Verastem, Inc.
Form 8-K
November 02, 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 29, 2016

Verastem, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-35403**	**27-3269467**
(State or other jurisdiction of incorporation)	(Commission file number)	(I.R.S. Employer Identification Number)

117 Kendrick Street, Suite 500 **Needham, MA**	**02494**
(Address of principal executive offices)	(Zip code)

(781) 292-4200

(Registrant s telephone number,

including area code)

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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 1.01 Entry into a Material Definitive Agreement

On October 29, 2016 (the Effective Date), Verastem, Inc. (the Company) entered into a license agreement with Infinity Pharmaceuticals, Inc. (Infinity), which the Company and Infinity amended and restated on November 1, 2016, effective as of October 29, 2016 (the License Agreement). Under the terms of the License Agreement, Infinity granted to the Company an exclusive worldwide license for the research, development, commercialization, and manufacture of products in oncology indications containing duvelisib, an investigational, oral, dual inhibitor of phosphoinositide-3 kinase (PI3K)-delta and PI3K-gamma (the Products). Following the Effective Date, the Company will assume financial responsibility for activities that are part of Infinity s ongoing duvelisib program, including a randomized, Phase 3 monotherapy clinical study in patients with relapsed/refractory chronic lymphocytic leukemia (the DUO Study), except that Infinity will assume financial responsibility for the shutdown of certain specified clinical studies up to a maximum of $4.5 million. Following a short transition period, the Company will assume all operational responsibility for the duvelisib program. The Company is obligated to use diligent efforts to develop and commercialize one Product. During the term of the License Agreement, Infinity has agreed not to research, develop, manufacture or commercialize duvelisib in any other indication in humans or animals.

Pursuant to the terms of the License Agreement, the Company is required to make the following payments to Infinity in cash or, at the Company s election, in whole or in part, in shares of Company common stock: (i) $6 million upon the completion of the DUO Study if the results of the DUO Study meet certain pre-specified criteria and (ii) $22 million upon the approval of a new drug application in the United States or an application for marketing authorization with a regulatory authority outside of the United States for a Product. For any portion of any of the foregoing payments which the Company elects to issue in shares of common stock in lieu of cash, the number of shares of common stock to be issued will be determined by multiplying (1) 1.025 by (2) the number of shares of common stock equal to (a) the amount of the payment to be paid in shares of common stock divided by (b) the average closing price of a share of common stock as quoted on NASDAQ for a twenty-day period following the public announcement of the applicable milestone event. The shares of common stock will be issued as unregistered securities, and the Company will have an obligation to promptly file a registration statement with the SEC to register such shares for resale. Any issuance of shares will be subject to the satisfaction of closing conditions, including that all material authorizations, consents, approvals and the like necessary for such issuance shall have been obtained.

The Company is also obligated to pay Infinity royalties on worldwide net sales of Products ranging from the mid-single digits to the high single-digits. The royalties will expire on a product-by-product and country-by-country basis until the latest to occur of (i) the last-to-expire patent right covering the applicable Product in the applicable country, (ii) the last-to-expire patent right covering the manufacture of the applicable Product in the country of manufacture of such Product, (iii) the expiration of non-patent regulatory exclusivity in such country and (iv) ten years following the first commercial sale of a Product in a country, provided that if royalties on net sales for a Product in the United States are payable solely on the basis of non-patent regulatory exclusivity, the applicable royalty on net sales for such Product in the United States will be reduced by 50%. The royalties are also subject to reduction by 50% of certain third-party royalty payments or patent litigation damages or settlements which might be required to be paid by the Company if litigation were to arise, with any such reductions capped at 50% of the amounts otherwise payable during the applicable royalty payment period.

In addition to the foregoing, the Company is obligated to pay Infinity an additional royalty of 4% on worldwide net sales of Products to cover the reimbursement of research and development costs owed by Infinity to Mundipharma International Corporation Limited (MICL) and Purdue Pharmaceutical Products L.P. (Purdue). Once Infinity has fully reimbursed MICL and Purdue, the royalty obligations will be reduced to 1% of net sales in the United States (Trailing MICL Royalties). The Trailing MICL

Royalties are payable until the later to occur of the last-to-expire of specified patent rights and the expiration of non-patent regulatory exclusivities in a country. Each of the above royalty rates is reduced by 50% on a product-by-product and country-by-country basis if the applicable royalty is payable solely on the basis of non-patent regulatory exclusivity. In addition, the Trailing MICL Royalties are subject to reduction by 50% of certain third-party royalty payments or patent litigation damages or settlements which might be required to be paid by the Company if litigation were to arise, with any such reductions capped at 50% of the amounts otherwise payable during the applicable royalty payment period.

The Company and Infinity have made customary representations and warranties and have agreed to certain customary covenants, including confidentiality and indemnification.

The License Agreement expires when each party no longer has any obligations to the other party. The Company has

the right to terminate the License Agreement upon at least 180 days prior written notice to Infinity at any time following the determination that the DUO Study has or has not met its pre-specified primary endpoint. Each party can terminate the License Agreement if the other party materially breaches or defaults in the performance of its obligations. If Infinity terminates for the Company s material breach, patent challenge, or insolvency, or if the Company terminates for convenience, then, at Infinity s request and subject to Infinity s execution of a waiver of certain types of damages, the Company will transition the duvelisib program back to Infinity at the Company s cost. If the Company terminates for Infinity s breach or insolvency, the Company will effect a more limited transition of the duvelisib program to Infinity at Infinity s request and cost, subject to Infinity s execution of a waiver of certain types of damages, and Infinity will thereafter pay to the Company a low single-digit royalty on net sales of Products.

Item 2.01 Completion of Acquisition or Disposition of Assets

The information under Item 1.01 of this Current Report on Form 8-K is incorporated herein by reference.

Item 8.01 Other Events

On November 2, 2016, the Company issued a press release announcing that it had entered into the License Agreement. A copy of such press release is filed as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits

(a) Financial Statements of Business Acquired

If financial statements are required by Item 9.01(a) of Form 8-K, the Company will file such financial statements by amendment within 71 calendar days after the date that this Current Report on Form 8-K is required to be filed.

(b) Pro Forma Financial Information

If pro forma financial information is required by Item 9.01(b) of Form 8-K, the Company will file such pro forma financial information by amendment within 71 calendar days after the date that this Current Report on Form 8-K is required to be filed.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by Verastem, Inc. on November 2, 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.

VERASTEM, INC.

By:	/s/ Joseph Chiapponi
Name:	Joseph Chiapponi
Title:	Vice President, Finance (Principal financial and accounting officer)

Date: November 2, 2016

EXHIBIT INDEX

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