

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): **December 9, 2013**

Emergent BioSolutions Inc.

(Exact Name of Registrant as Specified in Charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-33137**  
(Commission  
File Number)

**14-1902018**  
(IRS Employer  
Identification No.)

**2273 Research Boulevard, Suite 400, Rockville, Maryland**  
(Address of Principal Executive Offices)

**20850**  
(Zip Code)

Registrant's telephone number, including area code: **(301) 795-1800**

**Not applicable**

(Former Name or Former Address, if Changed Since Last Report)

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))
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**Item 8.01 Other Events.**

On December 9, 2013, Emergent BioSolutions Inc. announced positive interim results from a Phase 2 study evaluating the combination of otlertuzumab (TRU-016) and bendamustine versus bendamustine alone in people with relapsed chronic lymphocytic leukemia (CLL) (Study 16201). Overall response rate was the primary endpoint of the study. Data show that otlertuzumab in combination with bendamustine produced a higher response rate than bendamustine alone by International Workshop on CLL and National Cancer Institute response criteria. Overall incidence of adverse events, severe and serious adverse events were generally similar in both arms of the study. The Phase 2 data were presented at the American Society of Hematology annual meeting in New Orleans, Louisiana. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

On December 10, 2013, Emergent BioSolutions Inc. announced preliminary results from a Phase 1b single-arm, open-label study evaluating the safety and efficacy of otlertuzumab (TRU-016) in combination with rituximab in people with previously untreated chronic lymphocytic leukemia (CLL) (Study 16009). Data from the first cohort to have completed enrollment, presented during the American Society of Hematology annual meeting, showed that the combination was active and well tolerated. A copy of the press release is attached hereto as Exhibit 99.2 and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

99.1 Press Release issued by Emergent BioSolutions Inc. on December 9, 2013.

99.2 Press Release issued by Emergent BioSolutions Inc. on December 10, 2013.

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**SIGNATURE**

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: December 10, 2013

EMERGENT BIOSOLUTIONS INC.

By: /s/Robert G. Kramer

Robert G. Kramer

Executive Vice President and Chief Financial Officer

**Investor Contact**

Robert G. Burrows  
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**EMERGENT BIOSOLUTIONS PRESENTS POSITIVE INTERIM PHASE 2 DATA EVALUATING OTLERTUZUMAB (TRU-016) IN COMBINATION WITH BENDAMUSTINE IN PEOPLE WITH RELAPSED CHRONIC LYMPHOCYTIC LEUKEMIA**

**ROCKVILLE, Maryland—December 9, 2013**—Emergent BioSolutions Inc. (NYSE: EBS) today announced positive interim results from a Phase 2 study evaluating the combination of otlertuzumab (TRU-016) and bendamustine versus bendamustine alone in people with relapsed chronic lymphocytic leukemia (CLL) (Study 16201). Overall response rate was the primary endpoint of the study. Data show that otlertuzumab in combination with bendamustine produced a higher response rate than bendamustine alone by International Workshop on CLL (IWCLL) and National Cancer Institute (NCI) response criteria. Overall incidence of adverse events, severe and serious adverse events were generally similar in both arms of the study. The Phase 2 data were presented at the American Society of Hematology annual meeting in New Orleans, Louisiana.

Otlertuzumab is a humanized anti-CD37 mono-specific protein therapeutic that targets the CD37 signaling pathway involved in B-cell malignancies such as CLL, non-Hodgkin's lymphoma (NHL), diffuse large B-cell lymphoma (DLBCL) and other cancers of the blood. Otlertuzumab is built on Emergent's ADAPTIR™ (modular protein technology) platform, for the treatment of CLL.

"This is a revolutionary time in the treatment of CLL and we are pleased to present data that demonstrate proof of concept for otlertuzumab, a novel protein therapeutic," said Scott C. Stromatt, M.D., senior vice president and chief medical officer, Emergent BioSolutions. "We believe otlertuzumab has the potential for use in combination with existing or other experimental therapies to expand treatment options for people with CLL."

**About the Phase 2 (16201) Study**

In a Phase 2 multicenter, open-label, randomized, combination study, 65 patients with relapsed CLL who had 1-3 prior treatments were enrolled and randomized into one of two dosing schemes: 1) otlertuzumab (20 mg/kg) plus bendamustine (70mg/m<sup>2</sup>) or 2) bendamustine (70mg/m<sup>2</sup>) alone.

Results reported for subjects evaluable to date based on IWCLL criteria for the combination of otlertuzumab and bendamustine (n=29) showed the overall response rate (ORR) was 69 percent with a complete response (CR) rate of 14 percent. For bendamustine alone (n=31), the ORR was 32 percent with a CR rate of 3 percent. The NCI response rates for the combination of otlertuzumab and bendamustine (n=32) were 81 percent ORR and 22 percent CR compared to 64 percent ORR and 9 percent CR for bendamustine alone (n=33).

Overall incidence of adverse events, severe and serious adverse events were generally similar in both arms of the study. There was a greater incidence of severe neutropenia with the combination, but this did not result in a greater incidence of severe or serious infections. There was no increase in serious adverse events in the otlertuzumab plus bendamustine arm compared to the bendamustine arm.

**About Chronic Lymphocytic Leukemia (CLL)**

According to the American Cancer Society, CLL is the most common form of blood cancer. There are approximately 94,000 patients currently diagnosed with CLL in the U.S., with over 15,000 new cases diagnosed each year. Most cases of CLL (95 percent) start in white blood cells called B cells, the primary target of otlertuzumab.

**About Otlertuzumab (TRU-016)**

Otlertuzumab is a CD37-specific therapeutic protein in development for the treatment of B-cell malignancies such as CLL that was built on the ADAPTIR™ (modular protein technology) platform. CD37 is a tetraspanin protein expressed on the surface of normal and transformed B cells and demonstrates death signaling via SHP1.

**About the ADAPTIR™ Platform**

ADAPTIR monospecific proteins are single chain polypeptides that comprise three components: a binding domain (VL and VH), a hinge domain, and an effector domain (huFc). They have a differentiated structure from monoclonal antibodies and can generate a unique signaling response. In addition, ADAPTIR proteins may mediate complement dependent cytotoxicity and Fc dependent cytotoxicity, similar to monoclonal antibodies.

**About Emergent BioSolutions**

Emergent BioSolutions is a specialty pharmaceutical company seeking to protect and enhance life by offering specialized products to healthcare providers and governments to address medical needs and emerging health threats. Additional information about the company may be found at [www.emergentbiosolutions.com](http://www.emergentbiosolutions.com). Follow us @emergentbiosolu.

**Safe Harbor Statement**

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact, are forward-looking statements. Forward-looking statements in this press release include statements about the potential and therapeutic opportunity of otlertuzumab. These forward-looking statements are based on our current intentions, beliefs and expectations regarding future events. We cannot guarantee that any forward-looking statement will be accurate.

Investors should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from our expectations. Investors are, therefore, cautioned not to place undue reliance on any forward-looking statement. Any forward-looking statement speaks only as of the date of this press release, and, except as required by law, we do not undertake to update any forward-looking statement to reflect new information, events or circumstances.

There are a number of important factors that could cause the company's actual results to differ materially from those indicated by such forward-looking statements, including the success of our ongoing and planned clinical trials; the rate and degree of market acceptance and clinical utility of our products; the timing of and our ability to obtain and maintain regulatory approvals for our product candidates; and our commercialization, marketing and manufacturing capabilities and strategy. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement. Investors should consider this cautionary statement, as well as the risk factors identified in our periodic reports filed with the SEC, when evaluating our forward-looking statements.

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## **EMERGENT BIOSOLUTIONS' OTLERTUZUMAB (TRU-016) SHOWS POSITIVE RESULTS IN COMBINATION WITH RITUXIMAB IN PEOPLE WITH CLL**

**ROCKVILLE, Maryland—December 10, 2013**—Emergent BioSolutions Inc. (NYSE: EBS) today announced preliminary results from a Phase 1b single-arm, open-label study evaluating the safety and efficacy of otlertuzumab (TRU-016) in combination with rituximab in people with previously untreated chronic lymphocytic leukemia (CLL) (Study 16009). Data from the first cohort to have completed enrollment, presented during the American Society of Hematology annual meeting, showed that the combination was active and well tolerated.

Otlertuzumab is a humanized anti-CD37 monospecific protein therapeutic, built on Emergent's ADAPTIR™ (modular protein technology) platform, that targets the CD37 signaling pathway involved in B-cell malignancies such as CLL, non-Hodgkin's lymphoma (NHL), diffuse large B-cell lymphoma (DLBCL) and other cancers of the blood.

"Emergent is pleased with the data from Cohort 1 of this Phase 1b study that show the safety and activity of otlertuzumab in combination with rituximab," said Scott C. Stromatt, M.D., senior vice president and chief medical officer, Emergent BioSolutions. "The ability to possibly combine therapies like otlertuzumab with existing approved treatments or even future therapies could provide expanded treatment options to people with CLL."

### **About the Phase 1b (16009) Study**

The Phase 1b study, initiated in October 2012, was designed to evaluate the efficacy and safety of the combination of otlertuzumab and rituximab in patients with a diagnosis of CLL. In Cohort 1, twenty four previously untreated patients received otlertuzumab (20 mg/kg) followed by rituximab (375 mg/m<sup>2</sup> the first dose then 500 mg/m<sup>2</sup> for subsequent doses).

Overall response rate (ORR) by 2008 International Workshop on CLL (IWCLL) Response Criteria was the primary efficacy endpoint of the study. For the 20 patients who have necessary CT scans and have completed treatment, the ORR per IWCLL criteria was 50 percent. Complete response (CR), one of the secondary endpoints, was 5 percent. One patient was minimal residual disease (MRD) negative on examination of bone marrow by 5 color flow cytometry. The response by investigator assessment using National Cancer Institute criteria was an ORR of 96 percent and CR of 33 percent.

Otlertuzumab was well tolerated in Cohort 1. 54 percent of patients experienced infusion reactions, most of which were grade 1 or 2 with only two grade 3 reactions. None of the infusion reactions resulted in study drug discontinuation.

In April 2013, Emergent announced an expanded protocol to include two additional study cohorts to examine the combination of otlertuzumab and rituximab in relapsed CLL patients (Cohort 2) and to evaluate a lower dose of otlertuzumab in combination with rituximab in previously untreated patients (Cohort 3). Treatment and follow up are ongoing for patients in these expanded cohorts to determine response. Follow up of patients in all 3 cohorts will be continued in order to assess progression free survival.

### **About Chronic Lymphocytic Leukemia (CLL)**

According to the American Cancer Society, CLL is the most common form of blood cancer. There are approximately 94,000 patients currently diagnosed with CLL in the U.S., with over 15,000 new cases diagnosed each year. Most cases of CLL (95 percent) start in white blood cells called B cells, the primary target of otlertuzumab.

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