

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

September 5, 2015

Date of Report (Date of earliest event reported)

**Bellicum Pharmaceuticals, Inc.**

(Exact name of registrant as specified in its charter)

**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**

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))

**Item 8.01 Other Events.**

On September 5, 2015, a principal investigator for an ongoing phase I/II study of BPX-501 by Bellicum Pharmaceuticals, Inc. (the "Company") presented information on the trial (the "Information") at an international medical symposium held in Parma, Italy. A copy of the Information is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information contained in this Current Report on Form 8-K and in the accompanying Exhibit 99.1 are being furnished and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section and will not be incorporated by reference into any registration statement filed by the Company, under the Securities Act of 1933, as amended, unless specifically identified as being incorporated therein by reference. This Current Report on Form 8-K will not be deemed an admission as to the materiality of any information in this Current Report on Form 8-K that is being disclosed pursuant to Regulation FD.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

Exhibit Number	Description
99.1	Information Materials for Bellicum Pharmaceuticals, Inc.



INDEX TO EXHIBITS

Exhibit No.

Description

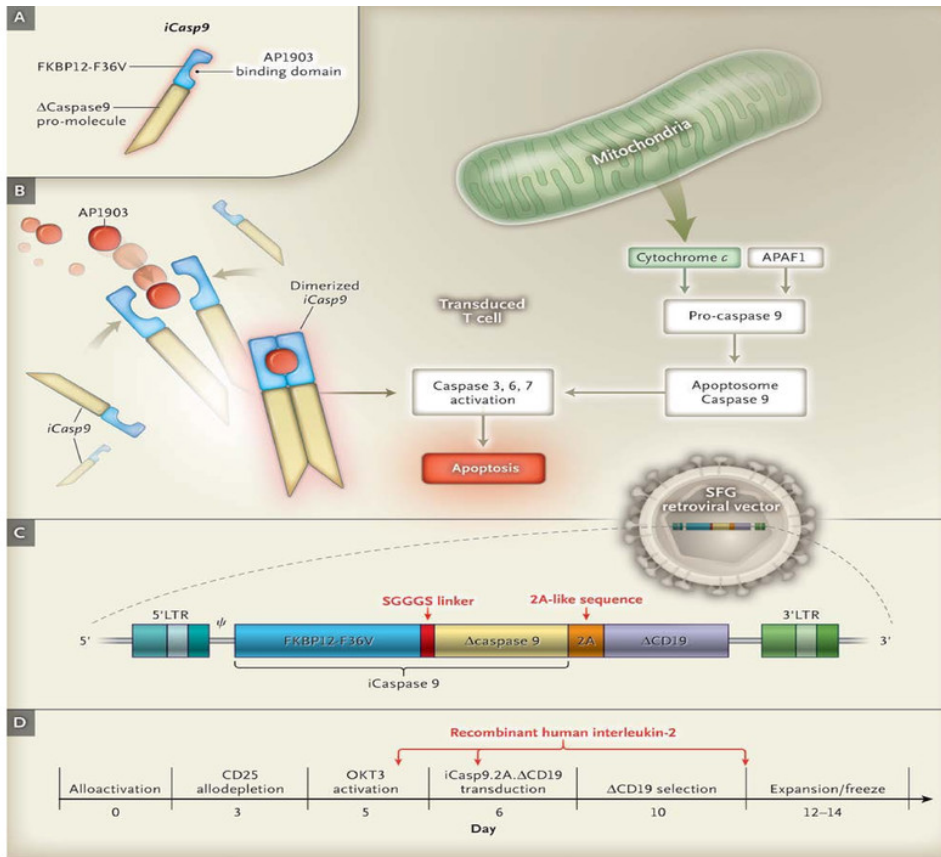
99.1

Information Materials for Bellicum Pharmaceuticals, Inc.

## **What's next.....**

**How can we quickly restore T-cell mediated immunity and, thus, further protect patients from life-threatening pathogens in the first 3 months after HSCT, while preventing GvHD occurrence?**

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**Phase I/II study of CaspaCide T cells from an HLA-partially matched family donor after negative selection of TCR  $\alpha\beta$ + T cells in pediatric patients affected by hematological disorders**

ClinicalTrials.gov identifier: NCT02065869

**Study sponsor:** Bellicum Pharmaceuticals

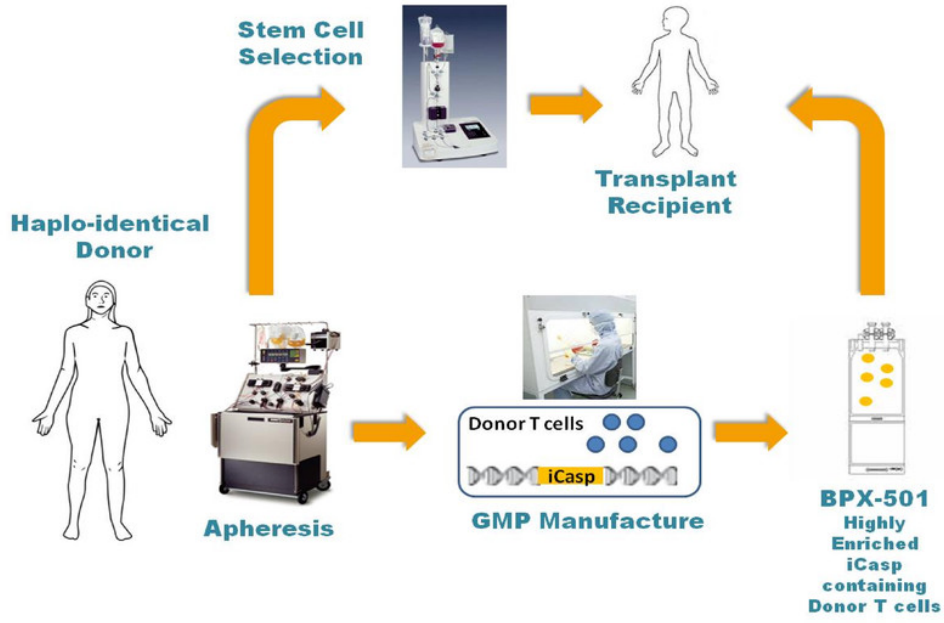
**Participating Centers:** Rome, Freiburg, London, Newcastle

**PI:** F. Locatelli

**Co-PIs:** A. Bertaina, P. Merli, B. Lucarelli, B. Strahm, W. Qasim, M. Slatter

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# CaspaCide T cell Clinical Schema





# Trial design

- This is a phase I-II open label study. The trial design consists of 3 cohorts, receiving escalation doses of BPX-501 of  $2.5 \times 10^5$ ,  $5 \times 10^5$ , and  $1 \times 10^6$  cells/kg, respectively. Dose escalation will occur according to a 3+3 design.
  - If none of the initial 3 patients in a cohort experiences a dose-limiting toxicity, another 3 patients will be treated at the next higher dose level. If one of the first three patients experiences a DLT, three more patients will be treated at the same dose level. Dose escalation will continue until at least 2 patients in a cohort of 3 to 6 patients experience dose limiting toxicities.
  - A Phase 2 extension will occur after dose escalation, enrolling at the highest tolerated dose for a maximum of 60 paediatric patients total, enrolled over a period of 12 months and the minimum active study follow-up for each patient will be 2 years. The maximum duration of the study will be 3 years.
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## HLA-haploidentical stem cell transplantation after removal of $\alpha\beta^+$ T and B cells in children with nonmalignant disorders

Alice Bertaina,<sup>1</sup> Pietro Merli,<sup>1</sup> Sergio Rutella,<sup>1,2</sup> Daria Pagliara,<sup>1</sup> Maria Ester Bernardo,<sup>1</sup> Riccardo Masetti,<sup>3</sup> Daniela Pende,<sup>4</sup> Michela Falco,<sup>5</sup> Rupert Handgretinger,<sup>6</sup> Francesca Moretta,<sup>1</sup> Barbarella Lucarelli,<sup>1</sup> Letizia P. Brescia,<sup>1</sup> Giuseppina Li Pira,<sup>1</sup> Manuela Testi,<sup>7</sup> Caterina Cancrini,<sup>8</sup> Nabil Kabbara,<sup>9</sup> Rita Carsetti,<sup>1</sup> Andrea Finocchi,<sup>8</sup> Alessandro Moretta,<sup>10</sup> Lorenzo Moretta,<sup>5</sup> and Franco Locatelli<sup>1,11</sup>

### Key Points

- Removal of  $\alpha\beta^+$  T and CD19<sup>+</sup> B cells is an effective strategy for successful HLA-haploidentical hematopoietic stem cell transplantation.
- The high probability of disease-free survival renders this transplant option attractive for any child with a nonmalignant disorder.

**TRANSPLANTATION**

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**First 30 patients included 15 with malignant disease and 15 with non malignant disorders**

<b>Non malignant disorders included in the study</b>	<b>15</b>
Severe combined immunodeficiency (SCID)	4
Wiskott-Aldrich syndrome (WAS)	3
Fanconi Anemia	4
Beta Thalassemia	3
Hemophagocytic lymphohistiocytosis	1



## **Clinical outcome of initial 15 children with non-malignant disorders in the study so far**

- **BPX-501 T cells engraft and expand in all patients**
  - **In no patients given BPX-501 cells did secondary graft failure occur**
  - **Grade II skin-only GvHD was observed in 1 patient, but it promptly responded to topical steroids;**
  - **None of the patients so far have developed chronic GvHD;**
  - **No patient died from transplantation-related complications and all children are alive and disease-free**
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# Expansion of iC9-transduced T cells in patient #002

## CD3+/CD19+ and CMV reactivation

