

84 October Hill Road, Suite 11, Holliston, Massachusetts 01746

(Address of Principal Executive Offices, including zip code)

(774)233-7300

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, \$0.01 par value

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
YES NO

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. YES NO

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES NO

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).
YES NO

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Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. "

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer "

Accelerated filer "

Non-accelerated filer " (Do not check if a smaller reporting company)

Smaller reporting company x

Emerging growth company x

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. "

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act. YES
" NO x

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of June 30, 2017 was approximately \$15,081,053. Shares of the registrant's common stock held by each officer and director and each person known to the registrant to own 10% or more of the outstanding voting power of the registrant have been excluded in that such persons may be deemed affiliates. This determination of affiliate status is not a determination for other purposes.

At March 30, 2018, there were 2,859,419 shares of the registrant's common stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Company's definitive Proxy Statement in connection with the 2018 Annual Meeting of Stockholders (the "Proxy Statement"), to be filed within 120 days after the end of the Registrant's fiscal year, are incorporated by reference into Part III of the Form 10-K amended by this Amendment No. 1. Except with respect to information specifically incorporated by reference in the Form 10-K amended by this Amendment No. 1, the Proxy Statement is not deemed to be filed as part hereof.

EXPLANATORY NOTE

The sole purpose of this Amendment No. 1 to the Annual Report on Form 10-K for the fiscal year ended December 31, 2017 (the "Form 10-K") of Biostage, Inc., as filed with the Securities and Exchange Commission on April 2, 2018, is to file Exhibit 101 to the Form 10-K in accordance with Rule 405 of Regulation S-T. Exhibit 101 provides the financial statements and related notes from the Form 10-K formatted in XBRL (eXtensible Business Reporting Language). Exhibit 101 was not filed with the Form 10-K previously and no other changes have been made to the Form 10-K.

This Amendment No. 1 to the Form 10-K does not reflect events that may have occurred subsequent to the original filing date of the Form 10-K and does not modify or update in any way disclosures made in the Form 10-K as originally filed.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

- (b) Exhibits: The exhibits listed in the accompanying Exhibit Index are filed as a part of this Amendment No. 1 to Annual Report on Form 10-K.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Biostage, Inc.
Date: April 3, 2018
By: /s/ James McGorry
James McGorry
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

| Signature | Title | Date |
|---|---|---------------|
| /s/ James McGorry James McGorry | Chief Executive Officer and Director (Principal Executive Officer) | April 3, 2018 |
| /s/ Thomas McNaughton Thomas McNaughton | Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer) | April 3, 2018 |

EXHIBIT INDEX

The following exhibits are filed as part of this Annual Report on Form 10-K. Where such filing is made by incorporation by reference to a previously filed document, such document is identified.

| Exhibit Number | Description of Exhibit |
|-----------------------------|---|
| <u>2.1</u> ⁽³⁾ | <u>Separation and Distribution Agreement between Biostage, Inc. and Harvard Bioscience, Inc. dated as of October 31, 2013.</u> |
| <u>3.1</u> ⁽¹⁾ | <u>Amended and Restated Certificate of Incorporation of Biostage, Inc.</u> |
| <u>3.2</u> ⁽¹⁴⁾ | <u>Certificate of Amendment to Amended and Restated Certificate of Incorporation of Biostage, Inc. dated March 30, 2016.</u> |
| <u>3.3</u> ⁽¹⁶⁾ | <u>Certificate of Amendment to Amended and Restated Certificate of Incorporation of Biostage, Inc. dated May 26, 2016.</u> |
| <u>3.4</u> ⁽¹⁴⁾ | <u>Amended and Restated By-laws of the Biostage, Inc.</u> |
| <u>3.5</u> ⁽²⁾ | <u>Certificate of Designations, Preferences and Rights of Series A Preferred Stock of Biostage, Inc. classifying and designating the Series A Junior Participating Cumulative Preferred Stock.</u> |
| <u>3.6</u> ⁽⁶⁾ | <u>Certificate of Designation of Series B Convertible Preferred Stock of Biostage, Inc. classifying and designating the Series B Convertible Preferred Stock.</u> |
| <u>3.8</u> ⁽¹⁷⁾ | <u>Certificate of Amendment to Amended and Restated Certificate of Incorporation of Biostage, Inc. dated April 26, 2017.</u> |
| <u>3.9</u> ⁽¹⁹⁾ | <u>Certificate of Designations, Preferences, Rights and Limitations of Series C Convertible Preferred Stock of Biostage, Inc. classifying and designating the Series C Convertible Preferred Stock.</u> |
| <u>3.10</u> ⁽¹⁹⁾ | <u>Certificate of Elimination of Series A Junior Participating Cumulative Preferred Stock.</u> |
| <u>3.11</u> ⁽²⁰⁾ | <u>Certificate of Amendment to Amended and Restated Certificate of Incorporation of Biostage, Inc. dated December 22, 2017.</u> |
| <u>3.12</u> ⁽²³⁾ | <u>Certificate of Designations, Preferences, Rights and Limitations of Series D Convertible Preferred Stock of Biostage, Inc. classifying and designating the Series D Convertible Preferred Stock.</u> |
| <u>4.1</u> ⁽¹⁾ | <u>Specimen Stock Certificate evidencing shares of common stock</u> |
| <u>4.2</u> ⁽⁷⁾ | <u>Specimen Series B Convertible Preferred Stock Certificate</u> |
| <u>4.3</u> ⁽¹⁰⁾ | <u>Registration Rights Agreement, dated December 15, 2015, between Biostage, Inc. and Aspire Capital Fund, LLC.</u> |
| <u>4.4</u> ⁽¹⁹⁾ | <u>Amendment No. 2 to Shareholder Rights Agreement, dated as of August 14, 2017 between Biostage, Inc. and Computershare Trust Company, N.A., as successor to Registrar and Transfer Company.</u> |
| <u>4.5</u> ⁽²³⁾ | <u>Form of Common Stock Purchase Warrant.</u> |
| <u>10.1</u> ⁽³⁾ | <u>Intellectual Property Matters Agreement between Biostage, Inc. and Harvard Bioscience, Inc. dated as of October 31, 2013.</u> |
| <u>10.2</u> ⁽³⁾ | <u>Product Distribution Agreement between Biostage, Inc. and Harvard Bioscience, Inc. dated as of October 31, 2013.</u> |
| <u>10.3</u> ⁽³⁾ | <u>Tax Sharing Agreement between Biostage, Inc. and Harvard Bioscience, Inc. dated as of October 31, 2013.</u> |
| <u>10.4</u> ⁽³⁾ | <u>Transition Services Agreement between Biostage, Inc. and Harvard Bioscience, Inc. dated as of October 31, 2013.</u> |

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- 10.5⁽³⁾ Sublease by and between Biostage, Inc. and Harvard Bioscience, Inc. dated as of October 31, 2013.
- 10.6#⁽³⁾ Employment Agreement between Biostage, Inc. and Thomas McNaughton dated as of October 31, 2013.
- 10.7⁽¹⁾ Form of Indemnification Agreement for Officers and Directors.
- 10.8⁽¹⁾ 2013 Equity Incentive Plan.
- 10.9⁽¹⁾ Employee Stock Purchase Plan.
- 10.10⁽¹⁾ Form of Incentive Stock Option Agreement.
- 10.11⁽¹⁾ Form of Non-Qualified Stock Option Agreement for executive officers.
- 10.12⁽¹⁾ Form of Non-Qualified Stock Option Agreement for directors.
- 10.13⁽¹⁾ Form of Deferred Stock Award Agreement.
- 10.14#⁽¹⁾ Director Compensation Arrangements.
- 10.15^{†4)} Sublicense Agreement dated as of December 7, 2012 between Biostage, Inc. and Harvard Bioscience, Inc., and related Trademark License Agreement, dated December 19, 2002, by and between Harvard Bioscience, Inc. and President and Fellows of Harvard College.
- 10.16⁽¹⁾ Patent Rights Assignment dated December 21, 2012 between Biostage, Inc. and Dr. Paolo Macchiarini.

- 10.17⁽¹⁾ Novel Surgery Agreement dated as of May 21, 2012 between Biostage, Inc. and State Budget Institution of Public Health Department Regional Clinical Hospital #1 and Vladimir Alekseevich Porhanov.
- 10.18⁽¹⁾ Novel Surgery Agreement dated as of May 24, 2012 between Biostage, Inc. and OSF Healthcare System, owner and operator of Saint Francis Medical Center and Children’s Hospital of Illinois, and Mark Holterman, M.D.
- 10.19⁽¹⁾ Amendment to Novel Surgery Agreement dated as of April 5, 2013 between Biostage, Inc. and OSF Healthcare System, owner and operator of Saint Francis Medical Center and Children’s Hospital of Illinois, and Mark Holterman, M.D.
- 10.20⁽¹⁾ Amendment to Novel Surgery Agreement dated as of June 26, 2013 between Biostage, Inc. and State Budget Institution of Public Health Department Regional Clinical Hospital #1 and Igor S. Polyakov.
- 10.21^{#(8)} Employment Agreement between Biostage, Inc. and James McGorry dated as of June 23, 2015.
- 10.22⁽¹²⁾ Securities Purchase Agreement, dated May 15, 2016, between Biostage, Inc. and the purchasers named therein.
- 10.23⁽¹²⁾ Form of Common Stock Purchase Warrant
- 10.24⁽¹²⁾ Engagement Letter, dated as of May 15, 2016, between Biostage, Inc. and Rodman & Renshaw, a unit of H.C. Wainwright & Co., LLC.
- 10.25⁽¹³⁾ Amendment to Engagement Letter, dated as of May 18, 2016, between Biostage, Inc. and Rodman & Renshaw, a unit of H.C. Wainwright & Co., LLC.
- 10.26^{#(16)} Letter Agreement, dated as of December 17, 2016, between Biostage, Inc. and Saverio LaFrancesca, M.D.
- 10.27⁽¹⁵⁾ Form of Securities Purchase Agreement.
- 10.28⁽¹⁵⁾ Form of Common Stock Purchase Warrant.
- 10.29⁽¹⁵⁾ Form of Placement Agent Common Stock Purchase Warrant.
- 10.30⁽¹⁵⁾ Engagement Agreement, dated as of January 3, 2017, between Biostage, Inc. and Rodman & Renshaw, a unit of H.C. Wainwright.
- 10.31⁽¹⁵⁾ Amendment to Engagement Agreement, dated February 7, 2017, between Biostage, Inc. and Rodman & Renshaw, a unit of H.C. Wainwright.
- 10.32⁽¹⁸⁾ Memorandum of Understanding, dated as of June 26, 2017, between Biostage, Inc. and First Pecos, LLC.
- 10.33⁽¹⁹⁾ Securities Purchase Agreement, dated August 11, 2017, between Biostage, Inc. and the purchasers named therein.
- 10.34⁽²²⁾ Memorandum of Understanding, dated as of December 11, 2017, between Biostage, Inc. and Bin Zhao.
- 10.35⁽²³⁾ Securities Purchase Agreement, dated December 27, 2017, between Biostage, Inc. and the purchasers named therein.
- 10.36⁽²³⁾ Securities Purchase Agreement, dated December 29, 2017, between Biostage, Inc. and Connecticut Children’s Medical Center.
- 21.1⁽¹⁶⁾ Subsidiaries of Biostage, Inc.
- 23.1⁽²⁵⁾ Consent of KPMG LLP.
- 31.1* Certification of Chief Financial Officer of Biostage., pursuant to Rules 13a-15(e) and 15d-15(e), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2* Certification of Chief Executive Officer of Biostage, Inc., pursuant to Rules 13a-15(e) and 15d-15(e), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1** Certification of Chief Financial Officer of Biostage, Inc., pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2** Certification of Chief Executive Officer of Biostage, Inc., pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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101.INS* XBRL Instance Document.

101.SCH* XBRL Taxonomy Extension Schema Document.

101.CAL* XBRL Taxonomy Extension Calculation Linkbase Document.

101.DEF* XBRL Taxonomy Extension Definition Linkbase Document.

101.LAB* XBRL Taxonomy Extension Label Linkbase Document.

101.PRE* XBRL Taxonomy Extension Presentation Linkbase Document.

- (1) Previously filed as an exhibit to the Company's Registration Statement on Form 10-12B (filed July 31, 2013) and incorporated by reference thereto.
- (2) Previously filed as an exhibit to the Company's Registration Statement on Form 8-A (filed October 31, 2013) and incorporated by reference thereto.
- (3) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on November 6, 2013) and incorporated by reference thereto.
- (4) Previously filed as an exhibit to the Company's Amendment No. 2 to Form S-1 Registration Statement (filed on February 15, 2013) and incorporated by reference thereto.
- (5) Previously filed as Exhibit 10.19 to the Registrant's Amendment No. 2 to Form S-1 Registration Statement (filed on February 15, 2013) and incorporated by reference thereto.
- (6) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on February 12, 2015) and incorporated by reference thereto.
- (7) Previously filed as an exhibit to the Company's Annual Report on Form 10-K (filed on March 27, 2015) and incorporated by reference thereto.
- (8) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on July 6, 2015) and incorporated by reference thereto.
- (9) Previously filed as an exhibit to the Company's Quarterly Report on Form 10-Q (filed on August 14, 2015) and incorporated by reference thereto.
- (10) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on December 15, 2015) and incorporated by reference thereto.
- (11) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on March 24, 2016) and incorporated by reference thereto.
- (12) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on May 16, 2016) and incorporated by reference thereto.
- (13) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on May 20, 2016) and incorporated by reference thereto.
- (14) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on March 31, 2016) and incorporated by reference thereto.
- (15)

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Previously filed as an exhibit to the Company's Amendment No. 2 to Form S-1 Registration Statement (filed on February 7, 2017) and incorporated by reference thereto.

- (16) Previously filed as an exhibit to the Company's Annual Report on Form 10-K (filed on March 17, 2017) and incorporated by reference thereto.
- (17) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on April 27, 2017) and incorporated by reference thereto.
- (18) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on June 27, 2017) and incorporated by reference thereto.
- (19) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on August 17, 2017) and incorporated by reference thereto.
- (20) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on December 22, 2017) and incorporated by reference thereto.
- (21) Previously filed as an exhibit to the Company's Form S-1 Registration Statement (filed on August 15, 2017) and incorporated by reference thereto.
- (22) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on December 14, 2017) and incorporated by reference thereto.
- (23) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on January 3, 2018) and incorporated by reference thereto.
- (24) Previously filed as an exhibit to the Company's Current Report on Form 8-K (filed on February 8, 2018) and incorporated by reference thereto.
- (25) Previously filed as an exhibit to the Company's Annual Report on Form 10-K (filed on April 2, 2018) and incorporated by reference thereto.

* Filed herewith.

This certification shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or **otherwise subject to the liability of that section, nor shall it be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934.

Management contract or compensatory plan or arrangement.

The schedules and exhibits to the Separation and Distribution Agreement have been omitted. A copy of any omitted § schedule or exhibit will be furnished to the SEC supplementally upon request. The Company will furnish to stockholders a copy of any exhibit without charge upon written request.

† Confidential portions of this exhibit have been redacted and filed separately with the SEC pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

