

**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): November 6, 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.

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

On November 6, 2018, Bellicum Pharmaceuticals, Inc. (the “Registrant”) issued a press release announcing its financial results for the third quarter ended September 30, 2018. 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 9.01 Financial Statements and Exhibits.****(d) Exhibits**

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press Release dated November 6, 2018.</a>





## Bellicum Pharmaceuticals Reports Third Quarter 2018 Financial Results and Provides Corporate Update

**HOUSTON, TX-November 6, 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 third quarter ended September 30, 2018, and provided an update on recent developments.

"We made significant progress during the quarter across our programs. Rivo-cel remains on track for MAA filing in the E.U. in 2019 for pediatric patients with acute leukemias and nonmalignant blood diseases," said Bellicum's President & CEO Rick Fair. "We also received and incorporated health authority input on our planned late-stage trial in adult AML and MDS and remain on track to initiate the trial by year-end."

Continued Mr. Fair: "In our GoCAR-T programs, we are nearing completion of the dose escalation portion of our Phase 1/2 study of BPX-601 in solid tumors, and expect to report preliminary results from the lower dose cohorts in patients with advanced pancreatic cancer in December. We also made substantial progress toward IND applications for two new dual-switch GoCAR-T candidates in 2019."

### PROGRAM HIGHLIGHTS AND CURRENT UPDATES

#### On Track to Initiate Phase 2/3 Study of Rivo-cel in Adult AML and MDS by Year-end

Based on impressive clinical trial results to date with rivo-cel<sup>TM</sup> (rivogenlecleucel, formerly called BPX-501) in pediatric leukemia patients, Bellicum is finalizing its plans to initiate a global Phase 2/3 trial in adult patients with intermediate/high-risk acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS) by the end of the year. The Company completed review of the study protocol with the U.S. FDA in the third quarter and has incorporated its input into the design of the trial.

#### Rivo-cel Pediatric Registration Trials on Track for E.U. Filing in 2019; Significant Data Update at ASH 2018

Prospective enrollment was recently completed in the BP-004 and C-004 E.U. registration trials of pediatric patients with leukemias, lymphomas and inherited blood disorders. These trials will serve as the basis for the Company's planned 2019 European Marketing Authorization Application regulatory filing. In December, Bellicum will present interim data at the American Society of Hematology (ASH) Annual meeting, with final results expected in early 2019. Among the highlights will be late interim analyses of the overall results from the BP-004 trial in children with acute leukemias and nonmalignant blood diseases, as well as the comparator C-004 trial-a multicenter, observational study of similar pediatric patients receiving a matched unrelated donor (MUD) transplant. Disease outcomes from several patient subsets, as well as the cumulative clinical experience of patients from BP-004 who received rimiducid to treat steroid refractory Graft-versus-Host-Disease will also be presented. ASH 2018 is being held in San Diego, California on December 1-4.

#### Commercial Planning Activities for Rivo-cel Continue to Advance in Europe

Under the recently appointed General Manager of Europe, Thierry Darcis, M.D., M.B.A., Bellicum continues to build out an E.U.-based team to prepare for the commercialization of rivo-cel, if approved. Dr. Darcis and his leadership team have extensive experience launching orphan products in Europe, and Dr.

Darcis has previously led successful product introductions for ViroPharma and NPS Pharmaceuticals. He also held leadership roles with Zogenix, Novartis and GlaxoSmithKline.

### **Initial Clinical Data on BPX-601 To Be Presented at ESMO Immuno-Oncology Conference**

BPX-601 is Bellicum's first GoCAR-T<sup>®</sup> clinical candidate incorporating the co-activation domain, iMC. The Company expects to report preliminary safety and translational findings from the lower cell-dose cohorts of its Phase 1 dose-escalation safety study in late-stage pancreatic cancer patients at the European Society for Medical Oncology Immuno-Oncology Conference in Geneva, Switzerland in December. The Company is evaluating BPX-601 in adults with relapsed or refractory pancreatic, gastric, and prostate cancers who test positive for prostate stem cell antigen (PSCA).

### **Preclinical Dual-Switch Candidates On Track to Enter Clinic in 2019**

Bellicum's research team continues to advance its next-generation GoCAR-T projects, which have been designed with both activation and safety switch technologies to potentially enhance efficacy and safety. The Company expects to submit IND applications for two new dual-switch GoCAR-T product candidates in 2019.

### **Third Quarter 2018 Financial Results**

Bellicum reported a net loss of \$23.8 million for the third quarter of 2018 and \$70.8 million for the nine months ended September 30, 2018, respectively, compared to a net loss of \$23.4 million and \$69.9 million for the comparable periods of 2017. The results included non-cash, share-based compensation charges of \$3.7 million and \$10.9 million for the third quarter and nine months ended September 30, 2018, and \$3.7 million and \$10.2 million for the comparable periods in 2017.

As of September 30, 2018, cash, restricted cash and investments totaled \$118.4 million. Based on current operating plans, Bellicum continues to expect that current cash resources will be sufficient to meet operating requirements through 2019.

Research and development expenses were \$16.4 million and \$51.4 million, for the three and nine months ended September 30, 2018, respectively, compared to \$18.1 million and \$51.4 million during the comparable periods in 2017.

General and administrative expenses were \$7.0 million and \$18.0 million for the three and nine months ended September 30, 2018, respectively, compared to \$4.6 million and \$16.0 million during the comparable periods in 2017.

At September 30, 2018, Bellicum had 43,351,159 shares of common stock outstanding.

### **About Rivo-cel (BPX-501)**

Rivo-cel<sup>™</sup> (rivogenlecleucel) is an allogeneic polyclonal T cell product designed to reduce relapse of leukemia following a stem cell transplant. The cell treatment contains a diverse repertoire of T cells which may contribute to a robust graft vs. leukemia effect. Rivo-cel's antiviral benefits may also reduce morbidity and mortality in patients susceptible to infection following a transplant. The product's CaspaCIDE<sup>®</sup> safety switch enables this approach by allowing physicians to reduce the number of alloreactive cells in the event of uncontrolled GvHD. Rivo-cel addresses a major unmet need in adult and pediatric leukemia, lymphoma and genetic blood disease patients following a haploidentical stem cell transplant.

### **About BPX-601**

BPX-601, the Company's first GoCAR-T<sup>®</sup> product candidate, incorporates iMC, Bellicum's inducible co-activation domain. iMC (inducible MyD88/CD40) is designed to provide a powerful boost to T cell proliferation and persistence, and enable the CAR-T to override key immune inhibitory mechanisms,

including PD-1 and TGF-beta. BPX-601 is being evaluated as a treatment for solid tumors expressing prostate stem cell antigen (PSCA), including pancreatic, prostate and gastric cancers.

### **About Bellicum Pharmaceuticals**

Bellicum is a clinical stage biopharmaceutical company striving to deliver cures through controllable cell therapies. The Company's next-generation product candidates are differentiated by powerful cell signaling technologies designed to produce more effective CAR-T, TCR and allogeneic T cell therapies. Its lead product candidate, rivo-cel™, is an allogeneic polyclonal T cell therapy that has shown promising clinical trial results in reducing leukemia relapse after a stem cell transplant. Bellicum's lead GoCAR-T® candidate, BPX-601, is designed to be a more efficacious CAR-T cell product capable of overriding key immune inhibitory mechanisms. 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. 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 rivo-cel™, BPX-601, rimiducid, CaspaCIDE®, iMC, dual switch, CAR-T and TCR programs; the effectiveness of rivo-cel and BPX-601, 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 timing and success of regulatory filings; our ability to build a successful commercial organization in Europe; our research and development activities relating to our GoCAR-T technologies; the presentation of our preclinical and clinical data at medical or scientific meetings and our cash uses and cash runway. 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 quarterly report on Form 10-Q for the three months ended September 30, 2018 and 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)**

	September 30,		December 31,	
	2018		2017	
Current Assets:				
Cash and cash equivalents	\$	53,027	\$	38,839
Investment securities, available-for-sale, short-term		59,720		60,057
Receivables and other current assets		2,792		2,754
Non-Current Assets:				
Investment securities, available-for-sale, long-term		—		1,368
Property and equipment, net		22,402		25,942
Restricted cash		5,635		6,190
Other assets		396		378
Total assets	\$	143,972	\$	135,528
Current Liabilities:				
Accounts payable and other accrued liabilities		10,680		9,679
Other current liabilities		3,743		2,477
Long-Term Liabilities:				
Long-term debt		35,609		34,946
Other liabilities, net of current portion		1,483		3,778
Total Stockholders' Equity		92,457		84,648
Total liabilities and stockholders' equity	\$	143,972	\$	135,528

**BELLICUM PHARMACEUTICALS, INC.****Unaudited Condensed Statements of Operations****(in thousands, except share and per share amounts)**

	September 30,			
	Three Months Ended		Nine Months Ended	
	2018	2017	2018	2017
Grant Revenues	\$ 292	\$ 126	\$ 808	\$ 254
Operating Expenses:				
Research and development	16,413	18,101	51,361	51,355
License fees	139	151	319	849
General and administrative	6,968	4,579	18,027	15,992
Total operating expenses	23,520	22,831	69,707	68,196
Operating loss	(23,228)	(22,705)	(68,899)	(67,942)
Interest expense, net of interest income	(573)	(726)	(1,917)	(1,919)
Net loss attributable to common shareholders	\$ (23,801)	\$ (23,431)	\$ (70,816)	\$ (69,861)
Net loss per share attributable to common shareholders, basic and diluted	\$ (0.55)	\$ (0.71)	\$ (1.81)	\$ (2.24)
Weighted-average common shares outstanding, basic and diluted	43,334,727	33,178,611	39,168,559	31,204,521





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Source: Bellicum Pharmaceuticals