



Verastem Oncology Reports First Quarter 2022 Financial Results and Highlights Recent Company Progress

May 9, 2022 at 4:05 PM EDT

Enrollment Completed in Selection Phases (Part A) of RAMP 201 and RAMP 202 Evaluating VS-6766 +/- Defactinib for the Treatment of Low-Grade Serous Ovarian Cancer and KRAS G12V Mutant Non-Small Cell Lung Cancer

Company Secured up to \$150 Million in Non-Dilutive Funding from Oxford Finance LLC; Expected Cash Runway Through 2025 to Support Continued Development and Potential Commercial Launches of VS-6766 and Defactinib

BOSTON--(BUSINESS WIRE)--May 9, 2022-- Verastem Oncology (Nasdaq: VSTM), a biopharmaceutical company committed to advancing new medicines for patients with cancer, today reported financial results for the three months ended March 31, 2022 and highlighted recent progress.

"In the first quarter of this year, we made significant progress building on our breakthrough therapy designation in recurrent low-grade serous ovarian cancer and advancing our development programs and scientific platform to establish VS-6766 as the backbone therapy for RAS-driven solid tumors. This includes completing enrollment for the selection phase of both our RAMP 201 trial in low-grade serous ovarian cancer and our RAMP 202 trial in KRAS G12V-mutant non-small cell lung cancer, with topline results planned for the second quarter and the second half of this year, respectively. Further, we initiated enrollment in the Phase 1/2 trial with Amgen to evaluate VS-6766 in combination with LUMAKRAS™ (sotorasib) in patients with KRAS G12C-mutant non-small lung cancer," said Brian Stuglik, Chief Executive Officer of Verastem Oncology. "At the same time, we strengthened our flexibility by entering into a term loan facility with Oxford, which combined with our financial resources will allow us to effectively advance our current development and commercial objectives, working to bring VS-6766 and defactinib to patients with high unmet needs."

First Quarter 2022 and Recent Highlights

Low Grade Serous Ovarian Cancer (LGSOC)

- Planned enrollment is complete in the selection phase (Part A; n=64) of the registration-directed Phase 2 RAMP 201 study investigating VS-6766 alone or in combination with defactinib for the treatment of recurrent LGSOC. Verastem plans to report topline results from Part A during the second quarter of 2022, following discussions with regulatory authorities.
- Enrollment has commenced in the expansion phase (Part B) of RAMP 201, with both treatment arms (VS-6766 alone and in combination with defactinib) currently advancing in all patients. Verastem expects to complete enrollment in Part B during the second half of 2022.
- Translational data presented at the American Association for Cancer Research (AACR) meeting in April provided mechanistic insights into the encouraging response rates and progression free survival observed in patients with LGSOC treated with VS-6766 with defactinib in the investigator-initiated FRAME study. These data support the ongoing registration-directed Phase 2 RAMP 201 study assessing VS-6766 with defactinib for patients with LGSOC regardless of KRAS status.

KRAS Mutant Non-Small Cell Lung Cancer (NSCLC)

- Planned enrollment is now complete in the selection phase (Part A; n=32) of the registration-directed RAMP 202 study investigating VS-6766 alone and in combination with defactinib in patients with KRAS G12V-mutant NSCLC. Enrollment has also been completed in the non-G12V mutant cohort in the selection phase (Part A). The Company expects to report topline results from Part A and initiate Part B during the second half of 2022, following discussions with regulatory authorities.
- Based on preclinical rationale, Verastem has added BRAF-mutant cohorts to the RAMP 202 study to efficiently evaluate VS-6766 with defactinib in BRAF-mutant NSCLC. In Part A of the study, the Company expects to enroll two cohorts comprised of 15 patients each to evaluate the combination in patients with V600E or non V600E BRAF mutations, respectively. These cohorts are open and enrolling.
- The Phase 1/2 RAMP 203 study evaluating VS-6766 in combination with Amgen's LUMAKRAS™ (sotorasib) in G12C-mutant NSCLC opened and is enrolling. The initial results are expected to be reported during the second half of 2022.

Corporate Updates

- Secured debt facility with Oxford Finance LLC for up to \$150 Million. Under the terms of the credit facility with Oxford Finance LLC, Verastem drew an initial \$25 million term loan at closing. The Company has the ability to access up to an additional \$125 million in a series of tranches, \$75 million of which is based on certain pre-determined milestones and \$50 million of which is available at the lender's discretion.
- With the credit facility and expected milestones related to the sale of COPIKTRA® (duvelisib) to Secura Bio Inc. (Secura) in 2020, the Company expects to have a cash runway through 2025 to support the continued development and potential commercial launches of VS-6766 and defactinib.
- Secura sublicensee, CSPC Pharmaceutical Group Limited (CSPC), obtained drug registration approval for duvelisib granted by the National Medical Products Administration of the People's Republic of China for the treatment of adult patients with relapsed or refractory follicular lymphoma after at least two prior systematic therapies, which entitles Verastem to a \$2.5 million milestone payment.
- Preclinical data presented at the American Association for Cancer Research (AACR) meeting in April continued to support the versatility of VS-6766 in RAS-driven tumors, including KRAS G12C-mutant NSCLC, low-grade serous ovarian cancer and cutaneous melanoma.

First Quarter 2022 Financial Results

Verastem Oncology ended the first quarter 2022 with cash, cash equivalents and investments of \$106.3 million.

Total revenue for the three months ending March 31, 2022 (2022 Quarter) was \$2.6 million, compared to \$1.0 million for the three months ended March 31, 2021 (2021 Quarter). Revenue for the 2022 Quarter was primarily comprised of one regulatory milestone for \$2.5 million achieved by Secura's sublicensee, CSPC. Revenue for the 2021 Quarter was primarily comprised of one regulatory milestone for \$0.8 million achieved by Secura's sublicensee, Sanofi.

Total operating expenses for the 2022 Quarter were \$19.6 million, compared to \$15.1 million for the 2021 Quarter.

Research & development expenses for the 2022 Quarter were \$13.6 million, compared to \$8.9 million for the 2021 Quarter. The increase of \$4.7 million, or 52.8%, primarily resulted from an increase in drug product and drug substance costs, contract research organization costs and investigator fees.

Selling, general & administrative expenses for the 2022 Quarter were \$5.9 million, compared to \$6.2 million for the 2021 Quarter. The decrease of \$0.3 million, or 4.8%, primarily resulted from lower consulting and professional fees.

Net loss for the 2022 Quarter was \$17.0 million, or \$0.09 per share (basic and diluted), compared to net loss of \$15.0 million, or \$0.09 per share (basic and diluted), for the 2021 Quarter.

For the 2022 Quarter, non-GAAP adjusted net loss was \$15.3 million, or \$0.08 per share (diluted), compared to non-GAAP adjusted net loss of \$12.4 million, or \$0.07 per share (diluted), for the 2021 Quarter. Please refer to the GAAP to Non-GAAP Reconciliation attached to this press release.

Use of Non-GAAP Financial Measures

To supplement Verastem Oncology's condensed consolidated financial statements, which are prepared and presented in accordance with generally accepted accounting principles in the United States (GAAP), the Company uses the following non-GAAP financial measures in this press release: non-GAAP adjusted net (loss) income and non-GAAP net (loss) income per share. These non-GAAP financial measures exclude certain amounts or expenses from the corresponding financial measures determined in accordance with GAAP. Management believes this non-GAAP information is useful for investors, taken in conjunction with the Company's GAAP financial statements, because it provides greater transparency and period-over-period comparability with respect to the Company's operating performance and can enhance investors' ability to identify operating trends in the Company's business. Management uses these measures, among other factors, to assess and analyze operational results and trends and to make financial and operational decisions. Non-GAAP information is not prepared under a comprehensive set of accounting rules and should only be used to supplement an understanding of the Company's operating results as reported under GAAP, not in isolation or as a substitute for, or superior to, financial information prepared and presented in accordance with GAAP. In addition, these non-GAAP financial measures are unlikely to be comparable with non-GAAP information provided by other companies. The determination of the amounts that are excluded from non-GAAP financial measures is a matter of management judgment and depends upon, among other factors, the nature of the underlying expense or income amounts. Reconciliations between these non-GAAP financial measures and the most comparable GAAP financial measures for the three months ended March 31, 2022 and 2021 are included in the tables accompanying this press release after the unaudited condensed consolidated financial statements.

About VS-6766

VS-6766 (formerly known as CH5126766 and RO5126766) is a RAF/MEK clamp that induces inactive complexes of MEK with ARAF, BRAF and CRAF potentially creating a more complete and durable anti-tumor response through maximal RAS pathway inhibition. VS-6766 is currently in late-stage development.

In contrast to other MEK inhibitors, VS-6766 blocks both MEK kinase activity and the ability of RAF to phosphorylate MEK. This unique mechanism allows VS-6766 to block MEK signaling without the compensatory activation of MEK that appears to limit the efficacy of other inhibitors. The U.S. Food and Drug Administration granted Breakthrough Therapy designation for the combination of Verastem Oncology's investigational RAF/MEK inhibitor VS-6766, with defactinib, its FAK inhibitor, for the treatment of all patients with recurrent low-grade serous ovarian cancer (LGSOC) regardless of KRAS status after one or more prior lines of therapy, including platinum-based chemotherapy.¹

Verastem Oncology is conducting Phase 2 registration-directed trials of VS-6766 alone and with defactinib in patients with recurrent LGSOC and in

patients with recurrent KRAS G12V-mutant NSCLC as part of its RAMP (Raf And Mek Program) clinical trials, RAMP 201 and RAMP 202, respectively. Verastem Oncology has also established clinical collaborations with Amgen and Mirati to evaluate LUMAKRAS™ (sotorasib) and adagrasib in combination with VS-6766 in KRAS G12C-mutant NSCLC as part of the RAMP 203 and RAMP 204 trials, respectively.

About Verastem Oncology

Verastem Oncology (Nasdaq: VSTM) is a development-stage biopharmaceutical company committed to the development and commercialization of new medicines to improve the lives of patients diagnosed with cancer. Our pipeline is focused on novel small molecule drugs that inhibit critical signaling pathways in cancer that promote cancer cell survival and tumor growth, including RAF/MEK inhibition and focal adhesion kinase (FAK) inhibition. For more information, please visit www.verastem.com.

Forward-Looking Statements Notice

This press release includes forward-looking statements about Verastem Oncology's strategy, future plans and prospects, including statements related to the potential clinical value of various of its clinical trials, the timing of commencing and completing trials, including topline data reports, and potential for additional development programs involving Verastem Oncology's lead compound. 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 VS-6766 in combination with other compounds, including defactinib, LUMAKRAS™ and others; the occurrence of adverse safety events and/or unexpected concerns that may arise from additional data or analysis or result in unmanageable safety profiles as compared to their levels of efficacy; 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 labeling and other matters that could affect the 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; 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; that our product candidates will experience manufacturing or supply interruptions or failures; 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; that we or Chugai Pharmaceutical Co., Ltd. will fail to fully perform under the VS-6766 license agreement; that we or our other collaboration partners may fail to perform under our collaboration agreements; that we may not have sufficient cash to fund our contemplated operations; 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 Secura Bio will achieve the milestones that result in payments to us under our asset purchase agreement with Secura Bio; that we will be unable to execute on our partnering strategies for VS-6766 in combination with other compounds; 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, 2021 as filed with the Securities and Exchange Commission (SEC) on March 28, 2022 and in any subsequent filings with the SEC. The forward-looking statements contained in this press release reflect Verastem Oncology'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.

References

¹ Verastem Oncology Press Release. Verastem Oncology Receives Breakthrough Therapy Designation for VS-6766 with Defactinib in Recurrent Low-Grade Serous Ovarian Cancer. May 24, 2021. Available at: <https://investor.verastem.com/news-releases/news-release-details/verastem-oncology-receives-breakthrough-therapy-designation-vs>. Accessed May 2022.

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Condensed Consolidated Balance Sheets

(in thousands)

(unaudited)

	March 31,	December 31,
	2022	2021
Cash, cash equivalents, & investments	\$ 106,278	\$ 100,256

Accounts receivable, net	2,644	516
Prepaid expenses and other current assets	4,517	4,968
Property and equipment, net	180	210
Right-of-use asset, net	2,183	2,302
Restricted cash and other assets	346	410
Total assets	\$ 116,148	\$ 108,662

Current Liabilities	\$ 16,886	\$ 18,590
Convertible senior notes	255	249
Long term debt	24,157	—
Lease Liability, long-term	2,079	2,264
Stockholders' equity	72,771	87,559
Total liabilities and stockholders' equity	\$ 116,148	\$ 108,662

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Condensed Consolidated Statements of Operations

(in thousands, except per share amounts)

(unaudited)

Three months ended March 31,

	2022	2021
Revenue:		
Sale of COPIKTRA license and related assets revenue	\$ 2,596	\$ 850
Transition services revenue	—	156
Total revenue	2,596	1,006
Operating expenses:		
Research and development	13,642	8,896
Selling, general and administrative	5,934	6,218
Total operating expenses	19,576	15,114

Adjusted net loss per share – diluted

\$ (0.08) \$ (0.07)

(non-GAAP Basis)

Weighted average common shares outstanding used in computing net loss per share—diluted 186,264 171,586



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Source: Verastem Oncology