Verastem Oncology Reports Second Quarter 2023 Financial Results and Highlights Recent Company Progress

August 8, 2023 at 4:05 PM EDT

Presented Positive Results from Part A of RAMP 201 Trial of Avutometinib and Defactinib in Recurrent Low-Grade Serous Ovarian Cancer (LGSOC) at American Society of Clinical Oncology Meeting

Established Design for RAMP 301 Phase 3 Confirmatory Trial of Avutometinib and Defactinib in Recurrent LGSOC

Strengthened Balance Sheet, Including Receipt of Gross Proceeds of $97.8M from June 2023 Public Offering, Bringing Company Cash, Cash Equivalents, and Investments to $183.1M as of June 30, 2023

BOSTON--(BUSINESS WIRE)--Aug. 8, 2023-- Verastem Oncology (Nasdaq: VSTM), a biopharmaceutical company committed to advancing new medicines for patients with cancer, today reported financial results for the second quarter ending June 30, 2023 and highlighted recent progress.

“We made significant advancements in the second quarter, including presenting positive results from the RAMP 201 trial of avutometinib and defactinib in recurrent LGSOC and finalizing the design of the confirmatory Phase 3 trial. Both are important milestones in our plan to file for accelerated approval in LGSOC based on mature results from RAMP 201 and data from the investigator sponsored FRAME trial,” said Dan Paterson, President and Chief Executive Officer, Verastem Oncology. “Our work to strengthen our balance sheet will enable our continued progress across our RAMP programs in LGSOC, non-small lung cancer and pancreatic cancer and support continued preparation for a potential commercial launch in LGSOC. We are encouraged by the progress we have made and believe we are well positioned to address significant unmet needs in RAS pathway-driven cancers.”

Second Quarter 2023 and Recent Highlights

Low Grade Serous Ovarian Cancer (LGSOC)

- The Company finalized the design of the Phase 3 confirmatory trial (RAMP 301) of avutometinib and defactinib in LGSOC versus standard of care (SOC) chemotherapy (pegylated liposomal doxorubicin, paclitaxel, topotecan) or hormone therapy (letrozole, anastrozole). RAMP 301 is an international collaboration between The GOG Foundation, Inc. (GOG) and the European Network of Gynaecological Oncological Trial groups (ENGOT) sponsored by Verastem Oncology. The trial will enroll approximately 270 patients who will be randomized to either the combination of avutometinib and defactinib or SOC. The primary endpoint is progression free survival (PFS) by blinded independent central review (BICR). Secondary endpoints include overall response rates, duration of response, disease control rate, safety and tolerability, patient reported outcomes and overall survival.
- RAMP 301 is the follow-up confirmatory study being conducted for full regulatory approval in recurrent LGSOC. The Company intends to file for accelerated approval with the U.S. Food and Drug Administration (FDA) for the combination of avutometinib and defactinib based on mature data from the Company’s Phase 2 registration-directed trial, RAMP 201, together with the results of the investigator-initiated FRAME trial.
- Data from Part A of the RAMP 201 trial were presented at the American Society of Clinical Oncology Meeting in June. Results included confirmed objective response rates (ORR) by BICR of 45% (13/29; 95% CI: 26%-64%). Overall, patients were heavily pretreated with a median of 4 prior systemic regimens (up to 11). Tumor shrinkage was observed in the majority of patients, 86% (25/29). The safety profile was tolerable and consistent with previously reported safety data. These results are consistent with the data that supported the Breakthrough Therapy Designation granted by the FDA for the combination in recurrent LGSOC after one or more prior lines of therapy, including platinum-based chemotherapy.

Other Programs

- In the Company’s RAMP 203 and RAMP 204 Phase 1/2 clinical trials, the combinations of avutometinib with Amgen’s LUMAKRAS® (sotorasib) (RAMP 203) and with Mirati’s KRAZATI® (adagrasib) (RAMP 204) are evaluated in patients with KRAS G12C mutant non-small cell lung cancer (NSCLC). RAMP 203 progressed to the recommendation of the Phase 2 dose (avutometinib 4 mg BIW PO and sotorasib 960 mg QD PO) and continues enrollment in Part B dose expansion in patients who are G12C inhibitor treatment naïve and in patients who experienced disease progression on prior G12C inhibitor monotherapy. Dose escalation is ongoing in RAMP 204.
- Enrollment is ongoing in the Company’s RAMP 205 Phase 1b/2 clinical trial evaluating avutometinib and defactinib in combination with SOC chemotherapy (GEMZAR® (gemcitabine) and ABRAXANE®) in patients with metastatic adenocarcinoma of the pancreas. The trial is supported by the Company’s receipt of the first “Therapeutic Accelerator Award” from the Pancreatic Cancer Action Network (PanCAN).

Corporate Updates

- Dan Paterson was promoted to President and Chief Executive Officer in July. During his tenure as President and Chief Operating Officer of Verastem Oncology, he spearheaded the acquisition of lead compound avutometinib and led strategic direction designed to accelerate the program's advancement. In connection with his appointment, Dan was also appointed to the Board of Directors. Dan succeeds Brian Stuglik who has retired from his role as Chief Executive Officer but remains a member of the Company's Board of Directors and leads the Board's recently designated Commercialization Committee.
- The Company strengthened the balance sheet in June 2023 by raising gross proceeds of approximately $97.8 million in a public offering of 8,489,409 shares of common stock and, in lieu of common stock to certain investors, pre-funded warrants to purchase an aggregate of 1,538,591 shares of common stock.
- Karin Tollefson was elected to Verastem Oncology's Board of Directors at the Company's annual meeting, alongside returning Board members Robert Gagnon and Brian Stuglik. Dr. Tollefson is the Senior Vice President and Head of Global Medical Affairs at Seagen Inc. Karin has 30 years of experience in the pharmaceutical industry and is a proven leader in global oncology development and medical affairs.

Second Quarter 2023 Financial Results

Verastem Oncology ended the second quarter of 2023 with cash, cash equivalents and investments of $183.1 million. Total operating expenses for the three months ended June 30, 2023 (the "2023 Quarter") were $20.3 million, compared to $21.4 million for the three months ended June 30, 2022 (the "2022 Quarter"). Recent historical operating expenses have ranged between $16.0M and $20.0M per quarter, which the Company does not anticipate will change significantly in the near term as the RAMP 301 trial commences.

Research & development expenses for the 2023 Quarter were $12.9 million, compared to $14.9 million for the 2022 Quarter. The decrease of $2.0 million, or 13.4%, primarily resulted from a decrease in drug product and drug substance costs and contract research organization costs.

Selling, general & administrative expenses for the 2023 Quarter were $7.4 million, compared to $6.5 million for the 2022 Quarter. The increase of $0.9 million, or 13.8%, was primarily related to increased consulting and professional fees as well as additional costs in anticipation of a potential launch of avutometinib and defactinib in LGSOC.

Net loss for the 2023 Quarter was $24.3 million, or $1.37 per share (basic and diluted, each as adjusted for the Company's reverse stock split), compared to net loss of $22.0 million, or $1.41 per share (basic and diluted, each as adjusted for the Company's reverse stock split) for the 2022 Quarter.

For the 2023 Quarter, non-GAAP adjusted net loss was $18.8 million, or $1.06 per share (diluted, as adjusted for the Company's reverse stock split), compared to non-GAAP adjusted net loss of $20.1 million, or $1.29 per share (diluted, as adjusted for the Company's reverse stock split) for the 2022 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 and non-GAAP adjusted net loss 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 and six months ended June 30, 2023, and 2022 are included in the tables accompanying this press release, after the unaudited condensed consolidated financial statements.

About Avutometinib (VS-6766)

Avutometinib 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. Avutometinib is currently in late-stage development.

In contrast to other MEK inhibitors, avutometinib blocks both MEK kinase activity and the ability of RAF to phosphorylate MEK. This unique mechanism allows avutometinib 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 clamp avutometinib, 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.

Verastem Oncology is currently conducting clinical trials with its RAF/MEK clamp avutometinib in RAS- driven tumors as part of its (**R**af **A**nd **M**ek **P**rogram). RAMP 201 is a registration-directed trial of avutometinib in combination with defactinib in patients with recurrent LGSOC. Verastem Oncology has established clinical collaborations with Amgen and Mirati to evaluate LUMAKRAS® (sotorasib) and KRAZATI® (adagrasib) in combination with avutometinib in KRAS G12C mutant NSCLC as part of the RAMP 203 and RAMP 204 trials, respectively. As part of the "Therapeutic Accelerator Award" Verastem Oncology received from PanCAN, Verastem Oncology is conducting RAMP 205, a Phase 1b/2 clinical trial evaluating avutometinib and defactinib with gemcitabine/nab-paclitaxel in patients with front-line metastatic pancreatic cancer.

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 its financial condition, its future operating expenses, the potential clinical value of various of its clinical trials, the timing of commencing and completing trials, including topline data reports and interactions with regulators. 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 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 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; that third- party payors (including government agencies) may not reimburse; that there may be competitive developments affecting our product candidates; that we may not attract and retain high quality personnel; 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, including as a result of conducting additional studies; that our target market for our product candidates might be smaller than we are presently estimating; that we or Chugai Pharmaceutical Co., Ltd. will fail to fully perform under the avutometinib license agreement; that we or our other collaboration partners may fail to perform under our collaboration agreements; 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 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 will achieve the milestones that result in payments to us under our asset purchase agreement with Secura; that we will be unable to execute on our partnering strategies for avutometinib 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 Verastem Oncology's Annual Report on Form 10-K for the year ended December 31, 2022 as filed with the Securities and Exchange Commission (SEC) on March 14, 2023 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 Verastem Oncology 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.

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Condensed Consolidated Balance Sheets

(in thousands)

(unaudited)

	June 30, 2023	December 31, 2022
Cash, cash equivalents, & investments	$ 183,086	$ 87,894
Accounts receivable, net	2	31
Prepaid expenses and other current assets	6,875	4,945
Property and equipment, net	40	92
Right-of-use asset, net	1,494	1,789

Restricted cash and other assets	261	299
Total assets	**$ 191,758**	**$ 95,050**

Current Liabilities	$ 20,787	$ 21,663
Long term debt	39,739	24,526
Lease liability, long-term	1,022	1,470
Preferred stock tranche liability	7,460	—
Convertible preferred stock	21,159	—
Stockholders' equity	101,591	47,391
Total liabilities, convertible preferred stock and stockholders' equity	**$ 191,758**	**$ 95,050**

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Condensed Consolidated Statements of Operations

(in thousands, except per share amounts)

(unaudited)

	Three months ended June 30,		**Six months ended June 30,**	
	2023	**2022**	**2023**	**2022**
Revenue:				
Sale of COPIKTRA license and related assets revenue	$ —	$ —	$ —	$ 2,596
Total revenue	—	—	—	2,596
Operating expenses:				
Research and development	12,893	14,888	24,908	28,530
Selling, general and administrative	7,399	6,514	14,728	12,448
Total operating expenses	20,292	21,402	39,636	40,978
Loss from operations	(20,292)	(21,402)	(39,636)	(38,382)
Other income (expense)	(40)	6	(47)	34
Interest income	1,122	84	2,098	130
Interest expense	(1,121)	(640)	(1,890)	(696)

Change in fair value of preferred stock tranche liability	(3,950)	—	(520)	—
Net loss	$ (24,281)	$ (21,952)	$ (39,995)	$ (38,914)
Net loss per share—basic and diluted[1]	$ (1.37)	$ (1.41)	$ (2.32)	$ (2.51)
Weighted average common shares outstanding used in computing:				
Net loss per share – basic and diluted[1]	17,732	15,539	17,231	15,530

(1) Amounts have been retroactively restated to reflect the 1-for-12 reverse stock split effected on May 31, 2023

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Reconciliation of GAAP to Non-GAAP Financial Information

(in thousands, except per share amounts)

(unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2023	**2022**	**2023**	**2022**
Net loss reconciliation				
Net loss (GAAP basis)	$ (24,281)	$ (21,952)	$ (39,995)	$ (38,914)
Adjust:				
Stock-based compensation expense	1,432	1,758	2,745	3,404
Non-cash interest, net	112	94	76	111
Change in fair value of preferred stock tranche liability	3,950	—	520	—
Severance and Other	—	—	38	—
Adjusted net loss (non-GAAP basis)	$ (18,787)	$ (20,100)	$ (36,616)	$ (35,399)
Reconciliation of net loss per share				
Net loss per share – diluted (GAAP Basis)[1]	(1.37)	(1.41)	(2.32)	(2.51)
Adjust per diluted share:				
Stock-based compensation expense[1]	0.08	0.11	0.16	0.22
Non-cash interest, net[1]	0.01	0.01	—	0.01

Change in fair value of preferred stock tranche liability[1]	0.22	—	0.03	—
Severance and Other[1]	—	—	—	—
Adjusted net loss per share – diluted (non-GAAP basis)[1]	$ (1.06)	$ (1.29)	$ (2.13)	$ (2.28)
Weighted average common shares outstanding used in computing net loss per share—diluted[1]	17,732	15,539	17,231	15,530

(1) Amounts have been retroactively restated to reflect the 1-for-12 reverse stock split effected on May 31, 2023

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Source: Verastem Oncology