Biostage, Inc.
Form 8-K
October 06, 2016

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): October 6, 2016

BIOSTAGE, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-35853**	**45-5210462**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

84 October Hill Road, Suite 11, Holliston, MA	**01746**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(774) 233-7300**

(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:

¨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 October 6, 2016, Biostage, Inc., or the Company, issued a press release announcing a regulatory update following its planned pre-Investigational New Drug, or IND, meeting with the U.S. Food and Drug Administration, or FDA, for the advancement of its lead product candidate, Cellspan™ Esophageal Implant, into human clinical studies. The regulatory update included that the Company now expects to file its IND application with the FDA by the end of the second quarter of 2017 based on its election to extend the duration of its ongoing GLP animal studies following the feedback provided by the FDA. The Company's meeting with the FDA and related feedback are discussed in more detail in the press release.

The press release is furnished as Exhibit 99.1 and investors should read the press release in its entirety, including the cautionary statement regarding forward looking statements therein. The forward looking statement above filed in this Form 8-k, as well as those furnished in the Exhibit 99.1 as noted below, involve known and unknown risks, uncertainties and other factors that may cause the Company's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Title
99.1	Press Release issued by Biostage, Inc. on October 6, 2016 (1)

(1) The press release is furnished as Exhibit 99.1. The information in Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the United States Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the United States Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

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.

BIOSTAGE, INC.
(Registrant)

October 6, 2016 **/s/ Thomas McNaughton**
(Date) Thomas McNaughton
Chief Financial Officer

INDEX TO EXHIBITS

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