
**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, 2022

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 Global 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 2, 2022 there were 210,090,850 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, 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 (VS-6766) (rapidly accelerated fibrosarcoma (“RAF”)/ mitogen-activated protein kinase kinase (“MEK”) program) and defactinib (focal adhesion kinase (“FAK”) program), the structure of our planned and pending clinical trials, and the timeline and indications for clinical development, regulatory submissions and commercialization of activities. 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 our actual results could differ materially from the results discussed in the forward-looking statements we make. Applicable risks and uncertainties include the risks and uncertainties, among other things, regarding: the uncertainties inherent in research and development of avutometinib (VS-6766) and defactinib, such as negative or unexpected results of clinical trials; whether and when applications for avutometinib (VS-6766) and defactinib may be filed with regulatory authorities in any jurisdictions; whether and when regulatory authorities in any jurisdictions may approve any such other applications that may be filed for avutometinib (VS-6766) and defactinib, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted and, if approved, whether avutometinib (VS-6766) or defactinib will be commercially successful in such jurisdictions; our ability to obtain, maintain and enforce patent and other intellectual property protection for avutometinib (VS-6766) and defactinib; the scope, timing, and outcome of any legal proceedings; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of avutometinib (VS-6766) and defactinib; 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 there may be competitive developments affecting our product candidates; that data may not be available when expected; that enrollment of clinical trials may take longer than expected; that avutometinib (VS-6766) or defactinib will cause unexpected safety events, experience manufacturing or supply interruptions or failures, or result in unmanageable safety profiles as compared to their levels of efficacy; 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 avutometinib (VS-6766) or defactinib; that we will be unable to in-license additional compounds or successfully initiate or complete the clinical development and eventual commercialization of our product candidates; that the development and commercialization of our product candidates will take longer or cost more than planned; that we may not have sufficient cash to fund our contemplated operations; that we may not attract and retain high quality personnel; that we or Chugai Pharmaceutical, Co. Ltd., will fail to fully perform under the license agreement; that our target market for our product candidates might be smaller than we are presently estimating; that we or Secura Bio, Inc. will fail to fully perform under the asset purchase agreement; 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, that our product candidates will not receive regulatory approval, become commercially successful products, or result in new treatment options being offered to patients; and that the duration and impact of COVID-19 may affect, precipitate or exacerbate one or more of the foregoing risks and uncertainties. Other risks and uncertainties include those identified in our Annual Report on Form 10-K for the year ended December 31, 2021 as filed with Securities and Exchange Commission (SEC) on March 28, 2022, in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, as filed with the SEC on August 8, 2022, 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, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 78,166	\$ 21,252
Short-term investments	25,810	79,004
Accounts receivable, net	74	516
Prepaid expenses and other current assets	4,709	4,968
Total current assets	108,759	105,740
Property and equipment, net	121	210
Right-of-use asset, net	1,927	2,302
Restricted cash	241	241
Other assets	47	169
Total assets	\$ 111,095	\$ 108,662
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 5,359	\$ 2,302
Accrued expenses	14,788	15,621
Deferred liabilities	965	—
Lease liability, short-term	761	667
Total current liabilities	21,873	18,590
Non-current liabilities:		
Convertible senior notes	268	249
Long-term debt	24,399	—
Lease liability, long-term	1,682	2,264
Total liabilities	48,222	21,103
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 5,000 shares authorized, no shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	—	—
Common stock, \$0.0001 par value; 300,000 shares authorized, 210,084 and 185,286 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	21	19
Additional paid-in capital	783,606	751,217
Accumulated other comprehensive income/(loss)	(39)	34
Accumulated deficit	(720,715)	(663,711)
Total stockholders' equity	62,873	87,559
Total liabilities and stockholders' equity	\$ 111,095	\$ 108,662

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>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Revenue:				
Sale of COPIKTRA license and related assets	—	—	\$ 2,596	\$ 902
Transition services revenue	—	2	—	606
Total revenue	—	2	2,596	1,508
Operating expenses:				
Research and development	11,288	9,325	39,818	27,951
Selling, general and administrative	6,421	5,523	18,869	18,455
Total operating expenses	17,709	14,848	58,687	46,406
Loss from operations	(17,709)	(14,846)	(56,091)	(44,898)
Other income	20	—	54	—
Interest income	316	40	446	141
Interest expense	(717)	(7,980)	(1,413)	(9,962)
Net loss	\$ (18,090)	\$ (22,786)	\$ (57,004)	\$ (54,719)
Net loss per share—basic and diluted	\$ (0.09)	\$ (0.13)	\$ (0.30)	\$ (0.31)
Weighted average common shares outstanding used in computing net loss per share—basic and diluted				
	197,151	179,861	189,999	174,524
Net loss	\$ (18,090)	\$ (22,786)	\$ (57,004)	\$ (54,719)
Unrealized gain (loss) on available-for-sale securities	91	(12)	(73)	(26)
Comprehensive loss	\$ (17,999)	\$ (22,798)	\$ (57,077)	\$ (54,745)

See accompanying notes to the condensed consolidated financial statements.

Verastem, Inc.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(unaudited)
(in thousands, except share data)

	Common stock		Additional paid-in capital	Accumulated other comprehensive income/ (loss)	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
Balance at December 31, 2021	185,286,480	\$ 19	\$ 751,217	\$ 34	\$ (663,711)	\$ 87,559
Net loss	—	—	—	—	(16,962)	(16,962)
Unrealized (loss) on available-for-sale marketable securities	—	—	—	(147)	—	(147)
Issuance of common stock resulting from at-the-market transactions, net	285,900	—	575	—	—	575
Issuance of common stock resulting from vesting of restricted stock units	699,635	—	—	—	—	—
Stock-based compensation expense	—	—	1,646	—	—	1,646
Issuance of common stock under Employee Stock Purchase Plan	57,636	—	100	—	—	100
Balance at March 31, 2022	186,329,651	\$ 19	\$ 753,538	\$ (113)	\$ (680,673)	\$ 72,771
Net loss	—	—	—	—	(21,952)	(21,952)
Unrealized (loss) on available-for-sale marketable securities	—	—	—	(17)	—	(17)
Issuance of common stock resulting from at-the-market transactions, net	1,006,444	—	1,240	—	—	1,240
Issuance of common stock resulting from exercise of stock options	76,539	—	92	—	—	92
Issuance of common stock resulting from vesting of restricted stock units	200,813	—	—	—	—	—
Stock-based compensation expense	—	—	1,758	—	—	1,758
Balance at June 30, 2022	187,613,447	\$ 19	\$ 756,628	\$ (130)	\$ (702,625)	\$ 53,892
Net loss	—	—	—	—	(18,090)	(18,090)
Unrealized gain on available-for-sale marketable securities	—	—	—	91	—	91
Issuance of common stock resulting from at-the-market transactions, net	22,281,059	2	25,532	—	—	25,534
Issuance of common stock resulting from vesting of restricted stock units	102,985	—	—	—	—	—
Issuance of common stock resulting from exercise of stock options	21,637	—	26	—	—	26
Stock-based compensation expense	—	—	1,356	—	—	1,356
Issuance of common stock under Employee Stock Purchase Plan	64,696	—	64	—	—	64
Balance at September 30, 2022	210,083,824	\$ 21	\$ 783,606	\$ (39)	\$ (720,715)	\$ 62,873
Balance at December 31, 2020	170,456,179	\$ 17	\$ 707,715	\$ 53	\$ (592,511)	\$ 115,274
Net loss	—	—	—	—	(15,031)	(15,031)
Unrealized (loss) on available-for-sale marketable securities	—	—	—	(19)	—	(19)
Issuance of common stock resulting from exercise of stock options	173,890	—	381	—	—	381
Issuance of common stock resulting from vesting of restricted stock units	1,047,271	—	(52)	—	—	(52)
Stock-based compensation expense	—	—	1,980	—	—	1,980
Issuance of common stock under Employee Stock Purchase Plan	53,372	—	76	—	—	76
Balance at March 31, 2021	171,730,712	\$ 17	\$ 710,100	\$ 34	\$ (607,542)	\$ 102,609
Net loss	—	—	—	—	(16,902)	(16,902)
Unrealized gain on available-for-sale marketable securities	—	—	—	5	—	5
Issuance of common stock resulting from exercise of stock options	330,758	—	361	—	—	361
Issuance of common stock resulting from vesting of restricted stock units	15,896	—	(38)	—	—	(38)
Stock-based compensation expense	—	—	2,170	—	—	2,170
Balance at June 30, 2021	172,077,366	\$ 17	\$ 712,593	\$ 39	\$ (624,444)	\$ 88,205
Net loss	—	—	—	—	(22,786)	(22,786)
Unrealized (loss) on available-for-sale marketable securities	—	—	—	(12)	—	(12)
Issuance of common stock under Employee Stock Purchase Plan	56,688	—	106	—	—	106
Issuance of common stock resulting from vesting of restricted stock units	1,327,445	—	—	—	—	—
Issuance of common stock resulting from exercise of stock options	78,375	—	155	—	—	155
Stock-based compensation expense	—	—	1,987	—	—	1,987
Conversion of 2020 Notes into common stock	8,615,384	1	27,999	—	—	28,000
Balance at September 30, 2021	182,155,258	\$ 18	\$ 742,840	\$ 27	\$ (647,230)	\$ 95,655

See accompanying notes to the condensed consolidated financial statements.

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

	Nine months ended September 30,	
	2022	2021
Operating activities		
Net loss	\$ (57,004)	\$ (54,719)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	89	176
Amortization of right-of-use asset and lease liability	(113)	(98)
Stock-based compensation expense	4,760	6,137
Amortization of deferred financing costs, debt discounts and premiums and discounts on available-for-sale marketable securities	231	9,287
Changes in operating assets and liabilities:		
Accounts receivable, net	442	134
Prepaid expenses, other current assets and other assets	1,349	(1,834)
Accounts payable	3,057	(1,038)
Accrued expenses and other liabilities	(833)	(1,614)
Deferred liabilities	965	—
Net cash used in operating activities	(47,057)	(43,569)
Investing activities		
Purchases of property and equipment	—	(196)
Purchases of investments	(15,340)	(53,258)
Maturities of investments	68,500	53,475
Net cash provided by investing activities	53,160	21
Financing activities		
Proceeds from long-term debt, net	24,148	—
Proceeds from the exercise of stock options and employee stock purchase program	282	1,079
Payment of deferred offering costs	—	(73)
Settlement of restricted stock for tax withholdings	—	(926)
Proceeds from the issuance of common stock, net	27,354	—
Net cash provided by financing activities	51,784	80
Increase (decrease) in cash, cash equivalents and restricted cash	57,887	(43,468)
Cash, cash equivalents and restricted cash at beginning of period	21,493	68,023
Cash, cash equivalents and restricted cash at end of period	\$ 79,380	\$ 24,555
Supplemental disclosure of non-cash investing and financing activities		
Conversion of 2020 Notes into common stock	\$ —	\$ 28,000
Deferred offering costs included in accounts payable and accrued expenses	\$ —	\$ 46

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 advancing new medicines for patients battling cancer. The Company’s pipeline is focused on novel anticancer agents that inhibit critical signaling pathways in cancer that promote cancer cell survival and tumor growth, particularly rapidly accelerated fibrosarcoma (“RAF”)/ mitogen-activated protein kinase kinase (“MEK”) inhibition and focal adhesion kinase (“FAK”) inhibition.

The Company’s most advanced product candidates, avutometinib (VS-6766) and defactinib, are being investigated in both preclinical and clinical studies for the treatment of various solid tumors, including, low-grade serous ovarian cancer (“LGSOC”), non-small cell lung cancer (“NSCLC”), colorectal cancer (“CRC”), pancreatic cancer, uveal melanoma, and endometrial cancer. The Company believes that avutometinib (VS-6766) may be beneficial as a therapeutic as a single agent or when used together in combination with defactinib, other agents, other pathway inhibitors or other current and emerging standard of care treatments in cancers that do not adequately respond to currently available therapies.

On September 24, 2018, the Company’s first commercial product, COPIKTRA® (duvelisib), was approved by the U.S. Food and Drug Administration (the “FDA”) for the treatment of adult patients with certain hematologic cancers including relapsed or refractory chronic lymphocytic leukemia/ small lymphocytic lymphoma after at least two prior therapies and relapsed or refractory follicular lymphoma after at least two prior systemic therapies. On August 10, 2020, the Company and Secura Bio, Inc. (“Secura”) entered into an asset purchase agreement (“Secura APA”). Pursuant to the Secura APA, the Company sold to Secura its exclusive worldwide license, including certain related assets for the research, development, commercialization, and manufacture in oncology indications of products containing COPIKTRA (duvelisib). The transaction closed on September 30, 2020. Refer to *Note 13. License, collaboration, and commercial agreements* for a detailed discussion of the Secura APA.

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, avutometinib (VS-6766) and defactinib, market acceptance and commercial success of the Company’s product candidates, avutometinib (VS-6766) 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, avutometinib (VS-6766) and defactinib, following regulatory approval, it will be unable to generate product revenue or achieve profitability and may need to raise additional capital.

The Company has historical losses from operations and anticipates that it may continue to incur operating losses as it continues the research and development of its product candidates. As of September 30, 2022 the Company had cash, cash equivalents, and investments of \$104.0 million, and an accumulated deficit of \$720.7 million. The Company expects its existing cash resources will be sufficient to fund its planned operations through at least 12 months from the date of issuance of these condensed consolidated financial statements.

The Company expects to finance the future development costs of its clinical product portfolio with its existing cash, cash equivalents, and investments, through future milestones and royalties received pursuant to the Secura APA, through our 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, there is no guarantee that any of these strategic or financing opportunities will be executed or executed on favorable terms, and some could be dilutive to existing stockholders. 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.

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, 2022 are not necessarily indicative of the results that may be expected for any other interim period or for the year ending December 31, 2022. 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, 2021, as filed with the Securities and Exchange Commission (“SEC”) on March 28, 2022.

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, 2021. During the nine months ended September 30, 2022, the Company did not adopt any additional significant accounting policies.

Recently Issued Accounting Standards Updates

In June 2016, the FASB issued ASU No. 2016-13, Measurement of Credit Losses on Financial Instruments (“ASU 2016-13”). ASU 2016-13 will replace the incurred loss impairment methodology under current GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. In November 2019, the FASB issued ASU 2019-10, Financial Instruments – Credit Losses (Topic 326), Derivatives (Topic 815), and Leases (Topic 842). This ASU delayed the required adoption for SEC filers that are smaller reporting companies as of their determination on November 15, 2019, until annual and interim periods beginning after December 15, 2022, with early adoption permitted. The Company has determined that as of November 15, 2019, it is a smaller reporting company and has not elected to early adopt this standard. The Company is currently evaluating the impact the adoption of the standard will have on its condensed consolidated financial statements and related disclosures.

In August 2020, the FASB issued No. ASU 2020-06, Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity’s Own Equity (Subtopic 815 – 40) (“ASU 2020-06”). ASU 2020-06 simplifies the complexity associated with applying U.S. GAAP for certain financial instruments with characteristics of liabilities and equity. More specifically, the amendments focus on the guidance for convertible instruments and derivative scope exception for contracts in an entity’s own equity. The ASU also simplifies the diluted earnings per share calculation in certain areas. For smaller reporting companies, ASU 2020-06 is effective for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. The Company is currently evaluating the impact ASU 2020-06 will have on its condensed consolidated financial statements and related disclosures.

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, 2022 the Company's cash, cash equivalents and investments were deposited at three 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.

As of September 30, 2022, there was one customer, Secura, that made up more than 60% of the Company's accounts receivable balance. The Company assesses the creditworthiness of all its customers and sets and reassesses customer credit limits to ensure collectability of any accounts receivable balances are assured.

For the nine months ended September 30, 2022, 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

During the nine months ended September 30, 2022, the Company was awarded the "Therapeutic Accelerator Award" grant from Pancreatic Cancer Network ("PanCAN") for up to \$3.8 million (the "PanCAN Grant"). The grant is expected to support a Phase 1b/2 clinical trial of avutometinib (VS-6766) in combination with defactinib entitled RAMP 205. The trial will evaluate whether blockade of KRAS signaling which is mutated in more than 90% of pancreatic tumors, along with chemotherapy and reduction of stromal density will improve outcomes for patients with pancreatic cancer. In August 2022, PanCAN agreed to provide the Company with an additional \$0.5 million for the collection and analysis of patient samples. The Company received \$1.0 million of cash proceeds in July 2022 which was initially recorded as deferred liabilities on the condensed balance sheet. The Company recorded less than \$0.1 million of the proceeds as a reduction of research and development expense during the three months ended September 30, 2022. As of September 30, 2022, the Company recorded \$1.0 million as deferred liabilities in the condensed consolidated balance sheet related to the PanCAN Grant.

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, 2022	December 31, 2021
Cash and cash equivalents	\$ 78,166	\$ 21,252
Restricted cash	1,214	241
Total cash, cash equivalents and restricted cash	\$ 79,380	\$ 21,493

Amounts included in restricted cash as of September 30, 2022 represent (i) cash received pursuant to the PanCAN Grant restricted for future expenditures for specific research and development activities 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 amounts of \$1.0 million and \$0.2 million, respectively. Amounts included in restricted cash as of December 31, 2021 represent 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. Cash received pursuant to the PanCAN Grant is included in prepaid expenses and other current assets on the condensed consolidated balance sheet as of September 30, 2022. The letters of credit are included in non-current restricted cash on the condensed consolidated balance sheets as of September 30, 2022 and December 31, 2021.

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, 2022			
	Total	Level 1	Level 2	Level 3
Financial assets				
Cash equivalents	\$ 77,187	\$ 54,314	\$ 22,873	\$ —
Short-term investments	25,810	—	25,810	—
Total financial assets	\$ 102,997	\$ 54,314	\$ 48,683	\$ —

Description	December 31, 2021			
	Total	Level 1	Level 2	Level 3
Financial assets				
Cash equivalents	\$ 19,302	\$ 19,302	\$ —	\$ —
Short-term investments	79,004	—	79,004	—
Total financial assets	\$ 98,306	\$ 19,302	\$ 79,004	\$ —

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, 2022 and December 31, 2021.

Fair Value of Financial Instruments

The fair value of the Company's 2018 issued 5.00% Convertible Senior Notes due 2048 (the "2018 Notes") was approximately \$0.3 million as of September 30, 2022, which equals the carrying value of the 2018 Notes as of September 30, 2022. The fair value of the 2018 Notes was approximately \$0.3 million as of December 31, 2021, which differed from the carrying value of the 2018 Notes of \$0.2 million as of December 31, 2021. The fair value of the 2018 Notes is influenced by the Company's stock price, stock price volatility, and current market yields and was determined using Level 3 inputs.

The fair value of the Company's long-term debt is determined using a discounted cash flow analysis with current applicable rates for similar instruments as of the condensed consolidated balance sheet date. The carrying value of the Company's long-term debt as of September 30, 2022, was approximately \$24.4 million. The Company estimates that the fair value of its long-term debt was approximately \$25.6 million as of September 30, 2022. There was no long-term debt outstanding as of December 31, 2021. 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, 2022			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash, cash equivalents & restricted cash:				
Cash and money market accounts	\$ 56,508	\$ —	\$ —	\$ 56,508
Corporate bonds, agency bonds and commercial paper (due within 90 days)	22,865	8	(1)	22,872
Total cash, cash equivalents & restricted cash:	\$ 79,373	\$ 8	\$ (1)	\$ 79,380
Investments:				
Corporate bonds, agency bonds and commercial paper (due within 1 year)	\$ 25,856	\$ 15	\$ (61)	\$ 25,810
Total investments	\$ 25,856	\$ 15	\$ (61)	\$ 25,810
Total cash, cash equivalents, restricted cash and investments	\$ 105,229	\$ 23	\$ (62)	\$ 105,190

	December 31, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash, cash equivalents & restricted cash:				
Cash and money market accounts	\$ 21,493	\$ —	\$ —	\$ 21,493
Total cash, cash equivalents & restricted cash:	\$ 21,493	\$ —	\$ —	\$ 21,493
Investments:				
Corporate bonds and commercial paper (due within 1 year)	\$ 78,970	\$ 48	\$ (14)	\$ 79,004
Total investments	\$ 78,970	\$ 48	\$ (14)	\$ 79,004
Total cash, cash equivalents, restricted cash and investments	\$ 100,463	\$ 48	\$ (14)	\$ 100,497

There were no realized gains or losses on investments for the three and nine months ended September 30, 2022 or 2021. There was one debt security in an unrealized loss position for more than 12 months as of September 30, 2022, with a fair value of \$5.0 million, and unrealized loss of less than \$0.1 million. There were no investments in an unrealized loss position for more than 12 months as of December 31, 2021. There were six debt securities in an unrealized loss position for less than 12 months as of September 30, 2022, with a fair value of \$16.4 million and

unrealized loss of less than \$0.1 million. There were three debt securities in an unrealized loss position for less than 12 months as of December 31, 2021, with a fair value of \$15.8 million and unrealized loss of less than \$0.1 million. The Company considered the decline in the market value for these securities to be primarily attributable to current economic conditions. As it was not more likely than not that the Company would be required to sell these securities before the recovery of their amortized cost basis, which may be at maturity, the Company did not consider these investments to be other-than-temporarily impaired as of September 30, 2022 and December 31, 2021, respectively.

6. Accrued expenses

Accrued expenses consist of the following (in thousands):

	September 30, 2022	December 31, 2021
Research and development expenses	\$ 8,163	\$ 9,311
Compensation and related benefits	3,393	3,892
Professional fees	678	785
Consulting fees	956	544
Interest	198	3
Commercialization costs	479	187
Other	921	899
Total accrued expenses	\$ 14,788	\$ 15,621

7. Debt

On March 25, 2022 (the “Closing Date”), the Company entered into a loan and security agreement (the “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”).

Pursuant to the Loan Agreement, the Company received an initial Term Loan of \$25.0 million on the Closing Date and may borrow an additional \$125.0 million of Term Loans at its option upon the satisfaction of certain conditions as follows:

- i. \$15.0 million (the “Term B Loan”), when the Company has either (a) received the Regulatory Milestone Payment (as defined in the Secura APA) from Secura of \$35.0 million which is due upon receipt of regulatory approval of COPIKTRA in the United States for the treatment of peripheral T-cell lymphoma (“PTCL”) or (b) received at least \$50.0 million in unrestricted cash proceeds from the sale or issuance of equity securities after the Closing Date (the “Term B Milestones”). The Company may draw the Term B Loan within 60 days after the occurrence of one of the Term B Milestones, but no later than March 31, 2023.
- ii. \$25.0 million (the “Term C Loan”), when the Company has received accelerated or full approval from the FDA of avutometinib (VS-6766) for the treatment of LGSOC (the “Term C Milestone”). The Company may draw the Term C Loan within 60 days after the occurrence the Term C Milestone, but no later than March 31, 2024.
- iii. \$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.
- iv. \$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. Beginning (i) April 1, 2024, if the Term B Loan is not made, (ii) April 1, 2025, if the Term B Loan is made, or (iii) April 1, 2026, if the Term B Loan is made and either (A) avutometinib (VS-6766) has received FDA approval for the treatment of LGSOC or (B) COPIKTRA has received

FDA approval for the treatment of PTCL, 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, 2022.

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, 2022 and December 31, 2021 are detailed below (in thousands):

	September 30, 2022	December 31, 2021
Principal loan balance	\$ 25,000	\$ —
Final Payment Fee	149	—
Debt issuance costs, net of accretion	(750)	—
Long-term debt, net of discount	<u>\$ 24,399</u>	<u>\$ —</u>

As of September 30, 2022, future principal payments due are as follows (in thousands):

2022	\$	—
2023		—
2024		6,250
2025		8,333
2026		8,333
2027		2,084
Total principal payments	\$	25,000

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 has 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, 2022, a right-of-use asset of \$1.9 million and lease liability of \$2.4 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,	
	2022	2021	2022	2021
Lease Expense				
Operating lease expense	\$ 221	\$ 221	\$ 664	\$ 664
Total Lease Expense	\$ 221	\$ 221	\$ 664	\$ 664
Other Information - Operating Leases				
Operating cash flows paid for amounts included in measurement of lease liabilities	\$ 262	\$ 257	\$ 777	\$ 761

September 30, 2022

Other Balance Sheet Information - Operating

Leases

Weighted average remaining lease term (in years)	2.8
Weighted average discount rate	14.6%

Maturity Analysis

2022	262
2023	1,060
2024	1,081
2025	546
Total	\$ 2,949
Less: Present value discount	(506)
Lease Liability	\$ 2,443

9. Convertible Senior Notes

2018 Notes

On October 17, 2018, the Company closed a registered direct public offering of \$150.0 million aggregate principal amount of 2018 Notes for net proceeds of approximately \$145.3 million. The 2018 Notes are governed by the terms of a base indenture for senior debt securities (the “2018 Base Indenture”), as supplemented by the first supplemental indenture thereto (the “2018 Notes Supplemental Indenture” and together with the 2018 Base Indenture, the “2018 Indenture”), each dated October 17, 2018, by and between the Company and Wilmington Trust, National Association (“Wilmington”), as trustee. The 2018 Notes are senior unsecured obligations of the Company and bear interest at a rate of 5.00% per annum, payable semi-annually in arrears on May 1 and November 1 of each year, beginning on May 1, 2019. The 2018 Notes will mature on November 1, 2048, unless earlier repurchased, redeemed or converted in accordance with their terms.

The 2018 Notes are convertible into shares of the Company’s common stock, par value \$0.0001 per share, together, if applicable, with cash in lieu of any fractional share, at an initial conversion rate of 139.5771 shares of common stock per \$1,000 principal amount of the 2018 Notes, which corresponds to an initial conversion price of approximately \$7.16 per share of common stock. Upon conversion, converting noteholders will be entitled to receive accrued interest on their converted 2018 Notes.

The Company has the right, exercisable at its option, to cause all 2018 Notes then outstanding to be converted automatically if the “Daily VWAP” (as defined in the 2018 Indenture) per share of the Company’s common stock equals or exceeds 130% of the conversion price on each of at least 20 VWAP Trading Days (as defined in the 2018 Indenture),

whether or not consecutive, during any 30 consecutive VWAP Trading Day period commencing on or after the date the Company first issued the 2018 Notes.

The Company assessed all terms and features of the 2018 Notes 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 2018 Notes, including the conversion, put and call features. The conversion feature was initially bifurcated as an embedded derivative but subsequently qualified for a scope exception to derivative accounting upon the Company's stockholders approving an increase in the number of authorized shares of Common Stock in December 2018. The Company determined that all other features of the 2018 Notes were clearly and closely associated with the debt host and did not require bifurcation as a derivative liability, 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, 2022.

2019 Notes

In the fourth quarter of 2019, the Company entered into privately negotiated agreements to exchange approximately \$121.7 million aggregate principal amount of the 2018 Notes for (i) approximately \$66.9 million aggregate principal amount of 5.00% Convertible Senior Second Lien Notes due 2048 (the "2019 Notes"), (ii) an aggregate of approximately \$12.1 million in 2018 Notes principal repayment and (iii) accrued interest on the 2018 Notes through the exchange date. As of March 31, 2020, all 2019 Notes have converted into shares of common stock and are no longer outstanding.

2020 Notes

On November 6, 2020, the Company entered into a privately negotiated agreement with an investor who was a holder of the Company's 2018 Notes to exchange approximately \$28.0 million aggregate principal amount of 2018 Notes for approximately \$28.0 million aggregate principal amount of newly issued 5.00% Convertible Senior Notes due 2048 (the "2020 Notes"). The issuance of the 2020 Notes closed on November 13, 2020. The 2020 Notes were governed pursuant to the Base Indenture between the Company and Wilmington, as trustee and collateral agent, dated as of October 17, 2018 as supplemented by the second supplemental indenture thereto, dated as of November 13, 2020, (the "2020 Notes Supplemental Indenture" and together with the Base Indenture, the "2020 Indenture").

The Company had the right, exercisable at its option, to cause all 2020 Notes then outstanding to be converted automatically if the "Daily VWAP" (as defined in the 2020 Indenture) per share of the Company's common stock equaled or exceeded 123.08% of the conversion price on each of at least 20 "VWAP Trading Days" (as defined in the 2020 Indenture), whether or not consecutive, during any 30 consecutive VWAP Trading Day period commencing on or after the date the Company first issued the 2020 Notes (the "2020 Notes Mandatory Conversion Option").

On July 1, 2021, the Company exercised the Company's 2020 Notes Mandatory Conversion Option for the aggregate principal amount of \$28.0 million of the Company's 2020 Notes. On July 16, 2021, the aggregate principal of \$28.0 million of 2020 Notes was converted into 8,615,384 shares of common stock. As a result, all 2020 Notes have converted into shares of common stock and are no longer outstanding.

10. Common stock

At-the-market equity offering programs

In August 2021, the Company entered into a sales agreement with Cantor Fitzgerald & Co. ("Cantor") pursuant to which the Company can offer and sell up to \$100.0 million of its common stock at the current market prices from time to time through Cantor as sales agent (the "August 2021 ATM"). During the three and nine months ended September 30, 2022, the Company sold 22,281,059 shares and 23,573,403 shares, respectively, under the August 2021 ATM for net proceeds of approximately \$25.5 million and \$27.4 million, respectively, (after deducting commissions and other offering expenses).

11. Stock-based compensation

Stock options

A summary of the Company's stock option activity and related information for the nine months ended September 30, 2022 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, 2021	16,264,098	\$ 3.56	6.7	\$ 2,601
Granted	940,375	1.26		
Exercised	(98,176)	1.20		
Forfeited/cancelled	(3,452,122)	5.55		
Outstanding at September 30, 2022	<u>13,654,175</u>	<u>\$ 2.92</u>	<u>7.2</u>	<u>\$ —</u>
Vested at September 30, 2022	<u>7,792,304</u>	<u>\$ 3.45</u>	<u>6.0</u>	<u>\$ —</u>

The fair value of each stock option granted during the nine months ended September 30, 2022 and 2021 was estimated on the grant date using the Black-Scholes option-pricing model using the following weighted-average assumptions:

	September 30,	
	2022	2021
Risk-free interest rate	2.83 %	0.76 %
Volatility	87 %	95 %
Dividend yield	—	—
Expected term (years)	5.7	5.9

Restricted stock units

A summary of the Company's restricted stock unit activity and related information for the nine months ended September 30, 2022 is as follows:

	Shares	Weighted- average grant date fair value per share
Outstanding at December 31, 2021	2,805,004	\$ 2.44
Granted	322,113	\$ 1.36
Vested	(419,745)	\$ 2.94
Forfeited/cancelled	(223,720)	\$ 2.28
Outstanding at September 30, 2022	<u>2,483,652</u>	<u>\$ 2.23</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 (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 Company has reserved 2,000,000 shares of common stock for the administration of the Amended and Restated 2018 ESPP. 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,	
	2022	2021
Risk-free interest rate	1.56 %	0.07 %
Volatility	77 %	68 %
Dividend yield	—	—
Expected term (years)	0.5	0.5

For the nine months ended September 30, 2022 and 2021, the Company recognized \$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, 2022, the Company issued 122,332 shares of common stock for proceeds of \$0.2 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. 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 stock options, restricted stock units, and employee stock purchase plan shares (using the “treasury stock” method), and the 2018 Notes (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:

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Outstanding stock options	13,654,175	12,947,009	13,654,175	12,947,009
Outstanding restricted stock units	2,483,652	1,749,979	2,483,652	1,749,979
2018 Notes	41,873	41,873	41,873	41,873
Employee stock purchase plan	77,700	29,328	77,700	29,328
Total potentially dilutive securities	16,257,400	14,768,189	16,257,400	14,768,189

13. License, collaboration and commercial agreements

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 PTCL 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 PTCL, (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.

In connection with the Secura APA, the Company and Secura entered into a transition services agreement (“Secura TSA”). Under the terms of the Secura TSA, the Company has provided certain support functions at Secura’s

direction for a term of less than one year from the date of execution (“Secura TSA Services”). Services performed were paid at a mutually agreed upon rate.

The Company evaluated the Secura APA and Secura TSA in accordance with ASC 606 as the Company concluded that the counterparty, Secura, is a customer. The Company identified the following performance obligations under the Secura APA and Secura TSA:

- 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”); and
- Secura TSA Services.

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. The Company has the right to consideration for TSA services in an amount that corresponds directly with the value to Secura of the Company’s performance to date. Consideration allocated to the Secura TSA Services will be recognized as such services are provided over the performance period using an output method based on the amount to which the Company has a right to invoice.

The Company determined \$0.1 million of future potential royalties the Company expects to receive pursuant to the Secura APA were not constrained as of September 30, 2022. When estimating the amount of royalties to be received that were not constrained, the Company used the expected value method as there are a range of possible outcomes. When estimating royalties to be received, the Company used a combination of internal projections and forecasts and data from external sources. The Company determined that all other future potential royalties were constrained under the guidance as of September 30, 2022. As part of the Company’s evaluation of the constraint on future royalties, the Company considered a number of factors in determining whether there is significant uncertainty associated with the future events that would result in royalty payments. Those factors include: the likelihood and magnitude of revenue reversals related to future royalties, the amount of variable consideration is highly susceptible to factors outside of the Company’s influence, the amount of time to resolve the uncertainty, and lack of significant history of selling COPIKTRA outside of the United States.

As the consideration for future royalties is conditional, the Company recorded a corresponding contract asset for the expected royalties. Portions of the contract asset are reclassified to accounts receivable when the right to consideration becomes unconditional. As of September 30, 2022 and December 31, 2021, the contract asset has been recorded within prepaid and other current assets on the condensed consolidated balance sheets.

The following table presents changes in the Company’s contract asset for the nine months ended September 30, 2022 (in thousands):

Contract Asset:	December 31, 2021	Additions	Reclassification to receivable	September 30, 2022
Contract asset - Secura	\$ 170	\$ 96	\$ (141)	\$ 125
Total	\$ 170	\$ 96	\$ (141)	\$ 125

During the first quarter of 2022, one regulatory milestone was achieved by Secura's sublicensee, CSPC, of which 50% of the milestone or \$2.5 million was paid to the Company pursuant to the Secura APA. The Company determined all other future potential milestones were excluded from the transaction price, as all other milestone amounts were fully constrained under the guidance as of September 30, 2022. As part of the Company's evaluation of the constraint, the Company considered a number of 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 a long period of time. All other future potential milestone payments were fully constrained as the risk of significant revenue reversal related to these amounts has not yet been resolved.

During the three and nine months ended September 30, 2022, the Company recognized \$0.0 million and \$2.6 million, respectively, of sale of COPIKTRA license and related assets revenue within the statements of operations and comprehensive loss. The sale of COPIKTRA license and related assets revenue for the nine months ended September 30, 2022 primarily related to one regulatory milestone for \$2.5 million achieved by Secura's sublicensee, CSPC, and \$0.1 million related to royalties on COPIKTRA sales in the nine months ended September 30, 2022, and future royalties expected to be received pursuant to the Secura APA that were not constrained.

During the three and nine months ended September 30, 2021, the Company recognized \$0.0 million and \$0.9 million, respectively, of sale of COPIKTRA license and related assets revenue within the statements of operations and comprehensive loss. The sale of COPIKTRA license and related assets revenue for the nine months ended September 30, 2021 primarily related to one regulatory milestone for \$0.8 million achieved by Secura's sublicensee and \$0.1 million related to future royalties expected to be received pursuant to the Secura APA. During the three and nine months ended September 30, 2021, the Company also recognized \$0.0 million and \$0.6 million, respectively, in transition services revenue within the statements of operations and comprehensive loss.

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, 2022 and 2021, respectively, due to the expected loss before income taxes to be incurred for the years ended December 31, 2022 and 2021, 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.

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, 2021. 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, 2021.

OVERVIEW

We are a late stage development biopharmaceutical company, with an ongoing registration directed trial, committed to advancing new medicines for patients battling cancer. Our pipeline is focused on novel anticancer agents that inhibit critical signaling pathways in cancer that promote cancer cell survival and tumor growth, particularly rapidly accelerated fibrosarcoma (“RAF”)/ mitogen-activated protein kinase kinase (“MEK”) inhibition and focal adhesion kinase (“FAK”) inhibition.

Our most advanced product candidates, avutometinib (VS-6766) and defactinib, are being investigated in both preclinical and clinical studies for the treatment of various solid tumors, including low-grade serous ovarian cancer (“LGSOC”), non-small cell lung cancer (“NSCLC”), colorectal cancer (“CRC”), pancreatic cancer, uveal melanoma, and endometrial cancer. We believe that avutometinib (VS-6766) may be beneficial as a therapeutic as a single agent or when used together in combination with defactinib, other agents, other pathway inhibitors, or other current and emerging standard of care treatments in cancers that do not adequately respond to currently available therapies.

Avutometinib (VS-6766) is an orally available first-in-class unique small molecule RAF/MEK clamp. In contrast to other MEK inhibitors commercially available and in development, avutometinib (VS-6766) is a dual RAF/MEK clamp that blocks both MEK kinase activity and the ability of RAF to phosphorylate MEK. MEK-only inhibitors (e.g. PD0325901) paradoxically induce MEK phosphorylation (“pMEK”) by relieving extracellular-signal-regulated-kinase (“ERK”)-dependent feedback inhibition of RAF which may limit their efficacy. By inhibiting RAF-mediated phosphorylation of MEK, avutometinib (VS-6766) has the advantage of not inducing pMEK. This unique mechanism of avutometinib (VS-6766) enables more effective inhibition of ERK signaling and may confer enhanced therapeutic activity against ERK-dependent, RAS or BRAF mutant tumors.

Avutometinib (VS-6766) has been shown to inhibit signaling and proliferation of tumor cell lines with a variety of mitogen-activated pathway kinase (“MAPK”) pathway alterations including Kirsten rat sarcoma viral oncogene homolog (“KRAS”), Harvey rat sarcoma viral oncogene homolog (“HRAS”), or B-Raf proto-oncogene serine/threonine kinase (“BRAF”) mutations, among others. Avutometinib (VS-6766) has also been shown to synergize with agents targeting the MAPK pathway including G12C inhibitors in KRAS mutant NSCLC and CRC in preclinical models and enhances the anti-tumor effects of anti-PD-1 in KRAS mutant NSCLC mouse models. Avutometinib (VS-6766) has shown compelling synergy with defactinib in preclinical models.

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 is a non-receptor tyrosine kinase encoded by the protein tyrosine kinase-2 (“PTK-2”) gene that is involved in cellular adhesion and, in cancer, metastatic capability. Defactinib targets malignant cells both directly and through modulation of the tumor microenvironment. Defactinib has received orphan drug designation in ovarian cancer in the United States, the European Union and Australia. Preclinical research by our scientists and collaborators at world-renowned research institutions has described the effect of FAK inhibition as enhancing immune response by decreasing immuno-suppressive cells, increasing cytotoxic T cells, and reducing stromal density, which allows tumor-killing immune cells to enter the tumor.

The combination of avutometinib (VS-6766) and defactinib has been found to be clinically active in patients with KRAS mutant tumors and has received breakthrough designation from the U.S. Food & Drug Administration (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.

In an ongoing investigator-initiated Phase 1/2 study (the “FRAME study”), the combination of avutometinib (VS-6766) and defactinib is being evaluated in patients with recurrent LGSOC, KRAS mutant NSCLC, KRAS-G12V mutant NSCLC, CRC, pancreatic cancer, and KRAS mutant endometrial cancer. Based on the LGSOC and KRAS-G12V NSCLC cohorts of the FRAME study, we initiated our registration directed trials entitled RAF and MEK Program (“RAMP”) 201 and 202.

In the fourth quarter of 2020, we commenced two registration-directed trials investigating avutometinib (VS-6766) as a monotherapy and in combination with defactinib. The registration-directed trials are entitled RAMP 201 and RAMP 202. RAMP 201 is an adaptive two-part multicenter, parallel cohort, randomized, open label trial to evaluate the efficacy and safety of avutometinib (VS-6766) alone and in combination with defactinib in patients with recurrent LGSOC. RAMP 202 is a Phase 2, adaptive two-part multicenter, parallel cohort, randomized, open-label trial to evaluate the efficacy and safety of avutometinib (VS-6766) alone and in combination with defactinib in patients with KRAS G12V mutant NSCLC, following treatment with a platinum-based regimen and immune checkpoint inhibitor. Additionally, we added several exploratory cohorts to the RAMP 202 study including KRAS non-G12V mutant NSCLC and BRAF (V600E and non-V600E) mutant NSCLC. Based on preclinical rationale, we added BRAF mutant cohorts (V600E and non-V600E) to the RAMP 202 study in order to efficiently evaluate the combination of avutometinib (VS-6766) with defactinib in BRAF-mutant NSCLC.

In June 2022, we completed a planned interim analysis of the RAMP 201 trial with the goal of selecting a go forward treatment regimen of either avutometinib (VS-6766) monotherapy or avutometinib (VS-6766) in combination with defactinib. The analysis indicated encouraging efficacy results with confirmed responses by independent review in patients treated with avutometinib (VS-6766) monotherapy and patients treated with avutometinib (VS-6766) in combination with defactinib. The findings also include confirmed responses by independent review in both KRAS mutant and KRAS wild-type LGSOC. At the time of the June 2022 planned interim analysis, there have been no additional safety signals with a continued favorable safety profile in both the monotherapy and combination treatment arms with approximately 6% of patients discontinuing due to adverse events.

In October 2022, we reported a second planned interim analysis of RAMP 201 trial had been completed. Based on the results of this analysis, which include independently confirmed responses and no new safety signals, we have a confirmed meeting with the FDA in the fourth quarter of 2022 to review the data set, discuss the go forward treatment regimen selection and align on the requirements to initiate a new drug application (“NDA”) submission. The RAMP 201 trial continues to enroll in all four cohorts (avutometinib (VS-6766) ± defactinib in KRAS mutant and KRAS wild-type patient populations) with full enrollment based on the study protocol expected by the end of 2022. We expect to provide an update after the upcoming meeting with the FDA.

In October 2022, we reported data from a planned interim analysis of Part A from the RAMP 202 trial among patients with KRAS G12V NSCLC treated with avutometinib (VS-6766) or the combination of avutometinib (VS-6766) and defactinib. The results did not meet the criteria to continue to the trial expansion phase. Also among patients with non-G12V KRAS mutant NSCLC, no KRAS subtype was identified for further clinical evaluation of avutometinib (VS-6766) with defactinib in this trial. We plan to present the Part A results of RAMP 202 at an upcoming medical congress.

In September 2021, we entered into a clinical collaboration agreement with Amgen, Inc. (“Amgen”) to evaluate the combination of avutometinib (VS-6766) with Amgen’s KRAS-G12C inhibitor LUMAKRAS™ (sotorasib) in a Phase 1/2 trial entitled RAMP 203. The Phase 1/2 trial will evaluate the safety, tolerability and efficacy of avutometinib (VS-6766) in combination with LUMAKRAS™ in patients with KRAS G12C-mutant 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 study will therefore investigate the potential benefits of a more complete vertical blockade of the RAS pathway with the combination of avutometinib (VS-6766) with LUMAKRAS™ (G12C inhibition) in KRAS G12C-mutant locally advanced or metastatic NSCLC. The RAMP 203 trial has advanced to cohort 2 of 4 mg avutometinib (VS-6766) in combination with 960 mg of LUMAKRAS™. Initial results from Part A (dose evaluation) are expected in the fourth quarter of 2022.

In November 2021, we entered into a clinical collaboration agreement with Mirati Therapeutics, Inc. (“Mirati”) to evaluate the combination of Mirati’s investigational KRAS-G12C inhibitor adagrasib with avutometinib (VS-6766) in KRAS G12C mutant NSCLC. The primary objective of this multi-center, single-arm, open-label Phase 1/2 trial entitled RAMP 204 is to determine the maximum tolerated dose and recommended Phase 2 dose for the combination of adagrasib and avutometinib (VS-6766) in patients with KRAS-G12C mutant NSCLC. The study will also investigate the safety, tolerability and efficacy of the combination in patients who have progressed on a KRAS-G12C inhibitor. The trial will build on preclinical data showing a deeper blockade of ERK pathway signaling resulting in enhanced anti-tumor efficacy with the combination of adagrasib and avutometinib (VS-6766) relative to either agent alone. The RAMP 204 trial is open and enrolling.

In May 2022, we received the first “Therapeutic Accelerator Award” from the Pancreatic Cancer Network (“PanCAN”) for up to \$3.8 million. The grant is expected to support a Phase 1b/2 clinical trial of avutometinib (VS-6766) in combination with defactinib entitled RAMP 205. The trial will evaluate whether blockade of KRAS signaling which is mutated in more than 90% of pancreatic tumors, along with chemotherapy and reduction of stromal density will improve outcomes for patients with pancreatic cancer. In August 2022, PanCAN agreed to provide us with an additional \$0.5 million for the collection and analysis of patient samples. We received \$1.0 million of cash proceeds in July 2022. We plan to open the RAMP 205 trial in the fourth quarter of this year.

In addition, avutometinib (VS-6766) and defactinib are currently being investigated in combination with immunotherapeutic and other agents through investigator sponsored trials (“ISTs”).

On August 10, 2020, we and Secura Bio, Inc. (“Secura”) signed an Asset Purchase Agreement (“Secura APA”) and on September 30, 2020, the transaction closed. Pursuant to the Secura APA, we sold our exclusive worldwide license for the research, development, commercialization, and manufacture in oncology indications of products containing duvelisib. With the transition of the duvelisib program to Secura, we are focusing our efforts on our lead product candidates, avutometinib (VS-6766) and defactinib.

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 and through our ownership period ending in September 2020. We have financed our operations to date primarily through public offerings of our common stock, sales of common stock under our at-the-market equity offering programs, our loan and security agreement executed with Hercules Capital, Inc. (“Hercules”) in March 2017, as amended, the upfront payments under our license and collaboration agreements with Sanofi, CSPC Pharmaceutical Group Limited (“CSPC”), and Yakult Honsha Co., Ltd. (“Yakult”), the upfront payment and milestone payments received under the Secura APA, the issuance of the 2018 Notes (defined herein) in October 2018, proceeds in connection with the private investment in public equity (the “PIPE”), and our loan and security agreement executed with Oxford Finance LLC (“Oxford”) in March 2022. With 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, 2022, we had an accumulated deficit of \$720.7 million. Our net loss was \$18.1 million, \$57.0 million, \$22.8 million and \$54.7 million for the three and nine months ended September 30, 2022 and 2021, respectively. We expect to incur significant expenses and may continue to incur operating losses for the foreseeable future as a result of the continued research and development of avutometinib (VS-6766) and defactinib. As of September 30, 2022, we had cash, cash equivalents and investments of \$104.0 million. We expect our existing cash resources will be sufficient to fund our planned operations through at least 12 months from the date of issuance of these condensed consolidated financial statements.

We expect to finance the future development costs of our clinical product portfolio with our existing cash, cash equivalents and investments, through future milestones and royalties received pursuant to the Secura APA, through our loan and security 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, there is no guarantee that any of these strategic or financing opportunities will be executed or executed on favorable terms, and some could be dilutive to existing stockholders. 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.

COVID-19 pandemic

The current COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting our employees, patients, communities and business operations, as well as the U.S. economy and financial markets. We have been carefully monitoring the COVID-19 pandemic and its impact on our operations. Our corporate headquarters remains open and we have adopted a hybrid work program allowing our employees the option to primarily work from home. Shortages in personnel in clinics and hospitals have caused some United States sites to institute limits on new clinical trials which could impact our ability to open new sites for our clinical trials. In addition, clinics in Europe and the United States continue to have delays in startup activities due to the ongoing pandemic and the increase in COVID-19 variant infections. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19, new variants, the actions taken to contain it or treat its impact and the economic impact on local, regional, national, and international markets.

For additional information on the various risks posed by the COVID-19 pandemic, please read *Item 1A. Risk Factors* included in our Annual Report on Form 10-K for our fiscal year ended December 31, 2021.

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, 2021, related to revenue recognition, accrued and prepaid research and development expenses, stock-based compensation, and leases. During the nine months ended September 30, 2022, there were no material changes to our critical accounting policies.

RESULTS OF OPERATIONS**Comparison of the three months ended September 30, 2022 and 2021**

	Three months ended September 30, (dollar amounts in thousands)			
	2022	2021	Change	% Change
Revenue:				
Transition services revenue	—	2	(2)	(100)%
Total revenue	—	2	(2)	(100)%
Operating expenses:				
Research and development	11,288	9,325	1,963	21%
Selling, general and administrative	6,421	5,523	898	16%
Total operating expenses	17,709	14,848	2,861	19%
Loss from operations	(17,709)	(14,846)	(2,863)	19%
Other income	20	—	20	100%
Interest income	316	40	276	690%
Interest expense	(717)	(7,980)	7,263	(91)%
Net loss	<u>\$ (18,090)</u>	<u>\$ (22,786)</u>	<u>\$ 4,696</u>	<u>(21)%</u>

Transition services revenue. Transition services revenue for the three months ended September 30, 2022 (the “2022 Quarter”) was \$0.0 million compared to less than \$0.1 million for the three months ended September 30, 2021 (the “2021 Quarter”). Transition services revenue was comprised of the revenue recognized for us providing certain support functions to Secura pursuant to the Secura TSA (as defined herein), which was entered into in connection with the Secura APA. The services were provided at a mutually agreed upon rate. The services were substantially completed in 2021 and there will not be revenue recorded in the future pursuant to the Secura TSA.

Research and development expense. Research and development expense for the 2022 Quarter was \$11.3 million compared to \$9.3 million for the 2021 Quarter. The \$2.0 million increase from the 2021 Quarter to the 2022 Quarter was primarily driven by an increase of \$0.6 million of drug substance and drug product costs, an increase of \$0.5 million of consulting costs, an increase of \$0.4 million of clinical supply costs, an increase of \$0.3 million of pre-clinical costs, and an increase of \$0.2 million of personnel related costs, including non-cash stock-based compensation.

Research and development expenses include product/ product candidate and/or project-specific costs, as well as unallocated costs. We allocate the expenses related to external research and development services, such as contract research organizations (“CRO”), clinical sites, 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, the cost of consultants who assist with the development of the Company’s 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 (VS-6766) are included in “avutometinib (VS-6766) manufacturing and non-clinical trial specific” category below as these costs relate to both the “avutometinib (VS-6766) ± defactinib” and “avutometinib (VS-6766) + other combinations” categories and are not specifically allocated to any particular project. Costs to produce defactinib are included in “avutometinib (VS-6766) ± 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, depreciation of equipment, 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 2022 Quarter and 2021 Quarter.

	<u>Three months ended September 30,</u>		
	<u>2022</u>	<u>2021</u>	<u>Change</u>
	(in thousands)		
Product/ product candidate / project specific costs			
Avutometinib (VS-6766) ± defactinib	\$ 4,560	\$ 4,379	\$ 181
Avutometinib (VS-6766) + other combinations	672	18	654
Avutometinib (VS-6766) manufacturing and non-clinical trial specific	1,541	1,173	368
COPIKTRA	(7)	2	(9)
Unallocated costs			
Personnel costs, excluding stock-based compensation	2,772	2,386	386
Stock-based compensation expense	417	515	(98)
Other unallocated expenses	1,333	852	481
Total research and development expense	<u>\$ 11,288</u>	<u>\$ 9,325</u>	<u>\$ 1,963</u>

The increase of avutometinib (VS-6766) ± defactinib costs of \$0.2 million from the 2021 Quarter to the 2022 Quarter is driven by an increase of \$1.0 million in defactinib drug product and drug substance costs partially offset by a decrease of \$0.8 million decrease in RAMP 202 trial costs. The increase of avutometinib (VS-6766) + other combinations costs of \$0.7 million from the 2021 Quarter to the 2022 Quarter is primarily driven by an increase of \$0.5 million of RAMP 203 trial costs, and an increase of \$0.2 million of RAMP 204 trial costs. The increase of avutometinib (VS-6766) manufacturing and non-clinical trial specific costs of \$0.4 million from the 2021 Quarter to the 2022 Quarter for primarily driven by an increase of \$0.4 million in pre-clinical costs.

Selling, general and administrative expense. Selling, general and administrative expense for the 2022 Quarter was \$6.4 million compared to \$5.5 million for the 2021 Quarter. The increase of \$0.9 million from the 2021 Quarter to the 2022 Quarter primarily resulted from an increase of \$0.5 million in commercial costs, an increase of \$0.4 million of consulting and professional fees, and other costs.

Other Income. Other income for the 2022 Quarter was less than \$0.1 million compared to \$0.0 million in the 2021 Quarter. Other income for the 2022 Quarter was comprised of changes in foreign currency exchange rates.

Interest income. Interest income increased from \$0.3 million for the 2022 Quarter compared to less \$0.1 million for the 2021 Quarter. The increase of \$0.3 million in interest income is primarily driven by an increase in interest rates on debt securities.

Interest expense. Interest expense for the 2022 Quarter was \$0.7 million compared to \$8.0 million for the 2021 Quarter. The decrease of \$7.3 million from the 2021 Quarter to the 2022 Quarter was primarily driven by \$7.8 million of non-cash interest expense recorded in the 2021 Quarter upon conversion of the 2020 Notes into common stock in July 2021 which is partially offset by the interest expense pursuant to the Loan Agreement (as defined herein) entered into with Oxford (as defined herein) on March 25, 2022.

Comparison of the nine months ended September 30, 2022 and 2021

	Nine months ended September 30, (dollar amounts in thousands)			
	2022	2021	Change	% Change
Revenue:				
Sale of COPIKTRA license and related assets	2,596	902	1,694	188%
Transition services revenue	—	606	(606)	(100)%
Total revenue	2,596	1,508	1,088	72%
Operating expenses:				
Research and development	39,818	27,951	11,867	42%
Selling, general and administrative	18,869	18,455	414	2%
Total operating expenses	58,687	46,406	12,281	26%
Loss from operations	(56,091)	(44,898)	(11,193)	25%
Other income	54	—	54	100%
Interest income	446	141	305	216%
Interest expense	(1,413)	(9,962)	8,549	(86)%
Net loss	\$ (57,004)	\$ (54,719)	\$ (2,285)	4%

Sale of COPIKTRA license and related assets revenue. Sale of COPIKTRA license and related assets revenue for the nine months ended September 30, 2022 (the “2022 Period”) was \$2.6 million compared to \$0.9 million for the nine months ended September 30, 2021 (the “2021 Period”). Sale of COPIKTRA license and related assets revenue for the 2022 Period was comprised of one regulatory milestone for \$2.5 million achieved by Secura’s sublicensee, CSPC, and \$0.1 million related to royalties on COPIKTRA sales in the 2022 Period and future royalties expected to be received pursuant to the Secura APA that are not constrained. Sale of COPIKTRA license and related assets revenue for the 2021 Period of \$0.9 million was comprised of \$0.8 million for a regulatory milestone achieved by Secura’s sublicensee, Sanofi, and \$0.1 million for royalties we expect to receive pursuant to the Secura APA from COPIKTRA sales by Secura’s sublicensees that are not constrained.

Transition services revenue. Transition services revenue for the 2022 Period was \$0.0 million compared to \$0.6 million for the 2021 Period. Transition services revenue was comprised of the revenue recognized for us providing certain support functions to Secura pursuant to the Secura TSA, which was entered into in connection with the Secura APA. The services were provided at a mutually agreed upon rate. The services were substantially completed in 2021 and there will not be revenue recorded in the future pursuant to the Secura TSA.

Research and development expense. Research and development expense for the 2022 Period was \$39.8 million compared to \$28.0 million for the 2021 Period. The \$11.8 million increase from the 2021 Period to the 2022 Period was primarily driven by an increase of \$4.6 million of drug substance and drug product costs, an increase of \$4.1 million of CRO costs, an increase of \$1.5 million of investigator fees, an increase of \$1.0 million of consulting costs, an increase of \$0.5 million of personnel costs, including non-cash stock compensation, an increase of \$0.4 million of clinical supply costs, and an increase of \$0.7 million of other costs, which is partially offset by a decrease of \$1.0 million of IST 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 2022 Period and 2021 Period.

	<u>Nine months ended September 30,</u>		
	<u>2022</u>	<u>2021</u>	<u>Change</u>
	(in thousands)		
<u>Product/ product candidate / project specific costs</u>			
Avutometinib (VS-6766) ± defactinib	\$ 18,487	\$ 11,692	\$ 6,795
Avutometinib (VS-6766) + other combinations	1,633	18	1,615
Avutometinib (VS-6766) manufacturing and non-clinical trial specific	6,425	3,602	2,823
COPIKTRA	79	1,045	(966)
<u>Unallocated costs</u>			
Personnel costs, excluding stock-based compensation	8,268	7,410	858
Stock-based compensation expense	1,337	1,685	(348)
Other unallocated expenses	3,589	2,499	1,090
Total research and development expense	<u>\$ 39,818</u>	<u>\$ 27,951</u>	<u>\$ 11,867</u>

The increase in avutometinib (VS-6766) ± defactinib costs of \$6.8 million from the 2021 Period to the 2022 Period is primarily driven by an increase of \$2.9 million of drug substance and drug product costs for defactinib, an increase of \$2.7 million in RAMP 201 clinical trial costs, an increase of \$0.8 million in RAMP 202 clinical trial costs, and an increase of \$0.4 million of other costs. The increase of avutometinib (VS-6766) + other combinations costs of \$1.6 million from the 2021 Period to the 2022 Period is primarily driven by an increase of \$1.3 million of RAMP 203 trial costs, and an increase of \$0.3 million of RAMP 204 trial costs. The increase in avutometinib (VS-6766) manufacturing and non-clinical trial specific costs of \$2.8 million from the 2021 Period to the 2022 Period is primarily driven an increase of \$1.5 million in drug substance and drug product costs for avutometinib (VS-6766), an increase of \$1.2 million of CRO costs, and an increase of \$0.1 million of pre-clinical costs. The research and development expense in the 2022 Period related to COPIKTRA primarily relates to COVID-19 investigator sponsored trials which were not part of the sale of COPIKTRA. The research and development expense in the 2021 Period related to COPIKTRA primarily relates to COVID-19 investigator sponsored trials and certain costs that were incurred in conjunction with providing transition services to Secura pursuant to the Secura TSA.

Selling, general and administrative expense. Selling, general and administrative expense for the 2022 Period was \$18.9 million compared to \$18.5 million for the 2021 Period. The increase of \$0.4 million from the 2021 Period to the 2022 Period primarily resulted from an increase of \$0.7 million of commercial costs, an increase of \$0.2 million in personnel related costs, including non-cash stock-based compensation, and an increase of \$0.3 million of travel and other costs, partially offset by a decrease of \$0.8 million of consulting and professional fees.

Other Income. Other income for the 2022 Period was \$0.1 million compared to \$0.0 million in the 2021 Period. Other income for the 2022 Period was comprised of a gain on the sale of fixed assets and changes in foreign currency exchange rates.

Interest income. Interest income for the 2022 Period was \$0.4 million compared to \$0.1 million for the 2021 Period. The increase of \$0.3 million in interest income is primarily driven by an increase in interest rates on debt securities.

Interest expense. Interest expense for the 2022 Period was \$1.4 million compared to \$10.0 million for the 2021 Period. The decrease of \$8.6 million from the 2021 Period to the 2022 Period was primarily driven by \$7.8 million of non-cash interest expense recorded in the 2021 Period upon conversion of the 2020 Notes into common stock in July 2021 and as a result of the conversion, there were no interest charges recorded for the 2020 Notes in the 2022 Period. The decrease is partially offset by the interest expense pursuant to the Loan Agreement (as defined herein) entered into with Oxford (as defined herein) on March 25, 2022.

LIQUIDITY AND CAPITAL RESOURCES

Sources of liquidity

We have financed our operations to date primarily through public and private offerings of our common stock, 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 issuance of 2018 Notes in October 2018, the proceeds in connection with the PIPE, and the Loan Agreement with Oxford. 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 milestones and royalties received pursuant to the Secura APA.

As of September 30, 2022 we had \$104.0 million of cash, cash equivalents, and investments. We primarily invest our cash, cash equivalents and investments in U.S. Government money market funds, 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, 2021 as filed with the Securities and Exchange Commission (“SEC”) on March 28, 2022, in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, as filed with the SEC on August 8, 2022, and in any subsequent filings with the SEC.

Cash flows

The following table sets forth the primary sources and uses of cash for the 2022 Period and the 2021 Period (in thousands):

	<u>Nine months ended September 30,</u>	
	<u>2022</u>	<u>2021</u>
Net cash (used in) provided by:		
Operating activities	\$ (47,057)	\$ (43,569)
Investing activities	53,160	21
Financing activities	51,784	80
Increase (decrease) in cash, cash equivalents and restricted cash	<u>\$ 57,887</u>	<u>\$ (43,468)</u>

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 was \$52.0 million and \$39.2 million for the 2022 Period and 2021 Period, respectively. Non-cash charges were primarily related to stock-based compensation expense in the 2022 Period and stock-based compensation expense and non-cash interest, net in the 2021 Period. Our cash inflow from operating activities due to changes in operating assets and liabilities was \$5.0 million for the 2022 Period and our cash outflow from operating activities due to changes in operating assets and liabilities was \$4.4 million for the 2021 Period. Cash inflow due to changes in operating assets and liabilities for the 2022 Period was primarily driven by an increase of \$3.1 million in accounts payable, a decrease of \$1.3 million of prepaid expenses, other current assets and other assets, and an increase of \$1.0 million in deferred liabilities. The decrease in prepaid expenses, other current assets, and other assets is exclusive of the \$1.0 million of cash received from PanCAN. Cash outflow due to changes in operating assets and liabilities for the 2021 Period was primarily driven by an increase of \$1.8 million in prepaid expenses, other current assets, and other assets, a decrease of \$1.6 million in accrued expenses and other liabilities, and a decrease of \$1.0 million in accounts payable. Cash used in operating activities was \$47.1 million and \$43.6 million for the 2022 Period and 2021 Period, respectively.

Investing activities. The cash provided by investing activities for the 2022 Period primarily relates to the net maturities of investments of \$53.2 million. The cash provided by investing activities for the 2021 Period primarily relates to the net maturities of investments of \$0.2 million, partially offset by purchases of fixed assets of \$0.2 million.

Financing activities. The cash provided by financing activities for the 2022 Period primarily represents \$27.4 million of net proceeds received under our at-the market equity offering program, \$24.1 million of net proceeds received from the Loan Agreement (as defined herein) with Oxford (as defined herein), and \$0.3 million of proceeds received related to exercise of stock options and employee stock purchase plan. The cash provided by financing activities for the 2021 Period primarily represents \$1.1 million of proceeds received related to exercise of stock options and employee stock purchase plan, partially offset by \$0.9 million in payments for settlement of restricted stock for tax withholdings and \$0.1 million in payments for deferred offering costs.

On March 25, 2022 (the “Closing Date”) we entered into a loan and security agreement (the “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 us up to an aggregate principal amount of \$150.0 million in a series of term loans (the “Term Loans”). The initial Term Loan of \$25.0 million was funded at the Closing Date of the Loan Agreement, an additional \$75.0 million will be available at our option upon achievement of certain milestones as outlined in *Note 7. Debt* to our unaudited condensed consolidated financial statements included in this quarterly report, and \$50.0 million is subject to the Lenders’ sole discretion.

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. Beginning (i) April 1, 2024, if the Term B Loan (as defined in *Note 7. Debt* to our unaudited condensed consolidated financial statements included in this quarterly report) is not made, (ii) April 1, 2025, if the Term B Loan is made, or (iii) April 1, 2026, if the Term B Loan is made and either (A) avotemetinib (VS-6766) has received FDA approval for the treatment of LGSOC or (B) COPIKTRA has received FDA approval for the treatment of peripheral T-cell lymphoma (“PTCL”), we 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.

We are required to make a final payment of 5.0% of the original principal amount of the Term Loans that were drawn, payable at maturity or upon any earlier acceleration or prepayment of the Term Loans. We 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, we granted Oxford a security interest in all of our 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.

In August 2021, we entered into a sales agreement with Cantor Fitzgerald & Co. (“Cantor”) pursuant to which we can offer and sell up to \$100.0 million of our common stock at the current market prices from time to time through Cantor as sales agent (“August 2021 ATM”). During the 2022 Period, we sold 23,573,403 shares under the August 2021 ATM for net proceeds of approximately \$27.4 million (after deducting commissions and other offering expenses). As of September 30, 2022, we can issue an aggregate amount of \$65.1 million of common stock under this program.

On October 17, 2018, we closed a registered direct public offering of \$150.0 million aggregate principal amount of our 2018 issued 5.00% Convertible Senior Notes due 2048 (the “2018 Notes”), for net proceeds of approximately

\$145.3 million. The 2018 Notes are governed by the terms of a base indenture for senior debt securities (the “Base Indenture”), as supplemented by the first supplemental indenture thereto (the “2018 Notes Supplemental Indenture” and together with the Base Indenture, the “2018 Indenture”), each dated October 17, 2018, by and between us and Wilmington Trust, National Association (“Wilmington”), as trustee. The 2018 Notes are senior unsecured obligations of us and bear interest at a rate of 5.00% per annum, payable semi-annually in arrears on May 1 and November 1 of each year. The 2018 Notes will mature on November 1, 2048, unless earlier repurchased, redeemed or converted in accordance with their terms.

The 2018 Notes are convertible into shares of our common stock, par value \$0.0001 per share, together, if applicable, with cash in lieu of any fractional share, at an initial conversion rate of 139.5771 shares of common stock per \$1,000 principal amount of the 2018 Notes, which corresponds to an initial conversion price of approximately \$7.16 per share of common stock. Upon conversion, converting noteholders will be entitled to receive accrued interest on their converted 2018 Notes.

We will have the right, exercisable at our option, to cause all 2018 Notes then outstanding to be converted automatically if the “Daily VWAP” (as defined in the 2018 Indenture) per share of our common stock equals or exceeds 130% of the conversion price, which equates to approximately \$9.31 per share, on each of at least 20 “VWAP Trading Days” (as defined in the 2018 Indenture), whether or not consecutive, during any 30 consecutive VWAP Trading Day period commencing on or after the date we first issued the 2018 Notes.

In the fourth quarter of 2019, we entered into privately negotiated agreements to exchange approximately \$121.7 million aggregate principal amount of the 2018 Notes for (i) approximately \$66.9 million aggregate principal amount of 5.00% Convertible Senior Second Lien Notes due 2048 (the “2019 Notes”), (ii) an aggregate of approximately \$12.1 million in 2018 Notes principal repayment and (iii) accrued interest on the 2018 Notes through the exchange date. As of March 31, 2020, all 2019 Notes have converted into shares of common stock and are no longer outstanding.

On November 6, 2020, we entered into a privately negotiated agreement with an investor who is a holder of our 2018 Notes to exchange approximately \$28.0 million aggregate principal amount of 2018 Notes for approximately \$28.0 million aggregate principal amount of newly issued 5.00% Convertible Senior Notes due 2048 (the “2020 Notes”). The issuance of the 2020 Notes closed on November 13, 2020. The 2020 Notes were governed pursuant to the Base Indenture between us and Wilmington dated as of October 17, 2018 as supplemented by the second supplemental indenture thereto dated as of November 13, 2020 (the “2020 Notes Supplemental Indenture” and together with the Base Indenture, the “2020 Indenture”).

We had the right, exercisable at our option, to cause all 2020 Notes then outstanding to be converted automatically if the “Daily VWAP” (as defined in the 2020 Indenture) per share of our common stock equals or exceeds 123.08% of the conversion price on each of at least 20 “VWAP Trading Days” (as defined in the 2020 Indenture), whether or not consecutive, during any 30 consecutive VWAP Trading Day period commencing on or after the date we first issued the 2020 Notes (“2020 Notes Mandatory Conversion Option”).

On July 1, 2021, we exercised our 2020 Notes Mandatory Conversion Option for the aggregate principal amount of \$28.0 million of the 2020 Notes. On July 16, 2021, the aggregate principal of \$28.0 million of 2020 Notes was converted into 8,615,384 shares of common stock. Upon conversion of the 2020 Notes, holders received a cash payment equal to the accrued and unpaid interest on the converted 2020 Notes. As a result, as of September 30, 2021, all 2020 Notes have converted into shares of common stock.

As of September 30, 2022 and December 31, 2021 there was \$0.3 million aggregate principal amount outstanding of 2018 Notes.

License and collaboration agreements

Secura

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

Pursuant to the Secura APA, we sold to Secura our exclusive worldwide license 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 duvelisib oncology program, including all commercialization efforts related to duvelisib in the United States and Europe, as well as our ongoing duvelisib clinical trials. Further, Secura assumed all obligations with existing collaboration partners developing and commercializing duvelisib, which include Yakult, CSPC, and Sanofi. Additionally, Secura assumed all royalty payment obligations due under the amended and restated license agreement with Infinity.

Pursuant to the terms of the Secura APA, Secura has paid us an up-front payment of \$70.0 million and has agreed to pay us (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 (“PTCL”) 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 PTCL, (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 our 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.

Secura’s royalty obligations remain in effect on a country-by-country basis upon the last to occur (a) 10 years from the first commercial sale of product containing duvelisib in such country or (b) the expiration of all valid patent claims covering products containing duvelisib in such country.

In connection with the Secura APA, we and Secura entered into a transition services agreement (“Secura TSA”). Under the terms of the Secura TSA, we provided certain support functions at Secura’s direction for a term of less than one year from the date of execution. Services performed were paid at a mutually agreed upon rate.

During the 2022 Period, we recognized \$2.6 million of sale of COPIKTRA license and related assets revenue primarily related to one regulatory milestone for \$2.5 million achieved by Secura’s sublicensee, CSPC, and \$0.1 million related to royalties on COPIKTRA sales in the 2022 Period and future royalties expected to be received pursuant to the Secura APA. During the 2021 Period, we recognized \$0.9 million of sale of COPIKTRA license and related assets revenue related to one regulatory milestone for \$0.8 million achieved by Secura’s sublicensee, Sanofi, and \$0.1 million related to future royalties expected to be received pursuant to the Secura APA. We also recognized \$0.6 million in transition services revenue for services provided during the 2021 Period.

Chugai Pharmaceutical Co., Ltd. (“Chugai”)

On January 7, 2020, we entered into a license agreement with Chugai (the “Chugai Agreement”) whereby Chugai granted us an exclusive worldwide license for the development, commercialization and manufacture of products containing avutometinib (VS-6766), a dual RAF/MEK clamp.

Under the terms of the Chugai Agreement, we received an exclusive right to develop and commercialize products containing avutometinib (VS-6766) at our own cost and expense. We paid Chugai a non-refundable payment of \$3.0 million in February 2020. We are further obligated to pay Chugai double-digit royalties on net sales of products

containing avutometinib (VS-6766), subject to reduction in certain circumstances. Chugai also obtained opt back rights to develop and commercialize avutometinib (VS-6766) (a) in the European Union, which option may be exercised through the date we submit an NDA to the FDA for a product which contains avutometinib (VS-6766) as the sole active pharmaceutical ingredient and (b) in Japan and Taiwan, which option may be exercised through the date we receive marketing authorization from the FDA for a product which contains avutometinib (VS-6766) as the sole active pharmaceutical ingredient. As consideration for executing either option, Chugai would have to make a payment to us calculated on our development costs to date. Chugai and we have made customary representations and warranties and have agreed to certain customary covenants, including confidentiality and indemnification.

Unless earlier terminated, the Chugai Agreement will expire upon the fulfillment of the royalty obligations to Chugai for the sale of any products containing the avutometinib (VS-6766), which royalty obligations expire on a product-by-product and country-by-country basis, upon the last to occur, in each specific country, of (a) expiration of valid patent claims covering such product or (b) 12 years from the first commercial sale of such product in such country.

We may terminate the Chugai Agreement upon 180 days' written notice. Subject to certain limitations, Chugai may terminate the Chugai Agreement upon written notice if we challenge any patent licensed by Chugai to us under the Chugai Agreement. Either party may terminate the license agreement in its entirety with 120 days' written notice for the other party's material breach if such party fails to cure the breach. Either party may also terminate the Chugai Agreement in its entirety upon certain insolvency events involving the other party.

Funding requirements

We expect to continue to incur significant expenses and may continue to incur operating losses. We anticipate that our expenses will continue and operating losses may continue as we:

- continue our ongoing clinical trials with our product candidates, avutometinib (VS-6766) and defactinib;
- initiate additional clinical trials for our product candidates;
- maintain, expand and protect our intellectual property portfolio;
- acquire or in-license other products and technologies;
- hire additional clinical, development and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and commercialization efforts; and
- establish and maintain a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval.

We expect our existing cash resources will be sufficient to fund our obligations for at least the next twelve months from the date of filing of this Quarterly Report on Form 10-Q. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, and the extent to which we may enter into collaborations with third parties for development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development of our current product candidates. Our future capital requirements will depend on many factors, including:

- the costs and timing of commercialization activities for our product candidates for which we expect to receive marketing approval;
- the scope, progress and results of our ongoing and potential future clinical trials;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs, timing and outcome of regulatory review of our product candidates (including our efforts to seek approval and fund the preparation and filing of regulatory submissions);
- revenue received from commercial sales our product candidates, should any of our other product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property related claims;

- our ability to establish collaborations or partnerships on favorable terms, if at all; and
- receipt of milestone payments and royalties pursuant to the Secura APA including timing of such receipt.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements, and through future milestones and royalties received pursuant to the Secura APA. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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, 2021. There have not been any material changes from the contractual obligations and commitments previously disclosed in such report.

OFF-BALANCE SHEET ARRANGEMENTS

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

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 \$104.0 million as of September 30, 2022, consisting of cash, U.S. Government money market funds, 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 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 September 30, 2022, an immaterial amount of our total liabilities were denominated in currencies other than the functional currency.

On March 25, 2022, we entered into the Loan Agreement, under which we borrowed \$25.0 million. 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 will 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 nine months ended September 30, 2022.

The 2018 Notes bear interest at a fixed rate and therefore have minimal exposure to changes in interest rates; however, because the interest rates are fixed, we may be paying a higher interest rate, relative to market, in the future if our credit rating improves or other circumstances change.

Item 4. Controls and Procedures.

Evaluation of disclosure controls and procedures

Our management, with the participation of our Chief Executive Officer and our Vice President of Finance, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2022. 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, 2022 our Chief Executive Officer and our Vice President of Finance 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, 2022, 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, 2021 as filed with the SEC on March 28, 2022 and in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, as filed with the SEC on August 8, 2022. There have been no material changes from the risk factors disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, and in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, other than as set forth below.

Our ability to receive future contingent consideration, including milestone payments and royalties, from the sale of our rights, title, and interest in COPIKTRA to Secura may be adversely affected by lower than expected COPIKTRA sales and Secura's ability to achieve other developmental and regulatory milestones

On September 30, 2020, we completed the disposition of the Company's rights, title, and interest in COPIKTRA to Secura. Under the terms of the Secura APA, we are entitled to contingent consideration, including milestone payments and royalties, dependent upon the further development and commercial success of COPIKTRA. On June 30, 2022, the FDA issued a drug safety communication warning that resulted from a clinical trial showing a possible increased risk of death with COPIKTRA compared to another medicine to treat chronic blood cancer called leukemia and lymphoma. The aforementioned clinical trial also found that COPIKTRA was associated with a higher risk of serious side effects, including infections, diarrhea, inflammation of the intestines and lungs, skin reactions, and high liver enzyme levels in the blood. In September 2022, the FDA's Oncologic Drug Advisory Committee ("ODAC") voted eight to four against COPIKTRA's use in patients with relapsed or refractory chronic lymphocytic leukemia/ small lymphocytic lymphoma after at least two prior therapies citing an unfavorable risk/benefit profile. The FDA drug safety communication warning, the FDA's ODAC vote, future actions by the FDA, and any safety concerns associated with COPIKTRA, perceived or real, may materially and adversely affect Secura's development and commercialization success of COPIKTRA and, consequently, our ability to receive future contingent consideration from our sale of our right, title, and interest in COPIKTRA to Secura.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

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	Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Annual Report on Form 10-K filed by the Registrant on March 12, 2019).
3.2	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 filed by the Registrant on March 12, 2019).
3.3	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).
3.4	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).
31.1*	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.
31.2*	Certification of Vice President, Finance 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.
32.1*	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.
32.2*	Certification of Vice President, Finance pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
99.1*	Press Release issued by Verastem, Inc. on November 3, 2022 (furnished herewith).
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

* Filed or furnished herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

VERASTEM, INC.

Date: November 3, 2022

By: _____ /s/ BRIAN M. STUGLIK

Brian M. Stuglik
Chief Executive Officer
(Principal executive officer)

Date: November 3, 2022

By: _____ /s/ DANIEL CALKINS

Daniel Calkins
Vice President, Finance
(Principal financial and accounting officer)

CERTIFICATIONS

I, Brian M. Stuglik, 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/ BRIAN M. STUGLIK

Brian M. Stuglik
Chief Executive Officer
(Principal executive officer)

Date: November 3, 2022

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

Daniel Calkins
Vice President, Finance
(Principal financial and accounting officer)

Date: November 3, 2022

**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, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Brian M. Stuglik, 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/ BRIAN M. STUGLIK

Brian M. Stuglik
Chief Executive Officer
(Principal executive officer)

Date: November 3, 2022

**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, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Daniel Calkins, Vice President of Finance, 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

Daniel Calkins
Vice President, Finance
(Principal financial and accounting officer)

Date: November 3, 2022



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

Combination Trials with Avutometinib (VS-6766) Ongoing as Part of Development Program Designed to Maximize Potential Across RAS Pathway-Driven Tumors

Company Confirms Q4 FDA Meeting Based on Encouraging Results to Date in Ongoing RAMP 201 Trial of Avutometinib (VS-6766) ± Defactinib in Low-Grade Serous Ovarian Cancer

RAMP Trials with Avutometinib (VS-6766) Combinations in KRAS G12C Mutant NSCLC and Frontline Metastatic Pancreatic Cancer on Track

BOSTON, MA – November 3, 2022 – Verastem Oncology (Nasdaq: VSTM), a biopharmaceutical company committed to advancing new medicines for patients with cancer, today reported financial results for the three months ended September 30, 2022, and highlighted recent progress.

“In the third quarter, we provided an overall update regarding our RAMP program with RAF/MEK clamp avutometinib (VS-6766), including the encouraging interim results of the RAMP 201 trial that are the basis for advancing our discussions with the FDA regarding the go forward treatment regimen selection and regulatory path forward. Building on our breakthrough therapy designation, our efforts are focused on rapidly advancing this program to make a difference for patients in this highly recurrent, chemotherapy-resistant cancer where no treatments are specifically approved and limited other treatment options are available,” said Brian Stuglik, CEO of Verastem Oncology. “Based on the response results and safety profile seen to date in the RAMP 201 trial, we are looking forward to the results of our broader development program which is aimed at maximizing combinations with avutometinib (VS-6766) across RAS pathway-driven tumors, including KRAS G12C mutant non-small cell lung cancer, frontline metastatic pancreatic cancer and KRAS mutant colorectal cancer.”

Second Quarter 2022 and Recent Highlights

Low Grade Serous Ovarian Cancer (LGSOC)

- Verastem recently conducted a second planned interim analysis of the ongoing RAMP 201 trial among patients with recurrent LGSOC. Based on the results, including independently confirmed responses and no new safety signals, the Company has confirmed a meeting with the U.S. Food and Drug Administration (FDA) by the end of the year to review the data set, to discuss the go forward treatment regimen selection and align on requirements to initiate a New Drug Application submission. The Company will provide an update after the upcoming meeting with the FDA.
 - Since the first interim analysis announced in June, the trial has been continuing with all four cohorts (avutometinib (VS-6766) ± defactinib in KRAS mutant and KRAS wild type patient populations) with full enrollment based on the study protocol expected by the end of the year.
-

KRAS Mutant Non-Small Cell Lung Cancer (NSCLC) Combination Studies

- The RAMP 203 Phase 1/2 trial to evaluate the safety, tolerability and efficacy of avutometinib (VS-6766) in combination with Amgen's KRAS G12C inhibitor LUMAKRAS™ (sotorasib) in patients with KRAS G12C mutant NSCLC, has advanced to Cohort 2 of 4 mg avutometinib (VS-6766) in combination with 960 mg of LUMAKRAS™. Initial safety results are expected by the end of the year.
- The RAMP 204 Phase 1/2 trial of avutometinib (VS-6766) and Mirati's adagrasib, which will determine the maximum tolerated dose and recommended Phase 2 dose for the combination and evaluate the safety, tolerability and efficacy of the combination in patients who have progressed on a KRAS G12C inhibitor, is open and enrolling.
- The RAMP 203 and 204 studies will investigate the potential benefits of a more complete vertical blockade of the RAS pathway as acquired resistance to KRAS G12C inhibitors in patients occurs predominantly through additional mutations in the RAS pathway, many of which could be addressed with a downstream inhibitor such as avutometinib (VS-6766).
- Results of the ongoing investigator-initiated trial of avutometinib (VS-6766) and everolimus in KRAS-mutant NSCLC are anticipated in the first half of 2023.
- In a planned analysis of the Part A data from the RAMP 202 trial among patients with KRAS G12V and non G12V NSCLC treated with the combination of avutometinib (VS-6766) and defactinib, no subtype was identified for further clinical evaluation of avutometinib (VS-6766) with defactinib in this trial. Verastem plans to present the Part A results of RAMP 202 at an upcoming medical congress.

Frontline Metastatic Pancreatic Cancer

- The Company announced plans to open the RAMP 205 Phase 1b/2 clinical trial of avutometinib (VS-6766) with defactinib in addition to standard of care chemotherapy (gemcitabine/nab-paclitaxel) in frontline metastatic pancreatic cancer in the fourth quarter of this year. The trial, in partnership with the Pancreatic Cancer Action Network (PanCAN) will evaluate whether blockade of KRAS signaling, which is mutated in more than 90% of pancreatic cancer tumors, along with chemotherapy and reduction of stromal density, will improve outcomes for patients with pancreatic cancer.

Corporate Updates

- Avutometinib has been accepted as the International Nonproprietary Name (INN) and United States Adopted Name (USAN) for VS-6766.
 - Intermittent dosing intellectual property for both avutometinib (VS-6766) alone (previously announced) and in combination with defactinib was recently allowed, extending patent coverage up to 2038 and 2040, respectively.
 - Anil Kapur, the Executive Vice President, Corporate Strategy and Chief Commercial Officer at Geron Corporation, was appointed to the Company's Board of Directors, effective October 20, 2022.
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Third Quarter 2022 Financial Results

Verastem Oncology ended the three months ended September 30, 2022 (2022 Quarter) with cash, cash equivalents and investments of \$104.0 million. Total operating expenses for the 2022 Quarter were \$17.7 million, compared to \$14.8 million for the three months ended September 30, 2021 (2021 Quarter).

Research and development expenses for the 2022 Quarter were \$11.3 million, compared to \$9.3 million for the 2021 Quarter. The increase of \$2.0 million, or 21.5%, primarily resulted from an increase in drug product and drug substance costs, consulting costs, clinical supply costs, pre-clinical costs, and personnel costs, including non-cash stock-based compensation.

Selling, general and administrative expenses for the 2022 Quarter were \$6.4 million, compared to \$5.5 million for the 2021 Quarter. The increase of \$0.9 million, or 16.4%, primarily resulted from an increase in commercial costs, and consulting and professional costs.

Net loss for the 2022 Quarter was \$18.1 million, or \$0.09 per share (basic and diluted), compared to net loss of \$22.8 million, or \$0.13 per share (basic and diluted), for the 2021 Quarter.

For the 2022 Quarter, non-GAAP adjusted net loss was \$16.6 million, or \$0.08 per share (diluted), compared to non-GAAP adjusted net loss of \$12.8 million, or \$0.07 per share (diluted), for the 2021 Quarter. Please refer to the GAAP to Non-GAAP Reconciliation attached to this press release.

Use of Non-GAAP Financial Measures

To supplement Verastem Oncology's condensed consolidated financial statements, which are prepared and presented in accordance with generally accepted accounting principles in the United States (GAAP), the Company uses the following non-GAAP financial measures in this press release: non-GAAP adjusted net loss 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. 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, 2022, and 2021 are included in the tables accompanying this press release after the unaudited condensed consolidated financial statements.

About Avutometinib (VS-6766)

Avutometinib is a RAF/MEK clamp that induces inactive complexes of MEK with ARAF, BRAF and CRAF potentially creating a more complete and durable anti-tumor response through maximal RAS pathway inhibition. Avutometinib is currently in late-stage development.

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

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

About Verastem Oncology

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

Forward-Looking Statements Notice

This press release includes forward-looking statements about Verastem Oncology's strategy, future plans and prospects, including statements related to the potential clinical value of various of its clinical trials, the timing of commencing and completing trials, including topline data reports, interactions with regulators and potential for additional development programs involving Verastem Oncology's lead compound. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," "can," "promising" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement.

Applicable risks and uncertainties include the risks and uncertainties, among other things, regarding: the success in the development and potential commercialization of our product candidates, including avutometinib in combination with other compounds, including defactinib, LUMAKRAS™ and others; the occurrence of adverse safety events and/or unexpected concerns that may arise from additional data or analysis or result in unmanageable safety profiles as compared to their levels of efficacy; our ability to obtain, maintain and enforce patent and other intellectual property protection for our product candidates; the scope, timing, and outcome of any legal proceedings; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of our product candidates; whether preclinical testing of our product candidates and preliminary or interim data from clinical trials will be predictive of the results or success of ongoing or later clinical trials; that the timing, scope and rate of reimbursement for our product candidates is uncertain; that third-party payors (including government agencies) may not reimburse; that there may be competitive developments affecting our product candidates; that data may not be available when expected; that enrollment of clinical trials may take longer than

expected; that our product candidates will experience manufacturing or supply interruptions or failures; that we will be unable to successfully initiate or complete the clinical development and eventual commercialization of our product candidates; that the development and commercialization of our product candidates will take longer or cost more than planned; that we or Chugai Pharmaceutical Co., Ltd. will fail to fully perform under the avutometinib license agreement; that we or our other collaboration partners may fail to perform under our collaboration agreements; that we may not have sufficient cash to fund our contemplated operations; that we may be unable to obtain adequate financing in the future through product licensing, co-promotional arrangements, public or private equity, debt financing or otherwise; that Secura Bio, Inc. will achieve the milestones that result in payments to us under our asset purchase agreement with Secura Bio, Inc.; that we will be unable to execute on our partnering strategies for avutometinib in combination with other compounds; that we will not pursue or submit regulatory filings for our product candidates; and that our product candidates will not receive regulatory approval, become commercially successful products, or result in new treatment options being offered to patients.

Other risks and uncertainties include those identified under the heading "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2021 as filed with the Securities and Exchange Commission (SEC) on March 28, 2022 and in any subsequent filings with the SEC. The forward-looking statements contained in this press release reflect Verastem Oncology's views as of the date hereof, and the Company does not assume and specifically disclaims any obligation to update any forward-looking statements whether as a result of new information, future events or otherwise, except as required by law.

References

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

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

	<u>September 30,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
Cash, cash equivalents, & investments	\$ 103,976	\$ 100,256
Accounts receivable, net	74	516
Prepaid expenses and other current assets	4,709	4,968
Property and equipment, net	121	210
Right-of-use asset, net	1,927	2,302
Restricted cash and other assets	288	410
Total assets	\$ 111,095	\$ 108,662
Current Liabilities	\$ 21,873	\$ 18,590
Convertible senior notes	268	249
Long term debt	24,399	—
Lease Liability, long-term	1,682	2,264
Stockholders' equity	62,873	87,559
Total liabilities and stockholders' equity	\$ 111,095	\$ 108,662

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

	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Revenue:				
Sale of COPIKTRA license and related assets revenue	\$ —	\$ —	\$ 2,596	\$ 902
Transition services revenue	—	2	—	606
Total revenue	<u>—</u>	<u>2</u>	<u>2,596</u>	<u>1,508</u>
Operating expenses:				
Research and development	11,288	9,325	39,818	27,951
Selling, general and administrative	<u>6,421</u>	<u>5,523</u>	<u>18,869</u>	<u>18,455</u>
Total operating expenses	<u>17,709</u>	<u>14,848</u>	<u>58,687</u>	<u>46,406</u>
Loss from operations	(17,709)	(14,846)	(56,091)	(44,898)
Other income	20	—	54	—
Interest income	316	40	446	141
Interest expense	(717)	(7,980)	(1,413)	(9,962)
Net loss	<u>\$ (18,090)</u>	<u>\$ (22,786)</u>	<u>\$ (57,004)</u>	<u>\$ (54,719)</u>
Net loss per share—basic and diluted	\$ (0.09)	\$ (0.13)	\$ (0.30)	\$ (0.31)
Weighted average common shares outstanding used in computing:				
Net loss per share – basic and diluted	197,151	179,861	189,999	174,524

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

	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Net loss reconciliation				
Net loss (GAAP basis)	\$ (18,090)	\$ (22,786)	\$ (57,004)	\$ (54,719)
Adjust:				
Stock-based compensation expense	1,356	1,987	4,760	6,137
Non-cash interest, net	120	7,959	231	9,287
Severance and Other	—	40	—	40
Adjusted net loss (non-GAAP basis)	<u>\$ (16,614)</u>	<u>\$ (12,800)</u>	<u>\$ (52,013)</u>	<u>\$ (39,255)</u>
Reconciliation of net loss per Share				
Net loss per share – diluted (GAAP Basis)	(0.09)	(0.13)	(0.30)	(0.31)
Adjust per diluted share:				
Stock-based compensation expense	0.01	0.01	0.02	0.04
Non-cash interest, net	—	0.05	—	0.05
Severance and Other	—	—	—	—
Adjusted net loss per share – diluted (non-GAAP basis)	<u>\$ (0.08)</u>	<u>\$ (0.07)</u>	<u>\$ (0.28)</u>	<u>\$ (0.22)</u>
Weighted average common shares outstanding used in computing net loss per share—diluted	197,151	179,861	189,999	174,524