

SIGA TECHNOLOGIES INC
Form 8-K
September 11, 2018

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): September 10, 2018

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

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| Delaware (State or other jurisdiction of incorporation or organization) | 0-23047 (Commission file number) | 13-3864870 (I.R.S. employer identification no.) |
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|---|---------------------|
| 31 East 62nd Street New York, New York (Address of principal executive offices) | 10065 (Zip code) |
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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))

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 1.01. Entry into a Material Definitive Agreement.

On September 10, 2018, SIGA Technologies, Inc., a Delaware corporation (the “Company”), issued a press release announcing that it has signed a multi-year contract (the “New BARDA Contract”) with the Biomedical Advanced Research and Development Authority (“BARDA”), a division of the U.S. Department of Health and Human Services’ Office of the Assistant Secretary for Preparedness and Response, for the delivery of oral and intravenous (IV) formulations of TPOXX® (“TPOXX”), the Company’s antiviral treatment for smallpox, to the Strategic National Stockpile. The New BARDA Contract also covers advanced development of the IV formulation of TPOXX and post-marketing activities for the oral formulation of TPOXX. The New BARDA Contract is valued at up to \$629 million, and consists of a five-year base period of performance and a total contract period of performance (base period plus option exercises) of up to ten years (if necessary). The contract contains base period activities and a series of options, and is designed to maintain a stockpile of 1.7 million courses of antiviral treatment for smallpox.

Under the New BARDA Contract, base period activities are valued at approximately \$52 million and include:

· Development activities for the IV formulation of TPOXX (IV TPOXX).

Delivery to the Strategic National Stockpile of a limited number of courses (approximately 35,700 courses) of the oral formulation of TPOXX (oral TPOXX) for an approximate value of \$11 million; such courses being readily available for delivery or to be manufactured using currently-held active pharmaceutical ingredient.

Delivery of bulk drug substance to be used for the manufacture of IV TPOXX and the use of such bulk drug substance to manufacture 20,000 courses of final drug product of IV TPOXX, with such activities having a total value of \$8 million for 7-day (14-vial) courses; additionally, the Company will be paid for the storage, if applicable, and delivery of final drug product of IV TPOXX.

With options valued at approximately \$577 million in total (if all options are fully exercised), the New BARDA Contract is primarily comprised of options that are exercisable at the sole discretion of BARDA.

Options within the contract include:

Series of options to procure up to approximately 1,452,300 courses in total of oral TPOXX (exclusive of the courses to be purchased for base period activities), with such options having a total value of up to approximately \$450 million.

Series of options to procure up to 192,000 courses in total (exclusive of the courses to be purchased for base period activities) of final drug product of IV TPOXX, with such options having a cumulative total value of up to approximately \$77 million for the combination of bulk drug substance and final drug product manufacturing; or alternatively, to procure up to 192,000 equivalent courses in total (exclusive of the equivalent courses to be purchased for base period activities) of bulk drug substance that could be used in the future for the manufacture of final drug product of IV TPOXX, with such alternative having a value of up to approximately \$31 million.

Series of options for vendor-managed storage of either bulk drug substance that would be used in the manufacture of the IV TPOXX or final drug product of IV TPOXX (total option value of approximately \$6 million).

Separate options to cumulatively provide up to approximately \$44 million of funding for post-marketing activities for oral TPOXX and IV TPOXX.

The New BARDA Contract becomes the third active contract between the Company and BARDA. Under its May 2011 procurement contract with BARDA, BARDA funded late-stage development of oral TPOXX for the treatment of smallpox, which culminated in the U.S. Food and Drug Administration (FDA) approval on July 13, 2018, and the acquisition of 2 million courses of oral TPOXX, which the Company has delivered. Under a development contract with BARDA, the Company receives funding from BARDA for the development of the IV formulation of TPOXX to provide a treatment option for patients who are too sick or unable to swallow oral capsules. It is anticipated that patients taking the IV formulation would eventually transition to the oral formulation, once they are able to swallow

capsules. To accommodate this dosing regimen, the New BARDA Contract includes an initial order and options for the purchase of up to 212,000 treatment courses (in total) of IV therapy, and each treatment course is expected to cover seven (7) days (14 vials) of treatment. Oral TPOXX approval and procurement is based upon 14 total days of therapy.

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The foregoing description is qualified in its entirety by reference to the New BARDA Contract, a copy of which is attached as Exhibit 10.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits

(d) The following exhibits are included in this report:

| Exhibit No. | Description |
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| <u>10.1</u> | Contract, dated as of September 10, 2018, between SIGA Technologies, Inc. and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services (portions of this exhibit have been omitted and separately filed with the Securities and Exchange Commission with a request for confidential treatment). |
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| <u>99.1</u> | Press Release, dated September 10, 2018. |
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SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, 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: September 10, 2018
