE switch consists of the Chemical Induction of Dimerization, or CID, binding domain coupled to the signaling domain of Caspase-9, an enzyme that is an integral part of the apoptotic, cell death pathway. If a patient experiences a serious side effect, the activator agent, rimiducid, is administered to trigger dimerization and activation of the safety switch, which in turn leads to selective apoptosis of the CaspaCIDE-expressing cells.

**About Bellicum Pharmaceuticals**

Bellicum is a clinical stage biopharmaceutical company focused on discovering and developing cellular immunotherapies for cancers and orphan inherited blood disorders. Bellicum is using its proprietary Chemical Induction of Dimerization (CID) technology platform to engineer and control components of the immune system. Bellicum is developing next-generation product candidates in some of the most important areas of cellular immunotherapy, including hematopoietic stem cell transplantation (HSCT), and CAR-T and TCR cell therapies. More information can be found at [www.bellicum.com](http://www.bellicum.com).

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Source: Bellicum Pharmaceuticals