SIGA TECHNOLOGIES INC
Form 8-K
August 09, 2016

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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): August 8, 2016

SIGA TECHNOLOGIES, INC.
(Exact name of registrant as specified in its charter)

Delaware	0-23047	13-3864870
(State or other jurisdiction of incorporation or organization)	(Commission file number)	(I.R.S. employer identification no.)

660 Madison Avenue, Suite 1700
New York, New York 10065
(Address of principal executive offices) (Zip code)

Registrant's telephone number, including area code: (212) 672-9100

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))

Item 8.01. Other Events.

On August 8, 2016, SIGA Technologies, Inc. ("SIGA") issued a press release announcing that it has received approval from its Data Safety Monitoring Board ("DSMB") to complete enrollment in the second and final cohort of healthy subjects for the Phase III clinical study for its lead drug candidate, TPOXX™ (tecovirimat), for the treatment of orthopoxvirus infections. This determination was based on review of safety data from the first 125 participants in the final cohort. The final cohort of this Phase III study is being conducted at eleven approved clinical investigation sites in a total of approximately 380 subjects.

The initial Phase III cohort of 40 subjects in this trial was completed in 2015 without any reports of serious adverse events. Since TPOXX™ (tecovirimat) is being developed under the FDA "Animal Rule," there are only safety and not efficacy endpoints in this clinical trial. This Phase III study is wholly funded by the Biomedical Advanced Research and Development Authority ("BARDA").

SIGA also announced that it has submitted its final pivotal animal study reports to the Food and Drug Administration (the "FDA"). As a result of both the DSMB decision and the submission of the FDA animal final study reports, SIGA is eligible for a milestone payment from BARDA of $20.5 million.

Item 9.01. Financial Statements and Exhibits.

(c) Exhibits

Exhibit No.	Description
99.1	Press Release, dated August 8, 2016.

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.

SIGA TECHNOLOGIES, INC.

By: /s/ Daniel J. Luckshire
Name: Daniel J. Luckshire
Title: Chief Financial Officer

Date: August 9, 2016