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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**FORM 10-Q**

**(Mark One)**

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the quarterly period ended September 30, 2024**

**OR**

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the transition period from            to**

**Commission file number: 001-35403**

**Verastem, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**117 Kendrick Street, Suite 500**

**Needham, MA**

(Address of principal executive offices)

**27-3269467**

(I.R.S. Employer  
Identification Number)

**02494**

(Zip Code)

**(781) 292-4200**

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Securities Exchange Act of 1934:

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 (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer     Accelerated filer     Non-accelerated filer     Smaller reporting company     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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of November 5, 2024 there were 44,506,526 shares of Common Stock outstanding.

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## FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements related to present facts or current conditions or historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, including our ability to continue as a going concern through one year from the date of the financial statements for the quarter ended September 30, 2024, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. Such statements relate to, among other things, the development and activity of our programs and product candidates, avutometinib (rapidly accelerated fibrosarcoma (“RAF”)/ mitogen-activated protein kinase kinase (“MEK”) program) and defactinib (focal adhesion kinase (“FAK”) program), the timing and outcome of the U.S. Food & Drug Administration’s (the “FDA”) review of our New Drug Application (“NDA”) submission for the avutometinib and defactinib combination in low-grade serous ovarian cancer (“LGSOC”), the structure of our planned and pending clinical trials, the potential clinical value of our 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, and the timeline and indications for clinical development, regulatory submissions and the potential for and timing of commercialization of our product candidates and potential for additional development programs involving the Company’s lead compound and the potential market opportunities, the expected outcome and benefits of our collaboration with GenFleet Therapeutics (Shanghai), Inc. (“GenFleet”), plans to initiate development studies outside of China, and estimated addressable markets for, of our drug candidates. The words “anticipate,” “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.

Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause our actual results could differ materially from those expressed or implied in the forward-looking statements we make. 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; that 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 review by the FDA of our NDA submission in recurrent Kirsten rat sarcoma viral oncogene homolog (“KRAS”) mutant LGSOC if enrollment in our confirmatory trial is not well underway at the time of review, 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 taking action on our NDA seeking accelerated approval; risks associated with preliminary and interim data, which may not be representative of more mature data, including with respect to interim duration of therapy data; 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 NDA submission for the avutometinib and defactinib combination in 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 the total addressable and target markets for our product candidates might be smaller than we are presently estimating; that we or Secura Bio, Inc. (“Secura”) will fail to fully perform under the asset purchase agreement with Secura, 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 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 our Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the Securities and Exchange Commission (“SEC”) on March 14, 2024, and in any subsequent filings with the SEC.

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. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make. The forward-looking statements contained in this Quarterly Report on Form 10-Q reflect our views as of the date hereof. We do not assume and specifically disclaim any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

**PART I—FINANCIAL INFORMATION**

**Item 1. Condensed Consolidated Financial Statements (unaudited).**

**Verastem, Inc.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
**(in thousands, except per share amounts)**

	September 30, 2024	December 31, 2023
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 113,175	\$ 77,909
Short-term investments	—	59,220
Grant receivable	200	—
Prepaid expenses and other current assets	7,287	6,553
Total current assets	120,662	143,682
Property and equipment, net	39	37
Right-of-use asset, net	625	1,171
Restricted cash	—	241
Other assets	5,052	4,587
Total assets	<u>\$ 126,378</u>	<u>\$ 149,718</u>
<b>Liabilities, convertible preferred stock and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 4,438	\$ 7,184
Accrued expenses	22,153	17,928
Note payable	133	—
Deferred liabilities	—	327
Lease liability, short-term	780	941
Current portion of long-term debt	9,870	—
Total current liabilities	37,374	26,380
Non-current liabilities:		
Long-term debt	30,647	40,086
Lease liability, long-term	—	530
Preferred stock tranche liability	—	4,189
Warrant liability	26,138	—
Total liabilities	94,159	71,185
Convertible preferred stock:		
Series B Convertible Preferred Stock, \$0.0001 par value; 2,144 shares designated at September 30, 2024 and December 31, 2023; 1,200 shares issued and outstanding at September 30, 2024 and December 31, 2023	21,159	21,159
Stockholders' equity:		
Preferred Stock, \$0.0001 par value; 5,000 shares authorized:		
Series A Convertible Preferred Stock, \$0.0001 par value; 1,000 shares designated, 1,000 shares issued and outstanding at September 30, 2024 and December 31, 2023	—	—
Common stock, \$0.0001 par value; 300,000 shares authorized, 40,262 and 25,281 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	4	3
Additional paid-in capital	902,032	882,248
Accumulated other comprehensive income	—	13
Accumulated deficit	(890,976)	(824,890)
Total stockholders' equity	11,060	57,374
Total liabilities, convertible preferred stock and stockholders' equity	<u>\$ 126,378</u>	<u>\$ 149,718</u>

See accompanying notes to the condensed consolidated financial statements.

**Verastem, Inc.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**  
**(unaudited)**  
**(in thousands, except per share amounts)**

	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	<u>2024</u>	<u>2023</u>	<u>2024</u>	<u>2023</u>
<b>Revenue:</b>				
Sale of COPIKTRA license and related assets	\$ —	\$ —	\$ 10,000	\$ —
<b>Total revenue</b>	<b>—</b>	<b>—</b>	<b>10,000</b>	<b>—</b>
<b>Operating expenses:</b>				
Research and development	24,754	13,946	60,523	38,854
Selling, general and administrative	12,276	7,363	32,843	22,091
<b>Total operating expenses</b>	<b>37,030</b>	<b>21,309</b>	<b>93,366</b>	<b>60,945</b>
Loss from operations	(37,030)	(21,309)	(83,366)	(60,945)
Other expense	(77)	(13)	(131)	(60)
Interest income	831	2,247	3,181	4,345
Interest expense	(1,148)	(1,129)	(3,416)	(3,019)
Change in fair value of preferred stock tranche liability	—	200	4,189	(320)
Change in fair value of warrant liability	13,457	—	13,457	—
<b>Net loss</b>	<b>\$ (23,967)</b>	<b>\$ (20,004)</b>	<b>\$ (66,086)</b>	<b>\$ (59,999)</b>
<b>Net loss per share—basic and diluted</b>	<b>\$ (0.60)</b>	<b>\$ (0.75)</b>	<b>\$ (2.11)</b>	<b>\$ (2.93)</b>
<b>Weighted average common shares outstanding used in computing net loss per share—basic and diluted</b>				
	40,258	26,790	31,350	20,452
<b>Net loss</b>	<b>\$ (23,967)</b>	<b>\$ (20,004)</b>	<b>\$ (66,086)</b>	<b>\$ (59,999)</b>
Unrealized gain (loss) on available-for-sale securities	—	48	(13)	49
<b>Comprehensive loss</b>	<b>\$ (23,967)</b>	<b>\$ (19,956)</b>	<b>\$ (66,099)</b>	<b>\$ (59,950)</b>

See accompanying notes to the condensed consolidated financial statements.

**Verastem, Inc.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND**  
**STOCKHOLDERS' EQUITY**  
**(unaudited)**  
**(in thousands, except share data)**

	Series B Convertible Preferred Stock		Series A Convertible Preferred Stock		Common stock		Additional paid-in capital	Accumulated other comprehensive income	Accumulated deficit	Total stockholders' equity
	Shares	Amount	Shares	Amount	Shares	Amount				
<b>Balance at December 31, 2023</b>	<b>1,200,000</b>	<b>\$ 21,159</b>	<b>1,000,000</b>	<b>\$ —</b>	<b>25,281,150</b>	<b>\$ 3</b>	<b>\$ 882,248</b>	<b>\$ 13</b>	<b>\$ (824,890)</b>	<b>\$ 57,374</b>
Net loss	—	—	—	—	—	—	—	—	(33,863)	(33,863)
Unrealized loss on available-for-sale marketable securities	—	—	—	—	—	—	—	(17)	—	(17)
Issuance of common stock resulting from vesting of restricted stock units	—	—	—	—	14,444	—	—	—	—	—
Issuance of common stock resulting from exercise of stock options	—	—	—	—	4,600	—	36	—	—	36
Issuance of common stock under Employee Stock Purchase Plan	—	—	—	—	7,475	—	49	—	—	49
Stock-based compensation expense	—	—	—	—	—	—	1,483	—	—	1,483
<b>Balance at March 31, 2024</b>	<b>1,200,000</b>	<b>\$ 21,159</b>	<b>1,000,000</b>	<b>\$ —</b>	<b>25,307,669</b>	<b>\$ 3</b>	<b>\$ 883,816</b>	<b>\$ (4)</b>	<b>\$ (858,753)</b>	<b>\$ 25,062</b>
Net loss	—	—	—	—	—	—	—	—	(8,256)	(8,256)
Unrealized gain on available-for-sale marketable securities	—	—	—	—	—	—	—	4	—	4
Issuance of common stock resulting from vesting of restricted stock units	—	—	—	—	12,986	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	1,905	—	—	1,905
Issuance of common stock resulting from exercise of stock options	—	—	—	—	17,378	—	136	—	—	136
Issuance of common stock upon exercise of pre-funded warrants	—	—	—	—	—	—	—	—	—	—
<b>Balance at June 30, 2024</b>	<b>1,200,000</b>	<b>\$ 21,159</b>	<b>1,000,000</b>	<b>\$ —</b>	<b>26,876,234</b>	<b>\$ 3</b>	<b>\$ 885,857</b>	<b>\$ —</b>	<b>\$ (867,009)</b>	<b>\$ 18,851</b>
Net loss	—	—	—	—	—	—	—	—	(23,967)	(23,967)
Issuance of common stock resulting from vesting of restricted stock units	—	—	—	—	44,300	—	—	—	—	—
Issuance of common stock under Employee Stock Purchase Plan	—	—	—	—	7,756	—	20	—	—	20
Stock-based compensation expense	—	—	—	—	—	—	1,935	—	—	1,935
Issuance of common stock and pre-funded warrants, net of issuance costs of \$1,179	—	—	—	—	13,333,334	1	14,220	—	—	14,221
<b>Balance at September 30, 2024</b>	<b>1,200,000</b>	<b>\$ 21,159</b>	<b>1,000,000</b>	<b>\$ —</b>	<b>40,261,624</b>	<b>\$ 4</b>	<b>\$ 902,032</b>	<b>\$ —</b>	<b>\$ (890,976)</b>	<b>\$ 11,060</b>

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	Series B Convertible Preferred Stock		Series A Convertible Preferred Stock		Common stock <sup>(1)</sup>		Additional paid-in capital <sup>(1)</sup>	Accumulated other comprehensive income	Accumulated deficit	Total stockholders' equity
	Shares	Amount	Shares	Amount	Shares	Amount				
<b>Balance at December 31, 2022</b>	—	\$ —	1,000,000	\$ —	16,711,761	\$ 2	\$ 784,912	\$ —	\$ (737,523)	\$ 47,391
Net loss	—	—	—	—	—	—	—	—	(15,714)	(15,714)
Unrealized gain on available-for-sale marketable securities	—	—	—	—	—	—	—	6	—	6
Issuance of common stock resulting from vesting of restricted stock units	—	—	—	—	17,658	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	1,313	—	—	1,313
Issuance of common stock under Employee Stock Purchase Plan	—	—	—	—	6,874	—	29	—	—	29
Issuance of Series B Convertible Preferred Stock, net of issuance costs of \$1,901 and preferred stock tranche liability of \$6,940	1,200,000	21,159	—	—	—	—	—	—	—	—
<b>Balance at March 31, 2023</b>	<b>1,200,000</b>	<b>\$ 21,159</b>	<b>1,000,000</b>	<b>\$ —</b>	<b>16,736,293</b>	<b>\$ 2</b>	<b>\$ 786,254</b>	<b>\$ 6</b>	<b>\$ (753,237)</b>	<b>\$ 33,025</b>
Net loss	—	—	—	—	—	—	—	—	(24,281)	(24,281)
Unrealized loss on available-for-sale marketable securities	—	—	—	—	—	—	—	(5)	—	(5)
Issuance of common stock resulting from vesting of restricted stock units	—	—	—	—	16,176	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	1,432	—	—	1,432
Issuance of common stock, and pre-funded warrants, net of issuance cost of \$6,351	—	—	—	—	8,489,409	1	91,419	—	—	91,420
<b>Balance at June 30, 2023</b>	<b>1,200,000</b>	<b>21,159</b>	<b>1,000,000</b>	<b>—</b>	<b>25,241,878</b>	<b>\$ 3</b>	<b>\$ 879,105</b>	<b>\$ 1</b>	<b>\$ (777,518)</b>	<b>\$ 101,591</b>
Net loss	—	—	—	—	—	—	—	—	(20,004)	(20,004)
Unrealized gain on available-for-sale marketable securities	—	—	—	—	—	—	—	48	—	48
Issuance of common stock resulting from vesting of restricted stock units	—	—	—	—	15,489	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	1,517	—	—	1,517
Issuance of common stock under Employee Stock Purchase Plan	—	—	—	—	7,396	—	28	—	—	28
<b>Balance at September 30, 2023</b>	<b>1,200,000</b>	<b>21,159</b>	<b>1,000,000</b>	<b>—</b>	<b>25,264,763</b>	<b>\$ 3</b>	<b>\$ 880,650</b>	<b>\$ 49</b>	<b>\$ (797,522)</b>	<b>\$ 83,180</b>

(1) Amounts have been retroactively restated to reflect the 1-for-12 reverse stock split effected on May 31, 2023, as applicable (see *Note 1. Nature of business* of the accompanying notes to the condensed consolidated financial statements).

See accompanying notes to the condensed consolidated financial statements.



**Verastem, Inc.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(unaudited)**  
**(in thousands)**

	<b>Nine months ended September 30,</b>	
	<b>2024</b>	<b>2023</b>
<b>Operating activities</b>		
Net loss	\$ (66,086)	\$ (59,999)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	19	57
Non-cash operating lease cost	(145)	(129)
Stock-based compensation expense	5,323	4,262
Amortization of deferred financing costs, debt discounts and premiums and discounts on available-for-sale marketable securities	(212)	(295)
Change in fair value of preferred stock tranche liability	(4,189)	320
Change in fair value of warrant liability	(13,457)	—
Changes in operating assets and liabilities:		
Accounts receivable, net	—	31
Grant receivable	(200)	—
Prepaid expenses, other current assets and other assets	(1,884)	(2,950)
Accounts payable	(2,746)	217
Accrued expenses and other liabilities	4,232	1,331
Deferred liabilities	(327)	325
Other long-term liabilities	—	51
Net cash used in operating activities	(79,672)	(56,779)
<b>Investing activities</b>		
Purchases of property and equipment	(28)	—
Purchases of investments	—	(83,883)
Maturities of investments	60,000	27,000
Net cash provided by (used in) investing activities	59,972	(56,883)
<b>Financing activities</b>		
Payments for loan amendment	(150)	—
Proceeds from issuance of Series B Convertible Preferred Stock, net	—	28,099
Proceeds from long-term debt, net	—	14,918
Proceeds from insurance premium financing	1,298	1,430
Payments on insurance premium financing	(1,165)	(1,284)
Proceeds from the exercise of stock options and employee stock purchase program	241	57
Proceeds from the issuance of common stock and pre-funded warrants, net	14,221	91,420
Proceeds from the issuance of warrants	39,595	—
Net cash provided by financing activities	54,040	134,640
Increase in cash, cash equivalents and restricted cash	34,340	20,978
Cash, cash equivalents and restricted cash at beginning of period	79,076	75,789
Cash, cash equivalents and restricted cash at end of period	\$ 113,416	\$ 96,767
<b>Supplemental disclosure of non-cash investing and financing activities</b>		
Issuance of preferred stock tranche liability	\$ —	6,940

See accompanying notes to the condensed consolidated financial statements.

**Verastem, Inc.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**(unaudited)**

**1. Nature of business**

Verastem, Inc. (the “Company”) is a late-stage development biopharmaceutical company, with an ongoing registration directed trial, committed to the development and commercialization of new medicines to improve the lives of patients diagnosed with cancer. The Company’s pipeline is focused on ras sarcoma (“RAS”)/ mitogen activated pathway kinase (“MAPK”) driven cancers, specifically novel drug candidates that inhibit signaling pathways critical to cancer cell survival and tumor growth, particularly RAF/MEK inhibition and FAK inhibition.

The Company’s most advanced product candidates, avutemetinib and defactinib, are being investigated in both preclinical and clinical studies for the treatment of various solid tumors, including, but not limited to LGSOC, non-small cell lung cancer (“NSCLC”), pancreatic cancer, colorectal cancer (“CRC”), and thyroid. The Company believes that avutemetinib may be beneficial as a therapeutic as a single agent or when used together in combination with defactinib, other pathway inhibitors or other current and emerging standard of care treatments in cancers that do not adequately respond to currently available therapies.

The condensed consolidated financial statements include the accounts of Verastem Securities Company and Verastem Europe GmbH, wholly-owned subsidiaries of the Company. All financial information presented has been consolidated and includes the accounts of the Company and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

The Company is subject to the risks associated with other life science companies, including, but not limited to, possible failure of preclinical testing or clinical trials, competitors developing new technological innovations, inability to obtain marketing approval of the Company’s product candidates, avutemetinib and defactinib, market acceptance and commercial success of the Company’s product candidates, avutemetinib and defactinib, following receipt of regulatory approval, and, protection of proprietary technology and the continued ability to obtain adequate financing to fund the Company’s future operations. If the Company does not obtain marketing approval and successfully commercialize its product candidates, avutemetinib and defactinib, following regulatory approval, it will be unable to generate product revenue or achieve profitability and may need to raise additional capital.

As of September 30, 2024, the Company had cash, cash equivalents, and investments of \$113.2 million. In accordance with applicable accounting standards, the Company evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company’s ability to continue as a going concern within 12 months after the date of the issuance of these condensed consolidated financial statements. The Company anticipates operating losses may continue for the foreseeable future since the Company does not yet have regulatory approval to sell any of its product candidates, and the Company continues to incur operating costs to execute its strategic plan, including costs related to research and development of its product candidates and commercial readiness activities. As a result of the assessment in accordance with the applicable accounting standards, these conditions raise substantial doubt about the Company’s ability to continue as a going concern for 12 months after the date the condensed consolidated financial statements are issued.

The Company expects to finance its operations with its existing cash, cash equivalents and investments, through potential future milestones and royalties received pursuant to the asset purchase agreement dated August 10, 2020, between the Company and Secura (the “Secura APA”), through the loan and security agreement with Oxford Finance LLC (“Oxford”), or through other strategic financing opportunities that could include, but are not limited to collaboration agreements, future offerings of its equity, or the incurrence of debt. However, given the risks associated with these potential strategic or financing opportunities, they are not deemed probable for purposes of the going concern assessment. If the Company fails to obtain additional future capital, it may be unable to complete its planned preclinical studies and clinical trials and obtain approval of certain investigational product candidates from the FDA or foreign regulatory authorities. Therefore, there is substantial doubt about the Company’s ability to continue as a going concern.

## Reverse Stock Split

On May 30, 2023, the Company filed a Certificate of Amendment to the Company's Restated Certificate of Incorporation, as amended to date, with the Secretary of State of the State of Delaware to effect a reverse stock split of the Company's issued and outstanding common stock, par value \$0.0001 at a ratio of 1-for-12 (the "Reverse Stock Split"), as authorized at the Company's 2023 annual meeting of stockholders held on May 15, 2023. The Company effected the Reverse Stock Split on May 31, 2023. No fractional shares were issued in connection with the Reverse Stock Split. Stockholders who otherwise were entitled to a fractional share of common stock were entitled to receive a price equal to the closing price of the common stock on the Nasdaq Capital Market on the date immediately preceding the Reverse Stock Split, as adjusted by the ratio of one share of common stock for every 12 shares of common stock, multiplied by the applicable fraction of a share. The number of shares of common stock that the Company is authorized to issue remains at 300,000,000 shares and the par value of its common stock remains unchanged at \$0.0001 per share.

The Company has retroactively restated the share and per share amounts in the unaudited condensed consolidated financial statements for the nine months ended September 30, 2023, to give retroactive effect to the Reverse Stock Split. Proportionate adjustments were made to the per share exercise price and number of shares of common stock issuable under all outstanding stock options, convertible notes and preferred stock. In addition, proportionate adjustments have been made to the number of shares of common stock issuable upon vesting of the restricted stock units and the number of shares of common stock reserved for the Company's equity incentive compensation plans. The condensed consolidated statements of convertible preferred stock and stockholders' equity reflect the impact of the Reverse Stock Split by reclassifying from "common stock" to "additional paid-in capital" in an amount equal to the par value of the decreased shares resulting from the Reverse Stock Split for the nine months ended September 30, 2023.

## 2. Summary of significant accounting policies

### Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in accordance with generally accepted accounting principles in the United States ("GAAP") for interim financial reporting and as required by Regulation S-X, Rule 10-01 under the assumption that the Company will continue as a going concern for the next twelve months. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements, or any adjustments that might result from the uncertainty related to the Company's ability to continue as a going concern. In the opinion of management, all adjustments (including those which are normal and recurring) considered necessary for a fair presentation of the interim financial information have been included. When preparing financial statements in conformity with GAAP, the Company must make estimates and assumptions that affect the reported amounts and related disclosures at the date of the financial statements. Actual results could differ from those estimates. Additionally, operating results for the three and nine months ended September 30, 2024 are not necessarily indicative of the results that may be expected for any other interim period or for the year ending December 31, 2024. For further information, refer to the financial statements and footnotes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the SEC on March 14, 2024.

### Significant Accounting Policies

The significant accounting policies are described in *Note 2. Significant accounting policies* in the Company's Annual Report on Form 10-K for the year ended December 31, 2023.

### Recently issued accounting standards updates

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures ("ASU 2023-07"), which is intended to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses and by extending the disclosure requirements to entities with a single reportable segment. The guidance is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal

years beginning after December 15, 2024. Early adoption is permitted. ASU 2023-07 is to be applied retrospectively to all prior periods presented in the financial statements. The Company is currently evaluating the potential impact of adopting this new guidance on the Company's condensed consolidated financial statements and related disclosures.

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures ("ASU 2023-09"). The guidance in ASU 2023-09 improves the transparency of income tax disclosures by greater disaggregation of information in the rate reconciliation and income taxes paid disaggregated by jurisdiction. The standard is effective for public companies for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact that the adoption of ASU 2023-09 may have on its condensed consolidated financial statements and related disclosures.

Other recent accounting pronouncements issued, but not yet effective, are not expected to be applicable to the Company or have a material effect on the condensed consolidated financial statements upon future adoption.

### **Concentrations of credit risk and off-balance sheet risk**

Cash, cash equivalents, investments and trade accounts receivable are financial instruments that potentially subject the Company to concentrations of credit risk. The Company mitigates this risk by maintaining its cash and cash equivalents and investments with high quality, accredited financial institutions. The management of the Company's investments is not discretionary on the part of these financial institutions. As of September 30, 2024, the Company's cash, cash equivalents and investments were deposited at four financial institutions and it has no significant off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts or other hedging arrangements.

For the nine months ended September 30, 2024, there was one customer, Secura, who individually accounted for all of the Company's revenue. Refer to *Note 13. License, collaboration and commercial agreements* for a detailed discussion of the Secura APA.

### **Proceeds from Grants**

In May 2022, the Company was awarded the "Therapeutic Accelerator Award" grant from Pancreatic Cancer Network ("PanCAN") for up to \$3.8 million (the "PanCAN Grant"). In August 2022, PanCAN agreed to provide the Company with an additional \$0.5 million for the collection and analysis of patient samples. The grant is supporting a Phase 1b/2 clinical trial of GEMZAR (gemcitabine) and ABRAXANE (Nab-paclitaxel) in combination with avutometinib and defactinib entitled RAMP 205. The RAMP 205 trial is evaluating whether combining avutometinib (to target KRAS mutant, which is found in more than 90% of pancreatic adenocarcinomas), and defactinib (to reduce stromal density and adaptive resistance to avutometinib) to the standard GEMZAR/ABRAXANE regimen improves outcomes for patients with such pancreatic cancers. The Company recognizes grants as contra research and development expense in the consolidated statement of operations and comprehensive loss on a systematic basis over the periods in which the Company recognizes as expenses the related costs for which the grants are intended to compensate. Eligible expenses incurred in excess of grant payments received up to the total amount of the PanCAN Grant are recorded as a grant receivable. Through September 30, 2024, the Company has received \$4.1 million of cash proceeds which was initially recorded as deferred liabilities on the balance sheet. The Company recorded \$0.0 million and \$2.0 million of the proceeds as a reduction of research and development expense during the three and nine months ended September 30, 2024, respectively. As of September 30, 2024, the company recorded \$0.2 million as a grant receivable related to the PanCAN Grants in the condensed consolidated balance sheet. As of December 31, 2023, the Company recorded \$0.3 million as deferred liabilities related to the PanCAN Grant in the condensed consolidated balance sheet.

### 3. Cash, cash equivalents and restricted cash

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the condensed consolidated balance sheets that sum to the total of the same such amounts shown in the condensed consolidated statements of cash flows (in thousands):

	September 30, 2024	December 31, 2023
Cash and cash equivalents	\$ 113,175	\$ 77,909
Restricted cash	241	1,167
<b>Total cash, cash equivalents and restricted cash</b>	<b>\$ 113,416</b>	<b>\$ 79,076</b>

Amounts included in restricted cash as of September 30, 2024 is cash held to collateralize outstanding letters of credit provided as a security deposit for the Company's office space located in Needham, Massachusetts in the amount of \$0.2 million. Amounts included in restricted cash as of December 31, 2023 represent (i) cash received pursuant to the PanCAN Grant restricted for expenditures for specific research and development activities of \$0.9 million and (ii) cash held to collateralize outstanding letters of credit provided as a security deposit for the Company's office space located in Needham, Massachusetts in the amount of \$0.2 million. The letters of credit are included in prepaid expenses and other current assets and non-current restricted cash on the condensed consolidated balance sheets as of September 30, 2024, and December 31, 2023 respectively. Cash received pursuant to the PanCAN Grant is included in prepaid expenses and other current assets on the condensed consolidated balance sheets as of December 31, 2023.

### 4. Fair value of financial instruments

The Company determines the fair value of its financial instruments based upon the fair value hierarchy, which prioritizes valuation inputs based on the observable nature of those inputs. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments and is not a measure of the investment credit quality. The hierarchy defines three levels of valuation inputs:

Level 1 inputs	Quoted prices in active markets for identical assets or liabilities that the Company can access at the measurement date.
Level 2 inputs	Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly.
Level 3 inputs	Unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the asset or liability.

#### *Items Measured at Fair Value on a Recurring Basis*

The following table presents information about the Company's financial instruments that are measured at fair value on a recurring basis (in thousands):

Description	September 30, 2024			
	Total	Level 1	Level 2	Level 3
<b>Financial assets</b>				
Cash equivalents	\$ 93,191	\$ 93,191	\$ —	\$ —
<b>Total financial assets</b>	<b>\$ 93,191</b>	<b>\$ 93,191</b>	<b>\$ —</b>	<b>\$ —</b>
Warrant liability	\$ 26,138	\$ —	\$ —	\$ 26,138

Description	December 31, 2023			
	Total	Level 1	Level 2	Level 3
<b>Financial assets</b>				
Cash equivalents	\$ 46,093	\$ 46,093	\$ —	\$ —
Short-term investments	59,220	5,992	53,228	—
<b>Total financial assets</b>	<b>\$ 105,313</b>	<b>\$ 52,085</b>	<b>\$ 53,228</b>	<b>\$ —</b>
Preferred stock tranche liability	\$ 4,189	\$ —	\$ —	\$ 4,189

The Company's cash equivalents and short-term investments consist of U.S. Government money market funds, corporate bonds, agency bonds and commercial paper of publicly traded companies. The investments and cash equivalents have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, utilizing third party pricing services or other market observable data. The pricing services utilize industry standard valuation models, including both income and market-based approaches and observable market inputs to determine value. These observable market inputs include reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, current spot rates and other industry and economic events. The Company validates the prices provided by third party pricing services by reviewing their pricing methods and matrices, obtaining market values from other pricing sources, analyzing pricing data in certain instances and confirming that the relevant markets are active. After completing its validation procedures, the Company did not adjust or override any fair value measurements provided by the pricing services as of September 30, 2024, or December 31, 2023.

*Preferred Stock tranche liability*

A preferred stock tranche liability was recorded as a result of the entry into the Securities Purchase Agreement (defined herein) (see *Note 10. Capital Stock*). The fair value measurement of the preferred stock tranche liability is classified as Level 3 under the fair value hierarchy. The fair value of the preferred stock tranche liability at inception and December 31, 2023 was determined using a Monte-Carlo simulation. The inputs to the Monte-Carlo include the risk-free rate, stock price volatility, expected dividends and remaining term. Significant increases or decreases in any of those inputs in isolation could result in a significantly lower or higher fair value measurement. The preferred stock tranche liability expired in July 2024 and is no longer outstanding.

Below are the inputs used to value the preferred stock tranche liability at December 31, 2023:

	December 31, 2023
Risk-free interest rate	5.13-5.52 %
Volatility	75 %
Dividend yield	—
Remaining term (years)	0.6

The following table represents a reconciliation of the preferred stock right liability recorded in connection with the entry into the Securities Purchase Agreement (in thousands):

<b>January 1, 2024</b>	<b>\$ 4,189</b>
Fair value adjustment	(4,189)
<b>September 30, 2024</b>	<b>\$ —</b>

*Warrant liability*

A warrant liability was recorded as a result the July 2024 Offering (defined herein) (see *Note 10. Capital Stock*). The fair value measurement of the warrant liability is classified as Level 3 under the fair value hierarchy. The fair value of the warrant liability at inception and September 30, 2024, was determined using the Black-Scholes valuation model. The inputs to the Black-Scholes valuation model include the risk-free rate, stock price volatility, expected dividends and remaining term. Significant increases or decreases in any of those inputs in isolation could result in a significantly lower or higher fair value measurement.

Below are the inputs used to value the warrant liability at July 23, 2024 and September 30, 2024:

	September 30, 2024	July 23, 2024
Risk-free interest rate	3.88 %	4.63 %
Volatility	118 %	132 %
Dividend yield	—	—
Remaining term (years)	1.3	1.5

The following table represents a reconciliation of the warrant liability (in thousands):

<b>July 23, 2024</b>	<b>\$ 39,595</b>
Fair value adjustment	(13,457)
<b>September 30, 2024</b>	<b>\$ 26,138</b>

#### Long-term debt

The fair value of the Company's long-term debt was determined using a discounted cash flow analysis with current applicable rates for similar instruments as of the condensed consolidated balance sheet dates. The Company estimates that the fair value of its long-term debt was approximately \$40.6 million as of September 30, 2024, which differs from the carrying value of \$40.5 million. The Company estimates that the fair value of its long-term debt was approximately \$39.6 million as of December 31, 2023, which differs from the carrying value of \$40.1 million. The fair value of the Company's long-term debt was determined using Level 3 inputs.

#### 5. Investments

Cash, cash equivalents, restricted cash and investments consist of the following (in thousands):

	September 30, 2024			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash, cash equivalents & restricted cash:				
Cash and money market accounts	\$ 113,416	\$ —	\$ —	\$ 113,416
<b>Total cash, cash equivalents &amp; restricted cash:</b>	<b>\$ 113,416</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 113,416</b>
	December 31, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash, cash equivalents & restricted cash:				
Cash and money market accounts	\$ 79,076	\$ —	\$ —	\$ 79,076
<b>Total cash, cash equivalents &amp; restricted cash:</b>	<b>\$ 79,076</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 79,076</b>
Investments:				
Corporate bonds, agency bonds and commercial paper (due within 1 year)	\$ 59,208	\$ 13	(1)	\$ 59,220
Total investments	\$ 59,208	\$ 13	\$ (1)	\$ 59,220
<b>Total cash, cash equivalents, restricted cash and investments</b>	<b>\$ 138,284</b>	<b>\$ 13</b>	<b>\$ (1)</b>	<b>\$ 138,296</b>

There were no realized gains or losses on investments for the three or nine months ended September 30, 2024, or 2023. Accrued interest receivable is excluded from the amortized cost and estimated fair value of the Company's investments. There was no accrued interest receivable on September 30, 2024. Accrued interest receivable of \$0.1 million is presented within prepaid expenses and other current assets on the condensed consolidated balance sheets at

December 31, 2023. There were zero and two debt securities in an unrealized loss position as of September 30, 2024, and December 31, 2023, respectively. None of these investments had been in an unrealized loss position for more than 12 months as of December 31, 2023. The Company considered the decline in the market value for these securities to be primarily attributable to current economic conditions and not credit related. At December 31, 2023, the Company had the intent and ability to hold such securities until recovery. As a result, the Company did not record any charges for credit-related impairments for its investments as of December 31, 2023.

The following is a summary of available-for-sale securities with unrealized losses for less than 12 months as of September 30, 2024 and December 31, 2023 (in thousands):

	September 30, 2024		December 31, 2023	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Corporate bonds, agency bonds and commercial paper (due within 1 year)	\$ —	\$ —	\$ 8,896	\$ (1)
<b>Total available-for-sale securities in an unrealized loss position</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 8,896</b>	<b>\$ (1)</b>

## 6. Accrued expenses

Accrued expenses consist of the following (in thousands):

	September 30, 2024	December 31, 2023
Accrued clinical trial expenses	\$ 9,319	\$ 6,518
Accrued contract manufacturing expenses	3,357	2,010
Accrued other research and development expenses	1,416	1,043
Accrued compensation and related benefits	4,629	4,796
Accrued professional fees	470	637
Accrued consulting fees	2,031	1,078
Accrued interest	306	316
Accrued commercialization costs	434	453
Accrued other	191	1,077
<b>Total accrued expenses</b>	<b>\$ 22,153</b>	<b>\$ 17,928</b>

## 7. Debt

On March 25, 2022 (the “Closing Date”), the Company entered into a loan and security agreement (the “Original Loan Agreement”) with Oxford, as collateral agent and a lender, and Oxford Finance Credit Fund III LP, as a lender (“OFCF III” and together with Oxford, the “Lenders”), pursuant to which the Lenders have agreed to lend the Company up to an aggregate principal amount of \$150.0 million in a series of term loans (the “Term Loans”). On January 4, 2024, the Company amended the Original Loan Agreement (as amended, the “Loan Agreement”) to extend the date by which it may draw down the Term C Loan from March 31, 2024, to March 31, 2025.

Pursuant to the Loan Agreement, the Company received an initial Term Loan of \$25.0 million on the Closing Date, and drew down the second term loan of \$15.0 million (the “Term B Loan”) on March 22, 2023, and may borrow an additional \$110.0 million of Term Loans at its option upon the satisfaction of certain conditions as follows:

- i. \$25.0 million (the “Term C Loan”), when the Company has received accelerated or full approval from the FDA of avotemetinib for the treatment of LGSOC (the “Term C Milestone”). The Company may draw the Term C Loan within 60 days after the occurrence of the Term C Milestone, but no later than March 31, 2025.
- ii. \$35.0 million (the “Term D Loan”), when the Company has achieved at least \$50.0 million in gross product revenue calculated on a trailing six-month basis (the “Term D Milestone”). The Company may draw the



- Term D Loan within 30 days after the occurrence of the Term D Milestone, but no later than March 31, 2025.
- iii. \$50.0 million (the “Term E Loan”), at the sole discretion of the Lenders.

The Term Loans bear interest at a floating rate equal to (a) the greater of (i) the one-month CME Secured Overnight Financing Rate and (ii) 0.13% plus (b) 7.37%, which is subject to an overall floor and cap. Interest is payable monthly in arrears on the first calendar day of each calendar month. As a result of the Term B Loan drawdown, beginning (i) April 1, 2025, or (ii) April 1, 2026, if either (A) avotemetinib has received FDA approval for the treatment of LGSOC or (B) COPIKTRA has received FDA approval for the treatment of peripheral T-cell lymphoma, the Company shall repay the Term Loans in consecutive equal monthly payments of principal, together with applicable interest, in arrears. All unpaid principal and accrued and unpaid interest with respect to each Term Loan is due and payable in full on March 1, 2027.

The Company is required to make a final payment of 5.0% of the original principal amount of the Term Loans that are drawn, payable at maturity or upon any earlier acceleration or prepayment of the Term Loans (the “Final Payment Fee”). The Company may prepay all, but not less than all, of the Term Loans, subject to a prepayment fee equal to (i) 3.0% of the principal amount of the applicable Term Loan if prepaid on or before the first anniversary date of the funding date of such Term Loan, (ii) 2.0% of the principal amount of the applicable Term Loan if prepaid after the first anniversary and on or before the second anniversary of the funding date of such Term Loan, and (iii) 1.0% of the principal amount of the applicable Term Loan if prepaid after the second anniversary of the applicable funding date of such Term Loan. All Term Loans are subject to a facility fee of 0.5% of the principal amount.

The Loan Agreement contains no financial covenants. The Loan Agreement includes customary events of default, including, among others, payment defaults, breach of representations and warranties, covenant defaults, judgment defaults, insolvency and bankruptcy defaults, and a material adverse change. The occurrence of an event of default could result in the acceleration of the obligations under the Loan Agreement, termination of the Term Loan commitments and the right to foreclose on the collateral securing the obligations. During the existence of an event of default, the Term Loans will accrue interest at a rate per annum equal to 5.0% above the otherwise applicable interest rate.

In connection with the Loan Agreement, the Company granted Oxford a security interest in all of the Company’s personal property now owned or hereafter acquired, excluding intellectual property (but including the right to payments and proceeds of intellectual property), and a negative pledge on intellectual property.

The Company assessed all terms and features of the Loan Agreement in order to identify any potential embedded features that would require bifurcation. As part of this analysis, the Company assessed the economic characteristics and risks of the Loan Agreement, including put and call features. The Company determined that all features of the Loan Agreement were clearly and closely associated with a debt host and did not require bifurcation as a derivative liability, or the fair value of the feature was immaterial to the Company’s financial statements. The Company reassesses the features on a quarterly basis to determine if they require separate accounting. There have been no changes to the Company’s assessment through September 30, 2024.

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The debt issuance costs and the Final Payment Fee have been recorded as a debt discount which are being accreted to interest expense through the maturity date of the Term Loan using the effective interest method. The components of the carrying value of the debt as of September 30, 2024, and December 31, 2023, are detailed below (in thousands):

	September 30, 2024	December 31, 2023
<b>Principal loan balance</b>	\$ 40,000	\$ 40,000
Final Payment Fee	1,037	661
Debt issuance costs, net of accretion	(520)	(575)
<b>Total Long-term debt, net of discount</b>	<b>40,517</b>	<b>40,086</b>
Current portion of long-term debt	9,870	—
<b>Long-term debt, net of current portion</b>	<b>\$ 30,647</b>	<b>\$ 40,086</b>

The following table sets forth total interest expense for the three-month and nine-month periods ended September 30, 2024 and 2023 (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Contractual Interest	\$ 947	\$ 950	\$ 2,835	\$ 2,529
Amortization of debt discount and issuance costs	71	60	204	175
Amortization of Final Payment Fee	130	119	377	315
<b>Total</b>	<b>\$ 1,148</b>	<b>\$ 1,129</b>	<b>\$ 3,416</b>	<b>\$ 3,019</b>

As of September 30, 2024, future principal payments due are as follows (in thousands):

2024	—
2025	15,000
2026	20,000
2027	5,000
<b>Total principal payments</b>	<b>\$ 40,000</b>

## 8. Leases

On April 15, 2014, the Company entered into a lease agreement for approximately 15,197 square feet of office and laboratory space in Needham, Massachusetts. Effective February 15, 2018, the Company amended its lease agreement to relocate within the facility to another location consisting of 27,810 square feet of office space (the “Amended Lease Agreement”). The Amended Lease Agreement extends the expiration date of the lease from September 2019 through June 2025. Pursuant to the Amended Lease Agreement, the initial annual base rent amount is approximately \$0.7 million, which increases during the lease term to \$1.1 million for the last twelve-month period.

The Company accounted for its Needham, Massachusetts office space as an operating lease. The Company’s lease contains an option to renew and extend the lease terms and an option to terminate the lease prior to the expiration date. The Company has not included the lease extension or the termination options within the right-of-use asset and lease liability on the condensed consolidated balance sheets as neither option is reasonably certain to be exercised. The Company’s lease includes variable non-lease components (e.g., common area maintenance, maintenance, consumables, etc.) that are not included in the right-of-use asset and lease liability and are reflected as an expense in the period incurred. The Company does not have any other operating or finance leases.

As of September 30, 2024, a right-of-use asset of \$0.6 million and lease liability of \$0.8 million are reflected on the condensed consolidated balance sheets. The elements of lease expense were as follows (dollar amounts in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
<b>Lease Expense</b>				
Operating lease expense	\$ 221	\$ 221	\$ 664	\$ 664
<b>Total Lease Expense</b>	<b>\$ 221</b>	<b>\$ 221</b>	<b>\$ 664</b>	<b>\$ 664</b>
<b>Other Information - Operating Leases</b>				
Operating cash flows paid for amounts included in measurement of lease liabilities	\$ 273	\$ 268	\$ 808	\$ 793

	September 30, 2024
<b>Other Balance Sheet Information - Operating Leases</b>	
Weighted average remaining lease term (in years)	0.7
Weighted average discount rate	14.6%
<b>Maturity Analysis</b>	
2024	273
2025	546
<b>Total</b>	<b>\$ 819</b>
Less: Present value discount	(39)
<b>Lease Liability</b>	<b>\$ 780</b>

## 9. Notes Payable

In February 2024, the Company entered into a finance agreement with AFCO Premium Credit LLC (“AFCO”). Pursuant to the terms of the agreement, AFCO loaned the Company the principal amount of \$1.3 million, which accrues interest at 8.3% per annum, to fund a portion of the Company’s insurance policies. The Company is required to make monthly payments of \$0.1 million through October 2024 including principal and interest. The agreement assigns AFCO a security interest in (i) all unearned premiums and dividends which may become payable under the insurance policies financed pursuant to this agreement, (ii) loss payments which reduce the unearned premiums, and (iii) the Company’s interest in any state insurance guarantee fund related to any of the insurance policies financed pursuant to this agreement. The outstanding balance at September 30, 2024 was \$0.1 million recorded as note payable on the condensed consolidated balance sheets.

## 10. Capital stock

### July 2024 Public Offering

On July 23, 2024, the Company entered into an underwriting agreement with Guggenheim Securities, LLC and Cantor Fitzgerald & Co. (“Cantor”), as representatives of the several underwriters relating to the underwritten offering, issuance and sale by the Company of: (i) 13,333,334 shares of the Company’s common stock, and accompanying warrants (the “Warrants”) to purchase up to 13,333,334 shares of common stock; and (ii) to certain investors, pre-funded warrants (the “July 2024 Pre-Funded Warrants”) to purchase up to 5,000,000 shares of common stock and accompanying Warrants to purchase 5,000,000 shares of common stock (collectively, the “July 2024 Offering”). Each share of common stock was sold with an accompanying Warrant at a combined price of \$3.00, and each July 2024 Pre-Funded Warrant was sold together with an accompanying Warrant at a combined price of \$2.999, which is equal to the combined offering price per share of common stock and accompanying Warrant less the \$0.001 exercise price of each July 2024 Pre-

Funded Warrant. The July 2024 Offering closed on July 25, 2024. The Company received approximately \$50.8 million in net proceeds, after deducting underwriting discounts and commissions and offering expenses.

Each July 2024 Pre-Funded Warrant has an exercise price equal to \$0.001 per underlying share of common stock. The July 2024 Pre-Funded Warrants are exercisable as of July 25, 2024, do not expire and are exercisable in cash or by means of a cashless exercise.

Each Warrant has an exercise price equal to \$3.50. Each Warrant is exercisable for one share of the Company's common stock (or, in certain limited circumstances in lieu of a share of common stock, a pre-funded warrant for one share of the Company's common stock at the warrant exercise price less the exercise price of the pre-funded warrant purchased). The Warrants are exercisable as of July 25, 2024 until their expiration on January 25, 2026. The Warrants are exercisable in cash or, in certain limited circumstances only, by means of a cashless exercise.

The exercise price and the number of shares of common stock issuable upon exercise of each Warrant or July 2024 Pre-Funded Warrant, as applicable, is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting the Company's common stock as well as upon any distribution of assets, including cash, stock or other property, to the Company's stockholders.

The Company may not effect the exercise of any Warrant or July 2024 Pre-Funded Warrant, and a holder will not be entitled to exercise any portion of any Warrant or July 2024 Pre-Funded Warrant if, upon giving effect to such exercise, the aggregate number of shares of common stock beneficially owned by the holder (together with its affiliates) would exceed 4.99% (or such higher percentage up to 19.99%, at the election of the holder) of the number of shares of the Company's common stock outstanding immediately after giving effect to the exercise, which percentage may be increased or decreased at the holder's election upon 61 days' notice to the Company subject to the terms of such Warrants or July 2024 Pre-Funded Warrants, as applicable, provided that such percentage may in no event exceed 19.99%. In the event that the exercise of a Warrant would cause the holder to beneficially own in excess of 4.99% (or such higher percentage up to 19.99%, at the election of the holder) of the total number shares of the Company's common stock outstanding immediately after giving effect to such exercise, the holder of a Warrant may elect to purchase a pre-funded warrant for one share of the Company's common Stock, rather than a share of common stock, at the Warrant exercise price less the exercise price of the pre-funded warrant purchased.

In addition, upon the consummation of an acquisition (as described in the Warrants agreements and July 2024 Pre-Funded Warrants agreements, as applicable), each Warrant and July 2024 Pre-Funded Warrant will automatically be converted into the right of the holder of such Warrant or July 2024 Pre-Funded Warrant, as applicable, to receive the kind and amount of securities, cash or other property that such holders would have received had they exercised such Warrant or July 2024 Pre-Funded Warrant, as applicable, immediately prior to such acquisition, without regard to any limitations on exercise contained in the Warrant agreements or July 2024 Pre-Funded Warrant agreements.

The Warrants meet the definition of a derivative pursuant to FASB Accounting Standard Codification 815, *Derivatives and Hedging*, and do not meet the derivative scope exception given the Warrants do not qualify under the indexation guidance. As a result, the Warrants were initially recognized as liabilities and measured at fair value using the Black-Scholes valuation model with subsequent changes in fair value recorded in earnings. The warrants were recorded at a fair value of \$39.6 million upon issuance and the Company allocated \$39.6 million of the proceeds to this liability and recorded this amount as warrant liability. On September 30, 2024, the fair value of the Warrants was determined to be \$26.1 million and the Company recorded this amount as warrant liability on the condensed consolidated balance sheets and the Company recorded the mark-to-market adjustment of \$13.5 million for the three and nine months ended September 30, 2024, under change in fair value of warrant liability within the condensed consolidated statements of operations and loss.

The July 2024 Pre-Funded Warrants cannot require cash settlement, are freestanding financial instruments that are legally detachable and separately exercisable from the shares of common stock and Warrants with which they were issued, are immediately exercisable, and do not embody an obligation for the Company to repurchase its common stock shares and permit the holders to receive a fixed number of shares of common stock upon exercise. Additionally, the July 2024 Pre-Funded Warrants do not provide any guarantee of value or return. Accordingly, the July 2024 Pre-Funded

Warrants are classified as a component of permanent equity. The Company allocated \$15.4 million of the proceeds to the July 2024 Pre-Funded Warrants and shares of common stock issued.

The Company incurred a total of \$4.2 million in issuance costs, which the Company allocated to the Warrants, and 2024 Pre-Funded Warrants and shares of common stock consistent with the allocation of proceeds. \$3.0 million of issuance costs were allocated to the Warrants and expensed within selling, general and administrative expenses in the condensed statements of operations and comprehensive loss for the three and nine months ended September 30, 2024. \$1.2 million of the issuance costs were allocated to the July 2024 Pre-Funded Warrants and shares of common stock and applied against additional paid-in capital.

### ***June 2023 Public Offering***

On June 15, 2023, the Company entered into an underwriting agreement (the “June 2023 Underwriting Agreement”) with RBC Capital Markets, LLC and Cantor, as representatives of several underwriters (the “June 2023 Underwriters”) to offer 7,181,409 shares of the Company’s common stock, at a price to the public of \$9.75 per share, less the underwriting discounts and commissions, and, in lieu of shares of common stock to certain investors, pre-funded warrants (the “June 2023 Pre-Funded Warrants”) to purchase up to an aggregate of 1,538,591 shares of common stock at a price to the public of \$9.749 per share of common stock underlying a pre-funded warrant, which represents the per share public offering price for the shares of common stock less the \$0.001 per share exercise price for each such share of common stock underlying a June 2023 Pre-Funded Warrant (the “June 2023 Offering”). In addition, the Company granted the June 2023 Underwriters an option to purchase, at the public offering price less underwriting discounts and commissions, an additional 1,308,000 shares of common stock, exercisable for 30 days from the date of the June 2023 Underwriting Agreement, which the June 2023 Underwriters exercised in full on June 16, 2023. The June 2023 Offering closed on June 21, 2023.

The Company could not have effected the exercise of any June 2023 Pre-Funded Warrant, and a holder was not entitled to exercise any portion of any June 2023 Pre-Funded Warrant if, upon giving effect to such exercise, the aggregate number of shares of common stock beneficially owned by the holder (together with its affiliates) would have exceeded 9.99% of the number of shares of common stock outstanding immediately after giving effect to the exercise, which percentage could have been increased or decreased at the holder’s election upon 61 days’ notice to the Company subject to the terms of such June 2023 Pre-Funded Warrant, provided that such percentage in no event exceeded 19.99%.

Each June 2023 Pre-Funded Warrant had an exercise price equal to \$0.001 per share of common stock. The exercise price and the number of shares of common stock issuable upon exercise of each June 2023 Pre-Funded Warrant was subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting the Company’s common stock as well as upon any distribution of assets, including cash, stock or other property, to the Company’s stockholders. The June 2023 Pre-Funded Warrants were exercisable as of June 21, 2023, did not expire and were exercisable in cash or by means of a cashless exercise. In addition, upon the consummation of an acquisition (as described in the June 2023 Pre-Funded Warrant agreements), each June 2023 Pre-Funded Warrant would have automatically been converted into the right of the holder of such June 2023 Pre-Funded Warrant to receive the kind and amount of securities, cash or other property that such holders would have received had they exercised such June 2023 Pre-Funded Warrant immediately prior to such acquisition, without regard to any limitations on exercise contained in the June 2023 Pre-Funded Warrants.

The June 2023 Pre-Funded Warrants could not have required cash settlement, were freestanding financial instruments that were legally detachable and separately exercisable from the shares of common stock with which they were issued, were immediately exercisable, and did not embody an obligation for the Company to repurchase its common stock shares and permitted the holders to receive a fixed number of shares of common stock upon exercise. Additionally, the June 2023 Pre-Funded Warrants did not provide any guarantee of value or return. Accordingly, the June 2023 Pre-Funded Warrants were classified as a component of permanent equity. After deducting for commissions and other offering expenses, the Company received net proceeds of approximately \$91.4 million from the sale of 8,489,409 shares of common stock and June 2023 Pre-Funded Warrants to purchase up to 1,538,591 shares of common stock.

During the quarter ended June 30, 2024, the holders exercised the June 2023 Pre-Funded Warrants representing 1,538,591 underlying shares of common stock, exercise price \$0.0001 per share, via cashless exercise resulting in the issuance of 1,538,201 shares of common stock. As of September 30, 2024, there were no June 2023 Pre-Funded Warrants outstanding.

### ***Series B Convertible Preferred Stock***

Under the amended and restated certificate of incorporation, the Company's board of directors has the authority, without further action by the stockholders, to issue up to 5,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

On January 24, 2023, the Company entered into a Securities Purchase Agreement (the "Securities Purchase Agreement") with certain purchasers pursuant to which the Company agreed to sell and issue to the purchasers in a private placement (the "Private Placement") up to 2,144,160 shares of its Series B convertible preferred stock, par value \$0.0001 per share (the "Series B Convertible Preferred Stock"), in two tranches. On January 24, 2023, the Company filed the Certificate of Designation of the Preferences, Rights and Limitations of the Series B Convertible Preferred Stock (the "Series B Convertible Preferred Stock Certificate of Designation") setting forth the preferences, rights and limitations of the Series B Convertible Preferred Stock with the Secretary of State of the State of Delaware. The Series B Convertible Preferred Stock Certificate of Designation became effective upon filing.

Each share of the Series B Convertible Preferred Shares is convertible into 3.5305 shares of the Company's common stock, such conversion rate reflects an adjustment to account for the Reverse Stock Split, at the option of the holders at any time, subject to certain limitations, including that the holder will be prohibited from converting Series B Convertible Preferred Stock into common stock if, as a result of such conversion, the holder, together with its affiliates, would beneficially own a number of shares of common stock above a conversion blocker, which is initially set at 9.99% (the "Conversion Blocker") of the total common stock then issued and outstanding immediately following the conversion of such shares of Series B Convertible Preferred Stock. Holders of the Series B Convertible Preferred Stock are permitted to increase the Conversion Blocker to an amount not to exceed 19.99% upon 60 days' notice.

The Company agreed to sell and issue in the first tranche of the Private Placement 1,200,000 shares of Series B Convertible Preferred Stock at a purchase price of \$25.00 per share of Series B Convertible Preferred Stock (equivalent to \$7.0812 per share of common stock on a post-Reverse Stock Split basis). The first tranche of the Private Placement closed on January 27, 2023. The Company received gross proceeds from the first tranche of the Private Placement of approximately \$30.0 million, before deducting fees to the placement agent and other offering expenses payable by the Company ("Series B Convertible Preferred Stock Proceeds").

In addition, the Company agreed to sell and issue in the second tranche of the Private Placement 944,160 shares of Series B Convertible Preferred Stock at a purchase price of \$31.77 per share of Series B Convertible Preferred Stock (equivalent to \$9.00 per share of common stock on a post-Reverse Stock Split basis) if at any time within 18 months following the closing of the first tranche the 10-day volume weighted average price of the Company's common stock (as quoted on Nasdaq and as calculated by Bloomberg) should reach at least \$13.50 per share, such threshold reflects an adjustment to account for the Reverse Stock Split (which may be further adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction as needed) with aggregate trading volume during the same 10-day period of at least \$25 million (the "Second Tranche Right"). The second tranche of the Private Placement is expected to close within seven trading days of meeting the second tranche conditions and will be subject to additional, customary closing conditions. If the Second Tranche Right conditions are satisfied, the Company anticipates receiving gross proceeds from the second tranche of the Private Placement of approximately \$30.0 million, before deducting fees to the placement agent and other offering expenses payable by the Company.

The Series B Convertible Preferred Stock ranks (i) senior to the common stock; (ii) senior to all other classes and series of equity securities of the Company that by their terms do not rank senior to the Series B Convertible

Preferred Stock; (iii) senior to all shares of the Company's Series A Convertible Preferred Stock the equity securities described in (i)-(iii), the "Junior Stock"); (iv) on parity with any class or series of capital stock of the Company hereafter created specifically ranking by its terms on parity with the Series B Convertible Preferred Stock (the "Parity Stock"); (v) junior to any class or series of capital stock of the Company hereafter created specifically ranking by its terms senior to any Series B Convertible Preferred Stock ("Senior Stock"); and (vi) junior to all of the Company's existing and future debt obligations, including convertible or exchangeable debt securities, in each case, as to distributions of assets upon liquidation, dissolution or winding up of the Company, whether voluntarily or involuntarily and as to the right to receive dividends.

In the event of the liquidation, dissolution or winding up of the affairs of the Company, whether voluntary or involuntary, after payment or provision for payment of the debts and other liabilities of the Company, and subject to the prior and superior rights of any Senior Stock, each holder of shares of Series B Convertible Preferred Stock will be entitled to receive, in preference to any distributions of any of the assets or surplus funds of the Company to the holders of the common stock and any of the Company's securities that are Junior Stock and *pari passu* with any distribution to the holders of any Parity Stock, an amount equal to \$1.00 per share of Series B Convertible Preferred Stock, plus an additional amount equal to any dividends declared but unpaid on such shares, before any payments shall be made or any assets distributed to holders of the common stock or any of our securities that Junior Stock.

So long as any shares of the Series B Convertible Preferred Stock remain outstanding, the Company cannot without the affirmative vote or consent of the holders of majority of the shares of the Series B Convertible Preferred Stock then-outstanding, in which the holders of the Series B Convertible Preferred Stock vote separately as a class: (a) amend, alter, modify or repeal (whether by merger, consolidation or otherwise) the Series B Convertible Preferred Stock Certificate of Designation, the Company's certificate of incorporation, or the Company's bylaws in any manner that adversely affects the rights, preferences, privileges or the restrictions provided for the benefit of, the Series B Convertible Preferred Stock; (b) issue further shares of Series B Convertible Preferred Stock or increase or decrease (other than by conversion) the number of authorized shares of Series B Convertible Preferred Stock; (c) authorize or issue any Senior Stock; or (d) enter into any agreement to do any of the foregoing that is not expressly made conditional on obtaining the affirmative vote or written consent of the majority of then-outstanding Series B Convertible Preferred Stock. Holders of Series B Convertible Preferred Stock are entitled to receive when, as and if dividends are declared and paid on the common stock, an equivalent dividend, calculated on an as-converted basis. Shares of Series B Convertible Preferred Stock are otherwise not entitled to dividends.

The Company classified the first tranche of the Series B Convertible Preferred Stock as temporary equity in the condensed consolidated balance sheets as the Company could be required to redeem the Series B Convertible Preferred Stock if the Company cannot convert the Series B Convertible Preferred Stock into shares of common stock for any reason including due to any applicable laws or by the rules or regulations of any stock exchange, interdealer quotation system, or other self-regulatory organization with jurisdiction over the Company which is not solely in the control of the Company. If the Company were required to redeem the Series B Convertible Preferred Stock, it would be based upon the volume-weighted-average price of common stock on an as converted basis on the date the holders provided a conversion notice to the Company. As of September 30, 2024, the Company did not adjust the carrying value of the Series B Convertible Preferred Stock since it was not probable the holders would be unable to convert the Series B Convertible Preferred Stock into shares of common stock due to any reason including due to any applicable laws or by the rules or regulations of any stock exchange, interdealer quotation system, or other self-regulatory organization with jurisdiction over the Company.

The Company evaluated the Second Tranche Right under Accounting Standard Codification 480, *Distinguishing Liabilities from Equity* ("ASC 480") and determined that it met the requirements for separate accounting from the initial issuance of Series B Convertible Preferred Stock as a freestanding financial instrument. The Company then determined the Second Tranche Right should be liability classified pursuant to ASC 480. As a result, the Company classified the Second Tranche Right as a non-current liability within the condensed consolidated balance sheets and the Second Tranche Right was initially recorded at fair value and is subsequently re-measured at fair value at the end of each reporting period. The fair value of the Second Tranche Right on the date of issuance was determined to be \$6.9 million based on a Monte-Carlo valuation and the Company allocated \$6.9 million of the Series B Convertible Preferred Stock Proceeds to this liability and recorded this amount as preferred stock tranche liability. On December 31, 2023, the fair

value of the Second Tranche Right was determined to be \$4.2 million and the Company recorded this amount as preferred stock tranche liability on the condensed consolidated balance sheets. The Second Tranche Right expired in July 2024 and is no longer outstanding. The Company recorded the mark-to-market adjustment of \$4.2 million for the nine months ended September 30, 2024, under change in fair value of preferred stock tranche liability within the condensed consolidated statements of operations and loss. The Company recorded the mark-to-market adjustment of \$0.2 million and \$0.3 million for the three and nine months ended September 30, 2023, respectively, under change in fair value of preferred stock tranche liability within the condensed consolidated statements of operations and loss.

The Company determined that all other features of the securities offered pursuant to the Securities Purchase Agreement were clearly and closely associated with the equity host and did not require bifurcation or the fair value of the feature was immaterial to the Company's condensed consolidated financial statements. The Company reassesses the features on a quarterly basis to determine if they require separate accounting. There have been no changes to the Company's original assessment through September 30, 2024.

### ***Series A Convertible Preferred Stock***

On November 4, 2022, the Company entered into an exchange agreement (the "Exchange Agreement") with Biotechnology Value Fund, L.P., Biotechnology Value Fund II, L.P., Biotechnology Value Trading Fund OS LP and MSI BVF SPV, LLC (collectively referred to as "BVF"), pursuant to which BVF exchanged 833,333 shares of the Company's common stock for 1,000,000 shares of newly designated Series A convertible preferred stock, par value \$0.0001 per share (the "Series A Convertible Preferred Stock") (the "Exchange").

Each share of the Series A Convertible Preferred Stock is convertible into 0.833 shares of the Company's common stock at the option of the holder at any time, subject to certain limitations, including that the holder will be prohibited from converting Preferred Stock into common stock if, as a result of such conversion, the holder, together with its affiliates, would beneficially own a number of shares of common stock above the Conversion Blocker, initially set at 9.99%, of the total common stock then issued and outstanding immediately following the conversion of such shares of Preferred Stock. Holders of the Series A Convertible Preferred Stock are permitted to increase the Conversion Blocker to an amount not to exceed 19.99% upon 60 days' notice.

Shares of Series A Convertible Preferred Stock generally have no voting rights, except as required by law and except that the consent of a majority of the holders of the outstanding Series A Convertible Preferred Stock will be required to amend the terms of the Series A Convertible Preferred Stock. In the event of the Company's liquidation, dissolution or winding up, holders of Series A Convertible Preferred Stock will participate pari passu with any distribution of proceeds to holders of common stock. Holders of Series A Convertible Preferred Stock are entitled to receive when, as and if dividends are declared and paid on the common stock, an equivalent dividend, calculated on an as-converted basis. Shares of Series A Convertible Preferred Stock are otherwise not entitled to dividends.

The Series A Convertible Preferred Stock (i) senior to any class or series of capital stock of the Company hereafter created specifically ranking by its terms junior to the Series A Convertible Preferred Stock; (ii) on parity with the common stock and any class or series of capital stock of the Company created specifically ranking by its terms on parity with the Series A Convertible Preferred Stock; and (iii) junior to the Series B Convertible Preferred Stock and to any class or series of capital stock of the Company created specifically ranking by its terms senior to any Series A Convertible Preferred Stock, in each case, as to distributions of assets upon liquidation, dissolution or winding up of the Company, whether voluntarily or involuntarily.

The Company evaluated the Series A Convertible Preferred Stock for liability or equity classification under ASC 480, and determined that equity treatment was appropriate because the Series A Convertible Preferred Stock did not meet the definition of the liability under ASC 480. Additionally, the Series A Convertible Preferred Stock is not redeemable for cash or other assets (i) on a fixed or determinable date, (ii) at the option of the holder, or (iii) upon the occurrence of an event that is not solely within control of the Company. As such, the Company recorded the Series A Convertible Preferred Stock as permanent equity.



## 11. Stock-based compensation

### *Option Exchange Program*

On January 17, 2024, the Company’s stockholders, upon recommendation of the board of directors, approved a one-time stock option exchange program (the “Option Exchange Program”) for certain employees, executive officers and non-employee directors of the Company who held certain underwater options and remained employed or otherwise engaged by the Company through the completion of the Exchange Offer. The Company’s offer to participate in the Option Exchange Program commenced on February 8, 2024, and expired on March 8, 2024 (the “Exchange Offer”). Pursuant to the Exchange Offer, 42 eligible holders elected to exchange, and the Company accepted for cancellation, eligible options to purchase an aggregate of 603,330 shares of the Company’s common stock (the “Exchanged Options”). On March 11, 2024, promptly following the expiration of the Exchange Offer, the Company granted new options to purchase 603,330 shares of common stock (the “New Options”), pursuant to the terms of the Exchange Offer and the Amended and Restated 2021 Equity Incentive Plan (the “2021 Plan”). The exercise price of the New Options granted was \$11.44 per share, which was the closing price of the Company’s common stock on the Nasdaq Capital Market on the grant date of the New Options.

The exchange of stock options was treated as a modification for accounting purposes. As a result of the Option Exchange Program, the Company will recognize incremental stock-based compensation expense of \$1.7 million over the requisite service period of the New Options, which is two or four years depending on whether the Exchanged Options were vested at the time of exchange. Since the Exchanged Options were not at-the-money on the modification date, the Company was precluded from utilizing the simplified method as described in SEC Staff Accounting Bulletin Topic 14.D.2 to calculate the expected term as a key assumption in the Black-Scholes pricing model. Therefore, the Company utilized the binomial lattice model to calculate the fair value of the Exchanged Options immediately prior to the exchange. The Company utilized the Black-Scholes option-pricing model to calculate the fair value of the New Options on the modification date. The Company will recognize the remaining unamortized stock compensation expense for the Exchanged Options on the modification date over the original requisite service period of the Exchanged Options.

### *Stock options*

A summary of the Company’s stock option activity and related information for the nine months ended September 30, 2024 is as follows:

	Shares	Weighted- average exercise price per share	Weighted- average remaining contractual term (years)	Aggregate intrinsic value (in thousands)
Outstanding at December 31, 2023	2,270,359	\$ 19.81	7.8	\$ 559
Granted	349,374	4.62		
Exercised	(21,978)	7.84		
Forfeited/cancelled	(197,146)	15.06		
Expired	(23,677)	162.38		
Cancelled under the Option Exchange Program	(603,330)	30.58		
Granted under the Option Exchange Program	603,330	11.44		
Outstanding at September 30, 2024	<u>2,376,932</u>	<u>\$ 11.80</u>	<u>8.5</u>	<u>\$ 18</u>
Vested at September 30, 2024	<u>710,319</u>	<u>\$ 17.53</u>	<u>7.2</u>	<u>\$ —</u>

The fair value of each stock option granted during the nine months ended September 30, 2024 and 2023 was estimated on the grant date using the Black-Scholes option-pricing model using the following weighted-average assumptions:

	<b>Nine months ended September 30,</b>	
	<b>2024</b>	<b>2023</b>
Risk-free interest rate	4.14 %	3.63 %
Volatility	98 %	91 %
Dividend yield	—	—
Expected term (years)	5.8	6.1

**Restricted stock units**

A summary of the Company’s restricted stock unit activity and related information for the nine months ended September 30, 2024 is as follows:

	Shares	Weighted- average grant date fair value per share
Outstanding at December 31, 2023	209,289	\$ 18.05
Granted	950,371	\$ 5.07
Vested	(78,657)	\$ 16.07
Forfeited/cancelled	(35,645)	\$ 15.43
Outstanding at September 30, 2024	<u>1,045,358</u>	<u>\$ 6.49</u>

**Employee stock purchase plan**

At the Special Meeting of Stockholders, held on December 18, 2018, the stockholders approved the 2018 Employee Stock Purchase Plan (“2018 ESPP”). On June 21, 2019, the board of directors of the Company amended and restated the 2018 ESPP, to account for certain non-material changes to the plan’s administration and, effective May 30, 2023, in connection with the Reverse Stock Split, the board of directors amended and restated the 2018 ESPP to account for the adjustments to the share reserves (the “Amended and Restated 2018 ESPP”). The Amended and Restated 2018 ESPP provides eligible employees with the opportunity, through regular payroll deductions, to purchase shares of the Company’s common stock at 85% of the lesser of the fair market value of the common stock on (a) the date the option is granted, which is the first day of the purchase period, and (b) the exercise date, which is the last business day of the purchase period. The Amended and Restated 2018 ESPP generally allows for two six-month purchase periods per year beginning in January and July, or such other periods as determined by the compensation committee of the Company’s board of directors. The fair value of shares expected to be purchased under the Amended and Restated 2018 ESPP was calculated using the following weighted-average assumptions:

	Nine months ended September 30,	
	2024	2023
Risk-free interest rate	5.31 %	5.16 %
Volatility	115 %	126 %
Dividend yield	—	—
Expected term (years)	0.5	0.5

For the nine months ended September 30, 2024 and 2023, the Company recognized less than \$0.1 million in each period of stock-based compensation expense under the Amended and Restated 2018 ESPP. During the nine months ended September 30, 2024, the Company issued 15,231 shares of common stock for proceeds of \$0.1 million under the Amended and Restated 2018 ESPP.

## 12. Net loss per share

Basic loss per common share is calculated by dividing net loss applicable to common stockholders by the weighted-average number of common shares outstanding during the period. For purposes of calculating net loss per share, weighted-average number of common shares outstanding includes the weighted average effect of the pre-funded warrants issued in June 2023 and in July 2024, the exercise of which requires little or no consideration for the delivery of shares of common stock. Diluted net loss per common share is calculated by increasing the denominator by the weighted-average number of additional shares that could have been outstanding from securities convertible into common stock, such as the warrants issued in July 2024, stock options, restricted stock units, and employee stock purchase plan shares (using the “treasury stock” method), and the 5.00% Convertible Senior Notes due 2048 (the “2018 Notes”), Series A Convertible Preferred Stock, and Series B Convertible Preferred Stock (using the “if-converted” method), unless their effect on net loss per share is anti-dilutive.

The following potentially dilutive securities were excluded from the calculation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect:

	<b>Three months ended September 30,</b>		<b>Nine months ended September 30,</b>	
	<b>2024</b>	<b>2023</b>	<b>2024</b>	<b>2023</b>
Outstanding stock options	2,376,932	2,120,555	2,376,932	2,120,555
Outstanding restricted stock units	1,045,358	225,675	1,045,358	225,675
2018 Notes	—	3,489	—	3,489
Warrants	18,333,334	—	18,333,334	—
Employee stock purchase plan	8,088	6,310	8,088	6,310
Series A Convertible Preferred Stock	833,333	833,333	833,333	833,333
Series B Convertible Preferred Stock	4,236,570	4,236,570	4,236,570	4,236,570
<b>Total potentially dilutive securities</b>	<b>26,833,615</b>	<b>7,425,932</b>	<b>26,833,615</b>	<b>7,425,932</b>

### 13. License, collaboration and commercial agreements

#### *GenFleet Therapeutics (Shanghai), Inc.*

On August 24, 2023, the Company entered into a collaboration and option agreement (“GenFleet Agreement”) with GenFleet, pursuant to which GenFleet granted the Company the option to obtain exclusive development and commercialization rights worldwide outside of mainland China, Hong Kong, Macau, and Taiwan (the “Territory”) for up to three oncology programs targeting ras sarcoma (“RAS”) pathway driven cancers (the “GenFleet Options”). The Company may exercise its GenFleet Options on a program-by-program basis.

The Company made an upfront payment of \$2.0 million to GenFleet in September 2023 and will provide \$1.5 million of research support (“GenFleet R&D Support Fee”) over the first three years of the GenFleet Agreement. In addition, pursuant to the GenFleet Agreement, upon achievement of certain development and commercial milestones, and upon the Company exercising its GenFleet Options, GenFleet will be entitled to receive payments of up to \$622.0 million. The Company paid GenFleet a \$3.0 million milestone during the three months ended September 30, 2024 upon GenFleet achieving a development milestone. The Company has also agreed to pay GenFleet royalties on net sales of licensed products in the Territory ranging from the mid to high single digits.

The Company may terminate the GenFleet Agreement in its entirety or on a program-by-program basis by providing 90 days written notice to GenFleet. Either party may terminate the GenFleet Agreement in its entirety or on a program-by-program and country-by-country basis, with 60 days’ written notice for the other party’s material breach if such party fails to cure the breach. Either party may also terminate the GenFleet Agreement in its entirety upon certain insolvency events involving the other party.

During the three and nine months ended September 30, 2024, the Company expensed \$3.0 million related to the development milestone payment made and \$0.1 million and \$0.4 million, respectively, related to the GenFleet R&D Support Fee within research and development expense in the consolidated statements of operations and comprehensive loss. During the three and nine months ended September 30, 2023, the Company expensed \$2.0 million related to the upfront payment and \$0.1 million related to the GenFleet R&D Support Fee within research and development expense in the consolidated statements of operations and comprehensive loss. The other future milestone payments are contingent in nature and will be recognized if and when the respective contingencies are resolved. If the Company elects to exercise its GenFleet Options, the related payment will be recognized if and when each respective GenFleet Option is elected.

#### *Secura*

On August 10, 2020, the Company and Secura signed the Secura APA and on September 30, 2020, the transaction closed.

Pursuant to the Secura APA, the Company sold to Secura its exclusive worldwide license, including related assets, for the research, development, commercialization, and manufacture in oncology indications of products containing duvelisib. The sale included certain intellectual property related to duvelisib in oncology indications, certain existing duvelisib inventory, claims and rights under certain contracts pertaining to duvelisib. Pursuant to the Secura APA, Secura assumed all operational and financial responsibility for activities that were part of the Company’s duvelisib oncology program, including all commercialization efforts related to duvelisib in the United States and Europe, as well as the Company’s ongoing duvelisib clinical trials. Further, Secura assumed all obligations with existing collaboration partners developing and commercializing duvelisib, which include Yakult Honsha Co., Ltd. (“Yakult”), CSPC Pharmaceutical Group Limited (“CSPC”), and Sanofi. Additionally, Secura assumed all royalty payment obligations due under the amended and restated license agreement with Infinity Pharmaceuticals, Inc.

Pursuant to the terms of the Secura APA, Secura has paid the Company an up-front payment of \$70.0 million in September 2020 and has agreed to pay the Company (i) regulatory milestone payments up to \$45.0 million, consisting of a payment of \$35.0 million upon receipt of regulatory approval of COPIKTRA in the United States for the treatment of peripheral T-cell lymphoma and a payment of \$10.0 million upon receipt of the first regulatory approval for the

commercial sale of COPIKTRA in the European Union for the treatment of peripheral T-cell lymphoma, (ii) sales milestone payments of up to \$50.0 million, consisting of \$10.0 million when total worldwide net sales of COPIKTRA exceed \$100.0 million, \$15.0 million when total worldwide net sales of COPIKTRA exceed \$200.0 million and \$25.0 million when total worldwide net sales of COPIKTRA exceed \$300.0 million, (iii) low double-digit royalties on the annual aggregate net sales above \$100.0 million in the United States, European Union, and the United Kingdom of Great Britain and Northern Ireland and (iv) 50% of all royalty, milestone and sublicense revenue payments payable to Secura under the Company's existing license agreements with Sanofi, Yakult, and CSPC, and 50% of all royalty and milestone payments payable to Secura under any license or sublicense agreement entered into by Secura in certain jurisdictions.

The Company evaluated the Secura APA in accordance with FASB Accounting Standards Codification 606 *Revenue from Contracts with Customers* ("ASC 606") as the Company concluded that the counterparty, Secura, is a customer. The Company identified a bundled performance obligation consisting of delivery of the duvelisib global license and intellectual property, certain existing duvelisib inventory, certain duvelisib contracts and clinical trials, certain regulatory approvals, and certain regulatory documentation and books and records (the "Bundled Secura Performance Obligation").

The Company concluded that the duvelisib global license and intellectual property were not distinct within the context of the contract (i.e. separately identifiable) because the other assets including certain existing duvelisib inventory, certain duvelisib contracts and clinical trials, certain regulatory approval, and certain regulatory documentation and books and records do not have stand-alone value from other duvelisib global license and intellectual property and Secura could not benefit from them without the duvelisib global license and intellectual property. Consistent with the guidance under ASC 606-10-25-16A, the Company disregarded immaterial promised goods and services when determining performance obligations.

The Company has determined that the upfront payment of \$70.0 million, future potential milestone payments and royalties including from Secura's sublicensees should be allocated to the delivery of the Bundled Secura Performance Obligation.

During the three months ended June 30, 2024, Secura achieved \$100.0 million of total worldwide net sales of COPIKTRA which triggered a \$10.0 million sales milestone payment to the Company under the Secura APA. The Company received the \$10.0 million milestone payment in July 2024. During the three and nine months ended September 30, 2024, the Company recognized \$0.0 million and \$10.0 million, respectively, of sale of COPIKTRA license and related assets revenue within the statements of operations and comprehensive loss. The Company determined all other future potential milestones and royalties were excluded from the transaction price, as all other milestone amounts were fully constrained under the guidance as of September 30, 2024. As part of the Company's evaluation of the constraint, the Company considered several factors in determining whether there is significant uncertainty associated with the future events that would result in the milestone payments. Those factors included: the likelihood and magnitude of revenue reversals related to future milestones, the amount of variable consideration that is highly susceptible to factors outside of the Company's influence and the uncertainty about the consideration is not expected to be resolved for an extended period of time. All future potential milestone payments were fully constrained as the risk of significant revenue reversal related to these amounts has not yet been resolved.

#### **14. Income taxes**

The Company did not record a federal or state income tax provision or benefit for the three and nine months ended September 30, 2024 or 2023, due to the expected loss before income taxes to be incurred for the years ended December 31, 2024 and 2023, as well as the Company's continued maintenance of a full valuation allowance against its net deferred tax assets.

#### **15. Commitments and contingencies**

The Company has no other commitments other than minimum lease payments as disclosed in *Note 8. Leases*.

## **16. Subsequent events**

The Company reviews all activity subsequent to the end of the quarter but prior to issuance of the condensed consolidated financial statements for events that could require disclosure or that could impact the carrying value of assets or liabilities as of the balance sheet date. The Company is not aware of any material subsequent events other than the following:

### **Series B Convertible Preferred Stock Conversion**

On October 18, 2024, holders of the Series B Convertible Preferred Stock elected to convert 1,200,000 shares of Series B Convertible Preferred Stock for 4,236,568 shares of the Company's common stock. On October 18, 2024, the Company issued 4,236,568 shares of its common stock to holders of the Series B Convertible Preferred Stock and as of the date these condensed financial statements are issued there are 0 shares of Series B Convertible Preferred Stock outstanding.

## Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

*You should read the following discussion and analysis of our financial condition and results of operations together with our condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q. The following discussion contains forward-looking statements that involve risks and uncertainties. Our actual results and the timing of certain events could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including those discussed below and elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for our fiscal year ended December 31, 2023. Please also refer to the sections under headings “Forward-Looking Statements” and “Risk Factors” in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for our fiscal year ended December 31, 2023.*

### OVERVIEW

We are a late-stage development biopharmaceutical company, with an ongoing registration directed trial, committed to the development and commercialization of new medicines to improve the lives of patients diagnosed with cancer. Our pipeline is focused on RAS/ MAPK driven cancers, specifically novel drug candidates that inhibit signaling pathways critical to cancer cell survival and tumor growth, particularly RAF/MEK inhibition and FAK inhibition.

Our most advanced product candidates, avutometinib and defactinib, are being investigated in both preclinical and clinical studies for the treatment of various solid tumors, including, but not limited to LGSOC, NSCLC, pancreatic cancer, CRC, and thyroid cancer. We believe that avutometinib may be beneficial as a therapeutic as a single agent or when used together in combination with defactinib, other pathway inhibitors, or other current and emerging standard of care treatments in cancers that do not adequately respond to currently available therapies.

Avutometinib is an orally available, first-in-class, small molecule RAF/MEK clamp that inhibits RAS/RAF/MEK, extracellular-signal-regulated-kinase (“ERK”) MAPK pathway which is involved in proliferation, migration, transformation, and survival of tumor cells. In contrast to other MEK-only inhibitors, avutometinib is a dual RAF/MEK clamp that blocks MEK kinase activity and induces the formation of dominant negative RAF-MEK complexes preventing phosphorylation of MEK by A-Raf proto-oncogene, serine/threonine kinase (“ARAF”), B-Raf proto-oncogene serine/threonine kinase (“BRAF”) and C-raf proto-oncogene serine/threonine kinase (“CRAF”). MEK-only inhibitors (e.g. trametinib) may have limited efficacy because they induce MEK phosphorylation (“pMEK”) by relieving dependent feedback inhibition of RAF. By inhibiting RAF-mediated phosphorylation of MEK, avutometinib has the potential advantage of not inducing pMEK. This unique mechanism of avutometinib enables it to inhibit ERK signaling more effectively and may confer enhanced therapeutic activity against MAPK pathway-driven cancers. We use the term “RAMP” to refer to our RAF and MEK Program.

Avutometinib inhibits MAPK pathway signaling and proliferation of tumor cell lines harboring MAPK pathway alterations including KRAS, neuroblastoma rat sarcoma viral oncogene homolog (“NRAS”), and BRAF mutations, among others. Avutometinib has demonstrated strong antitumor activity as monotherapy and in combination with (i) agents targeting parallel pathways (e.g. inhibitors of FAK, CDK4/6 and mTOR), (ii) agents targeting other nodes in the MAPK pathway (e.g. anti-EGFR, SOS1, KRAS G12C, and KRAS G12D inhibitors), (iii) chemotherapy, and (iv) anti-PD-1.

Defactinib is an oral small molecule inhibitor of FAK and proline-rich tyrosine kinase (“PYK2”) that is currently being evaluated as a potential combination therapy for various solid tumors. FAK and PYK2 are members of the same family of nonreceptor protein tyrosine kinases that integrate signals from integrin and growth factor receptors to regulate cell proliferation, survival, migration, and invasion. Defactinib disrupts malignant cells both directly and through modulation of the tumor microenvironment. Preclinical research by our scientists and collaborators indicates that FAK inhibition delays tumor progression in cancer models, which was associated with reduced stromal density and immunosuppressive cell populations. Furthermore, activation of FAK is a putative adaptive resistance mechanism to MAPK pathway inhibition, supporting the clinical evaluation of avutometinib in combination with defactinib for treatment of cancers harboring MAPK pathway alterations.



The combination of avutometinib and defactinib is clinically active in patients with KRAS mutant (“KRAS mt”) and KRAS wild-type (“KRAS wt”) recurrent LGSOC and has received breakthrough designation from the FDA for the treatment of all patients with recurrent LGSOC, regardless of KRAS status, after one or more prior lines of therapy including platinum-based chemotherapy. Avutometinib, alone or in combination with defactinib, has received orphan drug designation for the treatment of all patients with LGSOC in the United States. Defactinib has received orphan drug designation in ovarian cancer in the United States, the European Union, and Australia. In addition, the FDA granted orphan drug designation to avutometinib, in combination with defactinib, for the treatment of pancreatic cancer.

In the fourth quarter of 2020, we commenced a registration-directed trial, known as the RAMP 201 study, investigating avutometinib as a monotherapy and in combination with defactinib for the treatment of patients with recurrent LGSOC. The RAMP 201 study is an adaptive two-part multicenter, parallel cohort, randomized, open label trial to evaluate the efficacy and safety of avutometinib alone and in combination with defactinib in patients with recurrent LGSOC. The combination of avutometinib and defactinib has been declared the go-forward treatment regimen based on a higher rate of confirmed objective responses in a planned interim analysis with prespecified criteria, acknowledging the demonstrated contribution of defactinib.

In October 2024, we announced updated results from the RAMP 201 study with a data cutoff of June 30, 2024. The primary analysis of RAMP 201 study showed a confirmed overall response rate (“ORR”) by blinded independent central review of 31% (34/109; 95% CI: 23-41) in all evaluable patients with measurable disease with approximately 12 months of follow up. Among patients with KRAS mt LGSOC, the confirmed ORR was 44% (25/57; 95% CI: 31-58) and for patients with KRAS wt LGSOC the confirmed ORR was 17% (9/52; 95% CI: 8-30). The median duration of response was 31.1 months (95% CI: 14.8-31.1) in all evaluable patients, with 31.1 months (95% CI: 14.8-31.1) in the KRAS mt population and 9.2 months (95% CI: 5.5-NEi) in the KRAS wt population. The median progression-free survival was 12.9 months (95% CI: 10.9-20.2) in all evaluable patients, with 22 months (95% CI: 11.1-36.6) in the KRAS mt population and 12.8 months (95% CI: 7.4-18.4) in the KRAS wt population. The disease control rate at six or more months was 61% in the total evaluable population, 70% in KRAS mt population and 50% in KRAS wt population. The updated data continues to demonstrate avutometinib in combination with defactinib is generally well-tolerated, with a 10% discontinuation rate due to adverse events and no new safety signals were identified. The most common treatment-related adverse events (all grades, grade  $\geq 3$ ) for the combination were nausea (67.0%, 2.6%), diarrhea (58.3%, 7.8%), and increased blood creatine phosphokinase levels (60.0%, 24.3%).

In October 2024, we announced that a Type A meeting was held with the FDA during which we aligned with the FDA on our plans to complete our NDA submission for the combination of avutometinib and defactinib in October 2024 for adult patients with recurrent KRAS mt LGSOC, who received at least one prior systemic therapy, based on mature data from the RAMP 201 study. Subsequently in October 2024, we completed our NDA submission with the FDA for the investigational combination of avutometinib and defactinib for adults with recurrent KRAS mt LGSOC, who received at least one prior systemic therapy. We submitted the NDA under the FDA’s Accelerated Approval pathway and requested a Priority Review based on the combination’s potential to address significant unmet medical need among patients with recurrent LGSOC. If granted, the FDA review will be completed within six months following the 60-day filing period. If approved, we expect that avutometinib plus defactinib will be the first-ever FDA-approved treatment specifically for adult patients in the United States with recurrent KRAS mutant LGSOC. At this time, the FDA did not recommend pursuing accelerated approval of a KRAS wt indication. This strategic approach allows us to potentially reach the market more efficiently while mapping out a path forward with the FDA for the KRAS wt indication, including leveraging data from the ongoing RAMP 301 Phase 3 study. RAMP 301, which is currently enrolling patients with recurrent LGSOC regardless of KRAS mutation status, will serve as a confirmatory study for the initial indication and has potential to expand the indication regardless of KRAS mutation status. Obtaining approval of an NDA can be a lengthy, expensive, and uncertain process and the FDA has substantial discretion in the approval process and may refuse to accept any application, including requests such as ours for accelerated approval and priority review, or may decide that our data is insufficient for approval and require additional preclinical, clinical, or other studies. While we have engaged in discussions with the FDA with respect to the scope and nature of our NDA submission, the FDA may, for example, require additional data under the RAMP 301 study before approving the NDA for the scope we request, or at all. There can be no assurance regarding the timing and outcome of the FDA review and approval of our NDA submission.

We estimate the total annual incident addressable market opportunity for the combination of avutometinib and defactinib to be approximately \$300 million for KRAS mt and approximately \$374 million for KRAS wt populations. We estimate the total prevalent addressable market opportunity to be approximately \$1.7 billion for KRAS mt and approximately \$1.6 billion for KRAS wt populations, respectively. Our 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 several 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, our 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 11 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 data cutoff as of June 30, 2024. Amongst 115 patients, 58 enrolled with KRAS mutated LGSOC and 57 had wild-type, or non-mutated, KRAS. The estimated mean duration of therapy for all patients is 14.5 months. For KRAS mt, the estimated mean duration of therapy is 18.3 months and for KRAS wt, the estimated mean duration of therapy is 10.7 months.

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.

In December 2023, we announced initiation of a Phase 3 trial, known as the RAMP 301 study, to evaluate the combination of avutometinib and defactinib for the treatment of patients with recurrent LGSOC. The RAMP 301 study is a randomized global trial, evaluating the efficacy and safety of avutometinib and defactinib versus standard chemotherapy or hormonal therapy in patients with recurrent LGSOC. RAMP 301 is intended to serve as the confirmatory study required by the FDA to potentially convert an accelerated approval for the combination of avutometinib and defactinib for the treatment of LGSOC to full approval. We also intend to initiate discussions with global regulatory authorities, including those in Europe and Japan, to determine the regulatory path with the objective of ultimately seeking approval for the combination in additional regions. For RAMP 301, we are currently enrolling patients with LGSOC regardless of KRAS mutation status across the United States, United Kingdom, European Union, Canada, and Australia, and we plan to complete enrollment by the end of 2025.

In September 2021, we entered into a clinical collaboration agreement with Amgen, Inc. (“Amgen”) to evaluate the combination of avutometinib with Amgen’s KRAS G12C inhibitor LUMAKRAS® (sotorasib) in a Phase 1/2 study entitled RAMP 203. The Phase 1/2 trial began evaluating the safety, tolerability and efficacy of avutometinib in combination with LUMAKRAS in patients with KRAS G12C NSCLC who have not been previously treated with a KRAS G12C inhibitor, as well as in patients who have progressed on a KRAS G12C inhibitor. The trial built upon initial preclinical data showing enhanced anti-tumor efficacy with the combination of LUMAKRAS (KRAS G12C inhibition) and avutometinib (RAF/MEK inhibition) relative to either agent alone. In October 2023, we announced initial safety and pharmacokinetics results, as well as preliminary efficacy results, from the RAMP 203 study which were presented at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics in October 2023. These preliminary results showed a confirmed ORR of 25% (3/12) across efficacy-evaluable patients and seen in both KRAS G12C inhibitor resistant (14.3%; 1/7) and naïve (40%; 2/5) patients. In January 2024, the FDA granted fast track designation for combination of avutometinib and LUMAKRAS for the treatment of patients with KRAS G12C-mutant metastatic NSCLC who have received at least one prior systemic therapy and have not been previously treated with a KRAS G12C inhibitor. The RAMP 203 study has progressed to the recommended Phase 2 dose of 4 mg avutometinib in combination with 960 mg of LUMAKRAS for the doublet of avutometinib and LUMAKRAS. RAMP 203 is currently enrolling patients who have experienced disease progression on a KRAS G12C inhibitor in the dose expansion phase (Part B) and completed enrollment of patients without prior G12C treatment to the initial doublet dose expansion phase. Based on emerging data demonstrating improved tumor regressions in KRAS G12C-mutant NSCLC preclinical models when a FAK inhibitor is combined with a G12C inhibitor and avutometinib, defactinib was

added to the RAMP 203 study in new triplet cohorts in 2024. We expect to report updated interim data from the doublet combination of avutometinib plus LUMAKKRAS and provide initial safety data and a status of enrollment for the triplet combination of avutometinib, LUMAKKRAS and defactinib by the end of 2024.

In November 2021, we entered into a clinical collaboration agreement with Mirati Therapeutics, Inc. (“Mirati”) to evaluate the combination of avutometinib with Mirati’s KRAS G12C inhibitor KRAZATI® (adagrasib) in a Phase 1/2 trial entitled RAMP 204. The Phase 1/2 trial will evaluate the safety, tolerability and efficacy of avutometinib in combination with KRAZATI in patients with KRAS G12C NSCLC who have progressed on a KRAS G12C inhibitor. The trial will build on preclinical data showing a deeper blockade of MAPK pathway signaling resulting in enhanced anti-tumor efficacy with the combination of KRAZATI (KRAS G12C inhibition) and avutometinib (RAF/MEK inhibition) relative to either agent alone. In the fourth quarter of 2024, after discussion with Bristol Myers Squibb Company, who completed an acquisition of Mirati in the first quarter of 2024, and the RAMP 204 steering committee, we decided to close the RAMP 204 study to further enrollment in order to prioritize the RAMP 203 study. No new safety signals were identified in the RAMP 204 study and closure to further enrollment is not related to safety findings. The RAMP 203 study will be prioritized primarily because it covers both patients who are G12C treatment naïve and progressed and importantly includes the triplet treatment approach.

In May 2022, we received the first “Therapeutic Accelerator Award” from PanCAN for up to \$3.8 million. The grant is supporting a Phase 1b/2 clinical trial of avutometinib in combination with defactinib entitled RAMP 205. RAMP 205 is evaluating the safety, tolerability and efficacy of avutometinib and defactinib in combination with GEMZAR® (gemcitabine) and ABRAXANE® (Nab-paclitaxel) in patients with previously untreated metastatic adenocarcinoma of the pancreas. The RAMP 205 trial is evaluating whether combining avutometinib (to target mutant KRAS which is mutated in more than 90% of pancreatic adenocarcinomas) and defactinib (to reduce stromal density and adaptive resistance to avutometinib) to the standard GEMZAR/ABRAXANE regimen improves outcomes for patients with pancreatic adenocarcinoma. In August 2022, PanCAN agreed to provide us with an additional \$0.5 million for the collection and translational analysis of patient samples. The RAMP 205 trial is open and enrolling. Combination dose evaluation is ongoing. As of a data cut of May 14, 2024, we reported patients receiving the combination of avutometinib and defactinib with gemcitabine and Nab-paclitaxel in dose level 1 cohort achieved a confirmed ORR of 83% (5/6), one dose-limiting toxicity was observed in the dose level 1 cohort, and the dose level was subsequently cleared after additional patients were enrolled. The initial interim results were presented at the American Society of Clinical Oncology Annual Meeting in June 2024. We expect to report updated data from RAMP 205 study in the first quarter of 2025.

Furthermore, avutometinib and defactinib are currently being investigated in combination with immunotherapeutic and other agents through investigator sponsored trials (“ISTs”) for the treatment of various solid tumors, including, but not limited to, CRC, gynecological cancer with MAPK pathway alterations, breast cancer, thyroid cancer and melanoma.

In August 2023, we entered into a collaboration and option agreement (the “GenFleet Agreement”) with GenFleet pursuant to which GenFleet granted us 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”). We may exercise our GenFleet Options on a program-by-program basis. The collaboration builds on the strengths of both companies in oncology small molecule drug development, enabling us to partner our clinical development and regulatory expertise with GenFleet’s accomplished discovery capabilities. This synergistic collaboration includes our experience and established network of collaborators, including scientific and clinical experts in RAS biology and RAS pathway-driven cancers and GenFleet’s accomplishments with its KRAS G12C inhibitor program. In December 2023, we announced the selection of an orally bioavailable, potent and selective small molecule KRAS G12D (ON/OFF) inhibitor entitled VS-7375/GFH375 with a potential best-in-class profile as the lead program from our collaboration with GenFleet. An investigational new drug (“IND”) application by GenFleet in China for VS-7375/GFH375, was cleared in June 2024, following which GenFleet initiated a Phase 1/2 study in solid tumors with KRAS G12D mutation for VS-7375/GFH375 in China in June 2024. GenFleet has dosed several patients in the Phase 1/2 study in China evaluating VS-7375/GFH375 in patients with KRAS G12D-mutated advanced solid tumors which started in July 2024. The Phase 1 study is being conducted in approximately 20 hospitals in China and will evaluate the safety and efficacy of VS-7375/GFH375 in patients with advanced KRAS G12D mutant solid tumors. The Phase 1 study will determine the recommended Phase 2 dose and then

further evaluate in Phase 2 the efficacy and safety of VS-7375/GFH375 in patients with advanced solid tumors, such as pancreatic ductal adenocarcinoma, colorectal cancer and non-small cell lung cancer. After evaluating initial dose escalation data from the Phase 1 study in China, we anticipate filing an IND in the United States by first quarter of 2025.

Our operations to date have been organizing and staffing our company, business planning, raising capital, identifying and acquiring potential product candidates, undertaking preclinical studies and clinical trials for our product candidates and initiating U.S. commercial operations following the approval of COPIKTRA through our ownership period ending in September 2020. We have financed our operations to date primarily through public offerings of our common stock, pre-funded warrants, and warrants, offerings of convertible notes, sales of common stock under our at-the-market equity offering programs, our loan and security agreement executed with Hercules in March 2017, as amended, the upfront payments and milestone payments under our license and collaboration agreements with Sanofi, CSPC, and Yakult, the upfront payment and milestone payments received under the Secura APA, the proceeds in connection with the private investment in public equity (the “PIPE”), and our Loan Agreement with Oxford, sales of Series B Convertible Preferred Stock. Additionally, from our U.S. commercial launch of COPIKTRA on September 24, 2018, through our ownership period ending in September 2020, we financed a portion of our operations through product revenue.

As of September 30, 2024, we had an accumulated deficit of \$891.0 million. Our net loss was \$24.0 million, \$66.1 million, \$20.0 million and \$60.0 million for the three and nine months ended September 30, 2024 and 2023, respectively. As of September 30, 2024, we had cash, cash equivalents, and investments of \$113.2 million. In accordance with applicable accounting standards, we evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within 12 months after the date of the issuance of the consolidated financial statements. We anticipate operating losses may continue for the foreseeable future since we do not yet have regulatory approval to sell any of our product candidates, and we continue to incur operating costs to execute our strategic plan, including costs related to research and development of our product candidates and commercial readiness activities. As a result of the assessment in accordance with the applicable accounting standards, these conditions raise substantial doubt about our ability to continue as a going concern for 12 months after the date the condensed consolidated financial statements are issued.

We expect to finance our operations with our existing cash, cash equivalents and investments, through potential future milestones and royalties received pursuant to the Secura APA, through the Loan Agreement with Oxford, or through other strategic financing opportunities that could include, but are not limited to collaboration agreements, future offerings of our equity, or the incurrence of debt. However, given the risk associated with these potential strategic or financing opportunities, they are not deemed probable for purposes of the going concern assessment. If we fail to obtain additional future capital, we may be unable to complete our planned preclinical studies and clinical trials and obtain approval of certain investigational product candidates from the FDA or foreign regulatory authorities. Therefore, there is substantial doubt about our ability to continue as a going concern.

## **CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES**

Our discussion and analysis of our financial condition and results of operations is based upon our condensed consolidated financial statements prepared in accordance with U.S. generally accepted accounting principles. The preparation of these condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of certain assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our financial statements, and the amounts of revenues and expenses during the reported periods.

We believe that several accounting policies are important to understanding our historical and future performance. We refer to these policies as “critical” because these specific areas generally require us to make judgments and estimates about matters that are uncertain at the time we make the estimate, and different estimates—which also would have been reasonable—could have been used, which would have resulted in different financial results.

The critical accounting policies we identified in our most recent Annual Report on Form 10-K for the fiscal year ended December 31, 2023, related to revenue recognition, collaborative agreements, accrued and prepaid research and development expenses, and stock-based compensation. During the nine months ended September 30, 2024, there were no material changes to our critical accounting policies.

## RESULTS OF OPERATIONS

### Comparison of the three months ended September 30, 2024 and 2023

	Three months ended September 30, (dollar amounts in thousands)			
	2024	2023	Change	% Change
Revenue:				
Sale of COPIKTRA license and related assets	—	—	—	0%
Total revenue	—	—	—	0%
Operating expenses:				
Research and development	24,754	13,946	10,808	77%
Selling, general and administrative	12,276	7,363	4,913	67%
Total operating expenses	37,030	21,309	15,721	74%
Loss from operations	(37,030)	(21,309)	(15,721)	74%
Other expense	(77)	(13)	(64)	492%
Interest income	831	2,247	(1,416)	(63)%
Interest expense	(1,148)	(1,129)	(19)	2%
Change in fair value of preferred stock tranche liability	—	200	(200)	(100)%
Change in fair value of warrant liability	13,457	—	13,457	100%
Net loss	<u>\$ (23,967)</u>	<u>\$ (20,004)</u>	<u>\$ (3,963)</u>	<u>20%</u>

*Research and development expense.* Research and development expense for the three months ended September 30, 2024 (the “2024 Quarter”) was \$24.8 million compared to \$13.9 million for the three months ended September 30, 2023 (the “2023 Quarter”). The \$10.9 million increase from the 2023 Quarter to the 2024 Quarter was primarily driven by an increase of \$4.8 million in contract research organization (“CRO”) costs, an increase of \$1.8 million in consulting costs, an increase of \$1.7 million in investigator fees, an increase of \$1.0 million in milestone and upfront payments pursuant to the GenFleet Agreement, an increase of \$0.6 million in clinical supply, an increase of \$0.5 million in personnel costs, including non-cash stock compensation and an increase of \$0.5 million in drug substance and drug product manufacturing costs.

Research and development expenses consist of costs associated with our research activities, including the development of our product candidates. Research and development expenses include product/ product candidate and/or project-specific costs, as well as unallocated costs. We record expenses related to external research and development services, such as CROs, clinical sites, pass-through fees such as investigator fees, manufacturing organizations and consultants, by project and/or product candidate. We use our employee and infrastructure resources in a cross-functional manner across multiple research and development projects. Our project costing methodology does not allocate personnel, infrastructure and other indirect costs to specific clinical programs or projects.

Product/ product candidate/ project specific costs include:

- direct third-party costs, which include expenses incurred under agreements with CROs, pass-through fees, the cost of consultants who assist with the development of our product candidates on a program-specific basis, clinical site costs, and any other third-party expenses directly attributable to the development of the product candidates;
- costs related to contract manufacturing operations including manufacturing costs in connection with producing product candidates for use in conducting preclinical and clinical studies. Costs associated with manufacturing avutometinib are included in “Avutometinib manufacturing and non-clinical trial specific” category below as these costs relate to both the “Avutometinib + defactinib” and “Avutometinib + other combinations” categories and are not specifically allocated to any particular project. Costs to produce defactinib are included in “Avutometinib ± defactinib” below; and
- license fees.

Unallocated costs include:

- research and development employee-related expenses, including salaries, benefits, travel, and stock-based compensation expense;
- cost of consultants, including our scientific advisory board, who assist with our research and development but are not allocated to a specific program; and
- facilities, depreciation, and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, and laboratory supplies.

The table below summarizes our direct research and development expenses for our product/ product candidates/ projects and our unallocated research and development costs for the 2024 Quarter and the 2023 Quarter.

	<b>Three months ended September 30,</b>		
	<b>2024</b>	<b>2023</b>	<b>Change</b>
	(in thousands)		
<b><u>Product/ product candidate / project specific costs</u></b>			
Avutometinib ± defactinib	\$ 13,547	\$ 5,020	\$ 8,527
Avutometinib + other combinations	345	1,047	(702)
Avutometinib manufacturing and non-clinical trial specific	1,139	987	152
GenFleet	3,275	2,051	1,224
COPIKTRA	2	3	(1)
<b><u>Unallocated costs</u></b>			
Personnel costs, excluding stock-based compensation	3,540	3,111	429
Stock-based compensation expense	564	503	61
Other unallocated expenses	2,342	1,224	1,118
<b>Total research and development expense</b>	<b>\$ 24,754</b>	<b>\$ 13,946</b>	<b>\$ 10,808</b>

As a result of adding defactinib to the RAMP 203 study, we have classified RAMP 203 study costs incurred during the 2024 Quarter within “avutometinib ± defactinib” in the table above. RAMP 203 study costs incurred prior to 2024 Quarter remain classified within “avutometinib + other combinations” in the table above. The \$8.5 million increase in avutometinib ± defactinib costs from the 2023 Quarter to the 2024 Quarter was primarily driven by an increase in RAMP 301 study costs, an increase in drug metabolism and pharmacokinetics costs, an increase in RAMP 201 study costs, an increase in RAMP 205 study costs, and inclusion of RAMP 203 study costs within avutometinib ± defactinib classification starting in the 2024 Quarter, partially offset by a decrease in RAMP 202 study costs. The \$0.7 million decrease in avutometinib + other combinations costs is primarily driven by starting in the 2024 Quarter classifying RAMP 203 study costs within the “avutometinib ± defactinib classification. The \$1.2 million increase in GenFleet costs was primarily driven by a \$3.0 million development milestone payment made in 2024 Quarter compared to the \$2.0 million upfront payment made in the 2023 Quarter pursuant to the GenFleet Agreement.

*Selling, general and administrative expense.* Selling, general and administrative expense for the 2024 Quarter was \$12.3 million compared to \$7.4 million for the 2023 Quarter. The increase of \$4.9 million from the 2023 Quarter to the 2024 Quarter primarily resulted from \$3.0 million in July 2024 Offering financing fees in the 2024 Period, an increase of \$1.2 million in personnel costs, including non-cash stock compensation, and an increase of \$0.7 million in cost in anticipation of potential launch of avutometinib and defactinib in LGSOC.

*Other expense.* Other expense for the 2024 Quarter was \$0.1 million compared to less than \$0.1 million for the 2023 Quarter. Other expense for the 2024 Quarter and 2023 Quarter was comprised of transaction losses due to changes in foreign currency exchange rates.

*Interest income.* Interest income for the 2024 Quarter was \$0.8 million compared to \$2.2 million for the 2023 Quarter. The decrease of \$1.4 million from the 2023 Quarter to the 2024 Quarter in interest income was primarily due to the decrease in investment balances on short term investments and cash equivalents during each respective quarter.

*Interest expense.* Interest expense for the 2024 Quarter and 2023 Quarter was \$1.1 million. Interest expense for the 2024 Quarter and 2023 Quarter was primarily comprised of interest expense pursuant to the loan and security agreement entered into with Oxford on March 25, 2022.

*Change in fair value of preferred stock tranche liability.* The change in fair value of the preferred stock tranche liability was \$0.0 million for the 2024 Quarter compared to \$0.2 million income for the 2023 Quarter. The change in fair value of preferred stock tranche liability was comprised of the mark-to-market adjustment related to the second tranche right issued as part of the Securities Purchase Agreement. The fair value of the preferred stock tranche liability was \$0.0 million at the beginning of the 2024 Quarter and expired in July 2024 resulting in no adjustment in the 2024 Quarter. The fair value of the preferred stock tranche liability decreased from \$7.5 million at the beginning of the 2023 Quarter to \$7.3 million at the end of the 2023 Quarter resulting in \$0.2 million income in the 2023 Quarter.

*Change in fair value of warrant liability.* The change in fair value of warrant liability of \$13.5 million for the 2024 Quarter was comprised of the mark-to-market adjustment for the warrants issued as part of the July 2024 Offering which decreased primarily due to the decrease in our stock price from July 23, 2024 to end of 2024 Quarter. There was no warrant liability outstanding during the 2023 Quarter.

**Comparison of the nine months ended September 30, 2024 and 2023**

	Nine months ended September 30, (dollar amounts in thousands)			
	2024	2023	Change	% Change
<b>Revenue:</b>				
Sale of COPIKTRA license and related assets	\$ 10,000	\$ —	\$ 10,000	100%
<b>Total revenue</b>	<b>10,000</b>	<b>—</b>	<b>10,000</b>	<b>100%</b>
<b>Operating expenses:</b>				
Research and development	60,523	38,854	21,669	56%
Selling, general and administrative	32,843	22,091	10,752	49%
<b>Total operating expenses</b>	<b>93,366</b>	<b>60,945</b>	<b>32,421</b>	<b>53%</b>
Loss from operations	(83,366)	(60,945)	(22,421)	37%
Other expense	(131)	(60)	(71)	118%
Interest income	3,181	4,345	(1,164)	(27)%
Interest expense	(3,416)	(3,019)	(397)	13%
Change in fair value of preferred stock tranche liability	4,189	(320)	4,509	(1,409)%
Change in fair value of warrant liability	13,457	—	13,457	100%
<b>Net loss</b>	<b>\$ (66,086)</b>	<b>\$ (59,999)</b>	<b>\$ (6,087)</b>	<b>10%</b>

*Sale of COPIKTRA license and related assets revenue.* Sale of COPIKTRA license and related assets revenue for the nine months ended September 30, 2024 (the “2024 Period”) was \$10.0 million compared to \$0.0 million for the nine months ended September 30, 2023 (the “2023 Period”). Sale of COPIKTRA license and related assets revenue for the 2024 Period was comprised of one sales milestone of \$10.0 million due upon Secura achieving cumulative worldwide net sales of COPIKTRA exceeding \$100.0 million during the 2024 Period. The \$10.0 million milestone payment was received by us in July 2024.

*Research and development expense.* Research and development expense for the 2024 Period was \$60.5 million compared to \$38.9 million for the 2023 Period. The \$21.6 million increase from the 2023 Period to the 2024 Period was primarily driven by an increase of \$8.9 million in CRO costs, an increase of \$3.6 million in investigator fees, an increase of \$3.6 million in consulting costs, an increase of \$1.8 million in personnel costs, including non-cash stock compensation, an increase of \$1.6 million in clinical supply costs, an increase of \$1.0 million in milestone and upfront payments pursuant to the GenFleet Agreement, an increase of \$0.5 million in IST expenses, and an increase of \$0.6 million in other research and development costs.

The table below summarizes our direct research and development expenses for our product/ product candidates/ projects and our unallocated research and development costs for the 2024 Period and the 2023 Period.

	Nine months ended September 30,		
	2024	2023	Change
	(in thousands)		
<b><u>Product/ product candidate / project specific costs</u></b>			
Avutometinib ± defactinib	\$ 32,434	\$ 15,216	\$ 17,218
Avutometinib + other combinations	3,700	3,618	82
Avutometinib manufacturing and non-clinical trial specific	2,289	3,764	(1,475)
GenFleet	3,704	2,051	1,653
COPIKTRA	5	82	(77)
<b><u>Unallocated costs</u></b>			
Personnel costs, excluding stock-based compensation	10,699	9,002	1,697
Stock-based compensation expense	1,567	1,467	100
Other unallocated expenses	6,125	3,654	2,471
<b>Total research and development expense</b>	<b>\$ 60,523</b>	<b>\$ 38,854</b>	<b>\$ 21,669</b>

As a result of adding defactinib to the RAMP 203 study, we have classified RAMP 203 study costs incurred during the 2024 Quarter within “avutometinib ± defactinib” in the table above. RAMP 203 study costs incurred prior to



2024 Quarter remain classified within “avutometinib + other combinations” in the table above. The \$17.2 million increase in avutometinib ± defactinib costs from the 2023 Period to the 2024 Period was primarily driven by an increase in RAMP 301 study costs, an increase in drug metabolism and pharmacokinetics costs, an increase in RAMP 201 study costs, an increase in consulting costs, an increase in RAMP 205 study costs, and inclusion of RAMP 203 study costs incurred within the 2024 Quarter within avutometinib ± defactinib, partially offset by a decrease in RAMP 202 study costs. The \$1.5 million decrease in avutometinib manufacturing and non-clinical trial specific costs from the 2023 Period to the 2024 Period was primarily driven by a decrease in avutometinib drug substance costs. The \$1.7 million increase in GenFleet costs from the 2023 Period to the 2024 Period was primarily driven \$3.0 million development milestone payment made in 2024 Period compared to the \$2.0 million upfront payment made in the 2023 Period pursuant to the GenFleet Agreement.

*Selling, general and administrative expense.* Selling, general and administrative expense for the 2024 Period was \$32.8 million compared to \$22.1 million for the 2023 Period. The increase of \$10.7 million from the 2023 Period to the 2024 Period primarily resulted from an increase of \$4.7 million in costs in anticipation of potential launch of avutometinib and defactinib in LGSOC, an increase of \$3.6 million in personnel costs, including non-cash stock compensation, \$3.0 million in July 2024 Offering financing fees in the 2024 Period, and partially offset by \$0.6 million in financing fees for the Securities Purchase Agreement in the 2023 Period.

*Other expense.* Other expense for the 2024 Period and 2023 Period was \$0.1 million. Other expense for the 2024 Period was comprised of transaction losses due to changes in foreign currency exchange rates. Other expense for the 2023 Period was comprised of transaction losses due to changes in foreign currency exchange rates partially offset by a gain on sale of fixed assets.

*Interest income.* Interest income for the 2024 Period was \$3.2 million compared to \$4.3 million for the 2023 Period. The decrease of \$1.1 million from the 2023 Period to the 2024 Period was primarily driven by an decrease in investment balances on short term investments and cash equivalents during each respective period.

*Interest expense.* Interest expense for the 2024 Period was \$3.4 million compared to \$3.0 million for the 2023 Period. The increase of \$0.4 million from the 2023 Period to the 2024 Period was primarily driven additional interest expense in the 2024 Period pursuant to the Loan Agreement as a result of the additional \$15.0 million debt drawdown on March 22, 2023.

*Change in fair value of preferred stock tranche liability.* The change in fair value of the preferred stock tranche liability was \$4.2 million income for the 2024 Period compared to \$0.3 million expense for the 2023 Period. The change in fair value of preferred stock tranche liability was comprised of the mark-to-market adjustment related to the second tranche right issued as part of the Securities Purchase Agreement. The fair value of the preferred stock tranche liability decreased from \$4.2 million at the beginning of the 2024 Period and expired in July 2024 resulting in \$4.2 million income in the 2024 Period. The fair value of the preferred stock tranche liability increased from \$6.9 million upon issuance on January 24, 2023, to \$7.3 million at the end of the 2023 Period resulting in \$0.3 million expense in the 2023 Period.

*Change in fair value of warrant liability.* The change in fair value of warrant liability of \$13.5 million for the 2024 Period was comprised of the mark-to-market adjustment for the warrants issued as part of the July 2024 Offering which decreased primarily due to the decrease in our stock price from July 23, 2024 to end of 2024 Period There was no warrant liability outstanding during the 2023 Period.

## **LIQUIDITY AND CAPITAL RESOURCES**

### **Sources of liquidity**

We have financed our operations to date primarily through public and private offerings of our common stock, common warrants, pre-funded warrants, and warrants, offerings of convertible notes, sales of common stock under our at-the-market equity offering programs, our loan and security agreement executed with Hercules in March 2017, as amended, the upfront payments under our license and collaboration agreements with Sanofi, Yakult, and CSPC, the

upfront payment under the Secura APA, the proceeds in connection with the PIPE, the Loan Agreement with Oxford, and the issuance of Series B Convertible Preferred Stock. With the commercial launch of COPIKTRA in the United States in September 2018 through our ownership period ending in September 2020, we financed a portion of our operations through product revenue. As of September 30, 2020, we have sold our COPIKTRA license and no longer sell COPIKTRA in the United States. We expect to finance a portion of our business through future potential milestones and royalties received pursuant to the Secura APA.

As of September 30, 2024, we had \$113.2 million of cash, cash equivalents, and investments. We primarily invest our cash, cash equivalents and investments in U.S. Government money market funds, U.S. government agency bonds, corporate bonds and commercial paper of publicly traded companies.

Risks and uncertainties include those identified under *Item 1A. Risk Factors*, in our Annual Report on Form 10-K for the year ended December 31, 2023 as filed with the SEC on March 14, 2024, and under “*Risk Factors*” in this Quarterly Report on Form 10-Q.

### Cash flows

The following table sets forth the primary sources and uses of cash for the 2024 Quarter and the 2023 Quarter (in thousands):

	<u>Nine months ended September 30,</u>	
	<u>2024</u>	<u>2023</u>
Net cash (used in) provided by:		
Operating activities	\$ (79,672)	\$ (56,779)
Investing activities	59,972	(56,883)
Financing activities	54,040	134,640
<b>Increase in cash, cash equivalents and restricted cash</b>	<b><u>\$ 34,340</u></b>	<b><u>\$ 20,978</u></b>

*Operating activities.* The use of cash in both periods resulted primarily from our net losses adjusted for non-cash charges and changes in the components of working capital. Our cash outflow from net losses adjusted for non-cash charges and adjustments was \$78.7 million and \$55.8 million for the 2024 Period and the 2023 Period, respectively. Non-cash charges and adjustments for the 2024 Period were primarily related to the changes in fair value of the preferred stock tranche liability, the change in fair value of warrant liability and stock-based compensation expense. Non-cash charges and adjustments for the 2023 Period were primarily related to stock-based compensation expenses. Our cash outflow from operating activities due to changes in operating assets and liabilities was \$0.9 million and \$1.0 million for the 2024 Period and the 2023 Period, respectively. Cash outflow due to changes in operating assets and liabilities for the 2024 Period was primarily driven by a decrease of \$2.7 million of account payable, an increase of \$1.9 million of prepaid expenses, other current assets and other assets, a decrease of \$0.3 million of deferred liabilities, and an increase of \$0.2 million of grant receivable partially offset by an increase of \$4.2 million of accrued expenses and other liabilities. Cash outflow due to changes in operating assets and liabilities for the 2023 Period was primarily driven by an increase of \$3.0 million in prepaid expenses, other current assets and other assets partially offset by an increase of \$1.3 million in accrued expenses and other liabilities, an increase of \$0.3 million in deferred liabilities and an increase of \$0.2 million in accounts payable. The increases in both periods in prepaid expenses, other current assets, and other assets is exclusive of cash received from PanCAN and used on the RAMP 205 study. Cash used in operating activities was \$79.7 million and \$56.8 million for the 2024 Period and the 2023 Period, respectively.

*Investing activities.* The cash provided by investing activities for the 2024 Period relates to maturities of investments of \$60.0 million, partially offset by a purchase of property and equipment of less than \$0.1 million. The cash provided by investing activities for the 2023 Period relates to the net purchases of investments of \$56.9 million.

*Financing activities.* The cash provided by financing activities for the 2024 Period represents \$53.8 million of net proceeds received from the issuance of shares of common stock, pre-funded warrants, and warrants as part of the July 2024 Offering, \$1.3 million of proceeds received from insurance premium financing and \$0.2 million of proceeds received from exercise of stock options and our employee stock purchase plan, partially offset by \$1.2 million of

payments on insurance premium financing, and \$0.2 million of fees paid to the Lenders to amend our Loan Agreement with Oxford. The cash provided by financing activities for the 2023 Period primarily represents \$91.4 million of proceeds from our public offering in June 2023 of common stock and pre-funded warrants to purchase shares of our common stock, net of issuance costs, \$28.1 million of proceeds received from issuance of Series B Convertible Preferred Stock, net of issuance costs, \$14.9 million of proceeds received pursuant to the Loan Agreement, \$1.4 million of proceeds received from insurance premium financing and \$0.1 million of proceeds received related to our employee stock purchase plan, partially offset by \$1.3 million of payments on insurance premium financing. Refer to *Note 9. Notes Payable* to our unaudited condensed consolidated financial statements included in this quarterly report for additional details on the finance agreement with AFCO related to insurance premium financing and the monthly payments of principal and interest related thereto; *Note 7. Debt* to our unaudited condensed consolidated financial statements included in this quarterly report for additional details on the Loan Agreement; and *Note 10. Capital Stock* to our unaudited condensed consolidated financial statements included in this quarterly report for additional details on the July 2024 Offering of common stock, pre-funded warrants, and warrants, June 2023 Offering of common stock and pre-funded warrants, and the January 2023 offering of our Series B Convertible Preferred Stock.

## CONTRACTUAL OBLIGATIONS AND COMMITMENTS

The disclosure of our contractual obligations and commitments was reported in our Annual Report on Form 10-K for the year ended December 31, 2023. Except as previously disclosed in the Company's subsequent filings with the SEC, including this Quarterly Report on Form 10-Q, there have not been any material changes from the contractual obligations and commitments previously disclosed in such report.

### Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. We had cash, cash equivalents and investments of \$113.2 million as of September 30, 2024, consisting of cash, U.S. Government money market funds, U.S. government agency bonds, corporate bonds and commercial paper of publicly traded companies. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because most of our investments are interest bearing. Our available for sale securities are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short-term duration of most of our investment portfolio and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio.

We contract with CROs and contract manufacturers globally which may be denominated in foreign currencies. We may be subject to fluctuations in foreign currency rates in connection with these agreements. Transactions denominated in currencies other than the functional currency are recorded based on exchange rates at the time such transactions arise. As of June 30, an immaterial amount of our total liabilities were denominated in currencies other than the functional currency.

As of September 30, 2024, we have borrowed \$40.0 million under the Loan Agreement. The Term Loans under the Loan Agreement bear interest at a floating rate equal to (a) the greater of (i) the one-month CME Secured Overnight Financing Rate and (ii) 0.13% plus (b) 7.37%, which is subject to an overall floor and cap. Changes in interest rates can cause interest charges to fluctuate under the Loan Agreement. A 10% increase in current interest rates would have resulted in an immaterial increase in the amount of cash interest expense for the three and nine months ended June 30, 2024 due to the overall interest rate floor and cap.

### Item 4. Controls and Procedures.

#### Evaluation of disclosure controls and procedures

Our management, with the participation of our President and Chief Executive Officer (principal executive officer) and our Chief Financial Officer (principal financial and accounting officer), evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2024. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act of 1934 (Exchange Act), means controls and other procedures

of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2024, our President and Chief Executive Officer and our Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

**Changes in internal control over financial reporting**

There have been no changes in our internal control over financial reporting during the three months ended September 30, 2024, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**PART II—OTHER INFORMATION**

**Item 1. Legal Proceedings.**

None.

**Item 1A. Risk Factors.**

You should carefully review and consider the information regarding certain factors that could materially affect our business, financial condition or future results set forth under *Item 1A. Risk Factors* in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 as filed with the SEC on March 14, 2024 and in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, as filed with the SEC on August 8, 2024.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds and Issuer Purchases of Equity Securities.**

**RECENT SALES OF UNREGISTERED SECURITIES**

None.

**PURCHASE OF EQUITY SECURITIES**

We did not purchase any of our equity securities during the period covered by this Quarterly Report on Form 10-Q.

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Mine Safety Disclosures.**

None.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which Exhibit Index is incorporated herein by reference.

## EXHIBIT INDEX

3.1	<a href="#">Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Annual Report on Form 10-K for the fiscal year ended December 31, 2018, filed by the Registrant on March 12, 2019).</a>
3.2	<a href="#">Certificate of Amendment to the Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.2 to the Annual Report on Form 10-K for the fiscal year ended December 31, 2018, filed by the Registrant on March 12, 2019).</a>
3.3	<a href="#">Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.4 to Amendment No. 3 to the Registration Statement on Form S-1 (File No. 333-177677) filed by the Registrant on January 13, 2012).</a>
3.4	<a href="#">Certificate of Amendment to the Restated Certificate of Incorporation of Verastem, Inc. (incorporated by reference to Exhibit 3.1 to the Form 8-K filed by the Registrant with the Securities and Exchange Commission on May 21, 2020).</a>
3.5	<a href="#">Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Form 8-K filed by the Registrant with the Securities and Exchange Commission on November 7, 2022).</a>
3.6	<a href="#">Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Form 8-K filed by the Registrant with the Securities and Exchange Commission on January 25, 2023).</a>
3.7	<a href="#">Certificate of Amendment to the Restated Certificate of Incorporation of Verastem, Inc. (incorporated by reference to Exhibit 3.1 to the Form 8-K filed by the Registrant with the Securities and Exchange Commission on May 31, 2023).</a>
4.1	<a href="#">Form of Pre-Funded Warrant to Purchase Stock (incorporated by reference to Exhibit 4.1 to the Form 8-K filed by the Registrant with the Securities and Exchange Commission on July 25, 2024).</a>
4.2	<a href="#">Form of Warrant to Purchase Stock (incorporated by reference to Exhibit 4.2 to the Form 8-K filed by the Registrant with the Securities and Exchange Commission on July 25, 2024).</a>
31.1*	<a href="#">Certification of Principal Executive Officer pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
31.2*	<a href="#">Certification of Principal Financial and Accounting Officer pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
32.1*	<a href="#">Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
32.2*	<a href="#">Certification of Principal Financial and Accounting Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
99.1*	<a href="#">Press Release issued by Verastem, Inc. on November 6, 2024 (furnished herewith).</a>
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	The cover page from this Current Report on form 10-Q, formatted in Inline XBRL

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\* Filed or furnished herewith.



## CERTIFICATIONS

I, Daniel W. Paterson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Verastem, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ DANIEL W. PATERSON

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Daniel W. Paterson  
*President and Chief Executive Officer*  
*(Principal executive officer)*

Date: November 6, 2024



## CERTIFICATIONS

I, Daniel Calkins, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Verastem, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ DANIEL CALKINS

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Daniel Calkins  
*Chief Financial Officer*  
*(Principal financial and accounting officer)*

Date: November 6, 2024

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Verastem, Inc. (the "Company") for the period ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Daniel W. Paterson, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ DANIEL W. PATERSON

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Daniel W. Paterson  
*President and Chief Executive Officer*  
*(Principal executive officer)*

Date: November 6, 2024

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Verastem, Inc. (the "Company") for the period ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Daniel Calkins, Chief Financial Officer, of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ DANIEL CALKINS

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Daniel Calkins  
*Chief Financial Officer*  
*(Principal financial and accounting officer)*

Date: November 6, 2024

## Verastem Oncology Reports Third Quarter 2024 Financial Results and Highlights Recent Business Updates

*Completed rolling NDA submission for avutometinib and defactinib combination in recurrent KRAS mutant low-grade serous ovarian cancer in October 2024*

*Company seeking accelerated approval and priority review of its NDA submission for patients with KRAS mutant low-grade serous ovarian cancer; FDA filing decision expected before the end of 2024 with potential for FDA approval decision by mid-2025*

*Preparations for a potential U.S. commercial launch in mid-2025 are ongoing*

*Presented positive, updated safety and efficacy results from the RAMP 201 trial at the IGCS 2024 Annual Meeting in October 2024*

BOSTON--(BUSINESS WIRE)--November 6, 2024--Verastem Oncology (Nasdaq: VSTM), a biopharmaceutical company committed to advancing new medicines for patients with cancer, today announced business updates and reported financial results for the third quarter ended September 30, 2024.

“In the third quarter of 2024, we made advancements in our recurrent low-grade serous ovarian cancer program, including sharing updated Phase 2 RAMP 201 data demonstrating robust and durable response rates, tumor reductions across a majority of patients regardless of their KRAS mutation status, and low discontinuation rates due to adverse events. We also completed our rolling NDA submission for recurrent KRAS mutant low-grade serous ovarian cancer and strengthened our balance sheet,” said Dan Paterson, president and chief executive officer of Verastem Oncology. “Looking ahead to the fourth quarter of 2024, we anticipate an FDA decision on the acceptance of our NDA, plan to submit our updated RAMP 201 trial data for publication and expect to prepare a U.S. IND application for VS-7375, an oral KRAS G12D (ON/OFF) inhibitor.”

### Third Quarter 2024 and Recent Updates

#### ***Avutometinib and Defactinib Combination in Low-Grade Serous Ovarian Cancer (LGSOC)***

- Completed the rolling New Drug Application (NDA) submission for the combination of avutometinib and defactinib for adult patients with recurrent KRAS mutant LGSOC, who received at least one prior systemic therapy, in October 2024. The Company submitted the NDA under the U.S. Food and Drug Administration (FDA) Accelerated Approval pathway and requested Priority Review based on the combination’s potential to address significant unmet medical need among patients with recurrent LGSOC.
  - RAMP 301, which is currently enrolling patients with recurrent LGSOC regardless of KRAS mutation status across the U.S., UK, EU, Canada, and Australia, will serve as a confirmatory study for the initial indication and has potential to expand the indication regardless of KRAS mutation status. The Company plans to complete enrollment in RAMP 301 by the end of 2025. The Company plans to map
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out a path forward with the FDA for the KRAS wild-type indication, including the ability to leverage data from the ongoing RAMP 301 Phase 3 trial.

- Announced mature data from the RAMP 201 trial that continued to show robust and durable response rates with low discontinuation rates due to adverse events in patients with recurrent KRAS mutant or KRAS wild-type LGSOC who had a minimum follow-up of 12 months, at the International Gynecologic Cancer Society (IGCS) 2024 Annual Meeting on October 17, 2024. The primary analysis of the RAMP 201 trial, with a data cutoff of June 30, 2024, showed a confirmed overall response rate (ORR) by blinded independent central review (BICR) of 31% (34/109; 95% CI: 23-41), 44% (25/57; 95% CI: 31-58) in KRAS mutant LGSOC, and 17% (9/52; 95% CI: 8-30) in KRAS wild-type LGSOC. The majority (82%) of all patients had a reduction in their tumors, regardless of KRAS status. The updated data continue to demonstrate avutometinib in combination with defactinib is generally well-tolerated, with a 10% discontinuation rate due to adverse events (AEs) and no new safety signals.
- The Company continued its commercial preparation activities for a potential U.S. launch in mid-2025.
- The Japanese Gynecologic Oncology Group (JGOG) dosed the first patient in a Phase 2 Verastem sponsored clinical trial, called RAMP201J, evaluating the safety and efficacy of avutometinib in combination with defactinib for recurrent LGSOC in Japan in October 2024.

### ***Avutometinib in Combination with KRAS G12C Inhibitors in Non-Small Cell Lung Cancer (NSCLC)***

Following a thorough evaluation of the Company's lung cancer clinical development program, Verastem has decided to discontinue the Phase 1/2 RAMP 204 clinical trial evaluating the combination of avutometinib and adagrasib in patients with KRAS G12C-mutant NSCLC. There are no safety concerns with the RAMP 204 trial. The Company is prioritizing the Phase 1/2 RAMP 203 clinical trial, which is evaluating the doublet of avutometinib and sotorasib and the triplet combination of avutometinib and sotorasib plus defactinib in similar patient populations.

- Since the last update of RAMP 203 in October of 2023, enrollment to the doublet of avutometinib plus sotorasib for the KRAS G12C inhibitor naïve Stage I Part B cohort has recently completed, and per protocol patients are being followed to determine if the efficacy supports further expanded enrollment into Stage II. The KRAS G12C inhibitor prior-treated Stage I Part B cohort enrollment is nearly complete.
- Earlier this year, RAMP 203 was modified to include the triplet combination of avutometinib and sotorasib plus defactinib and the first safety cohort of this triplet has been fully enrolled. Preclinical data provide strong evidence that addition of a FAK inhibitor to the sotorasib and avutometinib doublet has the potential to deepen anti-tumor response and significantly delay tumor progression.
- Expect to report updated interim data from the doublet combination of avutometinib plus sotorasib and provide initial safety data and a status of enrollment for the triplet combination of avutometinib, sotorasib and defactinib in the RAMP 203 trial by the end of 2024.

### ***Avutometinib and Defactinib Combination in First-Line Metastatic Pancreatic Cancer***

- Preclinical data outlining the scientific rationale for the combination of avutometinib plus defactinib with standard of care chemotherapy was published in the October 23, 2024 edition of *Science Translational Medicine*.
  - Presented initial interim safety and efficacy results from the ongoing RAMP 205 trial of avutometinib and defactinib in combination with current standard of care gemcitabine and nab-paclitaxel in first-
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line metastatic pancreatic cancer on June 1, 2024, at the American Society of Clinical Oncology (ASCO) Annual Meeting.

- Expect to report updated data from the ongoing RAMP 205 trial in Q1 2025.

#### ***VS-7375/GFH375: Oral KRAS G12D (ON/OFF) Inhibitor***

- GenFleet began dosing several patients in the Phase 1/2 trial in China evaluating VS-7375/GFH375 in patients with KRAS G12D-mutated advanced solid tumors in July 2024.
- After evaluating initial dose escalation data from the Phase 1 study of VS-7375/GFH375 in China, Verastem anticipates filing a U.S. investigational new drug (IND) application by Q1 2025.
- Discovery/lead optimization continues for the second and third programs in the GenFleet collaboration.

#### **Third Quarter 2024 Financial Results**

Verastem Oncology ended the third quarter of 2024 with cash, cash equivalents and short-term investments of \$113.2 million which provides an expected cash runway through the potential approval of avutometinib and defactinib for recurrent LGSOC in mid-2025.

Total operating expenses for the three months ended September 30, 2024 (the "2024 Quarter") were \$37.0 million, compared to \$21.3 million for the three months ended September 30, 2023 (the "2023 Quarter").

Research & development expenses for the 2024 Quarter were \$24.8 million, compared to \$13.9 million for the 2023 Quarter. The increase of \$10.9 million, or 78.4%, was primarily related to contract research organization costs, consulting costs, investigator fees associated with ensuring continued rapid start-up of RAMP 301, and a clinical milestone expense that was reached in the GenFleet G12D program.

Selling, general & administrative expenses for the 2024 Quarter were \$12.3 million, compared to \$7.4 million for the 2023 Quarter. The increase of \$4.9 million, or 66.2%, was primarily related to a one-time cost associated with July 2024 financing activities, personnel costs, including non-cash stock compensation and additional costs in anticipation of a potential launch of avutometinib and defactinib in LGSOC.

Net loss for the 2024 Quarter was \$24.0 million, or \$0.60 per share (basic and diluted), compared to \$20.0 million, or \$0.75 per share (basic and diluted) for the 2023 Quarter.

For the 2024 Quarter, non-GAAP adjusted net loss was \$35.3 million, or \$0.88 per share (diluted) compared to non-GAAP adjusted net loss of \$19.0 million, or \$0.71 per share (diluted) for the 2023 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 net loss per share. These non-GAAP financial measures exclude certain amounts or expenses from the corresponding financial measures determined in accordance with GAAP.

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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 nine months ended September 30, 2024 and 2023 are included in the tables accompanying this press release after the unaudited condensed consolidated financial statements.

### **About the Avutometinib and Defactinib Combination**

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/MAPK pathway inhibition. In contrast to currently available MEK-only 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 MEK-only inhibitors.

Verastem Oncology is currently conducting clinical trials with avutometinib in RAS/MAPK driven tumors as part of its **Raf And Mek Program** or RAMP. Verastem is currently enrolling patients and activating sites for RAMP 301 (NCT06072781) an international Phase 3 confirmatory trial evaluating the combination of avutometinib and defactinib, a selective FAK inhibitor, versus standard chemotherapy or hormonal therapy for the treatment of recurrent low-grade serous ovarian cancer (LGSOC). RAMP 201 (NCT04625270) is a Phase 2 registration-directed trial of avutometinib in combination with defactinib in patients with recurrent LGSOC and enrollment has been completed for the RAMP 201 trial.

Verastem has completed its submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for the investigational combination of avutometinib and defactinib in adults with recurrent KRAS mutant LGSOC who received at least one prior systemic therapy in October 2024, with a potential FDA decision mid-2025. The FDA granted Breakthrough Therapy Designation of the investigational combination of avutometinib and defactinib for the treatment of patients with recurrent LGSOC after one or more prior lines of therapy, including platinum-based chemotherapy. Avutometinib alone or in combination with defactinib was also granted Orphan Drug Designation by the FDA for the treatment of LGSOC.

Verastem Oncology has established a clinical collaboration with Amgen to evaluate LUMAKRAS™ (sotorasib) in combination with avutometinib and defactinib in both treatment naive and in patients who progressed on a G12C inhibitor as part of the RAMP 203 trial (NCT05074810). Verastem has received Fast Track Designation from the FDA for the triplet combination in April 2024. RAMP 205 (NCT05669482), a

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Phase 1b/2 clinical trial evaluating avutometinib and defactinib with gemcitabine/nab-paclitaxel in patients with front-line metastatic pancreatic cancer, is supported by the PanCAN Therapeutic Accelerator Award. FDA granted Orphan Drug Designation to avutometinib and defactinib combination for the treatment of pancreatic cancer.

#### **About VS-7375/GFH375**

VS-7375/GFH375 is a potential best-in-class, potent and selective oral KRAS G12D (ON/OFF) inhibitor, identified as the lead discovery program from the Verastem Oncology discovery and development collaboration with GenFleet Therapeutics. GenFleet's IND for VS-7375/GFH375 was approved in China in June 2024 and the Phase 1/2 trial in KRAS G12D-mutant solid tumors was subsequently initiated and the first patient was dosed in July 2024. The collaboration includes three discovery programs, the first being the KRAS G12D inhibitor, and provides Verastem Oncology with exclusive options to license three compounds selected for collaboration after successful completion of pre-determined milestones in Phase 1 trials. The licenses would give Verastem Oncology development and commercialization rights outside of the GenFleet territories of mainland China, Hong Kong, Macau, and Taiwan.

#### **About Verastem Oncology**

Verastem Oncology (Nasdaq: VSTM) is a late-stage development 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 RAS/MAPK-driven cancers, specifically novel small molecule drugs that inhibit critical signaling pathways in cancer that promote cancer cell survival and tumor growth, including RAF/MEK inhibition and FAK inhibition. For more information, please visit [www.verastem.com](http://www.verastem.com) and follow us on LinkedIn.

#### **Forward-Looking Statements**

This press release includes forward-looking statements about, among other things, Verastem Oncology's programs and product candidates, strategy, future plans and prospects, including statements related to the expected timing for the FDA review of the rolling NDA submission for the avutometinib and defactinib combination in LGSOC, the structure of our planned and pending clinical trials, the potential clinical value of various of the Company's clinical trials, including the RAMP 201, 205 and 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 Verastem Oncology's lead compound, the expected outcome and benefits of our collaboration with GenFleet Therapeutics and the estimated addressable markets of our 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.

Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause our actual results to differ materially from those expressed or implied in

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the forward-looking statements we make. 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; that 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 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 the FDA taking action on our NDA seeking accelerated approval; risks associated with preliminary and interim data, which may not be representative of more mature data, including with respect to interim duration of therapy data; 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 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 the total addressable and target markets for our product candidates might be smaller than we are presently estimating; that we or Secura Bio, Inc. (Secura) will fail to fully perform under the asset purchase agreement with Secura,

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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 Therapeutics (Shanghai), Inc. (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 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 (SEC) on March 14, 2024 and in any subsequent filings with the SEC, which are available at [www.sec.gov](http://www.sec.gov). 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.

**For Investor and Media Inquiries:**

Julissa Viana

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**Verastem Oncology**  
**Condensed Consolidated Balance Sheets**  
(in thousands)  
(unaudited)

	<b>September 30, 2024</b>	<b>December 31, 2023</b>
Cash, cash equivalents & short-term investments	\$ 113,175	\$ 137,129
Grant receivable	200	—
Prepaid expenses and other current assets	7,287	6,553
Property and equipment, net	39	37
Right-of-use asset, net	625	1,171
Restricted cash and other assets	5,052	4,828
<b>Total assets</b>	<b>\$ 126,378</b>	<b>\$ 149,718</b>
<b>Current Liabilities</b>	<b>\$ 37,374</b>	<b>\$ 26,380</b>
Long term debt	30,647	40,086
Lease liability, long-term	—	530
Preferred stock tranche liability	—	4,189
Warrant liability	26,138	—
Convertible preferred stock	21,159	21,159
Stockholders' equity	11,060	57,374
<b>Total liabilities, convertible preferred stock and stockholders' equity</b>	<b>\$ 126,378</b>	<b>\$ 149,718</b>

**Verastem Oncology**  
**Condensed Consolidated Statements of Operations**  
(in thousands, except per share amounts)  
(unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Revenue				
Sale of COPIKTRA license and related assets	\$ —	\$ —	\$ 10,000	\$ —
Total revenue	—	—	10,000	—
Operating expenses:				
Research and development	24,754	13,946	60,523	38,854
Selling, general and administrative	12,276	7,363	32,843	22,091
Total operating expenses	37,030	21,309	93,366	60,945
Loss from operations	(37,030)	(21,309)	(83,366)	(60,945)
Other expense	(77)	(13)	(131)	(60)
Interest income	831	2,247	3,181	4,345
Interest expense	(1,148)	(1,129)	(3,416)	(3,019)
Change in fair value of preferred stock tranche liability	—	200	4,189	(320)
Change in fair value of warrant liability	13,457	—	13,457	—
Net loss	\$ (23,967)	\$ (20,004)	\$ (66,086)	\$ (59,999)
Net loss per share—basic and diluted	\$ (0.60)	\$ (0.75)	\$ (2.11)	\$ (2.93) <sup>(1)</sup>
Weighted average common shares outstanding used in computing:				
Net loss per share – basic and diluted	40,258	26,790	31,350	20,452 <sup>(1)</sup>

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

**Verastem Oncology**  
**Reconciliation of GAAP to Non-GAAP Financial Information**  
(in thousands, except per share amounts)  
(unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
<b>Net loss reconciliation</b>				
Net loss (GAAP basis)	\$ (23,967)	\$ (20,004)	\$ (66,086)	\$ (59,999)
<b>Adjust:</b>				
Stock-based compensation expense	1,935	1,517	35,323	4,262
Non-cash interest, net	201	(371)	(212)	(295)
Change in fair value of preferred stock tranche liability	—	(200)	(4,189)	320
Change in fair value of warrant liability	(13,457)	—	(13,457)	—
Severance and Other	10	47	619	85
<b>Adjusted net loss (non-GAAP basis)</b>	<b>\$ (35,278)</b>	<b>\$ (19,011)</b>	<b>\$ (78,002)</b>	<b>\$ (55,627)</b>
<b>Reconciliation of net loss per share</b>				
Net loss per share – diluted (GAAP Basis)	(0.60)	(0.75)	(2.11)	(2.93) <sup>(1)</sup>
<b>Adjust per diluted share:</b>				
Stock-based compensation expense	0.05	0.06	0.17	0.21 <sup>(1)</sup>
Non-cash interest, net	—	(0.01)	(0.01)	(0.02) <sup>(1)</sup>
Change in fair value of preferred stock tranche liability	—	(0.01)	(0.13)	0.02 <sup>(1)</sup>
Change in fair value of warrant liability	(0.33)	—	(0.43)	—
Severance and Other	—	—	0.02	—
<b>Adjusted net loss per share – diluted (non-GAAP basis)</b>	<b>\$ (0.88)</b>	<b>\$ (0.71)</b>	<b>\$ (2.49)</b>	<b>\$ (2.72)<sup>(1)</sup></b>
Weighted average common shares outstanding used in computing net loss per share—diluted	40,258	26,790	31,350	20,452 <sup>(1)</sup>

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