

Biostage, Inc.
Form 8-K
February 13, 2018

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): February 13, 2018

BIOSTAGE, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction

of incorporation)

001-35853

(Commission File Number) (IRS Employer Identification No.)

45-5210462

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))

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 7.01 Regulation FD Disclosure.

On Tuesday, February 13, 2018 at 9:00 AM (Eastern Time), Biostage, Inc., or the Company, hosted a conference call with investors, or the Investor Call, during which the Company provided an update on recent events at the Company and discussed other matters relating to the business, including operations, plans and outlook. These updates included, among other things:

An update regarding the compassionate use patient that received the first esophageal implant in May 2017 as part of a broader FDA approved compassionate use surgery. The 75 year old patient had a large tumor spanning his heart, lung, and esophagus. The surgery was performed to remove the tumor, repair the heart, one lung, and a section of the esophagus. Following the surgery, the patient was discharged and the hospital reported to the Company there had been clear signs of regeneration with respect to the esophageal implant. The Company was informed yesterday by the principle investigator, the patient's surgeon, that after living for over eight months following the surgery, the patient -had died. He stated that the cause of death was stroke, and that the stroke was unrelated to the Company's esophageal implant. The principle investigator also informed the Company that a preliminary autopsy shows the Company's esophageal implant resulted in a regenerated esophageal tube in the patient except for a very small (approximately 5mm) hole on the lateral wall that was right up against a synthetic graft inserted as part of the patient's heart repair on the pericardium in that same surgery. The synthetic graft on the pericardium was not related to the Company's esophageal implant product. The principle investigator also informed the Company that the esophageal regeneration in this patient was consistent with the regeneration previously observed in the Company's large-animal studies.

A replay of the Investor Call, including any questions and answers that occurred on the Investor Call following the scripted portion, will be available for one week following the call and can be accessed during that period by dialing (877) 660-6853 (domestic) or (201) 612-7415 (international) with Conference ID #: 13676470. Such replay will also be available for 60 days on the Events page of the Investors section on the Company's web site, www.biostage.com.

In addition, the Company posted an updated version of its investor presentation on its website, which the Company may use from time to time. Investors should read the updated investor presentation in its entirety, including the cautionary statement regarding forward looking statements in the beginning of the presentation.

This Form 8-k, the Investor Call and the updated investor presentation contain remarks regarding management's intentions, hopes, beliefs, expectations, or predictions of the future. These are forward looking statements that 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. As a result, you should not place undue reliance on any forward-looking statements. Some of the factors that could cause actual results to differ materially from those contemplated by such forward-looking statements are described under the heading "Item 1A. Risk Factors" in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 or in the Company's other periodic reports filed by the Company with the Securities and Exchange Commission. These documents are available in the Investors section of the Company's website and on the Securities and Exchange Commission's website. We encourage you to review these

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documents carefully. The forward-looking statements in this Form 8-k, on the Investor Call and in the updated investor presentation speak only as of the date of the respective disclosure. The Company expressly disclaims any obligation or undertaking to release publicly any updates or revisions to such statements to reflect any change in its expectations with regard thereto or any changes in the events, conditions or circumstances on which any such statement is based.

To view the updated investor presentation, please visit the following link:

<http://ir.biostage.com/events-and-presentations>

The information disclosed under this Item 7.01 is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and shall not be deemed incorporated by reference into any filing made under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such 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)

February 13, 2018 /s/ **Thomas McNaughton**
(Date) Thomas McNaughton
Chief Financial Officer