# 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, 2023

OR

O 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: 001-38672

# **ARVINAS, INC.**

(Exact name of registrant as specified in its Charter)

Delaware

(State or other jurisdiction of incorporation or organization)

5 Science Park 395 Winchester Ave. New Haven, Connecticut (Address of principal executive offices) 47-2566120 (I.R.S. Employer Identification No.)

> 06511 (Zip Code)

Registrant's telephone number, including area code: (203) 535-1456

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

	Trading	
Title of each class	Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.001 per share	ARVN	The Nasdaq Stock Market LLC

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  $\boxtimes$  No o

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  $\boxtimes$  No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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 Non-accelerated filer o Accelerated fileroSmaller reporting companyoEmerging growth companyo

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. o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  $\Box$  No  $\boxtimes$  As of November 3, 2023, the registrant had 55,025,504 shares of common stock, \$0.001 par value per share, outstanding.

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## CAUTIONARY NOTE REGARDING 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 of 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. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "might," "plan," "project," "target," "potential," "goals," "will," "would," "could," "continue" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this Quarterly Report on Form 10-Q include, among other things, statements about:

- the initiation, timing, progress and results of our current and future clinical trials of vepdegestrant (ARV-471), ARV-766 and bavdegalutamide (ARV-110), including statements regarding the period during which the results of the clinical trials will become available;
- the timing of, and our ability to obtain, marketing approval of vepdegestrant (ARV-471), ARV-766 and bavdegalutamide (ARV-110), and the ability of vepdegestrant (ARV-471), ARV-766, bavdegalutamide (ARV-110) and our other product candidates to meet existing or future regulatory standards;
- the potential achievement of milestones and receipt of payments under our collaborations, including our collaboration with Pfizer Inc., or Pfizer, entered into in July 2021, or the Vepdegestrant (ARV-471) Collaboration;
- our plans to pursue research and development of other product candidates;
- our plans to submit Investigational New Drug Applications and/or Clinical Trial Applications;
- the potential advantages of our platform technology and our product candidates;
- the extent to which our scientific approach and platform technology may potentially address a broad range of diseases and disease targets;
- the potential receipt of revenue from future sales of our product candidates;
- the rate and degree of market acceptance and clinical utility of our product candidates;
- our estimates regarding the potential market opportunity for our product candidates;
- our sales, marketing and distribution capabilities and strategy;
- our ability to establish and maintain arrangements for manufacture of our product candidates;
- our ability to enter into additional collaborations with third parties;
- our intellectual property position;
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- the impact of government laws and regulations; and
- our competitive position.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in our Annual Report on Form 10-K for the year ended December 31, 2022, filed on February 23, 2023, and this Quarterly Report on Form 10-Q, particularly in the "Risk Factors" sections, that we believe could cause actual results or events to differ materially from the forward-looking statements do

not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this Quarterly Report on Form 10-Q and the documents that we have filed as exhibits to this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may differ materially from what we expect. We do not assume any obligation to update any forward-looking statements except as required by applicable law.

Throughout this Quarterly Report on Form 10-Q, references to the "Company," "Arvinas," "we," "us," and "our," refer to Arvinas, Inc. and its consolidated subsidiaries, except where the context requires otherwise, or any one or more of them as the context may require, and "our board of directors" refers to the board of directors of Arvinas, Inc.

The Arvinas name and logo are our trademarks. We also own the service mark and the registered U.S. trademark for PROTAC®. This Quarterly Report on Form 10-Q contains references to our trademarks and service marks and to those belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Quarterly Report on Form 10-Q, including logos, artwork and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other entities' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

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# PART I-FINANCIAL INFORMATION

# Item 1. Financial Statements.

# **ARVINAS, INC. AND SUBSIDIARIES**

# **Condensed Consolidated Balance Sheets (unaudited)**

dollars and shares in millions, except per share amounts)		September 30, 2023	December 31, 2022
Assets	-		
Current assets:			
Cash and cash equivalents	\$	113.7	\$ 81.3
Restricted cash		5.5	5.5
Marketable securities		884.8	1,124.0
Accounts receivable		15.7	1.0
Other receivables		4.9	7.0
Prepaid expenses and other current assets		8.4	21.4
Total current assets		1,033.0	 1,240.2
Property, equipment and leasehold improvements, net		12.7	13.4
Operating lease right of use assets		3.0	4.4
Collaboration contract asset and other assets		9.6	10.8
Total assets	\$	1,058.3	\$ 1,268.8
Liabilities and stockholders' equity			
Current liabilities:			
Accounts payable and accrued liabilities	\$	91.0	\$ 74.7
Deferred revenue		224.2	218.6
Current portion of long term debt		0.2	_
Current portion of operating lease liability		1.9	1.8
Total current liabilities		317.3	 295.1
Deferred revenue		281.9	405.1
Long term debt		0.8	1.0
Operating lease liability		1.1	2.7
Total liabilities		601.1	 703.9
Commitments and Contingencies			
Stockholders' equity:			
Common stock, \$0.001 par value; 55.0 and 53.2 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively		0.1	0.1
Accumulated deficit		(1,177.9)	(965.4)
Additional paid-in capital		1,644.2	1,549.4
Accumulated other comprehensive loss		(9.2)	(19.2)
Total stockholders' equity		457.2	 564.9
Total liabilities and stockholders' equity	\$	1,058.3	\$ 1,268.8

See accompanying notes to the condensed consolidated financial statements

# Condensed Consolidated Statements of Operations and Comprehensive Loss (unaudited)

	For the Three Septen	 	For the Nine Months Ended September 30,					
(dollars and shares in millions, except per share amounts)	 2023	2022		2023		2022		
Revenue	\$ 34.6	\$ 33.2	\$	121.6	\$	93.6		
Operating expenses:								
Research and development	85.9	77.5		284.5		216.7		
General and administrative	22.6	20.0		73.3		64.5		
Total operating expenses	108.5	97.5		357.8		281.2		
Loss from operations	 (73.9)	 (64.3)		(236.2)		(187.6)		
Other income (expenses)								
Other expense, net		(0.2)		(1.1)		(0.4)		
Interest income, net	10.0	3.4		26.6		6.3		
Total other income	 10.0	3.2		25.5		5.9		
Net loss before income taxes and loss from equity method investment	 (63.9)	(61.1)		(210.7)		(181.7)		
Income tax (expense) benefit	_	(2.2)		0.7		(10.1)		
Loss from equity method investment	(0.1)	(2.9)		(2.5)		(7.8)		
Net loss	\$ (64.0)	\$ (66.2)	\$	(212.5)	\$	(199.6)		
Net loss per common share, basic and diluted	\$ (1.18)	\$ (1.24)	\$	(3.97)	\$	(3.76)		
Weighted average common shares outstanding, basic and diluted	 54.1	 53.2		53.6		53.1		

	For the Three Septen	 	For the Nine Months Ended September 30,					
(dollars in millions)	2023	2022		2023		2022		
Net loss	\$ (64.0)	\$ (66.2)	\$	(212.5)	\$	(199.6)		
Other comprehensive loss:								
Unrealized gain (loss) on available-for-sale securities	3.0	(2.8)		10.0		(20.2)		
Comprehensive loss	\$ (61.0)	\$ (69.0)	\$	(202.5)	\$	(219.8)		

See accompanying notes to the condensed consolidated financial statements

# Condensed Consolidated Statements of Changes in Stockholders' Equity (unaudited)

(dollars and shares in millions) For the Three Months Ended September 30, 2023 and 2022	Com	nmor	n Amount		Accumulated Deficit		Additional Paid-in Capital		Accumulated Other Comprehensive (Loss) Income		Total Stockholders' Equity
Balance as of June 30, 2023	53.4	\$	0.1	\$	(1,113.9)	\$	•	\$	(12.2)	\$	463.6
·	00.1	Ψ	0.1	Ψ	(1,110.0)	Ψ	16.7	Ψ	(12.2)	Ψ	16.7
Stock-based compensation	_		_				10.7		_		
Net loss	—				(64.0)		—		—		(64.0)
Issuance of common stock under equity incentive plans	0.1		_		_		1.9		_		1.9
Common stock issued, net of issuance costs of \$1.1 million	1.5		_		_		36.0		_		36.0
Unrealized gain on available-for-sale securities	_		_		_		_		3.0		3.0
Balance as of September 30, 2023	55.0	\$	0.1	\$	(1,177.9)	\$	1,644.2	\$	(9.2)	\$	457.2
Balance as of June 30, 2022	53.2	\$	0.1	\$	(816.3)	\$	1,508.8	\$	(22.0)	\$	670.6
Stock-based compensation	—		—		—		18.8		—		18.8
Net loss	—		—		(66.2)		—		—		(66.2)
Issuance of common stock under equity incentive plans	_		_		_		1.1		_		1.1
Unrealized loss on available-for-sale securities	_		_		_		_		(2.8)		(2.8)
Balance as of September 30, 2022	53.2	\$	0.1	\$	(882.5)	\$	1,528.7	\$	(24.8)	\$	621.5

(dollars and shares in millions)	Com	mo	n	– Accumulated Deficit		Additional	Accumulated Other			Total
For the Nine Months Ended September 30, 2023 and 2022	Shares		Amount			Paid-in Capital		Comprehensive (Loss) Income		Stockholders' Equity
Balance as of December 31, 2022	53.2	\$	0.1	\$	(965.4)	\$ 1,549.4	\$	(19.2)	\$	564.9
Stock-based compensation	—		_		—	54.9		—		54.9
Net loss	—		_		(212.5)	—		—		(212.5)
Issuance of common stock under equity incentive plans	0.3		_		_	3.9		_		3.9
Common stock issued, net of issuance costs of \$1.1 million	1.5		_		_	36.0		_		36.0
Unrealized gain on available-for-sale securities	_		_		_	_		10.0		10.0
Balance as of September 30, 2023	55.0	\$	0.1	\$	(1,177.9)	\$ 1,644.2	\$	(9.2)	\$	457.2
Balance as of December 31, 2021	53.0	\$		\$	(682.9)	\$ 1,469.2	\$	(4.6)	\$	781.7
Stock-based compensation	_		_		_	55.4		_		55.4
Net loss	_		_		(199.6)	_		_		(199.6)
Issuance of common stock under equity incentive plans	0.2		0.1		_	4.1		_		4.2
Unrealized loss on available-for-sale securities	_		_		_	_		(20.2)		(20.2)
Balance as of September 30, 2022	53.2	\$	0.1	\$	(882.5)	\$ 1,528.7	\$	(24.8)	\$	621.5

See accompanying notes to the condensed consolidated financial statements

# Condensed Consolidated Statements of Cash Flows (unaudited)

	For the Nine Months Ended September 30,							
(dollars in millions)		2023		2022				
Cash flows from operating activities:								
Net loss	\$	(212.5)	\$	(199.6)				
Adjustments to reconcile net loss to net cash used in operating activities:								
Depreciation and amortization		3.6		4.6				
Net accretion of bond discounts/premiums		(11.6)		6.5				
Loss on sale of marketable securities		0.9		0.4				
Amortization of right-of-use assets		1.4		1.5				
Amortization of collaboration contract asset		2.0		1.3				
Stock-based compensation		54.9		55.4				
Changes in operating assets and liabilities:								
Accounts receivable		(14.7)		14.0				
Other receivables		2.2		4.9				
Prepaid expenses and other current assets		12.3		(2.0)				
Accounts payable and accrued liabilities		16.0		(5.0)				
Operating lease liability		(1.5)		(1.5)				
Deferred revenue		(117.7)		(82.8)				
Net cash used in operating activities		(264.7)		(202.3)				
Cash flows from investing activities:								
Purchases of marketable securities		(665.7)		(702.2)				
Maturities of marketable securities		873.4		872.2				
Sales of marketable securities		52.3		59.1				
Purchases of property, equipment and leasehold improvements		(2.8)		(5.7)				
Net cash provided by investing activities		257.2		223.4				
Cash flows from financing activities:								
Proceeds from issuance of common stock		37.1		_				
Payment of common stock issuance costs		(1.1)		_				
Proceeds from exercise of stock options and issuance of ESPP shares		3.9		4.2				
Net cash provided by financing activities		39.9		4.2				
Net increase in cash, cash equivalents and restricted cash		32.4		25.3				
Cash, cash equivalents and restricted cash, beginning of the period		86.8		112.8				
Cash, cash equivalents and restricted cash, end of the period	\$	119.2	\$	138.1				
Supplemental disclosure of cash flow information:								
Purchases of property, equipment and leasehold improvements								
unpaid at period end	\$	—	\$	0.3				
Cash paid for taxes	\$	9.1	\$	8.1				

See accompanying notes to the condensed consolidated financial statements

## Notes to Condensed Consolidated Financial Statements (unaudited)

#### 1. Nature of Business and Basis of Presentation

Arvinas, Inc. and its subsidiaries ("Arvinas" or the "Company") is a clinical-stage biotechnology company dedicated to improving the lives of patients suffering from debilitating and life-threatening diseases through the discovery, development and commercialization of therapies that degrade disease-causing proteins.

The accompanying unaudited condensed consolidated financial statements include the accounts of Arvinas, Inc. and its subsidiaries. The financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X under the Securities Exchange Act of 1934, as amended ("Exchange Act"). Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to Securities and Exchange Commission ("SEC") rules. In the opinion of management, all adjustments (consisting of normal recurring adjustments) necessary for a fair presentation have been included. The condensed consolidated balance sheet as of December 31, 2022 has been derived from the Company's audited consolidated financial statements and notes thereto for the year ended December 31, 2022, forming part of Arvinas' 2022 Annual Report on Form 10-K filed with the SEC on February 23, 2023.

As previously disclosed in the Company's 2022 Annual Report on Form 10-K, the Company revised the accounting for its investment in Oerth Bio LLC ("Oerth Bio"). Accordingly, Arvinas recorded an adjustment to the unaudited condensed consolidated financial statements for the three and nine months ended September 30, 2022 that were previously included in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022. See Note 12, *Equity Method Investments*, for further details.

The preparation of the Company's unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires management to make certain estimates and assumptions that affect the reported amount of assets, liabilities, revenue and expenses. These estimates include assumptions and judgments based on historical experience, current conditions, future expectations and other factors the Company considers reasonable. These estimates are reviewed on an ongoing basis and revised as necessary. Actual results could differ from these estimates.

#### **Risks and Uncertainties**

The Company is subject to a number of risks similar to other biotechnology companies in the early stage, including, but not limited to, the need to obtain adequate additional funding, possible failure of preclinical testing or clinical trials, the need to obtain marketing approval for its product candidates, competitors developing new technological innovations, the need to successfully commercialize and gain market acceptance of the Company's products and protection of proprietary technology. If the Company does not successfully obtain regulatory approval, it will be unable to generate revenue from product sales or achieve profitability.

To date, the Company has not generated any revenue from product sales and expects to incur additional operating losses and negative operating cash flows for the foreseeable future. The Company has financed its operations primarily through sales of equity interests, proceeds from collaborations, grant funding and debt financing. The Company had cash, cash equivalents, restricted cash and marketable securities of approximately \$1.0 billion as of September 30, 2023.

## 2. Accounting Pronouncements and Significant Accounting Policies

## Accounting Pronouncements

The Company reviews new accounting standards as issued. As of September 30, 2023, the Company has not identified any new standards that it believes will have a material impact on the Company's financial statements.

# Significant Accounting Policies

There were no changes to the Company's significant accounting policies during the nine months ended September 30, 2023.

## 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 to the total amounts shown in the consolidated statements of cash flows for the nine months ended September 30, 2023 and 2022:

(dollars in millions)	Se	eptember 30, 2023	September 30, 2022
Cash and cash equivalents	\$	113.7	\$ 132.6
Restricted cash		5.5	5.5
Cash, cash equivalents and restricted cash	\$	119.2	\$ 138.1

Restricted cash represents a letter of credit collateralized by a certificate of deposit in the same amount as required under the terms of the Company's laboratory and office space lease entered into in May 2021 and amended in August 2022.

## 3. Research Collaboration and License Agreements

## Vepdegestrant (ARV-471) Collaboration Agreement

In July 2021, the Company entered into a Collaboration Agreement with Pfizer Inc. ("Pfizer") (the "Vepdegestrant (ARV-471) Collaboration Agreement") pursuant to which the Company granted Pfizer worldwide co-exclusive rights to develop and commercialize products containing the Company's proprietary compound ARV-471 (the "Licensed Products"). Under the Vepdegestrant (ARV-471) Collaboration Agreement, the Company received an upfront, non-refundable payment of \$650.0 million. In addition, the Company is eligible to receive up to an additional \$1.4 billion in contingent payments based on specific regulatory and sales-based milestones for the Licensed Products. Of the total contingent payments, \$400.0 million in regulatory milestones are related to marketing approvals and \$1.0 billion are related to sales-based milestones. There were no regulatory or sales-based milestone payments received through September 30, 2023.

The Company and Pfizer share equally all development costs, including costs of conducting clinical trials, for the Licensed Products, subject to certain exceptions. Except for certain regions described below, the parties will also share equally all profits and losses in commercialization and medical affairs activities for the Licensed Products in all other countries, subject to certain exceptions.

The Company will be the marketing authorization holder in the United States and, subject to marketing approval, book sales in the United States, while Pfizer will hold marketing authorizations outside the United States. The parties will determine which, if any, regions within the world will be solely commercialized by one party, and in such region the parties will adjust their share of profits and losses for the Licensed Products based on the role each party will be performing.

As a direct result of the Company's entry into the Vepdegestrant (ARV-471) Collaboration Agreement, the Company incurred direct and incremental costs to obtain the contract, paid to a financial advisor, totaling \$12.9 million. In accordance with ASC 340, *Other Assets and Deferred Costs*, the Company recognized an asset of \$12.9 million in collaboration contract asset and other assets in the condensed consolidated balance sheet at inception of the agreement, which is being amortized as general and administrative expense over the total estimated period of performance under the Vepdegestrant (ARV-471) Collaboration Agreement.



## Bayer Collaboration Agreement

In June 2019, the Company and Bayer AG entered into a Collaboration and License Agreement (the "Bayer Collaboration Agreement") setting forth the Company's collaboration with Bayer AG to identify or optimize proteolysis targeting chimeras ("PROTAC® targeted protein degraders") that mediate the degradation of target proteins. Under the terms of the Bayer Collaboration Agreement, the Company received an upfront, non-refundable payment of \$17.5 million in exchange for the use of the Company's technology license. Bayer AG was committed to fund an additional \$12.0 million through 2023, all of which was received as of September 30, 2023, including \$1.5 million and \$3.0 million in the nine months ended September 30, 2023 and 2022, respectively. These payments are being recognized over the total estimated period of performance.

The Company is also eligible to receive up to \$197.5 million in development milestone payments and up to \$490.0 million in salesbased milestone payments for all designated targets. In addition, the Company is eligible to receive, on net sales of PROTAC targeted protein degrader-related products, mid-single digit to low-double digit tiered royalties, which may be subject to reductions. There were no development or sales-based milestone payments or royalties received through September 30, 2023.

### Pfizer Research Collaboration Agreement

In December 2017, the Company entered into a Research Collaboration and License Agreement with Pfizer (the "Pfizer Research Collaboration Agreement"). Under the terms of the Pfizer Research Collaboration Agreement, the Company received an upfront, non-refundable payment and certain additional payments totaling \$28.0 million in 2018 in exchange for use of the Company's technology license and to fund Pfizer-related research as defined within the Pfizer Research Collaboration Agreement. These payments are being recognized as revenue over the total estimated period of performance. The Company is eligible to receive up to an additional \$37.5 million in non-refundable option payments if Pfizer exercises its options for all targets under the Pfizer Research Collaboration Agreement. The Company is also entitled to receive up to \$225.0 million in development milestone payments and up to \$550.0 million in sales-based milestone payments for all designated targets under the Pfizer Research Collaboration Agreement, as well as tiered royalties based on sales. During the nine months ended September 30, 2023 and 2022, the Company received payments totaling \$1.0 million and \$3.5 million which were included in accounts receivable as of December 31, 2022 and 2021, respectively, for additional targets and services which are being recognized as revenue over the total period of performance. There were no sales-based milestone payments or royalties received through September 30, 2023.

## **Restated Genentech Agreement**

In November 2017, the Company entered into an Amended and Restated Option, License, and Collaboration Agreement (the "Restated Genentech Agreement") with Genentech, Inc. and F. Hoffman-La Roche Ltd. (together "Genentech"), amending a previous Genentech agreement entered into in September 2015. Under the Restated Genentech Agreement, the Company received additional upfront, non-refundable payments of \$34.5 million (in addition to \$11.0 million received under the previous agreement in 2015) to fund Genentech-related research. Upfront non-refundable payments were recognized as revenue over the performance period.

The Company is eligible to receive up to \$44.0 million per target in development milestone payments, \$52.5 million in regulatory milestone payments and \$60.0 million in commercial milestone payments based on sales as well as tiered royalties based on sales. There were no development, regulatory or commercial milestone payments or royalties received through September 30, 2023.

Changes in the Company's contract balances for the nine months ended September 30, 2023 and 2022 were as follows:

(dollars in millions)	Se	eptember 30, 2023	September 30, 2022
Accounts receivable related to collaborations			
Beginning balance	\$	1.0	\$ 15.0
Additions		21.7	2.4
Payments received		(7.0)	(16.4)
Ending balance	\$	15.7	\$ 1.0
Accounts payable related to collaborations			
Beginning balance	\$	5.0	\$ —
Additions		31.0	_
Payments made		(6.7)	_
Ending balance	\$	29.3	\$ _
Contract assets: Collaboration contract asset			
Beginning balance	\$	10.7	\$ 12.5
Additions		_	_
Amortization		(2.0)	(1.3)
Ending balance	\$	8.7	\$ 11.2
Contract liabilities: Deferred revenue			
Beginning balance	\$	623.7	\$ 740.5
Revenue recognized from balances held at the beginning of the period		(119.1)	(85.8)
Additions to collaboration agreements		1.5	3.0
Ending balance	\$	506.1	\$ 657.7

During the nine months ended September 30, 2023, the Company recorded cumulative catch-up adjustments from contract modifications totaling \$(8.2) million, relating to performance obligations which were satisfied in prior periods. During the three months ended September 30, 2023 and the three and nine months ended September 30, 2022, the Company recorded no cumulative catch-up adjustments.

The aggregate amount of the transaction price allocated to performance obligations that were unsatisfied as of September 30, 2023 was \$506.1 million, which is expected to be recognized in the following periods:

(dollars in millions)	
Remainder of 2023	\$ 64.1
2024	200.9
2025	90.2
2026	55.3
2027	34.7
2028	10.8
Thereafter	50.1
Total	\$ 506.1

# 4. Marketable Securities and Fair Value Measurements

The Company's marketable securities consist of corporate bonds and government securities which are adjusted to fair value as of each balance sheet date based on quoted prices, which are considered Level 2 inputs.

The following is a summary of the Company's available-for-sale marketable securities measured at fair value on a recurring basis.

			Se	ptember 30, 2023		
(dollars in millions)	Valuation Hierarchy	Amortized Cost		Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate bonds	Level 2	\$ 821.6	\$	_	\$ (9.1)	\$ 812.5
Government securities	Level 2	72.4		—	(0.1)	72.3
Total		\$ 894.0	\$	_	\$ (9.2)	\$ 884.8

		December 31, 2022									
(dollars in millions)	Valuation Hierarchy	Amortized Cost		Gross Unrealized Gains		ed Unrealized			Fair Value		
Corporate bonds	Level 2	\$	1,008.0	\$	_	\$	(18.5)	\$	989.5		
Government securities	Level 2		135.2		_		(0.7)		134.5		
Total		\$	1,143.2	\$		\$	(19.2)	\$	1,124.0		

The Company does not intend to sell any investments prior to recovery of their amortized cost basis for any investment in an unrealized loss position. As such, the Company has classified these losses as temporary in nature.

The carrying values of accounts receivable and accounts payable and accrued liabilities approximate their fair values due to the short-term nature of these assets and liabilities.

## 5. Property, Equipment and Leasehold Improvements

Property, equipment and leasehold improvements consist of the following:

(dollars in millions)	September 30, 2023	December 31, 2022
Laboratory equipment	\$ 18.5	\$ 17.1
Leasehold improvements	11.5	10.9
Office equipment	2.6	2.0
Total property, equipment and leasehold improvements	32.6	 30.0
Less: accumulated depreciation and amortization	(19.9)	(16.6)
Property, equipment and leasehold improvements, net	\$ 12.7	\$ 13.4

Depreciation and amortization expense totaled \$1.2 million and \$1.6 million for the three months ended September 30, 2023 and 2022, respectively, and \$3.6 million and \$4.6 million for the nine months ended September 30, 2023 and 2022, respectively.

## 6. Right-of-Use Assets and Liabilities

The Company determines if an arrangement is a lease at inception. Operating leases are included in operating lease right-of-use ("ROU") assets and operating lease liabilities in the condensed consolidated balance sheets.

ROU assets represent the right to use an underlying asset for the lease term and lease liabilities represent the obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. As the Company's leases do not provide an implicit interest rate, the Company uses its incremental borrowing rate based on the information available at the lease commencement date in determining

the present value of lease payments, which ranges from 3.0% - 7.5%. Lease expense is recognized on a straight-line basis over the lease term. The Company considers options to extend or terminate leases in recognizing ROU assets and lease liabilities when it is reasonably certain that such options will be exercised.

In May 2021, the Company entered into a lease arrangement, which was amended in August 2022, for approximately 160,000 square feet of laboratory and office space, expected to be occupied in 2025. Once occupied, the base rent will range from \$7.7 million to \$8.8 million annually over a ten-year lease term.

In connection with the signing of the lease and the related amendment, and at the Company's election to increase the landlord's contribution to the tenant improvement allowance, the Company initially issued a letter of credit totaling \$4.5 million, which was subsequently increased to \$5.5 million, collateralized by a certificate of deposit in the same amount, which is presented as restricted cash in the consolidated balance sheets.

The Company has operating leases for its corporate office, laboratories and certain equipment, which expire no later than January 2026. The leases have a weighted average remaining term of 1.6 years.

The components of lease expense were as follows:

	Three Months Ended September 30,				Nine Months Ended September 30,				
(dollars in millions)	2	023		2022		2023		2022	
Operating lease cost	\$	0.5	\$	0.5	\$	1.5	\$	1	1.6

Supplemental cash flow information related to leases was as follows:

		Nine Months Ended September 30,				
(dollars in millions)	20	23	2022			
Cash paid for amounts included in the measurement of lease liabilities:						
Operating cash flows from operating leases	\$	1.5 \$	1.5			
Supplemental non-cash information:						
Right-of-use assets obtained in exchange for new lease obligations	\$	— \$	2.4			

Maturities of operating lease liabilities as of September 30, 2023, were as follows:

(dollars in millions)	
Remainder of 2023	\$ 0.4
2024	2.2
2025	0.5
2026	_
Total lease payments	 3.1
Less: imputed interest	(0.1)
Total	\$ 3.0

## 7. Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consisted of the following:

(dollars in millions)	ę	September 30, 2023	I	December 31, 2022
Accounts payable	\$	34.3	\$	5.7
Accrued liabilities				
Research and development expenses		36.0		35.9
Employee expenses		16.7		18.7
Professional fees and other		2.9		4.1
Income taxes		1.1		10.3
Total accounts payable and accrued liabilities	\$	91.0	\$	74.7

## 8. Long-Term Debt

Debt obligations consisted of the following:

(dollars in millions)	Maturity Date	Interest Rate	Se	ptember 30, 2023	 December 31, 2022
2018 Assistance Agreement Debt	09/28	3.25%	\$	1.0	\$ 1.0
Less: current installments				(0.2)	—
Total long-term debt			\$	0.8	\$ 1.0

In June 2018, the Company entered into an additional assistance agreement with the State of Connecticut (the "2018 Assistance Agreement") to provide funding for the expansion and renovation of laboratory and office space. The Company borrowed \$2.0 million under the 2018 Assistance Agreement in September 2018, of which \$1.0 million was forgiven upon meeting certain employment conditions. Borrowings under the agreement bear an interest rate of 3.25% per annum, with interest-only payments required for the first 60 months, and mature in September 2028. The 2018 Assistance Agreement requires that the Company be located in the State of Connecticut through September 2028, with a default penalty of repayment of the full original funding amount of \$2.0 million plus liquidated damages of 7.5% of the total amount of funding received.

In connection with an assistance agreement with the State of Connecticut entered into in 2014 under which all the borrowings by the Company were forgiven, the Company is required to be located in the State of Connecticut through January 2024, with a default penalty of repayment of the full original funding amount of \$2.5 million plus liquidated damages of 7.5%.

Minimum future principal payments on long-term debt for the years ending December 31 are as follows:

(dollars in millions)	
2023	\$ —
2024	0.2
2025	0.2
2026	0.2
2027	0.2
2028	0.2
Total	\$ 1.0

During the three and nine months ended September 30, 2023 and 2022, interest expense was immaterial.

## 9. Equity

### Equity Distribution Agreements

In August 2021, the Company entered into an Equity Distribution Agreement with Piper Sandler & Company ("Piper Sandler") and Cantor Fitzgerald & Co. ("Cantor"), as agents, pursuant to which the Company may offer and sell from time to time, through the agents, up to \$300.0 million of the common stock registered under the Company's universal shelf registration statement pursuant to one or more "at-the-market" offerings. During the three months ended September 30, 2023, the Company issued 1,449,275 shares of common stock under this agreement, resulting in net proceeds of approximately \$36.0 million, net of offering costs of approximately \$1.1 million.

## Stock-based Compensation

## 2018 Employee Stock Purchase Plan

In September 2018, the Company adopted the 2018 Employee Stock Purchase Plan (the "2018 ESPP"), with the first offering period under the 2018 ESPP commencing on January 1, 2020, by initially providing participating employees with the opportunity to purchase an aggregate of 311,850 shares of the Company's common stock. The number of shares of the Company's common stock reserved for issuance under the 2018 ESPP increased, pursuant to the terms of the 2018 ESPP, by additional shares equal to 1% of the Company's then-outstanding common stock, effective as of January 1 of each year. As of September 30, 2023, 2,440,434 shares remained available for purchase. During the nine months ended September 30, 2023 and 2022, the Company issued 78,528 and 24,898 shares of common stock, respectively, of common stock under the 2018 ESPP.

## Incentive Share Plan

In the Fourth Amendment to the Company's Incentive Share Plan (the "Incentive Plan") adopted in March 2018, the Company was authorized to issue up to an aggregate of 6,199,477 incentive units pursuant to the terms of the Incentive Plan. Generally, incentive units were granted at no less than fair value as determined by the board of managers and had vesting periods ranging from one to four years. The Incentive Plan was terminated in September 2018.

## 2018 Stock Incentive Plan

In September 2018, the Company's board of directors adopted, and the Company's stockholders approved, the 2018 Stock Incentive Plan (the "2018 Plan"), which became effective upon the effectiveness of the registration statement on Form S-1 for the Company's initial public offering. The number of shares of common stock initially available for issuance under the 2018 Plan equaled the sum of (1) 4,067,007 shares of common stock; plus (2) the number of shares of common stock (up to 1,277,181 shares) issued in respect of incentive units granted under the Incentive Plan that were subject to vesting immediately prior to the effectiveness of the registration statement that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by the Company at their original issuance price pursuant to a contractual repurchase right; plus (3) an annual increase on the first day of each fiscal year beginning with the fiscal year ended December 31, 2019 and continuing to, and including, the fiscal year ending December 31, 2028, equal to the lesser of 4,989,593 shares of the Company's common stock, 4% of the number of shares of the Company's common stock outstanding on the first day of the year or an amount determined by the Company's board of directors. As of September 30, 2023, 2,111,046 shares remained available for issuance under the 2018 Plan. Shares of common stock subject to outstanding equity awards that expire or are terminated, surrendered, or canceled without having been fully exercised or are forfeited in whole or in part are available for future grants of awards.



## Compensation Expense

During the three months ended September 30, 2023 and 2022, the Company recognized compensation expense of \$16.7 million and \$18.8 million, respectively, related to the issuance of incentive awards, including \$0.2 million and \$0.2 million, respectively, related to the 2018 ESPP. During the nine months ended September 30, 2023 and 2022, the Company recognized compensation expense of \$54.9 million and \$55.4 million, respectively, relating to the issuance of incentive awards, including \$0.7 million and \$0.5 million, respectively, related to the 2018 ESPP.

As of September 30, 2023, there was \$67.3 million of total unrecognized compensation expense that is expected to be amortized over a weighted average period of approximately 1.7 years.

## Stock Options

The fair value of the stock options granted during the nine months ended September 30, 2023 and 2022 was determined using the Black-Scholes option pricing model with the following assumptions:

	September 30, 2023	September 30, 2022
Expected volatility	71.5 - 74.2%	73.2 - 76.0%
Expected term (years)	5.5 - 7.0	5.5 - 7.0
Risk free interest rate	3.4% - 4.3%	1.5% - 3.3%
Expected dividend yield	0 %	0 %
Exercise price	\$23.23 - \$36.27	\$36.79 - \$78.91

Given the Company's common stock has not been trading for a sufficient period of time, the Company calculates volatility of its common stock by utilizing a weighted average of a collection of peer company volatilities and its own common stock volatility. The expected term is calculated utilizing the simplified method.

A summary of the stock option activity under the 2018 Plan during the nine months ended September 30, 2023 is presented below. These amounts include stock options granted to employees and directors.

(dollars in millions, except weighted average exercise price)	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Ag	gregate Intrinsic Value
Outstanding as of December 31, 2022	6,814,634	\$ 49.06	7.7	\$	34.5
Granted	1,743,351	\$ 33.25			
Exercised	(109,200)	\$ 19.01			
Forfeited	(445,796)	\$ 55.79			
Expired	(4,433)	\$ 71.30			
Outstanding as of September 30, 2023	7,998,556	\$ 45.67	7.4	\$	4.1
Vested and exercisable as of September 30, 2023	4,593,066	\$ 42.85	6.5	\$	4.1
Vested and expected to vest as of September 30, 2023	7,701,049	\$ 45.65	7.4	\$	4.1

The weighted-average grant date fair value per share of options granted during the nine months ended September 30, 2023 and 2022 was \$22.51 and \$39.69, respectively. The total intrinsic value of options exercised during the nine months ended September 30, 2023 and 2022 was \$0.9 million and \$7.6 million, respectively.

## Restricted Stock Units (RSUs)

A summary of RSU activity under the 2018 Plan during the nine months ended September 30, 2023 is presented below. These amounts include RSUs granted to employees.

	Shares	V	Weighted Average Grant Date Fair Value Per Share
Unvested RSUs as of December 31, 2022	489,216	\$	51.37
Granted	828,400	\$	33.19
Vested	(137,022)	\$	45.16
Forfeited	(54,696)	\$	41.20
Unvested RSUs as of September 30, 2023	1,125,898	\$	39.24

The total fair value of RSUs vested during the nine months ended September 30, 2023 and 2022 was \$6.2 million and \$0.9 million, respectively.

#### 10. Income Taxes

For the three months ended September 30, 2023, the Company did not recognize an income tax expense or benefit resulting in an effective tax rate of 0.0%, as compared to income tax expense of \$2.2 million resulting in an effective tax rate of (3.5)% in the same period for 2022. The primary reconciling items between the federal statutory rate of 21.0% for the three months ended September 30, 2023 and the Company's overall effective tax rate of 0.0% was the effect of equity compensation and the valuation allowance recorded against the full amount of its net deferred tax assets. The primary reconciling items between the federal statutory rate of 21.0% for the three months ended September 30, 2023 and the Company's overall effective tax rate of (3.5)% was the effect of equity compensation, deferred state income taxes and the valuation allowance recorded against the full amount of its net deferred tax assets.

For the nine months ended September 30, 2023, the Company recognized income tax benefit of \$0.7 million resulting in an effective tax rate of 0.3%, as compared to income tax expense of \$10.1 million resulting in an effective tax rate of (5.5)% in the same period for 2022. The primary reconciling items between the federal statutory rate of 21.0% for the nine months ended September 30, 2023 and the Company's overall effective tax rate of 0.3% was the effect of expected benefits from state net operating loss carryback claims offset by equity compensation and the valuation allowance recorded against the full amount of its net deferred tax assets. The primary reconciling items between the federal statutory rate of 21.0% for the nine months ended September 30, 2022 and the Company's overall effective tax rate of (5.5)% was the effect of equity compensation, generation of tax credits, deferred state income taxes and the valuation allowance recorded against the full amount of its net deferred tax assets and the valuation allowance recorded against the full amount of tax credits, deferred state income taxes and the valuation allowance recorded against the full amount of its net deferred tax assets.

A valuation allowance is established when it is more likely than not that some portion or all of a deferred tax asset will not be realized. The realization of deferred tax assets depends on the generation of future taxable income during the period in which related temporary differences become deductible. The Company continues to establish a full valuation allowance against its net deferred tax assets since it is more likely than not that benefits will not be realized, including those benefits created in the current year. This assessment is based on the Company's historical cumulative losses which provide strong objective evidence that cannot be overcome with projections of income, as well as the fact the Company expects continuing losses in the future.

## 11. Net Loss Per Share

Basic and diluted loss per common share was calculated as follows:

	For the Three Months Ended September 30,					hs Ended 30,		
(dollars and shares in millions, except per share amounts)		2023		2022		2023		2022
Net loss	\$	(64.0)	\$	(66.2)	\$	(212.5)	\$	(199.6)
Weighted average number of common shares outstanding - basic and diluted		54.1		53.2		53.6		53.1
Net loss per common share - basic and diluted	\$	(1.18)	\$	(1.24)	\$	(3.97)	\$	(3.76)

The Company reported net losses for each of the three and nine months ended September 30, 2023 and 2022, and therefore excluded all stock options and restricted stock units from the calculation of diluted net loss per common share as their inclusion would have had an anti-dilutive effect, as summarized below:

	For the Three and Nin Septembe	
(shares in millions)	2023	2022
Stock options	8.0	6.7
Restricted stock units	1.1	0.4
	9.1	7.1

#### 12. Equity Method Investments

In July 2019, the Company and Bayer CropScience LP ("Bayer LP") formed Oerth Bio, a joint venture to research, develop and commercialize PROTAC targeted protein degraders for applications in the field of agriculture. The Company and Bayer LP each held an initial ownership interest in Oerth Bio of 50%. A 15% ownership interest of Oerth Bio was reserved for the future grants of incentive units to employees and service providers and, as a result, the Company's ownership interest totaled 45.2% and 47.2% as of September 30, 2023 and 2022, respectively, as a result of vested incentive units.

In connection with the preparation of the Company's consolidated financial statements for the year ended December 31, 2022, the Company identified a prior period error related to the accounting of its investment in Oerth Bio in 2019. Previously, the Company disclosed that revenue of \$24.7 million was deferred and would be recognized if and when Oerth Bio recognized revenue associated with the license. The Company has determined that the consideration received for the amounts associated with the deferred revenue should have been constrained, because at the time Bayer LP had contributed only a portion of its full cash commitment to Oerth Bio, and Bayer LP had the right to all the cash contributed, but not yet spent, upon liquidation of Oerth Bio. The constrained revenue should have been recognized upon both cash being contributed by Bayer LP and the related cash spent by Oerth Bio on research and development activities. As such, for each period presented, the revenue recognized is accompanied by corresponding equity method losses of the same amount. As of September 30, 2023, the Company recognized the remaining constrained revenue and therefore will discontinue applying the equity method and not recognize addition equity losses until Oerth Bio returns to profitability.

The Company evaluated the error and determined that the related impact did not materially misstate the previously issued unaudited condensed consolidated financial statements for the three and nine months ended September 30, 2022. Although the Company concluded that the error was not material to its previously issued unaudited condensed consolidated financial statements, the Company has determined it is appropriate to adjust its previously issued unaudited condensed consolidated financial statements for the three and nine months ended September 30, 2022 to correct the error and improve comparability.



The following illustrates the effect of the correction of the immaterial error for the period presented. There was no impact to the balance sheets, net loss per common share, statements of cash flows or changes in stockholders' equity.

	Three Months Ended September 30, 2022							Nine Months Ended September 30, 2022							
(dollars in millions, except per share amounts)		previously reported		adjustments		as adjusted		as previously reported		adjustments		as adjusted			
Revenue	\$	30.3	\$	2.9	\$	33.2	\$	85.8	\$	7.8	\$	93.6			
Loss from operations	\$	(67.2)	\$	2.9	\$	(64.3)	\$	(195.4)	\$	7.8	\$	(187.6)			
Loss from equity method investment	\$	_	\$	(2.9)	\$	(2.9)	\$	_	\$	(7.8)	\$	(7.8)			
Net loss	\$	(66.2)	\$	_	\$	(66.2)	\$	(199.6)	\$		\$	(199.6)			
Net loss per common share - basic and diluted	\$	(1.24)	\$	_	\$	(1.24)	\$	(3.76)	\$	_	\$	(3.76)			
Comprehensive loss	\$	(69.0)	\$	—	\$	(69.0)	\$	(219.8)	\$	—	\$	(219.8)			

Net loss of Oerth Bio for the three months ended September 30, 2023 and 2022 totaled \$3.2 million and \$6.2 million, respectively. The Company recognized equity method losses of \$0.1 million and \$2.9 million for the three months ended September 30, 2023 and 2022, respectively. Net loss of Oerth Bio for the nine months ended September 30, 2023 and 2022 totaled \$8.5 million and \$16.3 million, respectively. The Company recognized equity method losses of \$2.5 million and \$7.8 million for the nine months ended September 30, 2023 and 2022, respectively.

As of September 30, 2023 and 2022, the Company's carrying value of the investment was zero.

The Company also provides Oerth Bio with compensated research, development and administrative services through a separate agreement. The services rendered by the Company during the three and nine months ended September 30, 2023 and 2022 were immaterial.

## 13. Commitments and Contingencies

From time to time, the Company may be subject to legal proceedings, claims and disputes that arise in the ordinary course of business. The Company accrues a liability for such matters when it is probable that future expenditures will be made and that such expenditures can be reasonably estimated. Significant judgment is required to determine both probability and the estimated amount, which could differ materially. Legal fees and other costs associated with such actions are expensed as incurred. The Company's accrual for such matters totaled \$10.0 million as of September 30, 2023, primarily related to a contract dispute that is in early stages. Due to the early stage of the dispute, the means of resolution are unknown and could involve contract modification and, or payment of consideration. An estimate of the possible range of loss associated with the dispute cannot be made at this time and the Company has accrued its best estimate as of September 30, 2023.

## **Clinical and Preclinical Development and Licensing Arrangements**

From time to time, the Company enters into contracts in the normal course of business with various third parties who support its clinical trials, preclinical research studies, and other services related to its development activities. The scope of the services under these agreements can generally be modified at any time, and the agreement can be terminated by either party after a period of notice and receipt of written notice.

In addition, under licensing and related arrangements to which the Company is a party, the Company may be obligated to make milestone payments to third parties. The payment obligations under these arrangements are contingent upon future events, such as achievement of specified milestones or generation of product sales, and the amount, timing and likelihood of such payments are not known.

#### FMI Agreement

In June 2022, the Company entered into a Master In Vitro Diagnostics Agreement (the "FMI Agreement") with Foundation Medicine, Inc. ("Foundation Medicine") for the development and

commercialization of one or more of Foundation Medicine's companion in vitro diagnostic assays for use with one or more of the Company's therapeutic products.

The FMI Agreement does not have a fixed duration, and the Company may terminate the FMI Agreement for convenience by providing adequate written notice to Foundation Medicine, subject to payment of applicable termination fees. Either party may terminate the FMI Agreement in its entirety for an uncured material breach by the other party, upon the bankruptcy or insolvency of the other party or by the mutual written agreement of both parties. Additionally, Foundation Medicine may terminate the FMI Agreement with respect to an applicable program, (a) if a reasonably necessary third party license is not secured by Foundation Medicine or if the Company does not consent to payments for such license, (b) if Foundation Medicine reasonably determines that further development of the applicable assay is not technically feasible or (c) following a certain number of years after the first commercial launch of the applicable assay for use with the applicable therapeutic product. Certain license and other rights and certain obligations of Foundation Medicine survive termination of the FMI Agreement. If the FMI Agreement is terminated in its entirety or with respect to any program, the Company has certain payment obligations remaining to Foundation Medicine and may also be required to pay a termination fee, if applicable.

#### Bavdegalutamide

In exchange for the development of FoundationOne® Liquid CDx as a companion diagnostic for use with bavdegalutamide for androgen receptor protein ("AR") metastatic castration-resistant prostate cancer ("mCRPC") in the United States and European Union, pursuant to the terms of the FMI Agreement, the Company is subject to success-based milestone payments of up to low to mid tens of millions of dollars, in addition to certain validation fees per sample and related pass-through costs.

#### ARV-766

In exchange for the development of FoundationOne® Liquid CDx as a companion diagnostic for use with ARV-766 for AR mCRPC in the United States and European Union, pursuant to the terms of the FMI Agreement, the Company is subject to success-based milestone payments of up to low tens of millions of dollars in addition to certain validation fees per sample and related pass-through costs.

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

The following discussion and analysis is meant to provide material information relevant to an assessment of the financial condition and results of operations of our company, including an evaluation of the amount and certainty of cash flows from operations and from outside sources, so as to allow investors to better view our company from management's perspective. You should read the following discussion and analysis of financial condition and results of operations together with our unaudited condensed consolidated financial statements and the related notes appearing elsewhere in this Quarterly Report on Form 10-Q and the consolidated financial statements and the related notes and discussion and analysis of financial condition and results of operations in our Annual Report on Form 10-K for the year ended December 31, 2022 filed on February 23, 2023. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth in the section titled "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022, filed on February 23, 2023 and elsewhere in this Quarterly Report on Form 10-Q, our actual results may differ materially from those anticipated in or implied by these forward-looking statements.

#### Overview

## **Our Business**

We are a clinical-stage biotechnology company dedicated to improving the lives of patients suffering from debilitating and lifethreatening diseases through the discovery, development and commercialization of therapies that degrade disease-causing proteins. We use our PROTAC Discovery Engine, our proprietary technology platform to engineer proteolysis targeting chimeras, or PROTAC targeted protein degraders, that are designed to harness the body's own natural protein disposal system to selectively and efficiently degrade and remove disease-causing proteins. We believe that our targeted protein degradation approach is a therapeutic modality that may provide distinct advantages over existing modalities, including traditional small molecule therapies and gene-based medicines. We have a robust preclinical pipeline of PROTAC protein degraders targeting a broad range of intracellular disease targets, including those representing proteins that currently cannot be addressed by existing small molecule therapies, commonly referred to as "undruggable" targets. We are using our PROTAC Discovery Engine to build an extensive pipeline of protein degradation product candidates to target diseases in areas of unmet need, including oncology (including immuno-oncology), neuroscience and other therapeutic areas. We have three investigational clinical stage programs: Vepdegestrant (ARV-471), a novel PROTAC estrogen receptor, or ER, protein degrader for the treatment of patients with locally advanced or metastatic ER positive / human epidermal growth factor receptor 2, or HER2, negative, or ER+/HER2-, breast cancer and ARV-766 and bavdegalutamide (ARV-110), each an oral PROTAC protein degrader that targets the androgen receptor protein, or AR, for the treatment of men with metastatic castration-resistant prostate cancer, or mCRPC.

## Vepdegestrant (ARV-471)

Vepdegestrant (ARV-471) is an investigational orally bioavailable PROTAC protein degrader designed to target and degrade the ER for the treatment of patients with locally advanced or metastatic ER+/HER2- breast cancer. We are co-developing vepdegestrant with Pfizer, Inc., or Pfizer, pursuant to a collaboration agreement that we and Pfizer entered into in July 2021. We granted Pfizer worldwide co-exclusive rights to develop and commercialize vepdegestrant.

In preclinical studies, vepdegestrant demonstrated near-complete ER degradation in tumor cells, induced robust tumor shrinkage when dosed as a single agent in multiple ER-driven xenograft models and showed superior anti-tumor activity when compared to a standard of care agent, fulvestrant, both as a single agent and in combination with a cyclin-dependent kinase, or CDK, 4/6 inhibitor.

In the first quarter of 2023, we and Pfizer gained alignment with the U.S. Food and Drug Administration, or the FDA, on an approach for the planned first-line, metastatic ER+/HER2- breast cancer Phase 3 trial (VERITAC-3) of vepdegestrant in combination with IBRANCE® (palbociclib) and in the second quarter of 2023, we, along with Pfizer, initiated the study-lead in of the VERITAC-3 Phase 3 clinical trial in combination with palbociclib as a first-line treatment in patients with ER+/HER2- locally advanced or metastatic breast cancer. Moving forward, we expect to continue enrollment in the study-lead in of the VERITAC-3 Phase 3 clinical trial to evaluate the dose of palbociclib (100 mg or 75 mg) in combination with 200 mg vepdegestrant once daily. The



objective of this trial is to select a dose of palbociclib (100 mg or 75 mg) that, when dosed with vepdegestrant 200 mg, results in a similar exposure and safety profile as palbociclib 125 mg in combination with aromatase inhibitors. This approach follows the recent analysis of data from the ongoing Phase 1b/2 combination trial of vepdegestrant with palbociclib, in which an increase in palbociclib exposure was observed relative to historical palbociclib pharmacokinetic data.

We evaluated and announced preliminary data from Part C of the ongoing Phase 1b/2 ARV-471-mBC-101 trial in the second quarter of 2023. Preliminary results from the Part C dose escalation trial (November 2022 data cutoff from the Phase 1b combination of vepdegestrant with palbociclib at 125 mg) demonstrate an observed clinical benefit rate (CBR; rate of confirmed complete response, confirmed partial response, or stable disease ≥24 weeks) of 60.7% (95% CI, 40.6 – 78.5) across all dose cohorts (17 of 28 CBR-evaluable patients; patients are CBR-evaluable if they received their first dose >24 weeks prior to the cut-off). We plan, with Pfizer, to present updated data for vepdegestrant at the San Antonio Breast Cancer Symposium, including new data from the Phase 1b trial assessing vepdegestrant in combination with palbociclib in December 2023.

In the second quarter of 2023, we presented vepdegestrant preclinical data at American Association for Cancer Research (AACR) annual meeting demonstrating the potential utility of vepdegestrant as an endocrine therapy backbone for combination with other targeted agents in early and late-stage ER+/HER2- breast cancer and the potential mechanisms of acquired resistance to vepdegestrant that may be associated with alterations within Receptor Tyrosine Kinase/MAPK signaling pathways rather than ER signaling or E3 ligase machinery.

Also in the second quarter of 2023, we announced the inclusion of vepdegestrant in the I-SPY-2 (Investigation of Serial Studies to Predict Your Therapeutic Response with Imaging And moLecular Analysis 2) trial sponsored by Quantum Leap. The I-SPY-2 Endocrine Optimization Platform study will include a vepdegestrant monotherapy arm and a vepdegestrant plus letrozole arm. We were also awarded Innovation Passport Designation for vepdegestrant by the U.K. Innovative Licensing and Access Pathway Steering Group in the second quarter of 2023.

We entered into a collaboration agreement with Pfizer and Carrick Therapeutics, Inc., or Carrick, to evaluate samuraciclib in combination with vepdegestrant as part of the TACTIVE-U study in the second quarter of 2023. In the third quarter of 2023, we received a Study May Proceed letter from the U.S. Food and Drug Administration, or FDA, for the planned Phase 1b/2 clinical trial evaluating vepdegestrant in combination with Pfizer's CDK4 inhibitor, and we expect to initiate this trial in the fourth quarter of 2023. We also expect to initiate an additional arm of the Phase 1b combination umbrella trial with Carrick's CDK7 inhibitor in the future.

In the third quarter of 2023, we continued enrollment in several clinical trials for the treatment of patients with ER+/HER2- metastatic breast cancer, including the following:

- the study lead-in of the VERITAC-3 Phase 3 clinical trial of vepdegestrant with palbociclib as a first-line treatment in patients with ER+/HER2- locally advanced or metastatic breast cancer;
- VERITAC-2, a Phase 3-second-line clinical trial of vepdegestrant as a monotherapy;
- TACTIVE-U, a Phase 1b/2 clinical trial of vepdegestrant in combination with multiple targeted therapies including abemaciclib and ribociclib;
- TACTIVE-E, a clinical trial of vepdegestrant in combination with everolimus; and
- TACTIVE-N, a clinical trial of vepdegestrant as a monotherapy in the neoadjuvant setting,

Also in the third quarter of 2023, we were awarded Innovation Passport Designation for vepdegestrant by the U.K. Innovative Licensing and Access Pathway Steering Group.

In October 2023, at the European Society for Medical Oncology (ESMO), we presented updated dose escalation data from the Phase 1/2 clinical trial with vepdegestrant showing continued strong anti-tumor activity and highly differentiated tolerability.

We expect to continue enrollment for the study lead-in for the VERITAC-3 Phase 3 trial and the Phase 1b combination umbrella trial evaluating combination of vepdegestrant with abemaciclib and with ribociclib. We expect to complete enrollment in the TACTIVE-N Phase 2 trial of vepdegestrant as a monotherapy in the

neoadjuvant setting in patients with ER+/HER2- localized breast cancer in 2024. We also expect to complete enrollment of the VERITAC-2 Phase 3 trial of vepdegestrant as a monotherapy in patients with metastatic breast cancer in the second half of 2024.

## ARV-766

ARV-766 is an investigational orally bioavailable PROTAC protein degrader designed to target AR with a different profile than bavdegalutamide, as a potential treatment for men with mCRPC. In preclinical studies, ARV-766 degraded all tested resistance-driving point mutations of AR, including L702H, a mutation associated with treatment with abiraterone and other AR-pathway therapies.

In the second quarter of 2023, we presented ARV-766 preclinical data and compound structure at the AACR annual meeting and in June 2023, we shared data from the Phase 1/2 dose escalation and expansion trial of ARV-766 for the treatment of men with mCRPC. The Phase 1 dose escalation portion of the ARV-766 trial was designed to assess its safety, tolerability, and pharmacokinetics in men with mCRPC who have progressed on standard of care therapies, as well as to identify recommended Phase 2 doses for further dose optimization. The Phase 2 expansion cohort was designed to evaluate the antitumor activity of ARV-766 at the two recommended doses (100 mg and 300 mg) and determine the appropriate dose for future development.

Data from the Phase 1/2 dose escalation and expansion trial (data cut off April 2023) showed that ARV-766 was well-tolerated and demonstrated promising activity in a heavily pre-treated, post-receipt of novel hormonal agents, or NHAs, all-comers patient population. In both the Phase 1 dose escalation and Phase 2 dose expansion, 100% of patients were previously treated with at least one or more NHAs. Patients had a median of four prior lines of therapy in the Phase 1 trial and five prior lines of therapy in the Phase 2 trial. Multiple prior therapies have been associated with a decreased responsiveness to AR-directed therapies and an increase in tumor heterogeneity. AR ligand binding domain, or LBD, mutations were present in 28% (13 of 47) of patients' tumors in the Phase 1/2 trial as determined by plasma DNA analysis. Overall, 42% of patients with AR LBD mutations achieved reductions in PSA levels of greater than or equal to 50%, or PSA50. In all patients with L702H mutations, three of five patients with achieved PSA50, and three of three patients with co-occurring T878/H875/L702 mutations achieved PSA50. Response Evaluation Criteria in Solid Tumors, or RECIST, partial responses were observed. Of four patients with AR LBD mutations where RECIST was evaluable, one achieved a confirmed partial response, and one achieved an unconfirmed partial response.

ARV-766 was well tolerated and the majority of treatment related adverse events, or TRAEs, have been Grade 1 or 2, with no Grade  $\geq$ 4 TRAEs and no dose limiting toxicities. Forty-seven patients across the Phase 1 and 2 trials were evaluable for safety and, of these patients, one patient discontinued treatment due to a TRAE in Phase 2 and two of 47 patients, both in Phase 1, were dose reduced due to TRAE.

As announced at ESMO in October 2023, interim data from an updated analysis of the ongoing Phase 1/2 trial of ARV-766 (data cutoff August 23, 2023), demonstrated broad signals of efficacy and favorable tolerability in mCRPC patients with tumors harboring any AR LBD mutations, including AR L702H. The data showed a PSA50 of 41% amongst 17 patients with tumors harboring any AR LBD mutation and a PSA 50 of 50% in patients with any tumor harboring an AR L702H mutation. ARV-766 was well-tolerated in data across 84 patients who were treated as of the last data cut-off, with no grade > 4 TRAEs. The most common TRAEs were grade 1 or 2 and included fatigue (29%), nausea (14%), vomiting (11%), and diarrhea (11%). The discontinuation rate due to TRAEs was 4%.

We plan to prioritize the initiation of a Phase 3 clinical trial with ARV-766 in mCRPC instead of the previously planned Phase 3 clinical trial for bavdegalutamide and expect to initiate discussions with regulatory authorities to align on the Phase 3 program by the second quarter of 2024 for this planned Phase 3 clinical trial. We expect to continue enrollment of Phase 2 dose expansion study with ARV-766, with progression free survival data anticipated in 2024. We also anticipate initiating a Phase 1b/2 trial for ARV-766 in combination with abiraterone in patients with AR-dependent tumors who have not previously received NHAs in the fourth quarter of 2023.

## Bavdegalutamide (ARV-110)

Bavdegalutamide (ARV-110) is an investigational orally bioavailable PROTAC protein degrader designed to target and degrade the AR for the treatment of men with mCRPC.

In preclinical studies, bavdegalutamide demonstrated activity of AR mutation or overexpression, both common mechanisms of resistance to currently available AR-targeted therapies. In 2019, we initiated a Phase 1/2 clinical trial of bavdegalutamide designed to assess the safety, tolerability and pharmacokinetics of bavdegalutamide and which trial also included measures of anti-tumor activity as secondary endpoints, including reduction in prostate specific antigen, or PSA, a well-recognized biomarker of prostate cancer progression.

In the third quarter of 2023 we completed enrollment in the Phase 1b combination trial of bavdegalutamide and abiraterone.

In October 2023, we presented interim data at ESMO from the Phase 1/2 trial with bavdegalutamide (data cut-off date August 11, 2023). In a post-NHA (median prior therapies = 4) mCRPC population, bavdegalutamide at the recommend Phase 2 dose (420 mg, oral, once daily) demonstrated:

- Median radiographic progression free survival, or rPFS of 11.1 months in patients harboring AR 878/875 mutations (n=26) and median rPFS of 8.2 months in patients with tumors harboring any AR LBD mutation except L702H alone (n=45)
- PSA50 rates of 54% in patients with tumors harboring AR 878/875 mutations and 36% in patients with tumors harboring any AR LBD mutation except L702H alone
- The presence of AR L702H mutations greatly diminished the efficacy of bavdegalutamide
  - In patients with any tumor harboring an AR L702H mutation the PSA50 was 8%
- Bavdegalutamide had a manageable tolerability profile with no grade > 4 treatment-related adverse events (TRAEs). The most common TRAEs were nausea (56%), fatigue (35%), vomiting (33%), decreased appetite (25%) and diarrhea (24%). The discontinuation rate due to TRAEs was 12%.

We expect to continue ongoing trial activities with bavdegalutamide (ARV-110-101 and ARV-110-103) as planned.

#### Pipeline

We are further diversifying our pipeline by developing new PROTAC targeted protein degraders against targets for which we believe protein degradation offers advantages to existing therapeutic modalities, including PROTAC degraders that are designed to reach targets in deep brain regions and are capable of being delivered through multiple routes of administration, including oral delivery. We have engineered PROTAC targeted protein degraders that, in preclinical studies, have successfully achieved blood-brain barrier penetration, a key step in developing drugs with the potential to treat neurodegenerative diseases. We believe there are many other indications for which our PROTAC technology may be advantageous.

In April 2023, we presented in-vivo and in-vitro data at AACR - Targeting RAS Special Conference demonstrating our G12D PROTAC degraders are potent, selective and led to tumor stasis in a mouse xenograft model with intermittent dosing and degradation of KRAS G12D provides an advantage vs. inhibition *in vitro* and *in vivo*. We also presented new preclinical data at the CHDI Foundation's Annual Huntington's Disease Therapeutics Conference showing our PROTAC degraders potently and selectively degraded soluble mutant huntingtin (mHTT) in multiple cellular readouts, including rodent neurons, while sparing wild-type HTT.

By year-end 2023, we expect to submit an investigational new drug, or IND, application or clinical trial application, or CTA, for our PROTAC degrader designed to target each of the BCL6 protein, a protein mutated in patients with different forms of Non-Hodgkins Lymphoma, including Diffuse Large B-Cell Lymphoma, and the LRRK2 protein, a protein kinase that has been genetically linked to some forms of Parkinson's Disease and Progressive supranuclear palsy (PSP). We also expect to progress at least two additional PROTAC protein degrader programs into IND-enabling or CTA-enabling studies by year-end 2023.

## **Our Operations**

We commenced operations in 2013. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, conducting discovery and research activities, filing patent applications, identifying potential product candidates, undertaking preclinical studies and clinical trials and

establishing arrangements with third parties for the manufacture of initial quantities of our product candidates. To date, we have not generated any revenue from product sales and have financed our operations primarily through sales of our equity interests, proceeds from our collaborations, grant funding and debt financing. Since inception through September 30, 2023, we raised approximately \$1.3 billion in gross proceeds from the sale of equity instruments and the exercise of stock options and had received an aggregate of \$783.0 million in payments primarily from collaboration partners.

We are a clinical-stage company. Vepdegestrant (ARV-471), ARV-766 and bavdegalutamide (ARV-110) are each in Phase 1/2 clinical trials and vepdegestrant is also in two Phase 3 clinical trials. In October 2023 we announced that we plan to prioritize the initiation of a Phase 3 clinical trial in mCRPC with ARV-766 following discussions with regulatory authorities, which discussions we expect will occur by the second quarter of 2024. Our other drug discovery activities are at the research and preclinical development stages. Our ability to generate revenue from product sales sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. Since inception, we have incurred significant operating losses and expect to incur increasing operating losses for at least the next several years due to costs associated with our ongoing and anticipated clinical activities in oncology, neurological and other disease areas to expand our pipeline, hiring additional personnel in research, clinical trials, quality and other functional areas, increased expenses incurred with contract manufacturing organizations to supply us with product for our preclinical studies and clinical trials and contract research organizations for the synthesis of compounds in our preclinical development activities, as well as other associated costs including the management of our intellectual property portfolio.

We do not expect to generate any revenue from sales of product in the near future, if ever. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research or product development programs or any future commercialization efforts, or 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.

## **Financial Operations Overview**

#### Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the near future. Our revenues to date have been generated through research collaboration and license agreements. Revenue is recognized ratably over our expected performance period under each agreement. We expect that any revenue recognized in the near term will be derived from our current collaboration agreements and any additional collaborations that we may enter into in the future. To date, we have not received any sales-based milestone payments or royalties under any of the collaboration agreements.

#### **Genentech License Agreement**

In September 2015, we entered into an Option and License Agreement with Genentech, Inc. and F. Hoffmann-La Roche Ltd, collectively referred to as Genentech, focused on PROTAC targeted protein degrader discovery and research for target proteins, or Targets, based on our proprietary platform technology, other than excluded Targets as described below. This collaboration was expanded in November 2017 through an Amended and Restated Option, License and Collaboration Agreement, which we refer to as the Restated Genentech Agreement.

Under the Restated Genentech Agreement, Genentech has the right to designate up to ten Targets for further discovery and research utilizing our PROTAC platform technology. Genentech may designate as a Target any protein to which a PROTAC targeted protein degrader, by design, binds to achieve its mechanism of action, subject to certain exclusions. Genentech also has the right to remove a Target from the collaboration and substitute a different Target that is not an excluded Target at any time prior to us commencing research on such Target or in certain circumstances following commencement of research by us.



At the time we entered into the original agreement with Genentech, we received an upfront payment of \$11.0 million, and at the time we entered into the Restated Genentech Agreement, we received an additional \$34.5 million in upfront and expansion target payments. We are eligible to receive payments aggregating up to \$44.0 million per Target upon the achievement of specified development milestones; payments aggregating up to \$52.5 million per Target (assuming approval of two indications) subject to the achievement of specified regulatory milestones; and payments aggregating up to \$60.0 million per PROTAC targeted protein degrader directed against the applicable Target, subject to the achievement of specified sales milestones. These milestone payments are subject to reduction if we do not have a valid patent claim covering the licensed PROTAC targeted protein degrader at the time the milestone is achieved. We are also eligible to receive, on net sales of licensed PROTAC targeted protein degraders, mid-single digit royalties, which may be subject to reductions.

## Pfizer Research Collaboration Agreement

In December 2017, we entered into a Research Collaboration and License Agreement with Pfizer, setting forth our collaboration to identify or optimize PROTAC targeted protein degraders that mediate for degradation of Targets, using our proprietary platform technology that are identified in the agreement or subsequently selected by Pfizer, subject to certain exclusions. We refer to this agreement as the Pfizer Research Collaboration Agreement.

Under the Pfizer Research Collaboration Agreement, Pfizer has designated a number of initial Targets. For each identified Target, we and Pfizer will conduct a separate research program pursuant to a research plan. Pfizer may make substitutions for any of the initial Target candidates, subject to the stage of research for such Target.

In the year ended December 31, 2018, we received an upfront non-refundable payment and certain additional payments totaling \$28.0 million in exchange for use of our technology license and to fund Pfizer-related research, as defined within the Pfizer Research Collaboration Agreement. We are eligible to receive up to an additional \$37.5 million in non-refundable option payments if Pfizer exercises its options for all targets under the Pfizer Research Collaboration Agreement. We are also entitled to receive up to \$225.0 million in development milestone payments and up to \$550.0 million in sales-based milestone payments for all designated targets under the Pfizer Research Collaboration Agreement, as well as mid- to high-single digit tiered royalties, which may be subject to reductions, on net sales of PROTAC targeted protein degrader-related products. In the nine months ended September 30, 2023 and 2022, we received payments totaling \$1.0 million and \$3.5 million which were included in accounts receivable as of December 31, 2022 and 2021, respectively, for additional targets and services.

#### **Bayer Collaboration Agreement**

In June 2019, we entered into a Collaboration and License Agreement, or the Bayer Collaboration Agreement, with Bayer AG, or, together with its controlled affiliates, Bayer, setting forth our collaboration to identify or optimize PROTAC targeted protein degraders that mediate for degradation of Targets, using our proprietary platform technology, that are selected by Bayer, subject to certain exclusions and limitations. The Bayer Collaboration Agreement became effective in July 2019.

Under the Bayer Collaboration Agreement, we and Bayer conduct a research program pursuant to separate research plans mutually agreed to by us and Bayer and tailored to each Target selected by Bayer. Bayer may make substitutions for any such initial Target candidates, subject to certain conditions and based on the stage of research for such Target. During the term of the Bayer Collaboration Agreement, we are not permitted, either directly or indirectly, to design, identify, discover or develop any small molecule pharmacologically-active agent whose primary mechanism of action is, by design, directed to the inhibition or degradation of any Target selected or reserved by Bayer, or grant any license, covenant not to sue or other right to any third party in the field of human disease under the licensed intellectual property for the conduct of such activities.

Under the terms of the Bayer Collaboration Agreement, we received an aggregate upfront non-refundable payment of \$17.5 million. Bayer was committed to fund a total of \$12.0 million in research funding payments through 2023, all of which was received from inception through March 31, 2023. We are also eligible to receive up to \$197.5 million in development milestone payments and up to \$490.0 million in sales-based

milestone payments for all designated Targets. In addition, we are eligible to receive, on net sales of PROTAC targeted protein degraderrelated products, mid-single digit to low-double digit tiered royalties, which may be subject to reductions.

## Pfizer Vepdegestrant (ARV-471) Collaboration Agreement

In July 2021, we entered into a Collaboration Agreement with Pfizer, or the Vepdegestrant (ARV-471) Collaboration Agreement, pursuant to which we granted Pfizer worldwide co-exclusive rights to develop and commercialize products containing our proprietary compound ARV-471, or the Licensed Products.

Under the Vepdegestrant (ARV-471) Collaboration Agreement, we received an upfront, non-refundable payment of \$650.0 million. In addition, we are eligible to receive up to an additional \$1.4 billion in contingent payments based on specified regulatory and sales-based milestones for the Licensed Products. Of the total contingent payments, \$400 million in regulatory milestones are related to marketing approvals and \$1.0 billion are related to sales-based milestones.

We and Pfizer share equally (50/50) all development costs (including costs for conducting any clinical trials) for the Licensed Products, subject to certain exceptions. Except for certain regions described below, we will also share equally (50/50) all profits and losses in commercialization and medical affairs activities for the Licensed Products in all other countries, subject to certain exceptions.

We will be the marketing authorization holder and, subject to marketing approval, book sales in the United States, while Pfizer will hold marketing authorizations outside the United States. We will determine with Pfizer which, if any, regions within the world will be solely commercialized by one party, and in such region the parties will adjust their share of all profits and losses for the Licensed Products based on the role each party will be performing.

Unless earlier terminated in accordance with its terms, the Vepdegestrant (ARV-471) Collaboration Agreement will expire on a Licensed Product-by-Licensed Product and country-by-country basis when such Licensed Products are no longer commercialized or developed for commercialization in such country. Pfizer may terminate the Vepdegestrant (ARV-471) Collaboration Agreement for convenience in its entirety or on a region-by-region basis subject to certain notice periods. Either party may terminate the Vepdegestrant (ARV-471) Collaboration Agreement for the other party's uncured material breach or insolvency. Subject to applicable terms of the Vepdegestrant (ARV-471) Collaboration Agreement, including certain payments to Pfizer upon termination for our uncured material breach, effective upon termination of the Vepdegestrant (ARV-471) Collaboration Agreement, we are entitled to retain specified licenses to be able to continue to exploit the Licensed Products.

Subject to specified exceptions, we and Pfizer have each agreed not to directly or indirectly research, develop, or commercialize any competing products outside of the Vepdegestrant (ARV-471) Collaboration Agreement anywhere in the world during the term of the Vepdegestrant (ARV-471) Collaboration Agreement.

#### **Operating Expenses**

Our operating expenses since inception have consisted solely of research and development costs and general and administrative costs.

#### **Research and Development Expenses**

Research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts, and the development of our product candidates, and include:

- salaries, benefits and other related costs, including stock-based compensation expense, for personnel engaged in research and development functions;
- expenses incurred under agreements with third parties, including CROs and other third parties that conduct research and
  preclinical activities on our behalf as well as third parties that manufacture our product candidates for use in our preclinical
  studies and clinical trials;



- costs of outside consultants, including their fees, stock-based compensation and related travel expenses;
- the costs of laboratory supplies and developing preclinical studies and clinical trial materials;
- facility-related expenses, which include direct depreciation costs of equipment and allocated expenses for rent and maintenance of facilities and other operating costs; and
- third-party licensing fees.

We expense research and development costs as incurred.

We typically use our employee and infrastructure resources across our development programs, and as such, do not track all of our internal research and development expenses on a program-by-program basis. The following table summarizes our research and development expenses for our AR program, which includes ARV-766 and bavdegalutamide, ER program, which includes vepdegestrant (ARV-471), and all other platform and exploratory research and development costs:

	For the Three Months Ended September 30,					For the Nine Months Ended September 30,					
(in millions)		2023		2022		2023		2022			
AR program development costs	\$	18.6	\$	13.4	\$	56.9	\$	40.7			
ER program development costs		22.3		16.1		82.1		51.1			
Other research and development costs		45.0		48.0		145.5		124.9			
Total research and development costs	\$	85.9	\$	77.5	\$	284.5	\$	216.7			

Research and development activities are central to our business model. We expect that our research and development expenses will continue to increase substantially for the foreseeable future as we continue to conduct our ongoing clinical trials for vepdegestrant, ARV-766 and bavdegalutamide, including our Phase 3 clinical trials for vepdegestrant and planned clinical trials of ARV-766, and continue to discover and develop additional product candidates. Research and development expenses related to vepdegestrant are shared equally with Pfizer since July 22, 2021, the effective date of the Vepdegestrant (ARV-471) Collaboration Agreement. The ER program development costs in the table above reflect the cost sharing with Pfizer.

We cannot determine with certainty the duration and costs of future clinical trials of vepdegestrant, ARV-766 and bavdegalutamide or any other product candidate we may develop or if, when, or to what extent we will generate revenue from the commercialization and sale of any product candidate for which we obtain marketing approval. We may never succeed in obtaining marketing approval for any product candidate. The successful development and commercialization of our product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- successful completion of preclinical studies and clinical trials;
- receipt and related terms of marketing approvals from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our product candidates;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- obtaining and maintaining third-party coverage and adequate reimbursement;
- maintaining a continued acceptable safety profile of the products following approval; and

effectively competing with other therapies.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in our clinical trials due to patient enrollment or other reasons, we would be required to expend significant additional financial resources and time on the completion of clinical development.

## General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation for personnel in our executive, finance, business development and administrative functions. General and administrative expenses also include legal fees relating to intellectual property and corporate matters; professional fees for accounting, auditing, tax and consulting services; insurance costs; travel expenses; and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expect that our general and administrative expenses will increase in the future as we increase our personnel headcount to support increased research and development activities relating to our product candidates and develop our commercial operations. We also expect to incur increased expenses associated with being a public company, including costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with the Nasdaq Stock Market and Securities and Exchange Commission requirements; director and officer insurance costs; and investor and public relations costs.

## Income Taxes

Since our inception in 2013 through December 31, 2022, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in any year or for our federal or state earned research and development tax credits, due to our uncertainty of realizing a benefit from those items. During the year ended December 31, 2022, we fully utilized our previously held federal net operating loss and federal credit carryforwards due to taxable income resulting from revenue recognition for tax purposes from our Vepdegestrant (ARV-471) Collaboration Agreement and the mandatory capitalization of qualified research and development expenses incurred on or after January 1, 2022 under the Tax Cuts and Jobs Act. For the nine months ended September 30, 2023 we recorded a tax benefit related to expected benefits from state net operating loss carryback claims. We expect to generate federal and state net operating losses and credit carryforwards in 2023 and future periods. The revenue recognition and capitalization of research expenses are timing differences for tax purposes and deferred tax assets were established. We have provided a valuation allowance against the full amount of the deferred tax assets since, in the opinion of management, based upon our earnings history, it is more likely than not that the benefits will not be realized.

As of September 30, 2023, Arvinas, Inc. had four wholly-owned subsidiaries organized as C-corporations: Arvinas Operations, Inc., Arvinas Androgen Receptor, Inc., Arvinas Estrogen Receptor, Inc., and Arvinas Winchester, Inc.

## **Critical Accounting Estimates**

Our management's discussion and analysis of financial condition and results of operations is based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our unaudited condensed consolidated financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses and the disclosure of contingent assets and liabilities in our unaudited condensed consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.



There have been no material changes to our critical accounting estimates from those described in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission on February 23, 2023.

#### **Results of Operations**

## Comparison of the Three and Nine Months Ended September 30, 2023 and 2022

	For the Three Months Ended September 30,					For the Nine Months Ended September 30,				For the		
(dollars in millions)		2023		2022	 \$ change		2023		2022		\$ change	
Revenue	\$	34.6	\$	33.2	\$ 1.4	\$	121.6	\$	93.6	\$	28.0	
Research and development expenses		(85.9)		(77.5)	(8.4)		(284.5)		(216.7)		(67.8)	
General and administrative expenses		(22.6)		(20.0)	(2.6)		(73.3)		(64.5)		(8.8)	
Other income		10.0		3.2	6.8		25.5		5.9		19.6	
Income tax (expense) benefit				(2.2)	2.2		0.7		(10.1)		10.8	
Loss from equity method investments		(0.1)		(2.9)	2.8		(2.5)		(7.8)		5.3	
Net loss	\$	(64.0)	\$	(66.2)	\$ 2.2	\$	(212.5)	\$	(199.6)	\$	(12.9)	

#### Revenues

Revenues for the three months ended September 30, 2023 totaled \$34.6 million, compared to \$33.2 million for the three months ended September 30, 2022. The increase of \$1.4 million was primarily due to an increase in revenue from the Vepdegestrant (ARV-471) Collaboration Agreement with Pfizer totaling \$6.4 million, partially offset by a decrease of \$2.8 million of previously constrained deferred revenue related to our Oerth Bio joint venture and a decrease of \$1.8 million of revenue under the Genentech Amended and Restated Option, License, and Collaboration Agreement as the performance period has concluded.

Revenues for the nine months ended September 30, 2023 totaled \$121.6 million, compared to \$93.6 million for the nine months ended September 30, 2022. The increase of \$28.0 million was primarily due to an increase in revenue from the Vepdegestrant (ARV-471) Collaboration Agreement with Pfizer totaling \$46.5 million, partially offset by a decrease of \$5.3 million of previously constrained deferred revenue related to our Oerth Bio joint venture, a decrease of \$3.4 million of revenue under the Genentech Amended and Restated Option, License, and Collaboration Agreement as the performance period has concluded and a net decrease in revenue totaling \$8.2 million due to extensions of the period of revenue recognition under both the Pfizer Research Collaboration Agreement and Bayer Collaboration Agreement.

## **Research and Development Expenses**

Research and development expenses for the three months ended September 30, 2023 totaled \$85.9 million, compared to \$77.5 million for the three months ended September 30, 2022. The increase of \$8.4 million was primarily due to increases in our AR and ER programs of \$5.2 million and \$6.2 million, respectively, offset by a decrease in our platform and exploratory programs of \$3.0 million. The increase over all of our programs was driven by clinical trial costs and related drug manufacturing costs of \$5.6 million within our AR and ER programs. Additionally, personnel and infrastructure related costs increased by \$2.4 million.

Research and development expenses for the nine months ended September 30, 2023 totaled \$284.5 million, compared to \$216.7 million for the nine months ended September 30, 2022. The increase of \$67.8 million was primarily due to increases in our AR and ER programs of \$16.2 million and \$31.0 million, respectively, as well as an increased investment in our platform and exploratory programs of \$20.6 million. The increase over all of our programs was primarily driven by clinical trial costs and related drug manufacturing

costs of \$33.1 million as we expanded our AR and ER programs into additional clinical trials. Expenses related to our platform and exploratory targets also increased by \$16.1 million as we continued to expand the number of protein targets in the exploratory and lead optimization phases and continued to make investments into our platform discovery efforts. Additionally, personnel and infrastructure related costs increased by \$18.5 million.

## General and Administrative Expenses

General and administrative expenses totaled \$22.6 million for the three months ended September 30, 2023, compared to \$20.0 million for the three months ended September 30, 2022. The increase of \$2.6 million was primarily due to increased personnel and infrastructure related costs of \$1.1 million, increased spending in developing our commercial operations of \$1.0 million and an increase in professional fees of \$0.5 million.

General and administrative expenses totaled \$73.3 million for the nine months ended September 30, 2023, compared to \$64.5 million for the nine months ended September 30, 2022. The increase of \$8.8 million was primarily due to an increase in professional fees of \$4.5 million, increased spending in personnel and infrastructure related costs of \$3.0 million and in developing our commercial operations of \$1.8 million, offset in part by reduced insurance costs of \$0.9 million.

#### Other Income

Other income totaled \$10.0 million for the three months ended September 30, 2023, compared to \$3.2 million for the three months ended September 30, 2022. The increase of \$6.8 million was primarily due to higher interest income from higher interest rates.

Other income totaled \$25.5 million for the nine months ended September 30, 2023, compared to \$5.9 million for the nine months ended September 30, 2022. The increase of \$19.6 million was primarily due to higher interest income of \$20.3 million from higher interest rates, offset in part by higher realized losses on our marketable securities of \$0.5 million and foreign exchange losses of \$0.2 million.

## Income Tax Expense

Income tax expense totaled zero for the three months ended September 30, 2023, compared to an income tax expense of \$2.2 million for the three months ended September 30, 2022. Current year tax expense was driven by valuation allowance recorded against the full amount of its net deferred tax assets. Prior year tax expense was driven by revenue recognition for tax purposes from our Vepdegestrant (ARV-471) Collaboration Agreement and the capitalization of research and development expenses incurred on or after January 1, 2022.

Income tax benefit totaled \$0.7 million for the nine months ended September 30, 2023, compared to an income tax expense of \$10.1 million for the nine months ended September 30, 2022. Current year tax benefit was driven by expected benefits from state net operating loss carryback claims. Prior year tax expense was driven by revenue recognition for tax purposes from our Vepdegestrant (ARV-471) Collaboration Agreement and the capitalization of research and development expenses incurred on or after January 1, 2022. Under the Tax Cuts and Jobs Act of 2017, qualified research expenses incurred after 2021 are no longer immediately deductible for tax purposes and instead must be amortized over 5 years for tax purposes. As a result of these items, we fully utilized our federal net operating loss and credit carryforwards in 2022, which resulted in income tax expense for the prior period.

# Loss from Equity Method Investment

Loss from equity method investment totaled \$0.1 million for the three months ended September 30, 2023, compared to \$2.9 million for the three months ended September 30, 2022. The decrease of \$2.8 million was due to fully recognizing the remaining constrained revenue and the equity method losses during the three months ended September 30, 2023. See Note 12, *Equity Method Investments*, to the unaudited condensed consolidated financial statements for further details.



Loss from equity method investment totaled \$2.5 million for the nine months ended September 30, 2023, compared to \$7.8 million for the nine months ended September 30, 2022. The decrease of \$5.3 million was due to lower net losses incurred by Oerth Bio for the nine months ended September 30, 2023 and fully recognizing the remaining constrained revenue and the related equity method losses during the three months ended September 30, 2023. See Note 12, *Equity Method Investments*, to the unaudited condensed consolidated financial statements for further details.

## Liquidity and Capital Resources

#### Overview

We do not currently have any approved products and have never generated any revenue from product sales. To date, we have financed our operations primarily through the sale of equity interests and through payments from collaboration partners, grant funding and loans from the State of Connecticut. Since inception through September 30, 2023, we had received an aggregate of \$783.0 million in payments from collaboration partners, grant funding and forgivable and partially forgivable loans from the State of Connecticut, and raised approximately \$1.3 billion in gross proceeds from the sale of equity interests and the exercise of stock options, including:

- October 2018: completion of our initial public offering in which we issued and sold an aggregate of 7,700,482 shares of common stock, for aggregate gross proceeds of \$123.2 million before fees and expenses;
- July 2019: sale of 1,346,313 shares of common stock to Bayer AG for aggregate gross proceeds of \$32.5 million;
- November 2019: completion of a follow-on offering in which we issued and sold 5,227,273 shares of common stock for aggregate gross proceeds of \$115.0 million before fees and expenses;
- September December 2020: sale of 2,593,637 shares of common stock in an "at-the-market offering" for aggregate gross proceeds of \$65.6 million before fees and expenses;
- December 2020: completion of a follow-on offering in which we issued and sold 6,571,428 shares of common stock for aggregate gross proceeds of \$460.0 million before fees and expenses;
- September 2021: issuance of 3,457,815 shares of common stock to Pfizer for aggregate gross proceeds of \$350.0 million; and
- July September 2023: sale of 1,449,275 shares of common stock in an "at-the-market offering" for aggregate gross proceeds of \$37.1 million before fees and expenses.

In May 2021, we entered into a lease, which was amended in August 2022, for approximately 160,000 square feet of laboratory and office space, expected to be occupied in 2025. Once occupied, the base rent will range from \$7.7 million to \$8.8 million annually over a tenyear lease term. In connection with the signing of the lease and the related amendment, and at our election to increase the landlord's contribution to the tenant improvement allowance, we initially issued a letter of credit totaling \$4.5 million, which was subsequently increased to \$5.5 million, collateralized by a certificate of deposit in the same amount.

In August 2021, we entered into an Equity Distribution Agreement with Piper Sandler & Company and Cantor Fitzgerald & Co., as agents, pursuant to which we may offer and sell from time to time, through the agents, up to \$300.0 million of the common stock registered under our universal shelf registration statement pursuant to one or more "at-the-market" offering. During the three months ended September 30, 2023, we issued 1,449,275 shares of common stock under this agreement, resulting in net proceeds of approximately \$36.0 million, net of offering costs of approximately \$1.1 million.

# Cash Flows

Our cash, cash equivalents, restricted cash and marketable securities totaled \$1.0 billion as of September 30, 2023 and \$1.2 billion as of December 31, 2022. We had an outstanding loan balance of \$1.0 million as of September 30, 2023 and December 31, 2022.



The following table summarizes our sources and uses of cash for the period presented:

	For the Nine I Septen		
(dollars in millions)	 2023	2022	\$ change
Net cash used in operating activities	\$ (264.7)	\$ (202.3)	\$ (62.4)
Net cash provided by investing activities	257.2	223.4	33.8
Net cash provided by financing activities	39.9	4.2	35.7
Net increase in cash, cash equivalents and restricted cash	\$ 32.4	\$ 25.3	\$ 7.1

## **Operating Activities**

Net cash used in operating activities for the nine months ended September 30, 2023 increased by \$62.4 million, compared with the nine months ended September 30, 2022, primarily due to an increase in our net loss of \$12.9 million, increased reduction in deferred revenue of \$34.9 million and a decrease in cash flows from accounts receivable of \$28.7 million, partially offset by changes in account payable and accrued expenses of \$21.0 million and prepaid expenses and other current assets of \$14.3 million. Non-cash charges decreased by \$18.5 million, primarily due to net accretion of bond discounts/premiums of \$18.1 million.

## **Investing Activities**

Net cash provided by investing activities for the nine months ended September 30, 2023 increased by \$33.8 million, compared with the nine months ended September 30, 2022, due to an increase in purchases and maturities of marketable securities in excess of net sales of \$30.9 million and a decrease in purchases of property and equipment of \$2.9 million.

## **Financing Activities**

Net cash provided by financing activities for the nine months ended September 30, 2023 increased by \$35.7 million, compared with the nine months ended September 30, 2022, primarily due to net proceeds received from our "at-the-market" offering of \$36.0 million.

## **Funding Requirements**

Since our inception, we have incurred significant operating losses. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future as we advance the preclinical and clinical development of our product candidates.

Specifically, we anticipate that our expenses will increase substantially if, and as we:

- continue clinical trials of our product candidate vepdegestrant (ARV-471) to treat patients with locally advanced or metastatic ER+/HER2- breast cancer, including progressing the study-lead in trial of VERITAC-3, a Phase 3 clinical trial of vepdegestrant in combination with palbociclib, VERITAC-2, a Phase 3 monotherapy clinical trial, a Phase 1b combination trial of vepdegestrant in combination with palbociclib, as well as a Phase 1b/2 trial with vepdegestrant with Pfizer's CDK4 inhibitor and initiate an additional arm of the Phase 1b/2 combination umbrella clinical trial of vepdegestrant with Carrick Therapeutics, Inc.'s CDK7 inhibitor;
- continue clinical trials of our product candidate ARV-766 for the treatment of men with mCRPC, including progressing the Phase 1/2 dose escalation and expansion trial of ARV-766, initiating a Phase 1b/2 dose escalation trial of ARV-766 in combination with abiraterone in patients who have not previously received novel hormonal agents and initiating a Phase 3 clinical trial with mCRPC of ARV-766, and initiating a Phase 3 clinical trial;
- continue ongoing clinical trials of our product candidate bavdegalutamide (ARV-110) for the treatment of men with mCRPC;
- submit IND and CTA applications for our BCL6 and our LRRK2 PROTAC protein degraders, respectively, with regulators;



- progress additional PROTAC protein degrader programs into IND- or CTA-enabling studies;
- apply our PROTAC Discovery Engine to advance additional product candidates into preclinical and clinical development;
- expand the capabilities of our PROTAC Discovery Engine;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- ultimately establish a sales, marketing and distribution infrastructure and scale up external manufacturing capabilities to commercialize any products for which we may obtain marketing approval;
- expand, maintain and protect our intellectual property portfolio;
- hire additional development, including clinical and regulatory, and scientific personnel; and
- add operational, financial and management information systems and personnel to support our research, product development and future commercialization efforts and continue to support our operations as a public company.

We had cash, cash equivalents, restricted cash and marketable securities totaling approximately \$1.0 billion as of September 30, 2023. We believe that our cash, cash equivalents, restricted cash and marketable securities as of September 30, 2023 will enable us to fund our planned operating expenses and capital expenditure requirements into 2026. We have based this estimate on assumptions that may prove to be wrong and we could use our capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the progress, costs and results of our ongoing and planned clinical trials for vepdegestrant (ARV-471), ARV-766 and bavdegalutamide (ARV-110) and any future clinical development of vepdegestrant, ARV-766 and bavdegalutamide;
- the scope, progress, costs and results of preclinical and clinical development for our other product candidates and development programs, including BCL6 and LRRK2;
- the number of, and development requirements for, other product candidates that we pursue, including our other oncology and neurodegenerative research programs;
- the success of our collaborations with Pfizer, Genentech and Bayer;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and
- our ability to establish additional collaboration arrangements with other biotechnology or pharmaceutical companies on favorable terms, if at all, for the development or commercialization of our product candidates.

As a result of these anticipated expenditures, we will need to obtain substantial additional financing in connection with our continuing operations. Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. Although we may receive potential future payments under our collaborations with Pfizer, Genentech and Bayer, we do not currently have any committed external source of funds. Adequate additional funds may not be available to us on

acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we may be required to delay, limit, reduce or terminate our research, product development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution 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.

## Borrowings

In June 2018, we entered into an additional assistance agreement with the State of Connecticut, or the 2018 Assistance Agreement, to provide funding for the expansion and renovation of laboratory and office space. We borrowed \$2.0 million under the 2018 Assistance Agreement in September 2018, of which \$1.0 million was forgiven upon meeting certain employment conditions. Borrowings under the agreement bear an interest rate of 3.25% per annum, with interest only payments required for the first 60 months, and mature in September 2028. The 2018 assistance agreement requires that we be located in the State of Connecticut through September 2028 with a default penalty of repayment of the full original funding amount of \$2.0 million plus liquidated damages of 7.5% of the total amount of funding received. As of September 30, 2023, \$1.0 million remains outstanding under the 2018 Assistance Agreement.

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

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. Our interest-earning assets consist of cash, cash equivalents, restricted cash and marketable securities. Interest income earned on these assets totaled \$26.6 million and \$6.3 million for the nine months ended September 30, 2023 and 2022, respectively. Our interest income is sensitive to changes in the general level of interest rates, primarily U.S. interest rates. As of September 30, 2023, our cash equivalents consisted of bank deposits and money market funds, and our marketable securities included interest-earning securities. Our outstanding debt totaled \$1.0 million as of September 30, 2023 and December 31, 2022 and carries a fixed interest rate of 3.25% per annum.

#### Item 4. Controls and Procedures.

## **Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2023. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the 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 Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures 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, without limitation, controls and procedures 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 accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our 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, 2023, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

## Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended September 30, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II—OTHER INFORMATION

## Item 1. Legal Proceedings.

From time to time, we may become involved in litigation or other legal proceedings arising in the ordinary course of business and regardless of outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of defense and settlement costs, diversion of management resources and other factors. We are not currently a party to any material legal proceedings.

## Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties discussed in "Part I, Item 1A, Risk Factors," in our Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on February 23, 2023 together with all of the other information contained in this Quarterly Report on Form 10-Q, including our unaudited condensed consolidated financial statements and the related notes appearing elsewhere in this Quarterly Report on Form 10-Q. The risk factor disclosure in our Annual Report on Form 10-K for the year ended December 31, 2022 is qualified by the information that is described in this Quarterly Report on Form 10-Q. If any of the risks described in our Annual Report on Form 10-K for the year ended December 31, 2022 actually occur, our business, prospects, operating results and financial condition could suffer materially. In such event, the trading price of our common stock could decline and you might lose all or part of your investment.

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

## **Recent Sales of Unregistered Securities**

We did not issue any securities that were not registered under the Securities Act during the three and nine months ended September 30, 2023.

## Item 5. Other Information

## **Director and Officer Trading Arrangements**

None of our directors or officers adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K) during the quarterly period covered by this Quarterly Report on Form 10-Q.



# Item 6. Exhibits.

Exhibit Number	Description
3.1	Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-38672) filed with the SEC on October 1, 2018).
3.2	<u>Second Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.1 to</u> the Registrant's Current Report on Form 8-K (File No. 001-38672) filed with the SEC on June 21, 2023).
31.1*	<u>Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the</u> <u>Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of</u> <u>2002.</u>
31.2*	<u>Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the</u> <u>Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of</u> <u>2002.</u>
32.1**	<u>Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to</u> <u>Section 906 of the Sarbanes-Oxley Act of 2002.</u>
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL 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.
104.00	Cover Page Interactive Date File (formatted as Inline XBRL and contained in Exhibit 101).

\* Filed herewith.

\*\* 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.

	Arvinas	s, Inc.
Date: November 7, 2023	By:	/s/ John Houston, Ph.D.
		John Houston, Ph.D. President and Chief Executive Officer (Principal Executive Officer)
Date: November 7, 2023	By:	/s/ Sean Cassidy
		Sean Cassidy
		Chief Financial Officer, Treasurer and Secretary (Principal Financial Officer)
Date: November 7, 2023	By:	/s/ David K. Loomis
		David K. Loomis
		Vice President and Chief Accounting Officer (Principal Accounting Officer)

## CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, John Houston, Ph.D., certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of Arvinas, Inc.;
- 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.

Date: November 7, 2023

By:

/s/ John Houston, Ph.D.

John Houston, Ph.D. President and Chief Executive Officer (Principal Executive Officer)

## CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Sean Cassidy, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of Arvinas, Inc.;
- 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.

Date: November 7, 2023

By:

/s/ Sean Cassidy

Sean Cassidy Chief Financial Officer and Treasurer (Principal Financial Officer)

## **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 of Arvinas, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

Date: November 7, 2023

/s/ John Houston, Ph.D.

Ву: John Houston, Ph.D. **President and Chief Executive Officer** (Principal Executive Officer)

## 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 of Arvinas, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (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 result of operations of the Company.

Date: November 7, 2023

By:

/s/ Sean Cassidy

Sean Cassidy Chief Financial Officer and Treasurer (Principal Financial Officer)