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): March 12, 2019

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

Delaware	**001-36783**	**20-1450200**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

2130 W. Holcombe Blvd., Ste. 800 **Houston, TX**	**77030**
(Address of principal executive offices)	**(Zip Code)**

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

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 x

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. x

Item 2.02 Results of Operations and Financial Condition.

On March 12, 2019, Bellicum Pharmaceuticals, Inc. (the "Registrant") issued a press release announcing its financial results for the fourth quarter ended December 31, 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

Exhibit No.	Description
99.1	Press Release dated March 12, 2019.

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.

Bellicum Pharmaceuticals, Inc.

Dated: March 12, 2019

By: /s/ Richard A. Fair

Richard A. Fair

President and Chief Executive Officer

Bellicum Pharmaceuticals Provides Operational Update and Reports Financial Results for the Fourth Quarter and Year Ended December 31, 2018

HOUSTON, TX-March 12, 2019-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, 2018.

“We believe that Bellicum is well-positioned for an exciting and eventful 2019 as a result of our investments to strengthen our clinical development and executive teams over the past 24 months,” said Bellicum’s President & CEO Rick Fair. “Based on promising preclinical and initial clinical data on BPX-601, we have prioritized GoCAR-T® candidates incorporating our iMC activation switch in our clinical development strategy. In addition to progressing our Phase 1/2 trial of BPX-601, we intend to submit IND applications for two novel, dual-switch GoCAR-T clinical programs in 2019. For rivo-cel™, we anticipate topline Phase 2 results in pediatric patients in the second quarter of 2019, which will form the basis for European Marketing Authorisation Application (MAA) submissions planned for late 2019.”

PROGRAM HIGHLIGHTS AND CURRENT UPDATES

Bellicum Advances and Expands Clinical Program for GoCAR-T Platform

BPX-601

- Bellicum completed enrollment in the dose-escalation portion of its ongoing Phase 1/2 study of BPX-601 in patients with advanced pancreatic cancer expressing prostate stem cell antigen (PSCA). Bellicum presented positive initial clinical data from Part 1 of the study at the ESMO Immuno-Oncology Congress in December 2018 and the Gastrointestinal Cancers Symposium in January 2019 that showed a promising safety profile. In several patients reported, enhanced cell expansion, prolonged cell persistence, and early evidence of clinical activity and disease control were observed. The trial protocol has been amended to add the complete lymphodepletion conditioning regimen cyclophosphamide/fludarabine (Cy/Flu) and to include patients with gastric and prostate cancers. Once this safety cohort has been completed, Bellicum plans to incorporate an additional cohort to evaluate repeat rimiducid dosing to re-activate iMC over time, which is intended to deepen and extend the treatment effect. Initial results from these cohorts are expected in 2019.

Controllable Dual-Switch Candidates

- BPX-603 is Bellicum’s first controllable dual-switch GoCAR-T product candidate, which incorporates both the iMC activation switch and the CaspaCIDe® safety switch. BPX-603 is designed to target solid tumors that express the human epidermal growth factor receptor 2 antigen (HER2). HER2 is a validated antigen for cancer therapies, and academic CAR-T cell clinical studies have shown evidence of antitumor activity. These CAR-T approaches targeting HER2 have been limited by modest clinical efficacy and off-tumor/on-target toxicity. Bellicum believes that its dual-switch GoCAR-T technology may be uniquely suited to improve upon these earlier efforts by driving greater efficacy through iMC activation while enabling clinicians to manage any treatment-emergent toxicities with CaspaCIDe. Bellicum expects to submit an IND application for BPX-603 and to initiate a clinical trial in 2019.

- BPX-802 is a dual-switch GoCAR-T product candidate targeting an antigen expressed in hematological malignancies. Bellicum expects to submit an IND application for BPX-802 in late 2019.

Company Prepares for Rivo-cel Registration in E.U. for Pediatric Patients and Initiates Global Trial for Adult and Adolescent Patients

- Bellicum presented late interim analyses of the pediatric study BP-004 at ASH in December 2018. The results demonstrated that 90.9% of rivo-cel treated patients experienced Event Free Survival (EFS) at 180 days compared to 87.7% of patients undergoing matched unrelated donor (MUD) HSCT. Non-inferiority on EFS versus MUD HSCT is the primary endpoint for European regulatory review. The results also demonstrated that rivo-cel treated patients had high rates of relapse-free (82.9%) and overall (94.4%) survival with a median follow up of 20 months. Lastly, the results demonstrated a best overall response rate of 70% in patients that developed advanced or steroid-refractory GvHD when treated with rimiducid, with the majority being complete responses.
- The Company expects topline results from the BP-004 study in the second quarter of 2019 and intends to submit MAAs for rivo-cel and rimiducid in late 2019.
- The Company recently initiated THRIVE, a pivotal randomized global Phase 2/3 clinical trial of rivo-cel in adult and adolescent patients 12 years and older with intermediate- and high-risk acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS). In the Phase 3 portion of the trial, patients will be randomized to receive either a/b T cell and B-cell depleted haploidentical HSCT plus rivo-cel without GvHD prophylaxis, or a haploidentical HSCT followed by cyclophosphamide post-transplant, commonly referred to as the “Baltimore regimen,” which is the current standard of care for haplo-HSCT in the U.S. and Europe.

CORPORATE UPDATES

Company Makes Key Additions to Management Team and Board of Directors; Forms Scientific and Clinical Advisory Board

- Atabak Mokari was appointed Chief Financial Officer. He brings 20 years of financial leadership in life sciences, medtech and healthcare investment banking, and joined the Company from IRIDEX Corporation, a NASDAQ-listed medical technology company where he served as Chief Financial Officer and VP Corporate Development.
- Aaron Foster, Ph.D., was promoted to Senior Vice President, Head of Research, and will oversee the Company’s research organization. Dr. Foster was previously Vice President, Translational Research & New Product Development. Prior to joining Bellicum in 2012, he was Assistant Professor at Baylor College of Medicine at the Center for Cell & Gene Therapy, where he led a group researching adoptive T cell therapies, cancer vaccines, and nanotherapeutics. Concurrently, David Spencer, Ph.D., stepped down from his operating role as Chief Technology Officer, and has assumed an advisory position on the Company’s Scientific Advisory Board.
- Judith Klimovsky, M.D., joined the Board of Directors, replacing Frank McGuyer. Dr. Klimovsky currently serves as Executive Vice President & Chief Development Officer of Genmab, an international biotechnology company developing antibody therapeutics for cancer, where she leads the company’s product development efforts.
- Company formed a new Scientific and Clinical Advisory Board comprised of the following individuals:
    - Malcom Brenner, M.D., Ph.D. (Baylor College of Medicine)
    - Marco Davila, M.D., Ph.D. (Moffitt Cancer Center)
    - Gianpietro Dotti, M.D. (University of North Carolina Lineberger Comprehensive Cancer Center and Professor for the Department of Microbiology and Immunology at UNC-Chapel Hill)
    - Daniel Powell Jr., Ph.D. (University of Pennsylvania, Perelman School of Medicine)
    - Naiyer Rizvi, M.D. (Columbia University Irving Medical Center)
    - Charles Sentman, Ph.D. (Dartmouth, Geisel School of Medicine)

- David Spencer, Ph.D. (Co-Founder, Bellicum Pharmaceuticals)

Fourth Quarter and Full Year 2018 Financial Results

Cash Position and Guidance: Bellicum reported cash, restricted cash and investments totaling $98.0 million as of December 31, 2018, compared to $106.5 million at December 31, 2017. Based on current operating plans, Bellicum expects that current cash resources will be sufficient to meet operating requirements through the end of 2019.

R&D Expenses: Research and development expenses were $19.8 million and $71.2 million for the fourth quarter and year ended December 31, 2018, respectively, compared to $14.3 million and $65.7 million during the comparable periods in 2017. The higher expenses in the fourth quarter and full year 2018 compared to respective periods in 2017 were primarily due to an increase in costs related to Bellicum's GoCAR-T product platform and general research and development expenses, partially offset by a decrease in expenditures related to rivo-cel.

G&A Expenses: General and administrative expenses were $7.0 million and $25.0 million for the fourth quarter and year ended December 31, 2018, respectively, compared to $5.1 million and $21.0 million during the comparable periods in 2017. The higher expenses in the fourth quarter and full year 2018 compared to respective periods in 2017 were primarily due to increased personnel related costs due to hiring additional employees.

Net Loss: Bellicum reported a net loss of $27.2 million for the fourth quarter of 2018 and $98.0 million for the year ended December 31, 2018, compared to a net loss of $21.9 million and $91.8 million for the comparable periods in 2017. The results included non-cash, share-based compensation charges of $3.0 million and $13.8 million for the fourth quarter and year ended December 31, 2018, respectively, and $3.4 million and $13.6 million for the comparable periods in 2017.

Shares Outstanding:

At December 31, 2018, Bellicum had 43,564,596 shares of common stock outstanding.

Upcoming Near-term Potential Milestones

- BPX-601 - Expect to report data from additional cohorts in ongoing Phase 1/2 clinical trial in 2019
  - Cy/Flu regimen cohort: mid-year 2019
  - Repeat rimiducid dosing cohort: late 2019
- BPX-603 - Expect IND submission and clinical trial initiation in 2019
- BPX-802 - Expect IND submission in late 2019
- Rivo-cel:
  - Expect topline results from the BP-004 study in the second quarter of 2019
  - Plan to submit MAAs for rivo-cel and rimiducid in late 2019

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 (U.S. 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 following the call.

About BPX-601

BPX-601, the Company's first GoCAR-T® 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, gastric, and prostate cancers.

About Rivo-cel (BPX-501)

Rivo-cel™ (rivogenlecleucel) is an allogeneic polyclonal T-cell product designed to accelerate immune recovery after HSCT and 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 anti-infective benefits may also reduce morbidity and mortality, as patients are highly susceptible to infection following a transplant. The product's CaspaCIDe® 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 inherited blood disease patients following a haploidentical stem cell transplant.

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 and allogeneic T cell therapies. 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. Bellicum's rivo-cel product candidate is an allogeneic polyclonal T cell therapy that has shown promising clinical trial results in reducing leukemia relapse after a stem cell transplant. More information can be found at 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 rivo-cel, rimiducid, BPX-601, BPX-603, BPX-802, and other cell therapy programs; our pipeline candidates' effectiveness, possible ranges of application and potential safety and curative effects 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 expansion of or changes to our ongoing clinical trials to new indications and diseases; the timing and success of regulatory filings for rivo-cel and rimiducid including our planned European Marketing Authorisation Applications (MAA); the speed and effectiveness of our preparations for potential commercialization in Europe if the MAAs are approved; the impact of our efforts to strengthen our clinical development and executive teams; 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 annual report on Form 10-K the year ended December 31, 2018. 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.

Audited Consolidated Condensed Balance Sheets
(in thousands)

	December 31, 2018	December 31, 2017
Current Assets:		
Cash and cash equivalents	$ 43,695	$ 38,839
Investment securities, available-for-sale, short-term	49,304	60,057
Receivables and other current assets	2,296	2,754
Non-Current Assets:		
Investment securities, available-for-sale, long-term	—	1,368
Property and equipment, net	20,878	25,942
Restricted cash	4,973	6,190
Other assets, net	355	378
Total assets	$ 121,501	$ 135,528
Current Liabilities:		
Accounts payable and other accrued liabilities	12,363	9,679
Other current liabilities	3,441	2,477
Long-Term Liabilities:		
Other liabilities, net of current portion	37,219	38,724
Total Stockholders' Equity	68,478	84,648
Total liabilities and stockholders' equity	$ 121,501	$ 135,528

BELLICUM PHARMACEUTICALS, INC.

Audited Consolidated Condensed Statements of Operations
(in thousands, except share and per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2018	2017	2018	2017
Grant Revenues	$ 312	$ (69)	$ 1,120	$ 185
Operating Expenses:				
Research and development	19,791	14,308	71,152	65,663
License fees	117	15	436	864
General and administrative	6,971	5,053	24,998	21,045
Total operating expenses	26,879	19,376	96,586	87,572
Operating loss	(26,567)	(19,445)	(95,466)	(87,387)
Interest and other income (expense), net	(653)	(687)	(2,570)	(2,606)
Loss on extinguishment of debt	—	(1,786)	—	(1,786)
Net loss attributable to common shareholders	$ (27,220)	$ (21,918)	$ (98,036)	$ (91,779)
Net loss per share attributable to common shareholders, basic and diluted	$ (0.63)	$ (0.66)	$ (2.44)	$ (2.89)
Weighted-average common shares outstanding, basic and diluted	43,382,010	33,226,475	40,230,580	31,714,164

Source: Bellicum Pharmaceuticals

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