

**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
(State or other jurisdiction
of incorporation)

001-35403
(Commission file number)

27-3269467
(I.R.S. Employer
Identification Number)

117 Kendrick Street, Suite 500
Needham, MA
(Address of principal
executive offices)

02494
(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:

- 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 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

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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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by Verastem, Inc. on November 2, 2016

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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)

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release issued by Verastem, Inc. on November 2, 2016



Verastem Licenses Duvelisib from Infinity Pharmaceuticals

Transaction Adds Complementary Late-Stage Product Candidate from a Clinically Validated Drug Class to Verastem's Pipeline

Duvelisib Has Demonstrated Clinical Activity in Lymphoid Malignancies

License of Duvelisib Aligns with Verastem's Focus on Targeting the Tumor Microenvironment

Verastem Management to Host Conference Call and Webcast at 8:30 a.m. ET Today

BOSTON, MA and CAMBRIDGE, MA — November 2, 2016 — Verastem, Inc. (NASDAQ: VSTM) and Infinity Pharmaceuticals, Inc. (NASDAQ: INFI), today announced that the companies entered into a license agreement under which Verastem licensed exclusive worldwide rights to develop and commercialize Infinity's oncology product candidate duvelisib. Duvelisib is an oral inhibitor of phosphoinositide-3-kinase (PI3K)-delta and PI3K-gamma being investigated for the treatment of hematologic cancers, including chronic lymphocytic leukemia (CLL), indolent non-Hodgkin lymphoma (iNHL) and T cell lymphomas. Verastem will pay to Infinity up to \$28 million in milestones, with positive data from DUO®, a Phase 3, randomized monotherapy study of duvelisib in patients with relapsed/refractory CLL, triggering the first milestone payment, and royalties on net sales.

"Duvelisib is a clinically validated, late-stage product candidate with a proven mechanism of action. This transaction has an attractive risk/reward profile given the modest financial investment prior to obtaining topline data from the DUO study, currently anticipated in the first half of 2017, as well as the potential applications for a variety of other lymphoid malignancies," said Robert Forrester, President and Chief Executive Officer of Verastem. "Duvelisib complements Verastem's oncology pipeline by augmenting our strategic focus of developing small molecule agents that target malignant cells both directly and through modulation of the tumor microenvironment. This transaction represents a positive step toward our goal of bringing new treatment options to patients with cancer. We are working closely with Infinity to ensure a smooth transition of the duvelisib program."

"The potential of duvelisib is supported by clinical data demonstrating anti-cancer activity and a manageable safety profile in a wide range of lymphoid malignancies, including relapsed/refractory iNHL, CLL and T cell lymphomas," said Gregory I. Berk, MD, Chief Medical Officer of Verastem. "While there have been significant advances recently in the treatment of lymphoid malignancies, not all patients experience benefits or can tolerate these treatments. There remains a need for new oral medicines, and the targeted inhibition of PI3K-delta and PI3K-gamma brings a unique approach designed to address both the malignant B cell and its supportive microenvironment. We look forward to reporting data from the DUO study, which could enable a submission for regulatory approval."

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"Infinity has always been committed to finding innovative ways to develop novel medicines which hold significant promise for people living with cancer. Verastem provides duvelisib the best opportunity to advance toward regulatory filings and potential commercialization given their oncology-focused capabilities and deep knowledge of the tumor microenvironment," stated Adelene Perkins, President and Chief Executive Officer of Infinity. "Additionally, the license of duvelisib fulfills an important strategic goal for Infinity by preserving cash while enabling our shareholders to participate in the value of the duvelisib program through potential milestone payments and royalties to Infinity."

Terms of Transaction

Under the terms of the license agreement, Verastem is obligated to pay to Infinity up to \$28 million in milestones. Infinity is entitled to receive two milestone payments, \$6 million upon positive data from the DUO study and \$22 million upon the first regulatory approval inside or outside of the U.S. Verastem will also pay Infinity tiered mid-to-high single-digit royalties on net sales and will be responsible for the single-digit-royalty on net sales of duvelisib owed by Infinity to MundiPharma International Corporation Limited and Purdue Pharmaceutical Products L.P.

Verastem's Expanded Oncology Pipeline

In addition to duvelisib, Verastem also holds worldwide rights to the tumor microenvironment-targeting focal adhesion kinase (FAK) inhibitors defactinib (VS-6063) and VS-4718. Verastem's lead FAK inhibitor, defactinib, is currently being evaluated in three separate clinical collaborations in combination with immunotherapeutic agents for the treatment of several different cancer types, including pancreatic, ovarian, non-small cell lung cancer, and mesothelioma. These studies are combination clinical trials with pembrolizumab or avelumab from Merck & Co. and Pfizer/Merck KGaA, respectively. Verastem also owns rights to the FAK inhibitor VS-4718 and the dual PI3K and mTORC1/2 inhibitor VS-5584 which are both currently being evaluated in Phase 1 clinical studies.

Financial Guidance

Based on current operating plans including duvelisib, Verastem expects to have sufficient cash, cash equivalents and short-term investments to fund its research and development programs and operations into 2018.

Conference Call Information

Verastem will host a conference call on November 2, 2016, at 8:30 a.m. ET to discuss the license agreement announced today. The call can be accessed by dialing 877-341-5660 (U.S. and Canada) or 315-625-3226 (international), and entering passcode 12230467. To access the live webcast, please use either the following link: <http://edge.media-server.com/m/p/vsavgfj6j> or visit the investors section of the Verastem website at www.verastem.com. A replay of the call will be available on the Company's website for a period of 180 days from today.

About the Tumor Microenvironment

The tumor microenvironment encompasses various cellular populations and extracellular matrices within the tumor or cancer niche that support cancer cell survival. This includes immunosuppressive cell populations such as regulatory T cells, myeloid-derived suppressor cells, M2 tumor-associated macrophages, as well as tumor-associated fibroblasts and extracellular matrix proteins which can hamper the entry and therapeutic benefit of cytotoxic immune cells and anti-cancer drugs. In addition to targeting the proliferative

and survival signaling of cancer cells, Verastem's compounds duvelisib, defactinib, VS-4718 and VS-5584 also target the tumor microenvironment as a mechanism of action to potentially improve a patient's response to therapy.

About Duvelisib

Duvelisib is an investigational, dual inhibitor of phosphoinositide 3-kinase (PI3K)-delta and PI3K-gamma, two enzymes that are known to help support the growth and survival of malignant B cells and T cells. PI3K signaling may lead to the proliferation of malignant B cells and is thought to play a role in the formation and maintenance of the supportive tumor microenvironment.(1),(2),(3) Duvelisib is currently being evaluated in late- and mid-stage clinical trials, including DUO®, a randomized, Phase 3 monotherapy study in patients with relapsed/refractory chronic lymphocytic leukemia (CLL)(4), and DYNAMO®, a single-arm, Phase 2 monotherapy study in patients with refractory indolent non-Hodgkin lymphoma (iNHL) that achieved its primary endpoint of overall response rate upon topline analysis of efficacy data(5). Duvelisib is also being evaluated for the treatment of hematologic malignancies through investigator-sponsored studies, including T cell lymphoma.(6) Information about duvelisib clinical trials can be found on www.clinicaltrials.gov.

About Defactinib

Defactinib (VS-6063) is an investigational inhibitor of Focal Adhesion Kinase (FAK), a non-receptor tyrosine kinase encoded by the PTK-2 gene that mediates oncogenic signaling in response to cellular adhesion and growth factors.(7) Based on the multi-faceted roles of FAK, defactinib is used to treat cancer through modulation of the tumor microenvironment, enhancement of anti-tumor immunity, and reduction of cancer stem cells.(8),(9) Defactinib is currently being evaluated in three separate clinical collaborations in combination with immunotherapeutic agents for the treatment of several different cancer types including pancreatic, ovarian, non-small cell lung cancer, and mesothelioma. These studies are combination clinical trials with pembrolizumab and avelumab from Merck & Co. and Pfizer/Merck KGaA, respectively.(10),(11),(12) Information about these and additional clinical trials evaluating the safety and efficacy of defactinib can be found on www.clinicaltrials.gov.

About Verastem, Inc.

Verastem, Inc. (NASDAQ:VSTM) is a biopharmaceutical company focused on discovering and developing drugs to improve outcomes for patients with cancer. Verastem is currently developing duvelisib, a dual inhibitor of phosphoinositide-3-kinase (PI3K)-delta and PI3K-gamma, which has successfully met its primary endpoint in a Phase 2 study and is currently being evaluated in a Phase 3 clinical trial in patients with chronic lymphocytic leukemia (CLL). Other clinical product candidates include focal adhesion kinase (FAK) inhibitors VS-6063 and VS-4718, and dual PI3K/mTOR inhibitor VS-5584. VS-6063 is currently being evaluated in three separate clinical collaborations in combination with immunotherapeutic agents for the treatment of several different cancer types, including pancreatic, ovarian and non-small cell lung cancer, and mesothelioma. Verastem's product candidates seek to treat cancer by modulating the local tumor microenvironment, enhancing anti-tumor immunity and reducing cancer stem cells. For more information, please visit www.verastem.com.

About Infinity Pharmaceuticals, Inc.

Infinity is an innovative biopharmaceutical company dedicated to advancing novel medicines for people with cancer. Infinity is advancing IPI-549, an oral immuno-oncology development candidate that selectively inhibits PI3K-gamma. A Phase 1 study in patients with advanced solid tumors is ongoing.(13) For more information on Infinity, please refer to Infinity's website at www.infi.com.

Verastem, Inc. forward-looking statements notice:

This press release includes forward-looking statements about Verastem's strategy, future plans and prospects, including statements regarding the development and activity of Verastem's product candidates, duvelisib, defactinib (VS-6063), VS-4718 and VS-5584, and Verastem's FAK, PI3K/mTOR programs generally, the structure of our planned and pending clinical trials and the timeline and indications for clinical development, including reporting top-line data, and regulatory submissions, our rights to develop or commercialize our product candidates and our ability to finance contemplated development activities and fund operations for a specified period. The words "anticipate," "appear," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement. Applicable risks and uncertainties include the risks that the preclinical testing of Verastem's product candidates and preliminary or interim data from clinical trials may not be predictive of the results or success of ongoing or later clinical trials; that data may not be available when expected, including for the Phase 3 DUO study; that enrollment of clinical trials may take longer than expected; that our product candidates will cause unexpected safety events or result in an unmanageable safety profile as compared to their level of efficacy; that duvelisib will be ineffective at treating patients with lymphoid malignancies; that Verastem will be unable to successfully initiate or complete the clinical development of its product candidates; that the development of Verastem's product candidates will take longer or cost more than planned; that Verastem may not have sufficient cash to fund its contemplated operations; that the cost of the transaction to Verastem will not provide the intended positive financial results; that Verastem or Infinity will fail to fully perform under the license agreement; that the transition of the duvelisib program from Infinity will not be completed; that Verastem will not pursue or submit regulatory filings for its product candidates, including for duvelisib in patients with CLL or iNHL; and that Verastem's product candidates will not receive regulatory approval, become commercially successful products, or result in new treatment options being offered to patients. Other risks and uncertainties include those identified under the heading "Risk Factors" in Verastem's Annual Report on Form 10-K for the year ended December 31, 2015 and in any subsequent SEC filings. The forward-looking statements contained in this press release reflect Verastem's current views with respect to future events, and Verastem does not undertake and specifically disclaims any obligation to update any forward-looking statements.

Infinity Pharmaceuticals, Inc. forward-looking statements notice:

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Such forward-looking statements include those regarding Infinity's expectations about: the receipt of milestone and royalty payments under the agreement with Verastem; the therapeutic and commercial potential of duvelisib and PI3K inhibition; Infinity's ability to transition the duvelisib program to Verastem; the preservation of Infinity's cash; and Infinity's ability to execute on its strategic plans. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from Infinity's current expectations. For example, there can be no guarantee that the transition of the duvelisib program to Verastem will be completed or that Infinity will receive any of the benefits of the agreement with Verastem including the receipt of milestone and royalty payments. Management's expectations and, therefore, any forward-looking statements in this press release could also be affected by risks and uncertainties relating to a number of other factors,

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including the following: Infinity's results of clinical trials and preclinical studies; a failure of Infinity and/or Verastem to fully perform under the license agreement; the content and timing of decisions made by the U.S. FDA and other regulatory authorities, investigational review boards at clinical trial sites and publication review bodies; Infinity's ability to obtain and maintain requisite regulatory approvals and to enroll patients in its clinical trial of IPI-549; unplanned cash requirements and expenditures; development of agents by Infinity's competitors for diseases in which Infinity is currently developing or intends to develop its product candidates; and Infinity's ability to obtain, maintain and enforce patent and other intellectual property protection for any product candidates it is developing. These and other risks which may impact management's expectations are described in greater detail under the caption "Risk Factors" included in Infinity's quarterly report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on August 9, 2016, and other filings filed by Infinity with the SEC. Any forward-looking statements contained in this press release speak only as of the date hereof, and Infinity expressly disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

CONTACTS:

Verastem, Inc.

Brian Sullivan
Director, Corporate Development
781-292-4214
bsullivan@verastem.com

Infinity Pharmaceuticals, Inc.

Jaren Irene Madden
Senior Director, Investor Relations and Corporate Communications
617-453-1336
Jaren.Madden@infi.com

References

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- (2) Reif K et al. Cutting Edge: Differential Roles for Phosphoinositide 3 kinases, p110-gamma and p110-delta, in lymphocyte chemotaxis and homing. *J Immunol* 2004;173:2236-2240.
- (3) Schmid M et al. Receptor Tyrosine Kinases and TLR/IL1Rs Unexpectedly activate myeloid cell PI3K, a single convergent point promoting tumor inflammation and progression. *Cancer Cell* 2011;19:715-727.
- (4) www.clinicaltrials.gov, NCT02004522
- (5) www.clinicaltrials.gov, NCT01882803
- (6) www.clinicaltrials.gov, NCT02783625, NCT02783625, NCT02158091
- (7) Schaller MD and Parsons JT. Focal adhesion kinase: an integrin-linked protein tyrosine kinase. *Trends Cell Biol.* 1993 3: 258-62.
- (8) Jiang H et al. Targeting focal adhesion kinase renders pancreatic cancers responsive to checkpoint immunotherapy. *Nat Med* 2016: Aug 22(8) 851-60.
- (9) Sulzmaier FJ et al. FAK in cancer: mechanistic findings and clinical applications. *Nature Rev Cancer.* 2014 14: 598-610.

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- (10) www.clinicaltrials.gov, NCT02546531
- (11) www.clinicaltrials.gov, NCT02943317
- (12) www.clinicaltrials.gov, NCT02758587
- (13) www.clinicaltrials.gov, NCT02637531

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