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): **July 23, 2024**

Verastem, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-35403**	**27-3269467**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

117 Kendrick Street, Suite 500, Needham, MA	**02494**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: **(781) 292-4200**

(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))

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common stock, $0.0001 par value per share	VSTM	The Nasdaq Capital Market

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 8.01 Other Events.

Initiation of Rolling NDA and Interim Duration of Therapy Data

As previously disclosed, in May 2024, Verastem, Inc. (the "Company" or "Verastem") initiated the rolling submission of a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") seeking accelerated approval of the combination of avutometinib and defactinib for patients with recurrent Kirsten rat sarcoma viral oncogene homolog ("KRAS") mutant ("KRAS mt") low-grade serous ovarian cancer ("LGSOC") who received at least one prior systemic therapy. The rolling review process allows Verastem to submit completed sections of an application for review by the FDA before all sections become available. The initial sections of the application will include the completed nonclinical and quality sections. The Company plans to seek the broadest label possible with mature RAMP 201 data to inform final indication. Previously, the FDA granted Orphan Drug Designation for the combination in LGSOC and Breakthrough Therapy Designation for the combination for treatment of patients with LGSOC with recurrent disease after one or more prior lines of therapy, including platinum-based chemotherapy. The Company plans to request a priority review of the NDA. Currently, there are no FDA-approved treatments specifically for recurrent LGSOC.

The Company estimates the total annual incident addressable market opportunity for this product candidate to be approximately $300 million for KRAS mt and approximately $270 million KRAS wild-type ("KRAS wt") populations, respectively. The Company estimates the total prevalent addressable market opportunity to be approximately $1.7 billion for KRAS mt and approximately $1.1 billion for KRAS wt populations, respectively. The Company's estimates of the patient population, pricing and revenue opportunities for its product candidates, including for KRAS mt and KRAS wt patients with LGSOC, are based on a number of internal and third-party estimates and assumptions, including, without limitation, internal forecasts, the median duration of treatment from initial interim clinical data and the assumed prices at which we can commercialize our product candidates. Specifically, the Company's estimates of total addressable market opportunities are based on: (a) estimated annual incidence of KRAS mt and KRAS wt populations of approximately 500 and 1,000 patients, respectively, (b) estimated prevalence of KRAS mt and KRAS wt populations of approximately 2,800 and 4,200 patients, respectively, (c) the average duration of therapy as observed in Verastem clinical trials of 18 months and eight months for KRAS mt and KRAS wt populations, respectively, and (d) an estimated cost of therapy of $34,000 per month consistent with other recent oncology drug launches.

The average duration of therapy included in this calculation is based, in part, on the estimated duration of therapy for patients dosed with the combination of avutometinib and defactinib for the combined Parts A, B, and C in RAMP 201 as of the latest data cutoff in February 2024. Amongst 115 patients, 58 enrolled with KRAS mutated LGSOC and 57 had wild-type, or non-mutated, KRAS. The estimated median duration of therapy for all patients is nine months and the estimated mean duration of therapy is 14 months. For KRAS mt, the estimated median duration of therapy is 14 months and the estimated mean duration of therapy is 18 months with 31 patients still on treatment as of the data cutoff date. For KRAS wt, the estimated median duration of therapy is seven months and the estimated mean duration of therapy is 11 months with 12 patients still on treatment as of the data cutoff date.

Estimated median duration of therapy was calculated using Kaplan-Meier methods. Estimated mean duration of therapy was calculated by projecting complete time on treatment for patients still on treatment by sampling from an exponential distribution conditional on the observed duration through the cutoff date.

GenFleet Collaboration

In August 2023, the Company entered into a collaboration and option agreement (the "GenFleet Agreement") with GenFleet Therapeutics (Shanghai), Inc. ("GenFleet") pursuant to which GenFleet granted the Company options to obtain exclusive development and commercialization rights worldwide outside of mainland China, Hong Kong, Macau, and Taiwan (the "GenFleet Territory") for up to three oncology programs targeting RAS pathway driven cancers (the "GenFleet Options"). The Company may exercise its GenFleet Options on a program-by-program basis. An investigational new drug application by GenFleet in China for GFH375/VS-7375, an oral KRAS G12D (ON/OFF) inhibitor, was cleared in June 2024, following which GenFleet initiated Phase 1/2 trial in solid tumors with KRAS G12D mutation for GFH375/VS-7375 in China in June 2024. In July 2024, the Company announced that the first patient had been dosed in a Phase 1/2 trial in China, conducted by GenFleet, evaluating GFH375/VS-7375, a KRAS G12D (ON/OFF) inhibitor. The Phase 1 study is being conducted in approximately 20 hospitals in China and will evaluate the safety and efficacy of GFH375/VS-7375 in patients with advanced KRAS G12D mutant solid tumors. The Phase 1 study will determine the recommended Phase 2 dose (RP2D) and then further evaluate in Phase 2 the efficacy and safety of GFH375/VS-7375 in patients with advanced solid tumors, such as pancreatic ductal adenocarcinoma, colorectal cancer and non-small cell lung cancer.

Note Regarding Presentation of Clinical Data and Market Opportunities

Interim, initial "top-line" and preliminary data or statistical analyses and projections based thereon, may not be predictive of the results from final, more mature clinical data.

Interim, initial "top-line," and preliminary data or statistical analyses from clinical trials, including the estimated and projected duration of therapy for RAMP 201 patients based on initial topline results with a minimum of five months follow up, may change as more mature patient data becomes available, may be more or less positive than the final data, and may be subject to audit and verification procedures that could result in material changes in the mature data. Thus, such interim and projected data should be considered carefully and with caution and may not necessarily be predictive of the results from final, more mature clinical data.

The estimated mean and median duration of therapy of patients in our RAMP 201 trial are based on interim clinical data and estimates and projections extrapolated thereof. Such interim results and the estimated projections based thereon may not be reproduced in any current or potential future clinical trials, and thus should be considered carefully and with caution, and may not necessarily be predictive of the results from final, more mature clinical data. More mature data from the RAMP 201 trial may materially differ from and be less positive than the interim and initial topline data reported herein Material adverse differences in final data, compared to preliminary or interim data, could severely and adversely affect our financial results, business and business prospects, including our estimates of the addressable market opportunity.

The market opportunities for our product candidates can be smaller than we estimate or the approvals that we obtain may be based on a narrower definition of the patient population.

The potential market opportunity for The Company's product candidates is difficult to estimate precisely. For example, the number of patients suffering from each of recurrent KRAS mutant LGSOC and KRAS wild-type LGSOC populations we are targeting is small and has not been established with precision. Due to the rarity of our target indications, there is no comprehensive patient registry or other method of establishing with precision the actual number of patients with KRAS mutant LGSOC and KRAS wild-type LGSOC. As a result, we have had to rely on other available sources to derive clinical prevalence estimates for our target indications. Management of the Company makes estimates, including those contained in this Current Report on Form 8-K, regarding the incidence and prevalence of target patient populations, the rate of recurrence and the median survival for particular diseases, including with respect to LGSOC, based on various third-party sources and internally generated analysis and use such estimates in making decisions regarding the Company's drug development strategy determining indications on which to focus in preclinical or clinical trials.

Management's estimates of the patient population, pricing and revenue opportunities for the Company's product candidates, including KRAS mt and KRAS wt for patients with LGSOC, are based on a number of internal and third-party estimates, including, without limitation, internal forecasts of potential market penetration, the median duration of treatment from initial interim clinical data and the assumed prices at which we can commercialize our product candidates. These estimates may be inaccurate or based on imprecise data. For example, if approved by the FDA, the market opportunity of the Company's product candidates will depend on, among other things, acceptance by the medical community, patient access, drug pricing and reimbursement. The number of patients in the addressable market may turn out to be lower than expected, patients may not be otherwise amenable to treatment with the Company's drugs, or new patients may become increasingly difficult to identify or gain access to, all of which may significantly harm the Company's business, financial condition, results of operations, and prospects. Further, if any approval that the Company obtains is based on a narrower definition of patient populations than the Company had anticipated, the potential market for the Company's product candidates will be smaller than management's current estimates. A smaller patient population in our target indications would have a materially adverse effect on the Company's ability to achieve commercialization and generate revenues.

Note Regarding Forward-Looking Statements

This Current Report on Form 8-K includes forward-looking statements about, among other things, the Company's programs and product candidates, strategy, future plans and prospects, the potential clinical value of various of its clinical trials, including the RAMP 201, RAMP 205 and RAMP 301 trials, the timing of commencing and completing trials, including topline data reports, interactions with regulators, the timeline and indications for clinical development, regulatory submissions and the potential for and timing of commercialization of product candidates and potential for additional development programs involving the Company's lead compound and the potential market opportunities expected outcome and benefits of the Company's collaboration with GenFleet, plans to initiate development studies outside of China, and estimated addressable markets for, of the Company's drug candidates. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," "can," "promising" 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 and uncertainties, among other things, regarding: the success in the development and potential commercialization of our product candidates, including avutometinib in combination with other compounds, including defactinib, LUMAKRAS™ and others; the uncertainties inherent in research and development, such as negative or unexpected results of clinical trials, the occurrence or timing of applications for our product candidates that may be filed with regulatory authorities in any jurisdictions; whether and when regulatory authorities in any jurisdictions may approve any such applications that may be filed for our product candidates, and, if approved, whether our product candidates will be commercially successful in such jurisdictions; our ability to obtain, maintain and enforce patent and other intellectual property protection for our product candidates; the scope, timing, and outcome of any legal proceedings; decisions by regulatory authorities regarding trial design, labeling and other matters that could affect the timing, availability or commercial potential of our product candidates; whether preclinical testing of our product candidates and preliminary or interim data from clinical trials will be predictive of the results or success of ongoing or later clinical trials; that the timing, scope and rate of reimbursement for our product candidates is uncertain; the market opportunities of our drug candidates are based on internal and third-party estimates which may prove to be incorrect; that third-party payors (including government agencies) may not reimburse; that there may be competitive developments affecting our product candidates; that data may not be available when expected; that enrollment of clinical trials may take longer than expected, which may delay our development programs, including delays in submission or review by the FDA of our NDA submission in recurrent KRAS mutant LGSOC if enrollment in our confirmatory trial is not well underway at the time of submission, or that the FDA may require the Company to have completed enrollment or to enroll additional patients in the Company's ongoing RAMP-301 confirmatory Phase 3 clinical trial prior to Verastem submitting or the FDA taking action on our NDA seeking accelerated approval; that our product candidates will cause adverse safety events and/or unexpected concerns may arise from additional data or analysis, or result in unmanageable safety profiles as compared to their levels of efficacy; that we may be unable to successfully validate, develop and obtain regulatory approval for companion diagnostic tests for our product candidates that require or would commercially benefit from such tests, or experience significant delays in doing so; that the mature RAMP 201 data and associated discussions with the FDA may not support the scope of our rolling NDA submission for the avutometinib and defactinib combination in LGSOC, including with respect to KRAS wild type LGSOC; that our product candidates may experience manufacturing or supply interruptions or failures; that any of our third-party contract research organizations, contract manufacturing organizations, clinical sites, or contractors, among others, who we rely on fail to fully perform; that we face substantial competition, which may result in others developing or commercializing products before or more successfully than we do which could result in reduced market share or market potential for our product candidates; that we will be unable to successfully initiate or complete the clinical development and eventual commercialization of our product candidates; that the development and commercialization of our product candidates will take longer or cost more than planned, including as a result of conducting additional studies or our decisions regarding execution of such commercialization; that we may not have sufficient cash to fund our contemplated operations, including certain of our product development programs; that we may not attract and retain high quality personnel; that we or Chugai Pharmaceutical Co., Ltd. will fail to fully perform under the avutometinib license agreement; that our total addressable and target markets for our product candidates might be smaller than we are presently estimating; that we or Secura Bio, Inc. will fail to fully perform under the asset purchase agreement with Secura Bio, Inc., including in relation to milestone payments; that we will not see a return on investment on the payments we have and may continue to make pursuant to the collaboration and option agreement with GenFleet, or that GenFleet will fail to fully perform under the agreement; that we may not be able to establish new or expand on existing collaborations or partnerships, including with respect to in-licensing of our product candidates, on favorable terms, or at all; that we may be that we may be unable to obtain adequate financing in the future through product licensing, co-promotional arrangements, public or private equity, debt financing or otherwise; that we will not pursue or submit regulatory filings for our product candidates; and that our 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 the Company's Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the Securities and Exchange Commission (the "SEC") on March 14, 2024, and in any subsequent filings with the SEC, including in this Current Report on Form 8-K, which are available at www.sec.gov and www.verastem.com.

As a result of these and other factors, we may not achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. The forward-looking statements contained in this Current Report on Form 8-K reflect the Company's views as of the date hereof, and the Company does not assume and specifically disclaims any obligation to update any forward-looking statements whether as a result of new information, future events or otherwise, except as required by law.

SIGNATURES

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.

Dated: July 23, 2024

By: /s/ Daniel W. Paterson
Daniel W. Paterson
President and Chief Executive Officer