

**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 June 30, 2022

OR

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

For the transition period from to .
Commission File Number: 001-38672

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:

Title of each class	Trading 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 No

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

As of July 29, 2022, the registrant had 53,205,299 shares of common stock, \$0.001 par value per share, outstanding.

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FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements 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,” “predict,” “project,” “target,” “potential,” “goals,” “will,” “would,” “could,” “should,” “continue” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

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 bavdegalutamide, ARV-471 and ARV-766, 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 bavdegalutamide, ARV-471 and ARV-766, and the ability of bavdegalutamide, ARV-471, ARV-766 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 ARV-471 Collaboration;
- our plans to pursue research and development of other product candidates;
- 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 COVID-19 on our business and operations;
- 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, 2021, filed on February 28, 2022, 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 that we make. Our 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 be materially different from what we expect. We do not assume any obligation to update any forward-looking statements except as required by applicable law.

In this Quarterly Report on Form 10-Q, unless otherwise stated or the context otherwise requires, references to the “Company,” “Arvinas,” “we,” “us,” and “our,” except where the context requires otherwise, refer to Arvinas, Inc. and its consolidated subsidiaries, 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.

We use Arvinas, the Arvinas logo, and other marks as trademarks in the United States and other countries. 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.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

ARVINAS, INC. AND SUBSIDIARIES

Condensed Consolidated Balance Sheets (unaudited)

<i>(dollars and shares in millions)</i>	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 93.2	\$ 108.3
Restricted cash	4.5	4.5
Marketable securities	1,250.0	1,394.3
Accounts receivable	1.4	15.0
Other receivables	6.7	10.7
Prepaid expenses and other current assets	20.6	19.7
Total current assets	1,376.4	1,552.5
Property, equipment and leasehold improvements, net	13.6	12.7
Operating lease right of use assets	5.3	3.9
Collaboration contract asset and other assets	11.7	12.5
Total assets	\$ 1,407.0	\$ 1,581.6
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 42.1	\$ 54.4
Deferred revenue	194.4	206.2
Current portion of operating lease liability	1.7	1.1
Total current liabilities	238.2	261.7
Deferred revenue	493.6	534.3
Long term debt	1.0	1.0
Operating lease liability	3.6	2.9
Total liabilities	736.4	799.9
Commitments and Contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value; 53.2 and 53.0 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	0.1	—
Accumulated deficit	(816.3)	(682.9)
Additional paid-in capital	1,508.8	1,469.2
Accumulated other comprehensive loss	(22.0)	(4.6)
Total stockholders' equity	670.6	781.7
Total liabilities and stockholders' equity	\$ 1,407.0	\$ 1,581.6

See accompanying notes to the condensed consolidated financial statements

ARVINAS, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations and Comprehensive Loss (unaudited)

(dollars and shares in millions, except per share amounts)

Condensed Consolidated Statements of Operations	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2022	2021	2022	2021
Revenue	\$ 31.3	\$ 5.5	\$ 55.5	\$ 11.1
Operating expenses:				
Research and development	75.3	43.0	139.2	77.9
General and administrative	24.3	14.4	44.5	26.7
Total operating expenses	99.6	57.4	183.7	104.6
Loss from operations	(68.3)	(51.9)	(128.2)	(93.5)
Other income (expenses)				
Other (expense) income, net	(0.1)	1.2	(0.2)	1.4
Interest income, net	1.8	0.4	2.9	0.8
Total other income	1.7	1.6	2.7	2.2
Net loss before income taxes	(66.6)	(50.3)	(125.5)	(91.3)
Income tax expense	(3.4)	—	(7.9)	—
Net loss	\$ (70.0)	\$ (50.3)	\$ (133.4)	\$ (91.3)
Net loss per common share, basic and diluted	\$ (1.32)	\$ (1.03)	\$ (2.51)	\$ (1.87)
Weighted average common shares outstanding, basic and diluted	53.2	48.9	53.1	48.7

(dollars in millions)

Condensed Consolidated Statements of Comprehensive Loss	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2022	2021	2022	2021
Net loss	\$ (70.0)	\$ (50.3)	\$ (133.4)	\$ (91.3)
Other comprehensive loss:				
Unrealized loss on available-for-sale securities	(3.3)	(0.2)	(17.4)	(1.0)
Comprehensive loss	\$ (73.3)	\$ (50.5)	\$ (150.8)	\$ (92.3)

See accompanying notes to the condensed consolidated financial statements

ARVINAS, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Changes in Stockholders' Equity (unaudited)
(dollars and shares in millions)

	Common		Accumulated Deficit	Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Total Stockholders' Equity
	Shares	Amount				
<i>For the Three Months Ended June 30, 2022 and 2021</i>						
Balance at March 31, 2022	53.1	\$ —	\$ (746.3)	\$ 1,488.3	\$ (18.7)	\$ 723.3
Stock-based compensation	—	—	—	20.0	—	20.0
Net loss	—	—	(70.0)	—	—	(70.0)
Proceeds from exercise of stock options	0.1	0.1	—	0.5	—	0.6
Unrealized loss on available-for-sale securities	—	—	—	—	(3.3)	(3.3)
Balance at June 30, 2022	<u>53.2</u>	<u>\$ 0.1</u>	<u>\$ (816.3)</u>	<u>\$ 1,508.8</u>	<u>\$ (22.0)</u>	<u>\$ 670.6</u>
Balance at March 31, 2021	48.8	\$ —	\$ (532.9)	\$ 1,148.3	\$ (0.2)	\$ 615.2
Stock-based compensation	—	—	—	14.6	—	14.6
Net loss	—	—	(50.3)	—	—	(50.3)
Restricted stock vesting	0.1	—	—	—	—	—
Proceeds from exercise of stock options	0.1	—	—	3.6	—	3.6
Unrealized loss on available-for-sale securities	—	—	—	—	(0.2)	(0.2)
Balance at June 30, 2021	<u>49.0</u>	<u>\$ —</u>	<u>\$ (583.2)</u>	<u>\$ 1,166.5</u>	<u>\$ (0.4)</u>	<u>\$ 582.9</u>

(dollars and shares in millions)

	Common		Accumulated Deficit	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
<i>For the Six Months Ended June 30, 2022 and 2021</i>						
Balance at December 31, 2021	53.0	\$ —	\$ (682.9)	\$ 1,469.2	\$ (4.6)	\$ 781.7
Stock-based compensation	—	—	—	36.6	—	36.6
Net loss	—	—	(133.4)	—	—	(133.4)
Proceeds from exercise of stock options	0.2	0.1	—	3.0	—	3.1
Unrealized loss on available-for -sale securities	—	—	—	—	(17.4)	(17.4)
Balance at June 30, 2022	<u>53.2</u>	<u>\$ 0.1</u>	<u>\$ (816.3)</u>	<u>\$ 1,508.8</u>	<u>\$ (22.0)</u>	<u>\$ 670.6</u>
Balance at December 31, 2020	48.5	\$ —	\$ (491.9)	\$ 1,133.5	\$ 0.6	\$ 642.2
Stock-based compensation	—	—	—	24.9	—	24.9
Net loss	—	—	(91.3)	—	—	(91.3)
Restricted stock vesting	0.1	—	—	—	—	—
Proceeds from exercise of stock options	0.4	—	—	8.1	—	8.1
Unrealized loss on available-for -sale securities	—	—	—	—	(1.0)	(1.0)
Balance at June 30, 2021	<u>49.0</u>	<u>\$ —</u>	<u>\$ (583.2)</u>	<u>\$ 1,166.5</u>	<u>\$ (0.4)</u>	<u>\$ 582.9</u>

See accompanying notes to the condensed consolidated financial statements

ARVINAS, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Cash Flows (unaudited)

<i>(dollars in millions)</i>	For the Six Months Ended June 30,	
	2022	2021
Cash flows from operating activities:		
Net loss	\$ (133.4)	\$ (91.3)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3.0	2.3
Net accretion of bond discounts/premiums	5.8	2.7
Forgiveness of debt income	—	(1.0)
Loss on sale of marketable securities	0.1	—
Amortization of right-of-use assets	1.0	0.6
Amortization of collaboration contract asset	0.8	—
Stock-based compensation	36.6	24.9
Changes in operating assets and liabilities:		
Accounts receivable	13.6	1.0
Other receivables	4.0	—
Prepaid expenses and other current assets	(1.0)	(9.1)
Accounts payable and accrued liabilities	(12.7)	(7.8)
Operating lease liability	(1.0)	(0.6)
Deferred revenue	(52.5)	(8.1)
Net cash used in operating activities	(135.7)	(86.4)
Cash flows from investing activities:		
Purchases of marketable securities	(469.1)	(538.0)
Maturities of marketable securities	555.9	82.6
Sales of marketable securities	34.3	—
Purchases of property, equipment and leasehold improvements	(3.5)	(1.5)
Net cash provided by (used in) investing activities	117.6	(456.9)
Cash flows from financing activities:		
Proceeds from exercise of stock options	3.0	8.1
Net cash provided by financing activities	3.0	8.1
Net decrease in cash, cash equivalents and restricted cash	(15.1)	(535.2)
Cash, cash equivalents and restricted cash, beginning of the period	112.8	588.4
Cash, cash equivalents and restricted cash, end of the period	\$ 97.7	\$ 53.2
Supplemental disclosure of cash flow information:		
Purchases of property, equipment and leasehold improvements unpaid at period end	\$ 0.5	\$ 0.3

See accompanying notes to the condensed consolidated financial statements

ARVINAS, INC. AND SUBSIDIARIES

Notes to Condensed Consolidated Financial Statements (unaudited)

1. Nature of Business and Basis of Presentation

Arvinas, Inc. and subsidiaries ("Arvinas" or "the Company") is a clinical-stage biopharmaceutical 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 the Company 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 at December 31, 2021 has been derived from the Company's audited consolidated financial statements at that date. The financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2021, forming part of Arvinas' 2021 Annual Report on Form 10-K filed with the SEC on February 28, 2022.

Certain reclassifications have been made to prior period financial information in order to conform with current period presentation. Accounts payable and Accrued expenses have been condensed into Accounts payable and accrued liabilities.

The preparation of the Company's unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires the use of estimates 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.

Concentration of Credit Risk and Other Risks and Uncertainties

The Company is subject to a number of risks similar to other biopharmaceutical 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 totaling \$1.3 billion as of June 30, 2022.

Impact of the Coronavirus ("COVID-19") Pandemic

As a result of the COVID-19 pandemic, many companies have experienced disruptions in their operations and in the markets they serve. The Company considered the impact of COVID-19 on the assumptions and estimates used and determined that there were no material adverse impacts on the Company's financial position and results of operations as of and for the six months ended June 30, 2022. The full extent of the future impacts of COVID-19 on the Company's operations remains uncertain. A prolonged outbreak could have a material adverse impact on the Company's financial results and business operations, including the timing and ability of the Company to complete certain clinical trials and other efforts required to advance its preclinical pipeline.

2. Accounting Pronouncements and Significant Accounting Policies

The Company reviews new accounting standards as issued. As of June 30, 2022, the Company has not identified any new standards that it believes will have a material impact on the Company's financial statements.

There were no changes to the Company's significant accounting policies during the six months ended June 30, 2022.

3. Research Collaboration and License Agreements

ARV-471 Collaboration Agreement

In July 2021, the Company entered into a Collaboration Agreement with Pfizer Inc. ("Pfizer") (the "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 ARV-471 Collaboration Agreement, the Company received an upfront, non-refundable payment of \$650.0 million. In addition, the Company will be 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.

The Company and Pfizer will 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 ARV-471 Collaboration Agreement, the Company incurred direct and incremental costs to obtain the contract 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 on 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 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 is committed to fund an additional \$12.0 million through 2023, of which of \$10.5 million was received through June 30, 2022. 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 sales-based 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 as of June 30, 2022.

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 six months ended June 30, 2022, the Company received payments totaling \$3.5 million, which was included in accounts receivable at December 31, 2021, for an additional target and additional services which are being recognized as revenue over the total period of performance. There were no sales-based milestone payments or royalties received as of June 30, 2022.

Genentech Modification

In November 2017, the Company entered into an Amended and Restated Option, License, and Collaboration Agreement (the "Genentech Modification") with Genentech, Inc. and F. Hoffman-La Roche Ltd. (together "Genentech"), amending a previous Genentech agreement. Under the Genentech Modification, the Company received additional upfront, non-refundable payments of \$34.5 million (in addition to \$11.0 million received under the previous agreement) to fund Genentech-related research. Under the Genentech Modification, Genentech has the right to designate up to ten targets. The Company is eligible to receive up to \$27.5 million in additional expansion target payments if Genentech exercises its options on all remaining targets. Upfront non-refundable payments are recognized as revenue over the total estimated period of performance.

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 as of June 30, 2022.

Information about changes in the Company's contract balances for the six months ended June 30, 2022 and 2021 is as follows:

<i>(dollars in millions)</i>	June 30, 2022	June 30, 2021
Accounts receivable		
Beginning balance	\$ 15.0	\$ —
Additions	1.4	—
Payments received	(15.0)	—
Ending balance	<u>\$ 1.4</u>	<u>\$ —</u>
Contract assets: Collaboration contract asset		
Beginning balance	\$ 12.5	\$ —
Amortization	(0.8)	—
Ending balance	<u>\$ 11.7</u>	<u>\$ —</u>
Contract liabilities: Deferred revenue		
Beginning balance	\$ 740.5	\$ 45.1
Revenue recognized from balances held at the beginning of the period	(55.5)	(11.1)
Additions to collaboration agreements	3.0	3.0
Ending balance	<u>\$ 688.0</u>	<u>\$ 37.0</u>

The aggregate amount of the transaction price allocated to performance obligations that are unsatisfied as of June 30, 2022 was \$688.0 million, which is expected to be recognized in the following periods:

(dollars in millions)

Remainder of 2022	\$	101.1
2023		190.0
2024		136.5
2025		100.4
2026		63.4
2027		34.1
Thereafter		62.5
Total	\$	688.0

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 at 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.

<i>June 30, 2022</i>						
<i>(dollars in millions)</i>	Valuation Hierarchy	Effective Maturity	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate bonds	Level 2	2022 - 2023	\$ 824.5	\$ —	\$ (8.0)	\$ 816.5
Corporate bonds	Level 2	2023 - 2025	363.3	—	(13.0)	350.3
Government securities	Level 2	2022 - 2023	79.9	—	(0.8)	79.1
Government securities	Level 2	2023 - 2024	4.3	—	(0.2)	4.1
Total			\$ 1,272.0	\$ —	\$ (22.0)	\$ 1,250.0

<i>December 31, 2021</i>						
<i>(dollars in millions)</i>	Valuation Hierarchy	Effective Maturity	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate bonds	Level 2	2022	\$ 784.0	\$ —	\$ (0.7)	\$ 783.3
Corporate bonds	Level 2	2023 - 2024	582.5	—	(3.8)	578.7
Government securities	Level 2	2022	32.4	—	(0.1)	32.3
Total			\$ 1,398.9	\$ —	\$ (4.6)	\$ 1,394.3

The carrying values of accounts receivable, 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 at:

<i>(dollars in millions)</i>	June 30, 2022		December 31, 2021	
Laboratory equipment	\$	15.8	\$	13.6
Leasehold improvements		10.0		8.4
Office equipment		1.5		1.4
Total property, equipment and leasehold improvements		27.3		23.4
Less: accumulated depreciation and amortization		(13.7)		(10.7)
Property, equipment and leasehold improvements, net	\$	13.6	\$	12.7

Depreciation and amortization expense totaled \$1.5 million and \$1.2 million for the three months ended June 30, 2022 and 2021, respectively, and \$3.0 million and \$2.3 million for the six months ended June 30, 2022 and 2021, 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. The incremental borrowing rate ranges from 3.0% - 4.1%. Lease expense is recognized on a straight-line basis over the lease term. Some of the Company's leases include options to extend or terminate the lease. The Company includes these options in the recognition of the Company's ROU assets and lease liabilities when it is reasonably certain that the Company will exercise such options.

In May 2021, the Company entered into a lease for approximately 160,000 square feet of laboratory and office space to be occupied in 2024. In connection with the signing of the lease, and at the Company's election to increase the landlord's contribution to the tenant improvement allowance, the Company issued a letter of credit for \$4.5 million, collateralized by a certificate of deposit in the same amount, which is presented as restricted cash at June 30, 2022. Once occupied, the base rent will range from \$7.7 million to \$8.8 million annually over a ten-year lease term.

The Company has operating leases for its corporate office, laboratories and certain equipment, which expire no later than January 31, 2026. The leases have a weighted average remaining term of 2.6 years.

The components of lease expense were as follows:

<i>(dollars in millions)</i>	Three Months Ended June 30,				Six Months Ended June 30,			
	2022		2021		2022		2021	
Operating lease cost	\$	0.5	\$	0.3	\$	1.1	\$	0.7

Supplemental cash flow information related to leases was as follows:

<i>(dollars in millions)</i>	Six Months Ended June 30,	
	2022	2021
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	\$ 1.0	\$ 0.6
Supplemental non-cash information:		
Right-of-use assets obtained in exchange for new lease obligations	\$ 2.4	\$ 3.2

Maturities of lease liabilities for operating leases as of June 30, 2022, are as follows:

<i>(dollars in millions)</i>		
Remainder of 2022	\$	0.8
2023		2.1
2024		2.1
2025		0.5
2026		—
Total lease payments		5.5
Less: imputed interest		(0.2)
Total	\$	5.3

7. Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities consisted of the following:

<i>(dollars in millions)</i>	June 30, 2022	December 31, 2021
Accounts payable	\$ 12.3	\$ 31.3
Accrued liabilities		
Research and development expenses	18.9	9.5
Employee expenses	8.7	12.4
Professional fees and other	2.2	1.2
Total accounts payable and accrued liabilities	\$ 42.1	\$ 54.4

8. Long-Term Debt

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 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. At June 30, 2022, \$1.0 million remains outstanding under the 2018 Assistance Agreement.

In connection with an Assistance Agreement with the State of Connecticut entered into in 2014 (the "2014 Assistant Agreement") 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 six months ended June 30, 2022 and 2021, 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” offering. During the six months ended June 30, 2022, no shares were issued under this agreement.

Share-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 increase, 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 June 30, 2022, 2,005,714 shares remained available for purchase. During the six months ended June 30, 2022 and 2021, the Company issued 5,749 and 12,050 shares, 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 common shares 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) 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 expired, terminated or were 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 June 30, 2022,

2,589,218 shares remained available for issuance under the 2018 Plan. Common shares 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 June 30, 2022 and 2021, the Company recognized compensation expense of \$20.0 million and \$14.6 million, respectively, relating to the issuance of incentive awards. During the six months ended June 30, 2022 and 2021, the Company recognized compensation expense of \$36.6 million and \$24.9 million, respectively.

At June 30, 2022, there was \$84.3 million of unrecognized compensation expense that is expected to be amortized over a weighted average period of approximately two years.

Stock Options

The fair value of the stock options granted during the six months ended June 30, 2022 and 2021 was determined using the Black-Scholes option pricing model with the following assumptions:

	June 30, 2022	June 30, 2021
Expected volatility	73.2 - 76.0%	75.9 - 78.0%
Expected term (years)	5.5 - 7.0	5.5 - 7.0
Risk free interest rate	1.5% - 3.3%	0.5% - 1.2%
Expected dividend yield	0 %	0 %
Exercise price	\$36.79 - \$78.91	\$66.82 - \$82.21

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 six months ended June 30, 2022 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)	Aggregate Intrinsic Value
Outstanding at December 31, 2021	5,343,254	\$ 44.98		
Granted	1,464,743	\$ 62.88		
Exercised	(147,409)	\$ 17.61		
Forfeited	(123,827)	\$ 58.27		
Outstanding at June 30, 2022	<u>6,536,761</u>	\$ 49.36	8.1	\$ 54.2
Exercisable at June 30, 2022	<u>3,071,122</u>	\$ 33.89	7.1	\$ 47.1

The weighted-average grant date fair value of options granted during the six months ended June 30, 2022 was \$41.41. The total intrinsic value of options exercised during the six months ended June 30, 2022 was \$7.1 million.

At June 30, 2022, there were 6,211,843 stock options under the 2018 Plan that have vested or are expected to vest.

Restricted Stock Awards

A summary of restricted stock award activity under the Incentive Plan during the six months ended June 30, 2022 is presented below. These amounts include restricted stock granted to employees and directors.

	Shares	Weighted Average Grant Date Fair Value Per Share
Unvested restricted stock at December 31, 2021	30,625	\$ 16.00
Vested	(29,305)	\$ 16.00
Cancelled	(1,320)	\$ 16.00
Unvested restricted stock at June 30, 2022	<u>—</u>	<u>\$ 16.00</u>

Restricted Stock Units

A summary of restricted stock unit activity under the 2018 Plan during the six months ended June 30, 2022 is presented below. These amounts include restricted stock units granted to employees.

	Shares	Weighted Average Grant Date Fair Value Per Share
Unvested restricted stock units at December 31, 2021	88,307	\$ 20.02
Granted	222,213	\$ 63.03
Vested	(38,490)	\$ 19.36
Cancelled	(5,114)	\$ 35.21
Unvested restricted stock units at June 30, 2022	<u>266,916</u>	<u>\$ 55.63</u>

At June 30, 2022, there were 221,552 restricted stock units under the 2018 Plan that have vested or are expected to vest.

10. Income Taxes

For the three months ended June 30, 2022, the Company recognized income tax expense of \$3.4 million resulting in an effective tax rate of 5.2%, as compared to income tax expense of zero resulting in an effective tax rate of 0.0% in the same period for 2021. The primary reconciling items between the federal statutory rate of 21.0% for the three months ended June 30, 2022 and the Company's overall effective tax rate of 5.2% 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. The primary reconciling items between the federal statutory rate of 21.0% for the three months ended June 30, 2021 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.

For the six months ended June 30, 2022, the Company recognized income tax expense of \$7.9 million resulting in an effective tax rate of 6.3%, as compared to income tax expense of zero resulting in an effective tax rate of 0.0% in the same period for 2021. The primary reconciling items between the federal statutory rate of 21.0% for the six months ended June 30, 2022 and the Company's overall effective tax rate of 6.3% 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. The primary reconciling items between

the federal statutory rate of 21.00% for the six months ended June 30, 2021 and the Company's overall effective tax rate of 0.00% was the effect of equity compensation 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 is projecting taxable income for the current year, and as a result projects current income tax expense for the year. The projection of taxable income is primarily due to revenue recognition for tax purposes from the ARV-471 Collaboration Agreement and the capitalization of qualified research and development expenses incurred on or after January 1, 2022, which upon recognition for tax purposes would create additional deferred tax assets. 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 at least five years for tax purposes. The Company continues to establish a full valuation allowance against the Company's net deferred tax assets since it is more likely than not that benefits will not be realized, including those created in the current year, given 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 June 30,		For the Six Months Ended June 30,	
	2022	2021	2022	2021
<i>(dollars and shares in millions, except per common share amounts)</i>				
Net loss	\$ (70.0)	\$ (50.3)	\$ (133.4)	\$ (91.3)
Weighted average number of common shares outstanding - basic and diluted	53.2	48.9	53.1	48.7
Net loss per common share - basic and diluted	\$ (1.32)	\$ (1.03)	\$ (2.51)	\$ (1.87)

The Company reported net losses for each of the three and six months ended June 30, 2022 and 2021, and therefore excluded all stock options, restricted stock awards 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 For the Three and Six Months Ended June 30,	
	2022	2021
<i>(shares in millions)</i>		
Stock options	6.5	5.4
Restricted stock awards	—	0.1
Restricted stock units	0.3	0.1
	6.8	5.6

12. Equity Method Investments

In July 2019, the Company and Bayer CropScience LP ("Bayer LP") formed a joint venture, Oerth Bio LLC ("Oerth"), to research, develop and commercialize PROTAC targeted protein degraders for applications in the field of agriculture. As Oerth is jointly controlled by the Company and Bayer LP, the Company accounts for its 50% interest using the equity method of accounting. The Company also provides to Oerth compensated research and development services and administrative services through a separate agreement. The services rendered by the Company during the three and six months ended June 30, 2022 and 2021 were immaterial.

Operating expenses and net loss of Oerth for the three months ended June 30, 2022 and 2021 totaled \$5.3 million and \$3.4 million, respectively. Operating expenses and net loss of Oerth for the six months ended June 30, 2022 and 2021 totaled \$10.2 million and \$6.1 million, respectively.

The carrying value of the investment has been reduced to zero and, as a result, no additional losses were recorded against the carrying value of the investment during the three and six months ended June 30, 2022 and 2021.

13. Commitments and Contingencies

On June 4, 2022, the Company entered into a Master In Vitro Diagnostics Agreement, effective as of June 4, 2022 with Foundation Medicine, Inc. (the "FMI Agreement") 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, including FoundationOne® Liquid CDx for use with bavdegalutamide for the diagnosis and treatment of mCRPC androgen receptor AR mutations.

In exchange for the development of FoundationOne® Liquid CDx as a companion diagnostic for use with bavdegalutamide 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 to mid tens of millions of dollars in addition to certain validation fees per sample and related pass-through costs.

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, if (a) a reasonably necessary third party license is not secured by Foundation Medicine or if we do not consent to payments for such license (b) 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.

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, 2021 filed on February 28, 2022. 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, 2021, filed on February 28, 2022 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 biopharmaceutical company dedicated to improving the lives of patients suffering from debilitating and life-threatening diseases through the discovery, development and commercialization of therapies to degrade disease-causing proteins. We use our PROTAC Discovery Engine, 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 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. Our small molecule PROTAC technology has the potential to address a broad range of intracellular disease targets, including those representing up to the 80% of 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 oncology (including immuno-oncology), neuroscience, and other therapeutic areas. Our three lead product candidates are bavdegalutamide, ARV-471, and ARV-766.

Bavdegalutamide

We are developing bavdegalutamide, an investigational orally bioavailable PROTAC protein degrader targeting the androgen receptor protein, or AR, for the treatment of men with metastatic castration-resistant prostate cancer, or mCRPC. We initiated a Phase 1 clinical trial of bavdegalutamide designed to assess the safety, tolerability and pharmacokinetics of bavdegalutamide, which also includes measures of anti-tumor activity as secondary endpoints, including reduction in prostate specific antigen, or PSA, a well-recognized biomarker of prostate cancer progression. We received fast track designation for bavdegalutamide for mCRPC in May 2019. We have completed dose escalation in the Phase 1 clinical trial. In the fourth quarter of 2020, we initiated ARDENT, the Phase 2 single agent expansion portion of the bavdegalutamide clinical trial. In the fourth quarter of 2021, we initiated a Phase 1b clinical trial with bavdegalutamide in combination with abiraterone for the treatment of men with mCRPC. In the second quarter of 2022, we met with the U.S. Food and Drug Administration, or FDA, to discuss the potential for an accelerated approval pathway with bavdegalutamide in molecularly defined mCRPC based on a single-arm Phase 2 trial and a confirmatory Phase 3 trial for full approval. FDA provided advice on the proposed registrational trial design, including patient eligibility, study design, and follow-up expectations. We also finalized a partnership with Foundation Medicine for the development of a companion diagnostic. After considering multiple factors, including input provided by the FDA, we believe a randomized, pivotal Phase 3 trial provides the best opportunity to enable simultaneous global regulatory submissions. Accordingly, we plan to initiate a Phase 3 trial to evaluate the safety and efficacy of bavdegalutamide for patients with AR T878X/875Y tumor mutations in the second half of 2023 with final dose selection for the planned Phase 3 trial based on data from additional patients enrolled in the ongoing Phase 1/2 trial. This further dose exploration will run concurrently with the company seeking regulatory guidance on final Phase 3 design.

ARV-471

We are developing ARV-471, an investigational orally bioavailable PROTAC protein degrader targeting the estrogen receptor protein, or ER, for the treatment of patients with locally advanced or metastatic ER positive / HER2 negative breast cancer. We initiated a Phase 1 clinical trial of ARV-471 designed to assess the safety, tolerability and pharmacokinetics of ARV-471, which also includes measures of anti-tumor activity as secondary endpoints. In the fourth quarter of 2020, we initiated a Phase 1b cohort expansion of ARV-471 in combination with Ibrance® (palbociclib). We have completed dose escalation in the Phase 1 clinical trial. In the first quarter of 2021, we initiated VERITAC, the Phase 2 single agent expansion cohort of the ARV-471 clinical trial. In July 2021, we entered into a collaboration agreement with Pfizer Inc., or Pfizer, pursuant to which we granted Pfizer worldwide coexclusive rights to develop and commercialize ARV-471. In December 2021, we presented data from the dose escalation portion of the Phase 1/2 clinical trial at the San Antonio Breast Cancer Symposium. In the fourth quarter of 2022, we plan to present data from the VERITAC Phase 2 dose expansion (with patients dosed at 200 and 500 mg). In the second half of 2022, we plan to initiate a Phase 1b clinical trial with ARV-471 in combination with everolimus in patients with metastatic breast cancer, initiate a Phase 1b combination trial with cyclin-dependent kinase, or CDK, inhibitors or other targeted therapies, initiate a Phase 2 clinical trial in patients with early breast cancer in the neoadjuvant setting and initiate two Phase 3 clinical trials in patients with metastatic breast cancer as a monotherapy and in combination. In the first half of 2023, we plan to present safety data from the Phase 1b combination study with palbociclib at a medical conference.

ARV-766

We are developing ARV-766, an investigational orally bioavailable PROTAC protein degrader for the treatment of 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, which bavdegalutamide did not degrade in preclinical studies. In 2021, we initiated a Phase 1 clinical trial for ARV-766 designed to assess the safety, tolerability and pharmacokinetics of ARV-766, which also includes measures of anti-tumor activity as secondary endpoints, including reduction in PSA. In the second half of 2022, we plan to present Phase 1 dose escalation data and initiate a Phase 2 expansion trial for the treatment of men with mCRPC.

Bavdegalutamide, ARV-471 and ARV-766 have all demonstrated potent and selective protein degradation in our preclinical studies. We believe favorable clinical trial results in these initial oncology programs would provide validation of our platform as a new therapeutic modality for the potential treatment of diseases caused by dysregulated intracellular proteins regardless of therapeutic area.

Our Operations

As a result of the COVID-19 pandemic, many companies have experienced disruptions in their operations and in the markets they serve. We have instated some and may take additional precautionary measures intended to help ensure our employees' well-being and minimize business disruption. We temporarily shut down our laboratories in mid-March 2020 and initiated work with biology contract research organizations, or CROs, but have since reopened our laboratories and our office-based employees are working in a hybrid of remote and in-person work. We considered the impact of COVID-19 on the assumptions and estimates used and determined that there were no material adverse impacts on our results of operations and financial position as of June 30, 2022. The full extent of the future impacts of COVID-19 on our operations remains uncertain. A prolonged outbreak could have a material adverse impact on our financial results and business operations, including the timing and our ability to complete certain clinical trials and other efforts required to advance our preclinical pipeline.

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 June 30, 2022, 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 \$780.5 million in payments primarily from collaboration partners.

We are a clinical-stage company. Bavdegalutamide and ARV-471 are each in Phase 1/2 clinical trials, ARV-766 is in a Phase 1 clinical trial and 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. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. Our net loss was \$133.4 million for the six months ended June 30, 2022. As of June 30, 2022, we had an accumulated deficit of \$816.3 million.

Our total operating expenses were \$183.7 million for the six months ended June 30, 2022. We anticipate that our expenses will increase substantially due to costs associated with our ongoing and anticipated clinical activities for bavdegalutamide, ARV-471, and ARV-766, development activities associated with our other product candidates, research 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, or CMOs, to supply us with product for our preclinical and clinical studies and CROs 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 revenue from sales of any product for many years, 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.

Recent Developments

On June 4, 2022, we entered into a Master In Vitro Diagnostics Agreement, effective as of June 4, 2022 with Foundation Medicine, Inc., or the FMI Agreement, 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 our therapeutic products, including FoundationOne® Liquid CDx for use with bavdegalutamide for the diagnosis and treatment of mCRPC androgen receptor AR mutations.

Pursuant to the terms of the FMI Agreement, amongst other intellectual property terms, we granted Foundation Medicine a worldwide non-exclusive license to certain data and intellectual property rights in order for Foundation Medicine to perform its obligations and exercise its rights under the FMI Agreement, for example to exploit its assays and make improvements to its platform. Additionally, non-exclusive, royalty-free, limited cross-licenses were granted for each party to use the other's trademarks in performing certain activities under the FMI Agreement.

We will be responsible for the development, including conducting clinical trials, of our therapeutic products (including bavdegalutamide) and Foundation Medicine will be responsible for the development of its assays for use with one or more of our therapeutic products. If we and Foundation Medicine are able to acquire the required regulatory approvals, Foundation Medicine will use commercially reasonable efforts to make the assay commercially available as an approved in vitro diagnostic for use with the applicable therapeutic product in the applicable market(s) and indication(s), and we will use commercially reasonable efforts to make the therapeutic product commercially available for use in the applicable market(s) and indication(s).

In exchange for the development of FoundationOne® Liquid CDx as a companion diagnostic for use with bavdegalutamide for AR mCRPC in the United States and European Union, pursuant to the terms of the FMI Agreement, we will pay Foundation Medicine 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.

The FMI Agreement does not have a fixed duration, and we 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. In the event that the parties are deadlocked as to certain matters, the other party's uncured material breach with respect to a program, or if a regulatory authority provides written notice of its determination that such regulatory authority will not grant a regulatory approval for the applicable assay for use with our therapeutic product or for our therapeutic product itself, either party may terminate the FMI Agreement with respect to the applicable program with adequate written notice to the other party. Additionally, Foundation Medicine may terminate the FMI Agreement with respect to an applicable program, if (a) a reasonably necessary third party license is not secured by Foundation Medicine or if we do not consent to payments for such license (b) 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, we have certain payment obligations remaining to Foundation Medicine and may also be required to pay a termination fee, if applicable. Neither party may assign the FMI Agreement without the prior written consent of the other party, except that a party may assign its rights and obligations, in whole but not in part, to an affiliate or successor in interest in the transfer or sale of all or substantially all of its business relating to the FMI Agreement.

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 foreseeable 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 for the next several years will be derived primarily 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 up to an aggregate of \$27.5 million in additional expansion target payments if Genentech exercises its options for all remaining Targets. We are also 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. We received payments totaling \$3.5 million in the six months ended June 30, 2022, and \$1.2 million and \$4.4 million in the years ended December 31, 2021 and 2020, 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 is committed to fund a total of \$12.0 million in research funding payments through 2023, of which \$10.5 million was received through June 30, 2022, subject to potential increases if our costs for research activities exceed the research funding payments allocated to a Target and certain conditions are met. 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 degrader-related products, mid-single digit to low-double digit tiered royalties, which may be subject to reductions.

Pfizer ARV-471 Collaboration Agreement

In July 2021, we entered into a collaboration agreement with Pfizer, or the 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 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 will 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 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 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 ARV-471 Collaboration Agreement for the other party's uncured material breach or insolvency. Subject to applicable terms of the ARV-471 Collaboration Agreement, including certain payments to Pfizer upon termination for our uncured material breach, effective upon termination of the 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 ARV-471 Collaboration Agreement anywhere in the world during the term of the 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 bavdegalutamide and ARV-766, ER program, which includes ARV-471, and all other platform and exploratory research and development costs:

(in millions)	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2022	2021	2022	2021
AR program development costs	\$ 11.3	\$ 12.7	\$ 27.4	\$ 19.9
ER program development costs	20.1	6.0	34.9	11.6
Other research and development costs	43.9	24.3	76.9	46.4
Total research and development costs	\$ 75.3	\$ 43.0	\$ 139.2	\$ 77.9

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 conduct clinical trials for bavdegalutamide, ARV-471 and ARV-766, including our ongoing Phase 1/2 clinical trials for bavdegalutamide and ARV-471 and our ongoing Phase 1 clinical trial for ARV-766, and continue to discover and develop additional product candidates. Research and development expenses related to ARV-471 are shared equally with Pfizer from July 22, 2021, the effective date of the ARV-471 Collaboration Agreement. The ER program development costs in the table above reflect the cost sharing with Pfizer.

We cannot reasonably estimate or determine with certainty the duration and costs of future clinical trials of bavdegalutamide, ARV-471 and ARV-766 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;
- successful initiation of clinical trials;
- successful patient enrollment in and completion of 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. 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, 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. As of December 31, 2021, we had federal net operating loss carryforwards of \$373.6 million, which begin to expire in 2033, state and local net operating loss carryforwards of \$346.9 million, and federal and state research and development tax credit carryforwards of \$15.2 million and \$4.5 million, respectively, which begin to expire in 2033 and 2036, respectively. We expect to fully utilize these net operating loss and credit carryforwards in the current year due to taxable income resulting from revenue recognition for tax purposes from our ARV-471 Collaboration Agreement and the capitalization of qualified research and development expenses incurred on or after January 1, 2022. 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 June 30, 2022, 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. Prior to December 31, 2018, these subsidiaries were separate filers for federal tax purposes.

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 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 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, 2021, filed with the Securities and Exchange Commission on February 28, 2022.

Results of Operations

Comparison of Three and Six Months Ended June 30, 2022 and 2021

(dollars in millions)	For the Three Months Ended June 30,			For the For the Six Months Ended June 30,		
	2022	2021	\$ change	2022	2021	\$ change
Revenue	\$ 31.3	\$ 5.5	\$ 25.8	\$ 55.5	\$ 11.1	\$ 44.4
Research and development expenses	75.3	43.0	32.3	139.2	77.9	61.3
General and administrative expenses	24.3	14.4	9.9	44.5	26.7	17.8
Other income	1.7	1.6	0.1	2.7	2.2	0.5
Income tax expense	(3.4)	—	(3.4)	(7.9)	—	(7.9)
Net loss	\$ (70.0)	\$ (50.3)	\$ (19.7)	\$ (133.4)	\$ (91.3)	\$ (42.1)

Revenues

Revenues for the three months ended June 30, 2022 totaled \$31.3 million, as compared to \$5.5 million for the three months ended June 30, 2021. The increase of \$25.8 million was primarily due to revenue from the ARV-471 Collaboration Agreement with Pfizer entered into during the third quarter of 2021.

Revenues for the six months ended June 30, 2022 totaled \$55.5 million, as compared to \$11.1 million for the six months ended June 30, 2021. The increase of \$44.4 million was primarily due to revenue from the ARV-471 Collaboration Agreement with Pfizer entered into during the third quarter of 2021.

Research and Development Expenses

Research and development expenses for the three months ended June 30, 2022 totaled \$75.3 million, compared with \$43.0 million for the three months ended June 30, 2021. The increase of \$32.3 million was primarily due to an increase in our continued investment in our platform and exploratory programs of \$19.6 million as well as an increase in expenses related to our ER program of \$14.1 million, offset by a decrease in expenses related to our AR program of \$1.4 million. The increase in spending over all of our programs was primarily due to increased personnel and personnel costs utilized across all of our programs of \$10.5 million, including \$3.5 million related to stock compensation expense. Clinical trial costs and related drug manufacturing costs increased by \$15.7 million as we expanded our AR and ER programs into additional clinical studies. ER program costs were offset by \$1.5 million of cost sharing billings to Pfizer in accordance with our ARV-471 Collaboration Agreement. Direct expenses related to our platform and exploratory targets increased by \$6.2 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.

Research and development expenses for the six months ended June 30, 2022 totaled \$139.2 million, compared with \$77.9 million for the six months ended June 30, 2021. The increase of \$61.3 million was primarily due to an increase in our continued investment in our platform and exploratory programs of \$30.5 million as well as increases in expenses related to our AR and ER programs of \$7.5 million and \$23.3 million, respectively. The increase in spending over all of our programs was primarily due to increased personnel and personnel costs utilized across all of our programs of \$19.7 million, including \$6.9 million related to stock compensation expense. Clinical trial costs and related drug manufacturing costs increased by

\$31.3 million as we expanded our AR and ER programs into additional clinical studies. ER program costs were offset by \$1.4 million of cost sharing billings to Pfizer in accordance with our ARV-471 Collaboration Agreement. Direct expenses related to our platform and exploratory targets increased by \$9.8 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.

General and Administrative Expenses

General and administrative expenses totaled \$24.3 million for the three months ended June 30, 2022, compared with \$14.4 million for the three months ended June 30, 2021. The increase of \$9.9 million was primarily due to an increase of personnel and facility related costs of \$6.9 million, including \$3.9 million of personnel and personnel related costs and \$1.2 million of stock compensation expense, and insurance, taxes and professional fees of \$2.9 million.

General and administrative expenses totaled \$44.5 million for the six months ended June 30, 2022, compared with \$26.7 million for the six months ended June 30, 2021. The increase of \$17.8 million was primarily due to an increase of personnel and facility related costs of \$12.3 million, including \$6.9 million of personnel and personnel related costs and \$3.5 million of stock compensation expense, and insurance, taxes and professional fees of \$5.2 million.

Other Income

Other income totaled \$1.7 million for the three months ended June 30, 2022, compared with \$1.6 million for the three months ended June 30, 2021. The increase of \$0.1 million was primarily due to higher interest income of \$1.4 million from higher investment balances and higher interest rates, offset in part by forgiveness of debt of \$1.0 million in 2021 equal to 50% of the then outstanding loan balance, related to the State of Connecticut loan upon our satisfaction of certain jobs criteria, and lower refundable research and development credits from the State of Connecticut of \$0.3 million, as we are no longer eligible to receive a cash refund for the research and development credits in the State of Connecticut.

Other income totaled \$2.7 million for the six months ended June 30, 2022, compared with \$2.2 million for the six months ended June 30, 2021. The increase of \$0.5 million was primarily due to higher interest income of \$2.1 million from higher investment balances and higher interest rates, offset in part by forgiveness of debt of \$1.0 million in 2021 equal to 50% of the then outstanding loan balance, related to the State of Connecticut loan upon our satisfaction of certain jobs criteria, and lower refundable research and development credits from the State of Connecticut of \$0.5 million, as we are no longer eligible to receive a cash refund for the research and development credits in the State of Connecticut.

Income Tax Expense

Income tax expense totaled \$3.4 million for the three months ended June 30, 2022, compared with zero for the three months ended June 30, 2021, primarily due to current income taxes resulting from revenue recognition for tax purposes from our ARV-471 Collaboration Agreement and the capitalization of research and development expenses incurred on or after January 1, 2022.

Income tax expense totaled \$7.9 million for the six months ended June 30, 2022, compared with zero for the six months ended June 30, 2021, primarily due to current income taxes resulting from revenue recognition for tax purposes from our 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 expect to fully utilize our federal net operating loss and credit carryforwards in the current year, resulting in current income tax expense for the period.

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 June 30, 2022, we had received an aggregate of \$780.5 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: our initial public offering in which we issued an aggregate of 7,700,482 shares of common stock, for aggregate gross proceeds of \$123.2 million before fees and expenses;
- July 2019: the 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 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 6,571,428 shares of common stock for aggregate gross proceeds of \$460.0 million before fees and expenses; and
- September 2021: issuance of 3,457,815 shares of common stock to Pfizer for aggregate gross proceeds of \$350.0 million.

In May 2021, we entered into a lease for approximately 160,000 square feet of laboratory and office space to be occupied in 2024. In connection with the signing of the lease, and at our election to increase the landlord's contribution to the tenant improvement allowance, we issued a letter of credit for \$4.5 million, collateralized by a certificate of deposit in the same amount. Once occupied, the base rent will range from \$7.7 million to \$8.8 million annually over a ten-year lease term.

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. At June 30, 2022, no shares have been issued under this agreement.

Cash Flows

Our cash, cash equivalents, restricted cash and marketable securities totaled \$1.3 billion as of June 30, 2022 and \$1.5 billion as of December 31, 2021. We had an outstanding loan balance of \$1.0 million as of each of June 30, 2022 and December 31, 2021.

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

	For the Six Months Ended June 30,	
	2022	2021
<i>(dollars in millions)</i>		
Net cash used in operating activities	\$ (135.7)	\$ (86.4)
Net cash provided by (used in) investing activities	117.6	(456.9)
Net cash provided by financing activities	3.0	8.1
Net decrease in cash, cash equivalents and restricted cash	\$ (15.1)	\$ (535.2)

Operating Activities

Net cash used in operating activities for the six months ended June 30, 2022 totaled \$135.7 million, primarily due to our net loss of \$133.4 million, a reduction in deferred revenue of \$52.5 million and a net reduction in accounts payable and accrued liabilities of \$12.7 million, partially offset by non-cash charges of \$47.3 million and a decrease in account and other receivables of \$17.6 million. Non-cash charges included stock compensation expense of \$36.6 million, net accretion of bond discounts/premiums of \$5.8 million, and depreciation and amortization of \$3.0 million.

Net cash used in operating activities for the six months ended June 30, 2021 totaled \$86.4 million, primarily due to our net loss of \$91.3 million, an increase in prepaid expenses primarily related to clinical trials and drug manufacturing contracts of \$9.1 million, a reduction in deferred revenue of \$8.1 million and a reduction in accounts payable and accrued liabilities of \$7.8 million, partially offset by non-cash charges of \$29.5 million. Non-cash charges were primarily stock compensation expense of \$24.9 million, depreciation and amortization of \$2.3 million and net accretion of bond discounts/premiums of \$2.7 million.

Investing Activities

Net cash provided by investing activities for the six months ended June 30, 2022 totaled \$117.6 million, attributable to maturities of marketable securities in excess of purchases of \$121.1 million, offset by purchases of property and equipment of \$3.5 million.

Net cash used in investing activities for the six months ended June 30, 2021 totaled \$456.9 million, attributable to purchases of marketable securities in excess of the maturities of marketable securities of \$455.4 million and purchases of property and equipment of \$1.5 million.

Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2022 totaled \$3.0 million, attributable to the proceeds from the exercise of stock options.

Net cash provided by financing activities for the six months ended June 30, 2021 totaled \$8.1 million, attributable to the proceeds from the exercise of stock options.

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. In addition, we expect to continue to incur additional costs associated with operating as a public company.

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

- continue a Phase 1/2 clinical trial of our product candidate bavdegalutamide and a Phase 1b clinical trial of bavdegalutamide in combination with abiraterone for the treatment of men with metastatic castration-resistant prostate cancer, or mCRPC, and initiate one or more additional Phase 1b clinical expansions of bavdegalutamide in combination with standard of care agents, in men with mCRPC;
- continue a Phase 1/2 clinical trial of our product candidate ARV-471 and a Phase 1b clinical trial of ARV-471 in combination with palbociclib, and initiate an additional Phase 1b cohort expansion in combination with a standard of care agent, each in patients with locally advanced or metastatic ER positive / HER2 negative breast cancer and initiate a window of opportunity study in early breast cancer;
- continue a Phase 1 clinical trial of our product candidate ARV-766 in men with mCRPC, and initiate a planned Phase 2 cohort expansion trial in the second half of 2022;
- 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 support our operations as a public company.

We had cash, cash equivalents, restricted cash and marketable securities totaling \$1.3 billion as of June 30, 2022. We believe that our cash, cash equivalents, restricted cash and marketable securities as of June 30, 2022 will enable us to fund our planned operating expenses and capital expenditure requirements multiple additional years beyond 2024. 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 clinical trials for bavdegalutamide, ARV-471 and ARV-766 and any future clinical development of bavdegalutamide, ARV-471 and ARV-766;
- the scope, progress, costs and results of preclinical and clinical development for our other product candidates and development programs;
- 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 January 2014, we entered into an Assistance Agreement with the State of Connecticut, or the 2014 Assistance Agreement, under which we borrowed \$2.5 million. Borrowings under the 2014 Assistance Agreement were forgivable if we maintained a minimum number of full-time jobs in the State of Connecticut for a minimum period at a minimum annual salary. Effective in March 2016, the full principal amount under the 2014 Assistance Agreement had been forgiven. While borrowings under the 2014 Assistance Agreement have been forgiven, we remain subject to an ongoing covenant to be located in the State of Connecticut through January 2024. Upon violation of this covenant, we would be required to repay the full original funding amount of \$2.5 million plus liquidated damages of 7.50%.

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 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. At June 30, 2022, \$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 \$2.9 million and \$0.8 million for the six months ended June 30, 2022 and 2021, respectively. Our interest income is sensitive to changes in the general level of interest rates, primarily U.S. interest rates. At June 30, 2022, 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 each of June 30, 2022 and December 31, 2021. Our outstanding debt as of June 30, 2022 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 June 30, 2022. 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 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 June 30, 2022, 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 June 30, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. We have not experienced any material impact to our internal control over financial reporting due to the COVID-19 pandemic. We are continually monitoring and assessing the COVID-19 pandemic on our internal controls to minimize the impact on their design and operating effectiveness.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

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 those 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, 2021 filed with the SEC on February 28, 2022 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, 2021 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, 2021 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 six months ended June 30, 2022.

Item 6. Exhibits.

Exhibit Number	Description
10.1*†	Master In Vitro Diagnostics Agreement between Foundation Medicine, Inc and Arvinas Operations, Inc. dated June 4, 2022.
31.1*	Certification of Principal Executive Officer 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.
31.2*	Certification of Principal Financial Officer 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.
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of 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.

† Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

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, Inc.

Date: August 4, 2022

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

Date: August 4, 2022

By: _____
Sean Cassidy
Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)

CERTAIN INFORMATION IN THIS DOCUMENT, MARKED BY [**] HAS BEEN OMITTED FROM THIS EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD LIKELY BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

MASTER IN VITRO DIAGNOSTICS AGREEMENT

between

FOUNDATION MEDICINE, INC.,

ARVINAS OPERATIONS, INC.

and, solely for purposes of Section 11.19 hereof,

ARVINAS, INC.

Dated as of June 4, 2022

MASTER IN VITRO DIAGNOSTICS AGREEMENT

This Master In Vitro Diagnostics Agreement (this “Agreement”) is effective as of June 4, 2022 (the “Effective Date”) by and between Foundation Medicine, Inc., a Delaware corporation with its principal place of business at 150 Second Street, Cambridge, Massachusetts 02141, United States (“FMI”), Arvinas Operations, Inc., a Delaware corporation with its principal place of business at 5 Science Park, 395 Winchester Avenue, New Haven, CT 06511 (“Company”) and, solely for purposes of Section 11.19 hereof, Arvinas, Inc., a Delaware corporation with its principal place of business at 5 Science Park, 395 Winchester Avenue, New Haven, CT 06511 (“Company Parent”). FMI and Company are sometimes referred to herein individually as a “Party” and collectively as the “Parties.”

RECITALS

WHEREAS, the Parties desire to collaborate to enable FMI to seek and obtain Regulatory Approval for one or more FMI Assays for use with one or more Company Products, in each case, as set forth in a Statement of Work (SOW) (each capitalized term as defined below) executed by each Party under this Agreement and according to the following terms and conditions; and

[**].

NOW, THEREFORE, in consideration of the premises and the mutual promises and conditions set forth herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

ARTICLE 1 DEFINITIONS

Unless otherwise specifically provided herein, the following terms shall have the following meanings:

1.1. “Activities” means the activities to be performed by a Party under an applicable SOW.

1.2. “Affiliate” means any Person that (i) directly or indirectly controls a Party, (ii) is directly or indirectly controlled by a Party, or (iii) is controlled, directly or indirectly, by the ultimate parent company of a Party. For purposes of this definition, “control” and, with correlative meaning, the term “controlled by” means the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other ownership interest of an organization or otherwise having the power to govern the financial and operating policies or to appoint the management of an organization. Notwithstanding the foregoing, for purposes of this Agreement, Roche Holding Ltd, of Basel, Switzerland and Chugai Pharmaceutical Co., Ltd., of Tokyo, Japan, and their respective direct or indirect subsidiaries (including in the case of Roche Holding Ltd, Genentech, Inc., Roche Diagnostics Corporation, Roche Molecular Systems, Inc. and their respective direct and indirect subsidiaries), other than direct or indirect subsidiaries of FMI, shall not be Affiliates of FMI (and thus shall constitute Third Parties for purposes of this Agreement).

1.3. [**].

1.4. “Analytical Validation Samples” means any Samples provided by Company or any of its Affiliates [**] For clarity, an Analytical Validation Sample may also be a Clinical Development Sample or Trial Enrollment Sample.

1.5. “Analytical Validation Studies” means any and all studies directed to establishing the accuracy, reliability, reproducibility, sensitivity, specificity, or other performance of any [**].

1.6. “Applicable Law” means applicable laws, rules and regulations, including any rules, regulations, guidance or other requirements of a Regulatory Authority, that may be in effect from time to time and applicable to a particular activity hereunder, and shall be deemed to include the applicable regulations and guidances of the FDA that constitute [**] (and, if and as appropriate under the circumstances, International Conference on Harmonization (ICH) guidance).

1.7. “Approved IVD” means, with respect to an IVD and country or territory, that such IVD has been granted Regulatory Approval for such country or territory for the intended use, including, for example, any required PMA Approval. The term “Approved IVD” is not intended, and shall not be construed, to include any IVD solely for research or investigational purposes.

1.8. “Assay Submission Package” means [**].

1.9. “CE Marking Approval” means completion of all conformity assessment procedures required under the IVD Directive or IVD Regulation, as applicable, including obtaining any necessary certifications by a Notified Body of the conformity of an in vitro diagnostic medical device with the requirements of the IVD Directive or IVD Regulation, as applicable, and applicable harmonized standards necessary for the manufacturer of such device to affix a CE mark and place such device on the market in the EU.

1.10. “Change of Control” means a transaction occurring after the Effective Date in which a Party or any parent company of such Party: (i) sells, conveys or otherwise disposes of all or substantially all of its property or business to which this Agreement relates; or (ii)(a) merges or consolidates with any other Person (other than a wholly-owned subsidiary of such Party or such parent company) or (b) effects any other transaction or series of transactions; in each case ((a) or (b)), such that the stockholders of such Party or such parent company immediately prior thereto, in the aggregate, no longer own, directly or indirectly, beneficially or legally, at least fifty percent (50%) of the outstanding voting securities or capital stock of the surviving Person following the closing of such merger, consolidation, other transaction or series of transactions.

1.11. “CLIA” means the Clinical Laboratory Improvement Amendments of 1988, their implementing regulations and guidance or any corresponding or similar foreign laws, regulations or guidance.

1.12. “Clinical Development Samples” means Samples obtained by or on behalf of Company or any of its Affiliates from subjects enrolled in Clinical Studies of any Company Product and provided to FMI for use in connection with the Activities. [**].

1.13. “Clinical Outcomes Data” means clinical data [**] generated in the conduct of Clinical Studies conducted by or on behalf of Company or any of its Affiliates with respect to a Company Product that are related to the safety or efficacy of such Company Product.

1.14. “Clinical Studies” means studies conducted in human subjects and required by Applicable Law or recommended by a Regulatory Authority to obtain or maintain Regulatory Approvals for a Therapeutic Product.

1.15. “Collaboration Data” means that portion of the [**].

- 1.16. “Collaboration IP” means [**].
- 1.17. “Collaboration Know-How” means Know-How that is conceived, generated or otherwise developed [**].
- 1.18. “Commercialization” means any and all activities directed to the preparation for sale of, offering for sale of, or sale of a product, including activities related to marketing, promoting, distributing and importing such product, and interacting with Regulatory Authorities regarding any of the foregoing. For clarity, when used in relation to an FMI Assay or other IVD, “Commercialization” includes activities directed to the preparation for the sale of, offering for sale of, or sale of a service using such FMI Assay or other IVD, including activities related to marketing and promoting such service, and interacting with Regulatory Authorities regarding any of the foregoing. When used as a verb, “to Commercialize” and “Commercializing” mean to engage in Commercialization, and “Commercialized” has a corresponding meaning.
- 1.19. “Commercially Reasonable Efforts” means such efforts that are consistent with the efforts and resources normally associated with good business practice and standards [**].
- 1.20. “Companion Diagnostic” means an Approved IVD that provides information essential to the safe and effective use of a corresponding Therapeutic Product or is otherwise necessary for the Regulatory Approval of a Therapeutic Product.
- 1.21. “Company Background IP” means [**].
- 1.22. “Company Product” means a Therapeutic Product identified in an SOW for Development or Commercialization with an FMI Assay identified in such SOW.
- 1.23. “Complementary Diagnostic” means an Approved IVD that provides information helpful to the safe and effective use of a corresponding Therapeutic Product, but that is not a Companion Diagnostic.
- 1.24. “Control” means, with respect to any (i) (a) Know-How, (b) Patent or (c) other intellectual property right; (ii) Regulatory Documentation; or (iii) material, possession of the right, whether directly or indirectly and whether by ownership, license or otherwise (other than by operation of the licenses and other grants in Sections 6.2 and 6.3), to grant a license, sublicense or other right (including the right to reference Regulatory Documentation) to or under such Know-How, Patent, other intellectual property right, Regulatory Documentation or material as provided for herein without violating the terms of any agreement with any Third Party.
- 1.25. “Deliverables” means the work product or other deliverables a Party agrees to provide to the other Party with respect to a project, as specified in the applicable SOW.
- 1.26. “Development” means activities relating to the development, optimization, validation or clinical testing of any product (including any Product), including activities relating to obtaining or maintaining Regulatory Approval of such product. When used as a verb, “Develop” means to engage in Development.
- 1.27. “Disclosing Party” means, with respect to Confidential Information, the Party that provides or is deemed to provide such Confidential Information to the other Party.
- 1.28. “Drug Approval Application” means a “new drug application” as defined in the FDCA, a “biologics license application” as defined in the FDCA, or any corresponding foreign

application in any country or territory, including, with respect to the EU, a marketing authorization application filed with the EMA pursuant to the centralized approval procedure or with the applicable Regulatory Authority of a country in the EU with respect to the mutual recognition procedure or any other national approval, and any supplement to any of the foregoing.

1.29. “EMA” means the European Medicines Agency and any successor agency thereto.

1.30. “European Union” or “EU” means that certain economic, scientific and political organization of member states known as the European Union, as it may be constituted from time to time, or any successor thereto.

1.31. “Exploit” means to make, have made, import, use, sell, offer for sale or otherwise exploit, including to research, Develop, Commercialize, register, manufacture, have manufactured, hold or keep (whether for disposal or otherwise), have used, export, transport, distribute, promote, market or have sold or otherwise dispose of. For clarity, when used in relation to any IVD, “Exploit” includes the performance of any service using such IVD, and the making, having made, import, use, sale or offer for sale or other exploitation of such IVD for use in connection with such service, including the research, Development, Commercialization, registration, manufacture, having manufactured, holding or keeping (whether for disposal or otherwise), having used, exportation, transportation, distribution, promotion, marketing or having sold or otherwise disposing of such IVD for use in connection with such service. “Exploitation” means the act of Exploiting.

1.32. “FDA” means the United States Food and Drug Administration and any successor agency thereto.

1.33. “FFDCA” means the United States Federal Food, Drug, and Cosmetic Act, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions and modifications thereto).

1.34. “FMI Assay” means [**].

1.35. “FMI Contracting Collaborator” means a Third Party with which FMI or any of its Affiliates has entered or enters into a contractual arrangement pursuant to which such Third Party collaborates with FMI in relation to, or is granted rights to Exploit, the FMI Technology Platform (or aspects thereof) or any IVD in countries or territories outside the United States.

1.36. “FMI Operational Documentation” means documents and information setting forth or associated with the internal practices, policies, procedures, and systems used by or on behalf of FMI or any of its Affiliates to conduct and [**] including all documents and information related to compliance with QSR and CLIA requirements in the United States and any corresponding or similar requirements under Applicable Law for any other country or territory.

1.37. “FMI Technology Platform” means FMI products or services for testing of specimens to identify [**] and related technologies and any improvements to any of the foregoing, in each case, existing as of the Effective Date or during the Term.

1.38. [**].

1.39. “IND” means (i) an investigational new drug application filed with the FDA for authorization to commence Clinical Studies or any corresponding or similar application in other countries

or regulatory jurisdictions and (ii) all supplements and amendments that may be filed with respect to the foregoing.

1.40. “Indication” means, as specified in an applicable SOW, a disease or condition that a Company Product may be used to treat or prevent, subject to Regulatory Approval.

1.41. “IVD” or “In Vitro Diagnostic” means a product or service for in vitro testing of patient or subject specimens, or other biological materials, for use in the diagnosis or evaluation of a disease, including to identify any genomic alterations or signatures, or for the prediction or monitoring of a response to any Therapeutic Product (or other agent) or other prognostic use, whether used for research, exploratory purposes, or as a clinical diagnostic. The term “IVDs” includes “Investigation Use Only” products, “Research Use Only” products, Companion Diagnostics, Complementary Diagnostics and other IVDs.

1.42. “IVD Directive” means Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, as amended from time to time, and as implemented in the EU member states under national law, or any statutory modification, extension or re-enactment thereof.

1.43. “IVD Regulation” means Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 210/227/EU.

1.44. “Know-How” means all tangible and intangible: information, techniques, technology, practices, trade secrets, inventions (whether patentable or not), methods, know-how, data (including [**]), results (including [**]), analytical and quality control data, descriptions, software and algorithms, in each case, of a scientific or technical nature, excluding [**] Documentation and [**] Documentation.

1.45. “Market” means, on a Company Product-by-Company Product and Indication-by-Indication basis, as specified in an applicable SOW, a country or territory for which the Parties intend to Develop and seek Regulatory Approval of an FMI Assay for use with such Company Product for such Indication to enable the Commercialization of such FMI Assay in such country or territory.

1.46. “Materials” means Samples or other biological materials, compounds, reagents and supplies that Company delivers or causes to be delivered to FMI in connection with an SOW.

1.47. “Notified Body” means an entity licensed, authorized or approved by the applicable government agency, department or other authority to assess and certify the conformity of an in vitro diagnostic medical device with the requirements of the IVD Directive or IVD Regulation, as applicable, and applicable harmonized standards.

1.48. “Patents” means: (i) all national, regional and international patents and patent applications, including provisional patent applications; (ii) all patent applications claiming priority from such patent applications, provisional applications or from an application claiming priority from either of these, including divisionals, continuations, continuations-in-part, converted provisionals and continued prosecution applications; (iii) any and all patents that have issued or in the future issue from the foregoing patent applications ((i) and (ii)), including utility models, petty patents, innovation patents and design patents and certificates of invention; (iv) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations, reviews and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((i), (ii) and (iii)); and (v) any similar rights, including so-called pipeline protection or

any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any of such foregoing patent applications and patents.

1.49. “Permitted Representative” means a representative duly authorized by Company who shall be bound by written confidentiality and non-use obligations no less stringent than those set forth in this Agreement, and shall explicitly exclude any direct competitors of FMI

1.50. “Person” means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

1.51. “PMA” means (i) a premarket approval application filed with the FDA or any corresponding or similar application in other countries or regulatory jurisdictions and (ii) all supplements and amendments that may be filed with respect to the foregoing.

1.52. “PMA Approval” means approval in accordance with Section 515 of the FDCA and 21 C.F.R. Part 814 of a PMA, including approval of supplemental PMAs (including those supplemental PMAs reviewed using the ‘Real-Time Review’ process), by the FDA for a Class III device or similar approval in other countries or regulatory jurisdictions.

1.53. “Product” means, in the case of Company, any Company Product and, in the case of FMI, any FMI Assay, in each case, as designated in an applicable SOW.

1.54. “Program,” as such term is used in relation to partial termination of this Agreement, or to any consequences of any such partial termination, means, collectively, an applicable FMI Assay, Company Product, Indication and Market covered by an SOW. For clarity, an SOW may cover [**].

1.55. “Quality System Regulation” or “QSR” means the requirements applicable to manufacturers of finished medical devices (including design control and current good manufacturing practices) pertaining to the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use, as specified in 21 C.F.R. Part 820 and FDA’s guidance documents, and all successor applicable regulations and guidance documents thereto.

1.56. “Receiving Party” means, with respect to Confidential Information, the Party that receives or is deemed to receive such Confidential Information from the other Party or its agents.

1.57. “Regulatory Approval” means any and all clearances, approvals, licenses, registrations or authorizations of any Regulatory Authority necessary to commercially distribute, sell or market a product (including a Company Product or an FMI Assay) in a country or territory, including, in the case of an IVD, any required certificates of conformity from a Notified Body and the manufacturer’s formal declaration of conformity that the IVD complies with the requirements for CE marking.

1.58. “Regulatory Authority” means any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other government entities regulating or otherwise exercising authority with respect to the Exploitation of Therapeutic Products or IVDs (including Products) in any country, regulatory jurisdiction or territory, including the FDA for the United States and the EMA for the European Union, and any Notified Body that has responsibility for the regulation of any IVD for any country, regulatory jurisdiction or territory, and any successor(s) to any of the foregoing.

1.59. “Regulatory Documentation” means: all (i) applications (including all INDs, Drug Approval Applications, investigational device exemption filings, 510(k)s, de novo determinations, humanitarian device exemption filings and PMAs), registrations, licenses, authorizations and approvals (including Regulatory Approvals); and (ii) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority), including all adverse event files and complaint files; in each case ((i) and (ii)), relating to an FMI Assay or a Company Product.

1.60. “Samples” means biological materials, including human tissue and its derivatives or components (e.g., cell lines and DNA), as may be further identified in an applicable SOW, which may include [**] Samples, as applicable.

1.61. “Selected Biomarker(s)” means the one or more biomarkers identified in an applicable SOW as relevant to an FMI Assay and a Company Product.

1.62. “Senior Officer” means, with respect to FMI, its Vice President of Biopharma and Corporate Alliances and with respect to Company, its Chief Scientific Officer, or their respective designees.

1.63. “SOW” or “Statement of Work” means a plan executed by an authorized representative of both Parties under this Agreement that details a project, in the form provided as Attachment A.

1.64. “SOW Effective Date” means, with respect to an SOW, the date on which such SOW becomes effective, as set forth in such SOW.

1.65. “Statistical Analysis Plan” means any statistical analysis plan used or developed for use in performing any statistical analysis under the applicable SOW for the purpose of [**].

1.66. “Therapeutic Product” means any product that constitutes or contains a chemical or biologic substance for the medical cure, treatment or prevention of disease.

1.67. “Third Party” means any Person other than FMI, Company and their respective Affiliates.

1.68. [**].

1.69. “Trademark Rights” means any word, name, symbol, color, shape, designation or any combination thereof, including any trademark, service mark, trade name, corporate name, brand name, sub-brand name, trade dress, product configuration, program name, delivery form name, certification mark, collective mark, logo (including corporate logo), tagline, slogan, design or business symbol, that functions as an identifier of source or origin, whether or not registered and all statutory and common law rights therein and all registrations and applications therefor, together with all goodwill associated with, or symbolized by, any of the foregoing.

1.70. “Trial Enrollment Samples” means Samples obtained by or on behalf of Company or any of its Affiliates in connection with any Clinical Study of a Company Product and provided to FMI for testing in order to determine the eligibility of a patient for enrollment in such Clinical Study.

1.71. “United States” or “U.S.” means the United States of America and its territories and possessions (including the District of Columbia and Puerto Rico).

1.72. Each of the following terms is defined in the Section set forth opposite such term:

Term	Section
Agreement	Preamble
Alliance Manager	4.3
Breaching Party	10.3.1
Breach Notice	10.3.1
Company	Preamble
Company Collaboration IP	6.1.1(ii)
Company Indemnitees	9.2
Company Trademark Rights	6.2.2
Confidential Information	7.1.1
Dispute	11.5.1
Effective Date	Preamble
Fee Schedule	5.1
FMI	Preamble
FMI Collaboration IP	6.1.1(i)
FMI Indemnitees	9.1
FMI Trademark Rights	6.2.1
[**]	[**]
Indemnitee	9.3
Indemnitor	9.3
IRB/Ethics Committee	2.4.2
Joint Collaboration IP	6.1.1(iii)
Joint Project Team or JPT	4.1
Losses	9.1
Non-Breaching Party	10.3.1
Notice Period	10.3.1
Officials	8.2.1
[**]	[**]
Payment Breach	10.3.1
Payments	8.2.1
Qualified Assignee	5.3
[**]	[**]
Subcontractor	11.3
Taxes	5.4
Term	10.1
Third Party Claims	9.1
[**]	[**]
[**]	[**]

ARTICLE 2
STATEMENTS OF WORK AND PROJECTS

2.1. Statements of Work.

2.1.1. **In General.** In the event the Parties agree that a project should be conducted under this Agreement, then the Parties may negotiate, prepare and execute an SOW for such project. Upon execution of one or more SOWs, such SOW(s) shall be deemed to be incorporated into and subject to the terms and conditions of this Agreement, and this Agreement (including such SOW(s)) shall constitute the entire agreement between the Parties with respect to the subject matter of such SOW(s). If there is a conflict between the terms of this Agreement and the terms of an SOW, then the terms of this Agreement shall prevail, unless such SOW specifically and expressly supersedes this Agreement on a specific matter, in which case the terms of the SOW shall prevail, but only with respect to such SOW and such matter. Nothing herein shall create an express or implied obligation on the part of either Party to enter into any other agreement or any SOW(s).

2.1.2. **Additional Markets.** In the event that Company desires to Commercialize a Company Product for an Indication in a country or territory that is not a Market with respect to such Company Product and Indication, where the relevant Regulatory Authorities for such country or territory require that a Companion Diagnostic for such Company Product be available in such country or territory for any such Commercialization, Company may provide written notice to FMI of such desire and specifying such country or territory. Without limiting Section 2.1.1, the Parties shall discuss in good faith whether to amend the applicable SOW or enter into a new SOW to provide for FMI to conduct further Development of, and seek Regulatory Approval for, the applicable FMI Assay for use as a Companion Diagnostic for such Company Product for such Indication for such country or territory, and to provide for additional milestones or other payments to FMI in connection therewith. Upon the Parties entering into such amendment or new SOW, such additional country or territory will be considered a Market under the applicable SOW.

2.2. **Performance of Activities.** Each Party shall^[**]to perform the Activities, including the provision of any ^[**], in each case, assigned or allocated to it under an applicable SOW. Notwithstanding the foregoing, the Parties acknowledge that each Party's performance under each SOW ^[**] For clarity, as between the Parties, (i) Company shall, at its own expense, be responsible for the Development of the Company Product(s), including the conduct of the Clinical Studies for the Company Product(s)^[**].

2.3. **Coordination.** FMI shall keep Company reasonably informed, through the applicable JPT, of its Development Activities for each FMI Assay Developed under an SOW for use with a Company Product for each applicable Market and Indication. Company shall keep FMI reasonably informed, through the applicable JPT, of its Development activities (including any Activities) for each Company Product for which an FMI Assay is Developed under an SOW, to the extent that such Development activities could reasonably impact Development of such FMI Assay.

2.4. Materials.

2.4.1. **In General.** Company shall provide to FMI, free of charge, the Materials specified in each SOW. Without limitation to the foregoing, (i) Company shall provide to FMI, free of charge, any ^[**]. If FMI determines that any Materials provided by or on behalf of Company do not conform to their descriptions under the applicable SOW or are not suitable for the Activities under the applicable SOW, then Company shall provide new or replacement Materials.

2.4.2. **Use and Disclosure.** ^[**].

2.4.3. **Samples Requirements.** Company shall ensure that all Samples transferred by or on behalf of Company to FMI under this Agreement will be or have been collected,

stored, handled, transported, and delivered in a manner appropriate to ensure compliance with all Applicable Law. To the extent Applicable Law requires any informed consent or other authorization for the collection or provision to FMI of any such Samples or any accompanying data, or for the use by or on behalf of FMI as permitted by this Agreement and any applicable SOW of any such Samples or accompanying data, then Company shall ensure that such informed consent or other authorization is obtained with a scope that permits such activities. With respect to any such Sample or accompanying data, (i) at FMI's reasonable request, Company shall provide to FMI (a) a copy of any protocol for any Clinical Study pursuant to which such Sample or data was obtained and the institutional review board or other ethics committee ("IRB/Ethics Committee") approval thereof, (b) a copy of any other necessary IRB/Ethics Committee approvals, (c) any applicable form of informed consent or other authorization and (d) a written attestation that all necessary approvals, informed consents or other authorizations have been obtained, and (ii) to the extent any amendment to any such protocol or form of informed consent or other authorization would impact the use of any FMI Assay in connection with a Clinical Study pursuant to any SOW, Company shall promptly inform FMI in writing of such amendment and provide to FMI any applicable updated versions of the items described in clauses (i)(a)-(d) above. FMI shall handle, store, use and, as applicable, transport the Samples provided to it by or on behalf of Company in a manner consistent with all Applicable Law. Company shall not, without first obtaining FMI's prior written consent and appropriate informed consent, if applicable, deliver to FMI personally identifiable healthcare information or other data that could potentially identify a specific individual, in connection with the Samples or otherwise. Upon Company's prompt written request following the end of the term of an SOW, FMI shall, at Company's sole expense, return to Company any unused Samples associated with such SOW that were provided to FMI by or on behalf of Company.

2.5. Regulatory Approval of FMI Assays, Company Products and Rights of Reference.

2.5.1. FMI Assays.

(i) FMI shall, at its own expense, have the sole right to prepare, obtain and maintain Regulatory Approvals for, and to conduct communications with the Regulatory Authorities regarding Regulatory Approvals for, any FMI Assay. As between the Parties, all Regulatory Documentation (including all Regulatory Approvals) generated by FMI or any of its Affiliates with respect to any FMI Assay anywhere in the world and all FMI Operational Documentation shall be owned by, and shall be the sole property and held in the name of, FMI or its designee. At FMI's reasonable request, Company shall provide FMI with any Regulatory Documentation and other information (including Collaboration Data) in the Control and possession of Company or any of its Affiliates with respect to each Company Product as may be necessary for, or reasonably requested by, FMI or any of its Affiliates to obtain or maintain Regulatory Approvals for any FMI Assay Developed under this Agreement. Without limiting the foregoing:

(a) if FMI determines that [**] then, at FMI's request, Company shall, at its option, either [**] and

(b) in the event that a Regulatory Authority requires post-PMA Approval or post-CE Marking Approval activities that are not Activities set forth in a development plan included in an applicable SOW as a condition of obtaining or maintaining PMA Approval or CE Marking Approval (as applicable) for use of any FMI Assay Developed pursuant to such SOW(s) with any Company Product for a Market and Indication, then [**].

(ii) FMI shall provide Company with an opportunity to review and comment on all regulatory filings that are [**] for use with the applicable Company Product for the applicable Indication, in each case, to the extent any such filing involves [**] such Company Product [**]

FMI shall [**] consider in good faith Company's comments with respect thereto to the extent relating to such Company Product; provided that in no event shall FMI be obligated to delay the submission of any such regulatory filing due to Company's failure to provide its comments in a timely manner. To the extent legally permissible, FMI shall provide Company with an opportunity to attend any scheduled meeting with a Regulatory Authority for the applicable Market(s) regarding obtaining Regulatory Approval of the applicable FMI Assay for use as an Approved IVD with the applicable Company Product for the applicable Indication solely to the extent such meeting includes (or is reasonably anticipated to include) a material discussion of such Company Product. At FMI's reasonable request, Company shall participate in any such scheduled meeting. Notwithstanding anything contained in this Section 2.5 or any term or condition of this Agreement to the contrary, Company acknowledges and agrees that FMI shall have no obligation to provide or disclose to Company any documents or other materials (including Regulatory Documentation or other information) with respect to [**].

2.5.2. Company Products.

(i) Company shall, at its own expense, have the sole right to prepare, obtain and maintain Regulatory Approvals for, and to conduct communications with Regulatory Authorities regarding Regulatory Approvals for, any Company Product. As between the Parties, all Regulatory Documentation (including all Regulatory Approvals) generated by Company or any of its Affiliates with respect to any Company Product anywhere in the world shall be owned by, and shall be the sole property and held in the name of, Company or its designee. At Company's reasonable request, FMI shall provide Company with any Regulatory Documentation and other information in the Control and possession of FMI or any of its Affiliates with respect to each FMI Assay Developed pursuant to this Agreement (including Collaboration Data) as may be necessary for, or reasonably requested by, Company or any of its Affiliates to refer to such FMI Assay in obtaining or maintaining Regulatory Approvals for any Company Product for each applicable Indication.

(ii) Company shall provide FMI with an opportunity to review and comment on all regulatory filings that are required to be made to obtain Regulatory Approval of the applicable Company Product for the applicable Indication(s) and applicable Market(s) for use with the applicable FMI Assay, in each case, to the extent any such filing involves a material discussion of such FMI Assay and which discussion has not been the subject of a prior opportunity for review and comment by FMI. Company shall consider in good faith FMI's comments with respect thereto to the extent relating to such FMI Assay; provided that in no event shall Company be obligated to delay the submission of any such regulatory filing due to FMI's failure to provide its comments in a timely manner. To the extent legally permissible, Company shall provide FMI with an opportunity to attend any scheduled meeting with a Regulatory Authority for the applicable Market(s) regarding obtaining Regulatory Approval of the applicable Company Product for the applicable Indication solely to the extent such meeting includes (or is reasonably anticipated to include) a material discussion of an applicable FMI Assay. At Company's reasonable request, FMI shall participate in any such scheduled meeting.

2.5.3. Rights of Reference.

(i) Company shall, and shall ensure that its Affiliates shall, upon request provide FMI (and FMI's designated Affiliates, (sub)licensees and subcontractors) with any appropriate letters or other similar documentation necessary to authorize such Person to cross-reference and rely (on a non-exclusive basis) upon the contents of Company's or any of its Affiliate's (or, to the extent Controlled by Company or any of its Affiliates, any of their respective (sub)licensee's) Regulatory Documentation for any Company Product [**].

(ii) FMI shall, and shall ensure that its Affiliates shall, upon request provide Company (and Company's designated Affiliates and (sub)licensees) with any appropriate letters

or other similar documentation necessary to authorize such Person to cross-reference and rely (on a non-exclusive basis) upon the contents of FMI's or any of its Affiliate's (or, to the extent Controlled by FMI or any of its Affiliates, any of their respective (sub)licensee's) Regulatory Documentation for any FMI Assay Developed [**] pursuant to this Agreement [**].

2.6. Compliance; Audits.

2.6.1. Compliance. Each of FMI and Company shall, and shall cause its Affiliates, and shall require its (sub)licensees and Subcontractors, to comply in all material respects with all Applicable Law with respect to its Development activities under this Agreement.

2.6.2. Audits. During the Term and no more than [**], on not less than [**] days' prior written notice and during FMI's normal business hours, Company shall have the right to audit or have audited by a Permitted Representative, solely to the extent necessary to confirm FMI's compliance with CLIA, QSR and other Applicable Law with respect to the conduct of the Activities, [**] Notwithstanding anything to the contrary in this Section 2.6.2:

(a) any audit conducted by or on behalf of Company [**] shall be deemed an audit under this Section 2.6.2[**] any audit conducted by or on behalf of Company under this Section 2.6.2 shall be deemed an audit[**] provided, however, that if Company [**] notifies FMI of any such audit [**]; and

(b) if any Regulatory Authority wishes to conduct an inspection on one or more days reserved for Company to conduct, or have conducted, any audit pursuant to this Section 2.6.2, then FMI shall have the right, upon written or telephonic notice to Company and without liability, to cancel such audit and shall work with Company in good faith to reschedule such audit for one or more days that does not conflict with such inspection.

2.6.3. Permitted Representatives. To the extent Company elects to utilize the services of a Permitted Representative to perform an audit permitted by Section 2.6.2, the selection of such Permitted Representative shall be approved by FMI. Any auditor (including any Permitted Representative) shall be subject to FMI's confidentiality, security and safety policies, and any audit shall not be unreasonably disruptive to FMI's business operations, and shall be reasonable in scope and duration. Any information, records or other materials provided by FMI in connection with such audit as well as any report, summary or other documentation resulting from such audit shall constitute FMI's Confidential Information.

2.7. Non-Exclusive Relationship. The Parties agree that this Agreement and any applicable SOW, and the relationship of the Parties hereunder and thereunder, are non-exclusive, including in the following non-limiting respects. [**].

ARTICLE 3 COMMERCIALIZATION

3.1. Coordination on Commercialization Activities. Unless a different time period is specified in an applicable SOW, no later than [**] months prior to the planned final submission to the applicable Regulatory Authority of an application for Regulatory Approval for an FMI Assay for use with the applicable Company Product for a given Market and Indication, the applicable JPT shall commence discussions of the high-level strategy (i) for FMI to make or cause to be made commercially available an FMI Assay for use with the Company Product for such Market and such Indication and (ii) for Company to make or cause to be made commercially available such Company Product for such Market and such

Indication, to the extent relevant to FMI's activities pursuant to clause (i) of this sentence. The JPT shall serve as a forum for the Parties to discuss periodically such strategies and to coordinate such activities as appropriate from time to time or as the Parties may further agree.

3.2. FMI Obligations. Following receipt of the required Regulatory Approvals for the applicable FMI Assay for use with the applicable Company Product for the applicable Market(s) and Indication(s), [**]; provided that such obligation is not intended and shall not be construed to require FMI to engage in any promotion or marketing for any FMI Assay (for clarity, including any such promotion or marketing specific to any Company Product).

3.3. Company Obligations. Following receipt of the required Regulatory Approvals for both (i) the applicable Company Product and (ii) the applicable FMI Assay for use with such Company Product, in each case ((i) and (ii)), for the applicable Market(s) and Indication(s), [**].

3.4. Commercialization Terms. As between the Parties, Company shall have the sole right to establish the terms of sale for, and otherwise Commercialize, any Company Product and FMI shall have the sole right to establish the terms of sale for, and otherwise Commercialize, any FMI Assay, in each case, [**].

3.5. Statements and Compliance with Applicable Law. Each Party shall and shall cause its Affiliates and Subcontractors to, comply in all material respects with all Applicable Law with respect to the Commercialization of, in the case of FMI, any FMI Assay Developed, or constituting an Approved IVD, for use with a Company Product, and in the case of Company, any Company Product.

ARTICLE 4 COLLABORATION MANAGEMENT

4.1. Joint Project Teams. Within [**] days after the effective date of each SOW, the Parties shall establish a joint project team (each, a "Joint Project Team" or "JPT") for the project under such SOW, which shall consist of [**] representatives from each Party, each with the requisite experience and seniority to enable such representatives to make decisions on behalf of the Party such representative represents with respect to the issues falling within the jurisdiction of such JPT. For clarity, a representative of a Party may represent such Party on more than one JPT. [**]. Each Party may substitute one or more of its representatives to the JPT, or its designated chairperson, on written notice to the other Party.

4.1.1. Functions of Joint Project Teams. Each JPT shall: (i) serve as a forum for coordinating the Parties' efforts to carry out a project under an applicable SOW and for discussing progress in relation to the same [**] (ii) discuss proposed amendments to the applicable SOW from time to time (and, for clarity, any amendments shall be effective only if approved by the Parties in writing in accordance with Section 11.8); (iii) discuss the overall strategy, including the submission plans, for obtaining and maintaining Regulatory Approval of (a) each FMI Assay for use with the applicable Company Product for the applicable Indication and Market and (b) each Company Product, to the extent relating to or likely to impact any applicable FMI Assay or Regulatory Approval thereof; (iv) discuss in good faith revised milestone events and milestone payment amounts contained in the applicable Fee Schedule to the extent such revision is provided for pursuant to Section 5.2; and (v) conduct such other responsibilities as may be assigned to each JPT hereunder or in accordance with this Agreement or an applicable SOW, or as may be mutually agreed by the Parties in writing.

4.2. General Provisions Applicable to Joint Project Teams. Each JPT shall meet as agreed by the Parties, in person [**] or by teleconference or video conference. The chairperson of the

applicable JPT shall be responsible for calling meetings, coordinating the creation of meeting agendas, and circulating minutes of each meeting for approval by the Parties. A meeting of a given JPT shall require the presence of at least [**] appointed by each Party. Representatives of the Parties on a JPT may attend meetings thereof either in person or by telephone, video conference or similar means in which each participant can hear what is said by, and be heard by, the other participants. Representation by proxy shall be allowed. Alliance Managers and other employees or consultants of a Party who are not representatives of the Parties on a JPT may attend meetings of such JPT; provided that such attendees (i) are subject to written obligations of confidentiality and non-use with respect to Confidential Information substantially similar to the obligations of confidentiality and non-use of the applicable Party pursuant to Article 7 (with a duration of confidentiality and non-use that is commercially reasonable under the circumstances); and (ii) in the case of non-employees of a Party, such attendance shall be subject to the consent of the other Party, which shall not be unreasonably withheld, conditioned or delayed. Each Party shall be responsible for all of its own expenses of participating in JPT meetings.

4.2.1. **Decision-Making.** The Parties agree that each JPT's role shall be limited to coordination and providing a forum for discussion with regard to matters within the functions of such JPT and [**] provided that this sentence is not intended, and shall not be construed, to relieve either Party from its obligations under this Agreement.

4.2.2. **Limitations on Authority.** Each Party shall retain the rights, powers, and discretion granted to it under this Agreement and no such rights, powers, or discretion shall be delegated to or vested in any JPT unless such delegation or vesting of rights is expressly provided for in this Agreement or an applicable SOW, or the Parties otherwise expressly so agree in writing. No JPT shall have the power to amend, modify, or waive compliance with any provision of this Agreement or any applicable SOW.

4.3. **Alliance Managers.** Each Party shall appoint [**] who shall oversee contact between the Parties for all matters between meetings of the JPTs and shall have such other responsibilities as the Parties may agree in writing after the Effective Date (the "Alliance Manager"). Each Party's Alliance Manager may be replaced at any time on written notice to the other Party. The Alliance Managers shall not have decision-making authority. For clarity, each Party's Alliance Manager may, if elected by such Party, also serve as a representative of such Party on one or more JPTs.

ARTICLE 5 PAYMENTS AND RECORDS

5.1. **Fee Schedules for SOWs.** Each SOW shall include a schedule of fees applicable to the project performed thereunder (each, a "Fee Schedule"), which may generally include: (i) agreed milestone payments by Company upon the achievement of corresponding milestone events set forth in such SOW and (ii) per Sample acquisition (as applicable) and testing fees for any genomic profiling activities under such SOW.

5.2. **Milestones.** Company shall pay to FMI the non-refundable, non-creditable milestone payments as specified in each applicable SOW upon the achievement of the corresponding milestone events and in accordance with the provisions of this Article 5. Company acknowledges and agrees that the inclusion of any milestone events with respect to any FMI Assay in an applicable SOW shall not be construed as implying that such milestone events can or will be achieved. In the event that [**] then the Parties shall discuss in good faith and adopt revised milestone events and milestone payment amounts or other fee adjustments to ensure FMI is fully compensated for the performance of Development Activities under the applicable SOW.

5.3. **Covenant of Company.** Company covenants to FMI that, if Company assigns this Agreement to a Third Party, then, unless otherwise agreed by the Parties in writing, Company shall remain responsible for all payments hereunder; provided that if Company assigns this Agreement to a Third Party that is a Qualified Assignee in accordance with Section 11.4.1, then Company shall no longer be responsible for such payments as of the effective date of such assignment to the extent the obligation to make such payments is assumed in writing by such Qualified Assignee. “Qualified Assignee” means, [**].

5.4. **Miscellaneous.** FMI shall invoice Company (i) following achievement of the applicable milestone event with respect to milestone payments and (ii) [**] with respect to other payments. Each invoice shall be submitted electronically and shall contain a statement of the milestone event achieved or other Activities performed with respect to the applicable payments [**] Company shall pay each invoice within [**] days of receipt thereof. All payments to FMI shall be remitted by deposit of United States Dollars in the requisite amount to such bank account as FMI may from time to time designate by notice to Company. Neither Party shall have the right to offset any amount owed by the other Party to such first Party under or in connection with this Agreement. All fees set forth in this Agreement are exclusive of sales and use taxes, including all applicable goods and services tax, value-added tax (VAT), local taxes, applicable duties, electronic delivery taxes, excise taxes, levies and import fees (collectively, “Taxes”). If applicable, Company shall pay any Taxes that are imposed by Applicable Law in connection with payments by Company to FMI under this Agreement. If any payment owed FMI is not paid when due, then Company shall pay interest thereon (before and after any judgment) at an annual rate (but with interest accruing on a daily basis) of [**] percent ([**]%), such interest to run from the date on which such payment became due until payment thereof in full together with such interest.

ARTICLE 6 INTELLECTUAL PROPERTY

6.1. Collaboration IP.

6.1.1. **Ownership and Use of Collaboration IP.** Subject to the license grant in Section 6.3, as between the Parties:

- (i) FMI shall own all right, title and interest in and to:
 - (a) [**];
 - (b) [**];
 - (c) [**]; and
 - (d) [**].
- (ii) Company shall own all right, title and interest in and to:
 - (a) [**];
 - (b) [**];
 - (c) [**];
 - (d) [**]; and

- (e) [**].
- (iii) The Parties shall each own an equal, undivided interest in and to:
 - (a) [**];
 - (b) [**]; and
 - (c) [**].
- (iv) [**].

(v) Each Party shall make reasonable efforts to promptly disclose to the other Party in writing the conception, reduction to practice, generation or other development by or on behalf of such first Party or any of its Affiliates of any invention included in the Joint Collaboration IP. FMI shall make reasonable efforts to promptly disclose to Company in writing the conception, reduction to practice, generation or other development by or on behalf of FMI or any of its Affiliates of any invention included in the Company Collaboration IP. Company shall make reasonable efforts to promptly disclose to FMI in writing the conception, reduction to practice, generation or other development by or on behalf of Company or any of its Affiliates of any invention included in the FMI Collaboration IP. Except as expressly set forth in this Section 6.1.1(v) and as required pursuant to Section 2.5.1 neither Party shall have the affirmative duty to disclose any Collaboration IP to the other Party.

(vi) Each Party shall, and does hereby, assign, and shall cause its Affiliates and its and their (sub)licensees to so assign, to the other Party, without additional compensation, such right, title and interest in and to any Know-How, improvements and other inventions, as well as any intellectual property rights with respect thereto (including Patents), as is reasonably necessary to fully effect ownership as provided for in this Section 6.1.1.

6.1.2. Prosecution and Maintenance of Patents Within Collaboration IP. As between the Parties, Company shall have the sole right, but not the obligation, using counsel of its own choice, to prepare, file, prosecute and maintain Patents within the Company Collaboration IP, worldwide, and to be responsible for any related interference, re-issuance, re-examination, review, opposition proceedings and patent term extensions, in each case, at its sole cost and expense. As between the Parties, FMI shall have the sole right, but not the obligation, using counsel of its own choice, to prepare, file, prosecute and maintain Patents within the FMI Collaboration IP worldwide, and to be responsible for any related interference, re-issuance, re-examination, review, opposition proceedings and patent term extensions, in each case, at its sole cost and expense. In the case of any Patents within the Joint Collaboration IP, [**]. Notwithstanding the foregoing, the Parties shall cooperate and implement reasonable Patent filing and prosecution strategies (including filing divisionals, continuations or otherwise) so that, to the extent reasonably feasible, claims that cover the inventions constituting Company Collaboration IP, FMI Collaboration IP and Joint Collaboration IP, are pursued in mutually exclusive patent applications.

6.1.3. Enforcement and Defense of Collaboration IP. As between the Parties, Company, at its sole cost and expense and using counsel of its own choice, shall have the sole right, but not the obligation, to prosecute infringement or misappropriation of and to defend any alleged or threatened assertion of invalidity or unenforceability with respect to Company Collaboration IP. As between the Parties, FMI, at its sole cost and expense and using counsel of its own choice, shall have the sole right, but not the obligation, to prosecute infringement or misappropriation of and to defend any alleged or threatened assertion of invalidity or unenforceability with respect to FMI Collaboration IP. In the case of any Joint Collaboration IP, [**].

6.2. Trademark License Grants.

6.2.1. Subject to Section 6.2.3, FMI, on behalf of itself and its Affiliates, hereby grants to Company and its Affiliates a non-exclusive, royalty-free right and license, with the right to grant sublicenses, to use the FMI Trademark Rights, if applicable, for use in performance of the Activities and to refer to any FMI Assay constituting an Approved IVD for use with each Company Product in Exploiting such Company Product, in each case, for the applicable Indication(s) and Market(s); provided, however, that any such reference shall be limited to information included in the label for such FMI Assay for the applicable Market. Company agrees that any use of the FMI Trademark Rights by Company or its Affiliates or sublicensees shall inure to the benefit of FMI. For purposes of this Agreement, "FMI Trademark Rights" means (i) any Trademark Rights used by or on behalf of FMI or any of its Affiliates in connection with the Commercialization of any FMI Assay (other than the Trademark Rights Controlled by Company and any of its Affiliates) that are Controlled by FMI or any of its Affiliates as of the Effective Date or during the Term; and (ii) the domain names Controlled by FMI or any of its Affiliates as of the Effective Date or during the Term, which domain names incorporate one or more of the Trademark Rights described in clause (i) as all or part of their URL address.

6.2.2. Subject to Section 6.2.3, Company, on behalf of itself and its Affiliates, hereby grants to FMI and its Affiliates a non-exclusive, royalty-free right and license, with the right to grant sublicenses, to use the Company Trademark Rights, if applicable, for use in performance of the Activities and in Exploiting any FMI Assay constituting an Approved IVD for use with each Company Product, in each case, for the applicable Indication(s) and Market(s); provided, however, that any reference to Company or the applicable Company Product made under such right and license shall be limited to information included in the label for such Company Product for the applicable Market. FMI agrees that any use of the Company Trademark Rights by FMI or its Affiliates or sublicensees shall inure to the benefit of Company. For purposes of this Agreement, "Company Trademark Rights" means (i) any Trademark Rights used by or on behalf of Company or any of its Affiliates in connection with the Commercialization of the Company Product(s) (other than the Trademark Rights Controlled by FMI and any of its Affiliates) that are Controlled by Company or any of its Affiliates as of the Effective Date or during the Term; and (ii) the domain names Controlled by Company or any of its Affiliates as of the Effective Date or during the Term, which domain names incorporate one or more of the Trademark Rights described in clause (i) as all or part of their URL address.

6.2.3. Each Party and its Affiliates shall, and shall require that any sublicensee shall, [**].

6.3. [**].

6.4. Third Party Licenses.

6.4.1. FMI shall promptly notify Company in writing in the event [**].

6.4.2. With regard to any [**].

6.4.3. Except as otherwise provided in this Section 6.4, each Party shall be [**] responsible for any other [**] fees that it or any of its Affiliates may incur in performing [**]. For clarity, nothing in this Section 6.4 is intended to restrict Company from pursuing any [**] Therapeutic Product.

6.5. Restricted Data. Prior to providing any [**] notwithstanding anything to the contrary in this Agreement or any SOW, the provisions of Attachment B shall apply.

6.6. Retained Rights. Neither Party grants to the other Party under this Agreement any intellectual property licenses or rights, express or implied, by estoppel or otherwise, other than those licenses or rights explicitly set forth in this Agreement. [**].

ARTICLE 7 CONFIDENTIALITY AND NON-DISCLOSURE

7.1. Confidentiality Obligations.

7.1.1. During the Term and for a period of [**] years thereafter, each Party shall and shall cause its officers, directors, employees and agents to (i) keep confidential, in a manner consistent with such Party's treatment of its own confidential or proprietary information, but in no event less than reasonable measures, (ii) not publish or otherwise disclose, directly or indirectly, except to the extent such disclosure is expressly permitted by the terms of this Agreement or any applicable SOW, and (iii) not use, except for the purposes of fulfilling its obligations or exercising its rights under this Agreement, in each case ((i)-(iii)), any Confidential Information of the other Party. "Confidential Information" of a Party means all data, materials and information, including all Know-How and other business, financial, legal or technical information, in any form (written, oral, photographic, electronic, magnetic, or otherwise) provided by or on behalf of such Party or its Affiliate to the other Party or its Affiliate in connection with this Agreement or an applicable SOW, whether prior to, on or after the Effective Date, that is marked or otherwise identified as confidential or proprietary at the time of disclosure or that a reasonable person would, by its nature, understand to be confidential or proprietary, including all copies thereof.

7.1.2. Notwithstanding Section 7.1.1, (i) the terms of this Agreement and each SOW shall be deemed the Confidential Information of both Parties (and both Parties shall be deemed to be the Receiving Party and the Disclosing Party with respect thereto); (ii) Confidential Information constituting Know-How included in the FMI Collaboration IP shall be deemed the Confidential Information of FMI (and FMI shall be deemed to be the Disclosing Party and Company shall be deemed to be the Receiving Party with respect thereto); (iii) Confidential Information constituting Know-How included in the Company Collaboration IP shall be deemed the Confidential Information of Company (and Company shall be deemed to be the Disclosing Party and FMI shall be deemed to be the Receiving Party with respect thereto); and (iv) Confidential Information constituting Know-How included in the Joint Collaboration IP shall be deemed the Confidential Information of both Parties (and both Parties shall be deemed to be the Receiving Party and the Disclosing Party with respect thereto).

7.1.3. Notwithstanding the foregoing provisions of this Section 7.1, Section 7.1.1 shall not apply to the Receiving Party with respect to any Confidential Information of the Disclosing Party to the extent it can be established by the Receiving Party through competent evidence that such Confidential Information: (i) is or hereafter becomes publicly available through no breach of any obligation of confidentiality by the Receiving Party; (ii) is subsequently received by the Receiving Party from a Third Party who is not bound by any obligation of confidentiality with respect to such information; (iii) was in the Receiving Party's possession prior to disclosure by the Disclosing Party without any obligation of confidentiality with respect to such information; or (iv) is independently developed by or for the Receiving Party without reference to the Disclosing Party's Confidential Information; provided that the exceptions under clauses (iii) and (iv) shall not apply to the Receiving Party with respect to Confidential Information that a Party generates but is deemed to be the Receiving Party with respect thereto pursuant to Section 7.1.2. Notwithstanding anything to the contrary herein, the exceptions set forth in this Section 7.1.3 shall not apply with respect to the terms of this Agreement or any SOW.

7.2. Permitted Disclosures. The Receiving Party may disclose Confidential Information of the Disclosing Party to the extent that such disclosure is: (i) made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial or local governmental or regulatory body of competent jurisdiction or, if in the reasonable opinion of the Receiving Party's legal counsel, such disclosure is otherwise required by Applicable Law, including by the U.S. Securities Exchange Commission, or by any stock exchange upon which such Party's securities are listed or to which an application for listing has been submitted; provided, however, that the Receiving Party shall first have given notice to the Disclosing Party (to the extent permitted by Applicable Law) and given the Disclosing Party a reasonable opportunity to quash such order or to obtain a protective order or confidential treatment requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued; (ii) subject to the Disclosing Party's prior written consent, not to be unreasonably withheld, conditioned or delayed, made by or on behalf of the Receiving Party to a patent authority for purposes of obtaining or enforcing Patents included in the Collaboration IP, in a manner not inconsistent with Section 6.1; (iii) made by or on behalf of the Receiving Party to potential or actual investors or acquirers as may be reasonably necessary in connection with their evaluation of such potential or actual investment or acquisition; [**] provided, however, in each case ((i)-(v)), that the Receiving Party shall take reasonable measures to assure confidential treatment of such information, to the extent such protection is available; and provided, further, that in the that case of clause (iii) or (v) such Persons shall be subject to obligations of confidentiality and non-use with respect to such Confidential Information substantially similar to the obligations of confidentiality and non-use of the Receiving Party pursuant to this Article 7 (with a duration of confidentiality and non-use that is commercially reasonable under the circumstances).

7.3. Use of Name. Except as expressly provided herein, including Section 6.2, in connection with this Agreement or any Activities hereunder, neither Party shall mention or otherwise use the name, logo or Trademark Rights of the other Party or any of its Affiliates or any of its or their (sub)licensees (or any abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material or other form of publicity without the prior written approval of such other Party. The restrictions imposed by this Section 7.3 shall not prohibit either Party from (i) making any disclosure identifying the other Party to the extent required in connection with its exercise of its rights or obligations under this Agreement or any applicable SOW or (ii) making any disclosure identifying the other Party that is required by Applicable Law or the rules of a stock exchange on which the securities of the Party making such disclosure are listed (or to which an application for listing has been submitted).

7.4. Public Announcements. Neither Party shall issue any public announcement, press release or other public disclosure regarding the terms of this Agreement or the terms of any SOW without the other Party's prior written consent, except for any such disclosure that is, in the opinion of the disclosing Party's counsel, required by Applicable Law and with respect to which reasonable prior notice and opportunity to comment thereon is given to the other Party.

7.5. Publication. Each Party recognizes that the publication of papers regarding results of and other information regarding activities under this Agreement or any applicable SOW, including oral presentations and abstracts, may be beneficial to both Parties; provided that such publications are subject to reasonable controls to protect Confidential Information. Accordingly, each Party shall have the right to review and approve (not to be unreasonably delayed or withheld) any paper proposed for publication by the other Party, including any oral presentation or abstract, which includes Collaboration Data [**] or which otherwise includes Confidential Information of the other Party the disclosure of which in such publication is not otherwise permitted under Section 7.1 or 7.2. Notwithstanding the foregoing, (i) if a Party requests approval to publish or publicly present any Confidential Information constituting Know-How included in the Joint Collaboration IP, the other Party shall consider such request in good faith, and (ii) the publishing or presenting Party shall (a) subject to

clause (i) above, comply with the other Party's request to delete from any such paper or presentation any Confidential Information of the other Party the disclosure of which in such publication is not otherwise permitted under Section 7.1 or 7.2 and (b) withhold publication of any such paper or presentation for up to [**] days after such other Party's written request in order to permit the Parties to obtain patent protection if either Party deems it reasonably necessary.

7.6. Return of Confidential Information. Upon expiration or termination of this Agreement or an applicable SOW for any reason, either Party may request in writing and the non-requesting Party shall either, with respect to Confidential Information of the other Party to which such non-requesting Party does not retain rights under the surviving provisions of this Agreement or such SOW: (i) promptly destroy all copies of such Confidential Information in the possession or control of the non-requesting Party and confirm such destruction in writing to the requesting Party; or (ii) promptly deliver to the requesting Party, at the requesting Party's sole cost and expense, all copies of such Confidential Information in the possession or control of the non-requesting Party. Notwithstanding the foregoing, the non-requesting Party shall be permitted to retain such Confidential Information (a) to the extent reasonably necessary or useful for purposes of performing any continuing obligations or exercising any ongoing rights hereunder or under any SOW and, in any event, a single copy of such Confidential Information for archival purposes and (b) any computer records or files containing such Confidential Information that have been created solely by such non-requesting Party's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with such non-requesting Party's standard archiving and back-up procedures, but not for any other uses or purposes. All Confidential Information shall continue to be subject to the terms of this Agreement for the period set forth in Section 7.1.1.

ARTICLE 8 REPRESENTATIONS, WARRANTIES AND COVENANT

8.1. Representations, Warranties and Covenant.

8.1.1. Mutual Representations, Warranties and Covenant. FMI and Company each represents and warrants to the other Party, as of the Effective Date, and, in the case of any representation and warranty as it relates to an SOW, as of the applicable SOW Effective Date, and covenants to the other Party that: (i) it is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization and has all requisite power and authority, corporate or otherwise, to execute, deliver and perform this Agreement; (ii) the execution and delivery of this Agreement and the applicable SOW and the performance by it of the transactions contemplated hereby have been, or in the case of an SOW, will be as of the applicable SOW Effective Date, duly authorized by all necessary corporate action on its part; (iii) this Agreement is, and, in the case of the applicable SOW, will be as of the applicable SOW Effective Date, a legal, valid and binding obligation of such Party enforceable against it in accordance with the terms and conditions hereof and thereof, subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance and general principles of equity (whether enforceability is considered a proceeding at law or equity); (iv) it is not under [**] any obligation, contractual or otherwise, to any Person that conflicts with the terms of this Agreement; and (v) neither it nor any of its Affiliates [**] has been debarred or is subject to debarment and neither it nor any of its Affiliates [**] will use in any capacity, in connection with the Activities to be performed under this Agreement, any Person who has been debarred pursuant to Section 306 of the FFDCFA or who is the subject of a conviction described in such section. Each Party covenants that it will inform the other Party in writing promptly upon becoming aware that it or any such Person who is performing Activities hereunder is debarred or is the subject of a conviction described in Section 306 of the FFDCFA, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of its or its

Affiliates' knowledge, is threatened, relating to the debarment or conviction of it or any such Person performing Activities hereunder.

8.1.2. **Additional Representation and Warranty and Covenant of Each Party.** Each Party represents and warrants to the other Party, as of the Effective Date, and, as it relates to an SOW, as of the applicable SOW Effective Date, and covenants to the other Party that, subject to Section 11.4.2, each Party has and will at all times have all rights with respect to any [**].

8.2. Covenants of the Parties.

8.2.1. Each Party agrees that neither it, nor anyone acting on its behalf, shall, either directly or indirectly, offer, make, or promise any payment of money or other assets in connection with this Agreement (collectively, "Payments") to any government or political party officials, officials of international public organizations, candidates for public office, or persons acting on behalf of any of the foregoing (collectively, "Officials") where such Payments would violate Applicable Law.

8.2.2. Each Party acknowledges that no employee of the other Party or its Affiliates shall have authority to give direction, either written or oral, relating to the making of any commitment by such first Party or its agents to any Third Party in violation of the terms of this Section 8.2.

8.3. **DISCLAIMER OF WARRANTIES.** NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, THAT THE OBJECTIVES OF ANY SOW CAN OR WILL BE ACHIEVED OR AS TO THE TIMING OR COST AND EXPENSE ASSOCIATED WITH THE ACHIEVEMENT OF ANY SUCH OBJECTIVES. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES HEREUNDER, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE AND EACH PARTY SPECIFICALLY DISCLAIMS HEREUNDER ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY PATENTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

ARTICLE 9 INDEMNITY

9.1. **Indemnification of FMI.** Company shall defend FMI, its Affiliates and its and their respective [**]; except in the cases of clause (i) and clause (ii), for any Losses to the extent arising from or occurring as a result of (a) [**].

9.2. **Indemnification of Company.** FMI shall defend Company, its Affiliates, and its and their respective [**]; except in the cases of clause (i) and clause (ii), for any Losses to the extent arising from or occurring as a result of [**].

9.3. **Indemnification Procedures.** A Party seeking indemnification (an "Indemnitee") shall (i) provide the indemnifying Party ("Indemnitor") with written notice, within a reasonable time after notice of any applicable Third Party Claim is received by Indemnitee; (ii) allow Indemnitor to have sole control of the defense or settlement of the Third Party Claim; provided, however, that Indemnitor shall not settle any Third Party Claim in a manner which may impose any obligation on or have a material adverse impact on Indemnitee without the prior written consent of the Indemnitee; and

(iii) provide Indemnitor with reasonable assistance, information and authority reasonably necessary to perform Indemnitor's obligations.

9.4. LIMITATIONS OF LIABILITY.

9.4.1. SPECIAL, INDIRECT AND OTHER LOSSES. [**].

9.4.2. GENERAL LIMITATION. [**].

ARTICLE 10
TERM AND TERMINATION

10.1. Term. The term of this Agreement (the "Term") commences on the Effective Date and continues until terminated in accordance with Section 10.2, 10.3 or 10.4; provided, however, that each SOW shall become effective as of the applicable SOW Effective Date.

10.2. Company Termination at Will. Subject to the terms and conditions of any applicable SOW, including any termination fees provided for therein, Company may terminate this Agreement, either in its entirety or on a SOW-by-SOW or on a Program-by-Program basis, for convenience by providing written notice of its intent to terminate to FMI, in which case, such termination shall be effective [**] days after FMI's receipt of such written notice.

10.3. Termination of this Agreement in its Entirety.

10.3.1. Material Breach. Without limiting its other rights or remedies under this Agreement, either Party (in such capacity, the "Non-Breaching Party") may terminate this Agreement in its entirety (including all SOWs then in effect) immediately upon written notice to the other Party in the event the other Party (in such capacity, the "Breaching Party") (i) has breached any of its material obligations under this Agreement and (ii) has failed to cure such breach within [**] days following receipt of written notice from the Non-Breaching Party of such breach (such period of time, the "Notice Period" and such written notice, with respect to any material breach under this Section 10.3.1 or Section 10.4.1, a "Breach Notice"); provided that such Notice Period shall be [**] days in the event of a failure to make any payment when due ("Payment Breach") and provided further that, except for Payment Breaches, the Notice Period will automatically be extended for a period of time, not to exceed [**] days following delivery of the Breach Notice, in the event that (a) such breach cannot be cured within the Notice Period and (b) the Breaching Party commences actions to cure such breach within the Notice Period and thereafter diligently continues such actions.

10.3.2. Mutual Agreement. The Parties may terminate this Agreement in its entirety (including all SOWs then in effect) at any time by mutual written agreement.

10.3.3. Insolvency. If either Party: (i) files for protection under bankruptcy or insolvency laws; (ii) makes an assignment for the benefit of creditors; (iii) appoints or suffers appointment of a receiver or trustee over substantially all of its property that is not discharged within [**] days after such filing; (iv) proposes a written agreement of composition or extension of its debts; (v) proposes or is a party to any dissolution or liquidation; (vi) files a petition under any bankruptcy or insolvency act or has any such petition filed against it that is not discharged within [**] days of the filing thereof; or (vii) admits in writing its inability generally to meet its obligations as they fall due in the general course, then the other Party may terminate this Agreement in its entirety (including all SOWs then in effect) effective immediately upon written notice to such Party.

10.4. Termination of this Agreement with respect to a Program.

10.4.1. **Material Breach.** Without limitation to Section 10.3.1, if the Breaching Party has breached any of its material obligations under this Agreement with respect to a Program, in addition to any other right or remedy the Non-Breaching Party may have, the Non-Breaching Party may terminate this Agreement with respect to such Program immediately upon written notice to the Breaching Party in the event that (i) the Non-Breaching Party has delivered a Breach Notice to the Breaching Party and (ii) the Breaching Party has failed to cure the applicable breach within the Notice Period; provided that such Notice Period shall be [**] days in the event of a Payment Breach; and provided further that, except for Payment Breaches, the Notice Period will automatically be extended for a period of time, not to exceed [**] days following delivery of the Breach Notice, in the event that (a) such breach cannot be cured within the Notice Period and (b) the Breaching Party commences actions to cure such breach within the Notice Period and thereafter diligently continues such actions.

10.4.2. **Mutual Agreement.** The Parties may terminate this Agreement with respect to any Program at any time by mutual written agreement.

10.4.3. **Deadlock.** In the event that either Party declares a deadlock with respect to a Program in accordance with Section 11.5.2, then either may terminate this Agreement with respect to such Program by providing [**] days' prior written notice to the other Party; provided that the Parties shall continue to discuss the issues with respect to which the applicable Party declared a deadlock in good faith during such notice period; and provided, further, that such termination shall not become effective at the end of such notice period if FMI agrees to proceed without revisions to the milestone events, milestone payment amounts or other fee adjustments or the Parties otherwise reach agreement on the issue(s) with respect to which a Party declared such deadlock.

10.4.4. **Inability to Obtain Regulatory Approval for an FMI Assay.** In the event that an applicable Regulatory Authority provides written notice of its determination that such Regulatory Authority will not grant a Regulatory Approval for an FMI Assay for use with an applicable Company Product for an applicable Market and Indication, then, following receipt of such notice, either Party may terminate this Agreement with respect to the applicable Program by providing [**] days' prior written notice to the other Party.

10.4.5. **Inability to Obtain Regulatory Approval for a Company Product.** In the event that an applicable Regulatory Authority provides written notice of its determination that such Regulatory Authority will not grant a Regulatory Approval for a Company Product for an applicable Market and Indication, then, following receipt of such notice, either Party may terminate this Agreement with respect to the applicable Program by providing [**] days' prior written notice to the other Party.

10.4.6. **Inability to Secure Third Party Licenses.** [**].

10.4.7. **Other Termination Rights of FMI.**

(i) [**].

(ii) [**].

10.5. **Rights in Bankruptcy.** All rights and licenses granted under or pursuant to this Agreement (including any SOW) by Company or FMI are and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, licenses of rights to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that the Parties, as licensees of such rights under this Agreement,

shall retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction.

10.6. Certain Consequences of Termination.

10.6.1. Termination of Agreement in its Entirety. If this Agreement is terminated in its entirety pursuant to Section 10.2 or 10.3, then the following terms and conditions shall apply (without limitation to Section 10.8), except in the event of termination by Company pursuant to Section 10.3.1:

- (i) [**];
- (ii) [**];
- (iii) [**];
- (iv) the license granted by Company to FMI in Section 6.2.2 shall survive in the case of any such termination occurring after Regulatory Approval of any FMI Assay for use as an Approved IVD with a Company Product; and
- (v) [**].

10.6.2. Post-Termination Payment Obligations.

(i) Payment of Amounts Due. If this Agreement is terminated in its entirety or with respect to any Program, or portion thereof, then Company shall (if applicable, with respect to the terminated Program):

- (a) [**];
- (b) [**];
- (c) [**];
- (d) [**]; and
- (e) [**].

The amounts due from Company to FMI pursuant to this Section 10.6.2 shall be paid within [**] days after FMI provides Company an invoice with respect thereto (or, with respect to clauses (a) through (e) above, by the date on which such amount is due under Section 5.4, if earlier).

(ii) Termination Fees. Without limitation to any other amounts that may become payable pursuant to Section 10.6.2(i), if (a) Company terminates this Agreement in its entirety or with respect to any Program pursuant to Section 10.2 and (b) any applicable SOW provides for payment of a termination fee in connection with such termination, then Company shall pay to FMI such termination fee within [**] days after FMI provides Company an invoice therefor.

10.7. Remedies. Except as otherwise expressly provided herein, termination of this Agreement or any SOW in accordance with the provisions hereof shall not limit remedies that may otherwise be available in law or equity.

10.8. Accrued Rights; Surviving Obligations.

10.8.1. Termination of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination, including, for clarity, any payments owed to FMI in relation to the period prior to such termination, regardless of whether a termination fee is paid. Such termination shall not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement. Without limiting the foregoing, Sections 2.4.2, 2.4.3, 2.5.1(i) (first and second sentences only, except as otherwise provided in this Section 10.8.1), [**] (in each case, to the extent provided in Section 10.6.1 or 10.8.2), 2.5.1(ii) (last sentence only), 2.5.2(i) (first and second sentences only), [**], 2.7, 3.4, 5.4 (as to amounts accrued as of the effective date of termination and, mutatis mutandis, amounts owed pursuant to Section 10.6.2 or otherwise upon or after termination), 6.1, 6.2.2 (to the extent provided in Section 10.6.1 [**]), 6.2.3 (to the extent the license in Section 6.2.2 survives), 6.3 [**], and only to the extent provided in Section 10.6.1 [**]), 6.4.3, 6.5 (and Attachment B), 6.6, 8.3, 10.5, 10.6, 10.7 and this Section 10.8 and Article 1 (to the extent necessary to interpret the remaining surviving provisions), Article 7 (in case of Sections 7.1 and 7.2, for the period set forth in Section 7.1.1), Article 9 and Article 11 (for clarity, including Section 11.19) (provided, however, that Section 11.5 shall survive solely for purposes of any Dispute arising in connection with the application of Section 10.6 or this Section 10.8 or any Dispute arising prior to the effective date of termination) shall survive the termination or expiration of this Agreement for any reason.

10.8.2. If this Agreement is terminated with respect to any Program pursuant to Section 10.2 or 10.4, then following such termination, the provisions of this Agreement shall remain in effect, except that the rights and obligations of the Parties hereunder shall exclude rights and obligations to the extent directed to such Program, and such Program shall be excluded from the role and responsibilities of the JPTs; provided, however, that (a) subject to clauses (b) and (c) below, each of the provisions listed in the last sentence of Section 10.8.1 shall survive with respect to such Program (as would apply in the case of termination of this Agreement in its entirety), (b) if this Agreement is terminated with respect to such Program (or in its entirety) by Company pursuant to Section 10.2 after the filing of an application for Regulatory Approval of the applicable FMI Assay for use with the applicable Company Product for the applicable Market and Indication, then (1) [**].

10.8.3. Except to the extent otherwise expressly provided in this Agreement, including Sections 10.6.2, 10.8.1 or 10.8.2, or in any applicable SOW, (i) in the case of any termination of this Agreement in its entirety, all SOWs shall terminate in their entirety and the provisions thereof shall not survive after the applicable termination date, and (ii) in the case of any termination of this Agreement with respect to a Program, (a) any SOW that covers such Program [**] shall terminate in its entirety and the provisions thereof shall not survive after the applicable termination date, (b) any SOW that covers such Program and one or more other Programs shall terminate [**], and (c) any SOW that does not cover such Program shall not terminate, and the provisions thereof remain in effect without modification.

ARTICLE 11 MISCELLANEOUS

11.1. Force Majeure. In the event either Party shall be delayed or hindered in or prevented from the performance of any act required hereunder by reasons of strike, lockouts, labor troubles, restrictive government or judicial orders or decrees, riots, insurrection, war, acts of God, inclement weather, disease outbreak, epidemic, pandemic or other similar reason or a cause beyond such Party's control (including, for clarity, the COVID-19 pandemic or any associated government restrictions or disruptions or shortages of labor, materials or power, communications, transportation or other similar services), then performance of such act shall be excused for the period of such delay, other than the payment of monies when due hereunder. Any timelines affected by such force majeure shall be extended for a period equal to that of the delay. Notice of the start and stop of any such force majeure shall be provided to the other Party.

11.2. **Export Control.** This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries that may be imposed on the Parties from time to time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other governmental entity in accordance with Applicable Law.

11.3. **Subcontracting.** Subject to the terms of this Agreement, each Party shall have the right to engage Affiliates or Third Parties (including in connection with the grant of a license to one or more Third Party (sub)licensees) to perform its obligations under this Agreement (each such Third Party, a “Subcontractor”); [**] the extent that a Party utilizes its Affiliates or engages Subcontractors after the Effective Date to perform tasks within the scope of any SOW, such Party shall ensure all such Affiliates or Subcontractors are obligated to treat the other Party’s Confidential Information as confidential based on commercially reasonable terms and conditions. [**].

11.4. **Assignment; Affiliates.**

11.4.1. Except as provided in Section 11.3, neither this Agreement nor any rights or obligations hereunder shall be assignable or otherwise transferable, in whole or in part, by a Party without the prior written consent of the other Party, except that each Party shall have the right, without such consent (but subject to Section 5.3 in the case of Company), to effect such assignment or transfer, in whole but not in part: (i) to any of its Affiliates (provided, however, that under this clause (i) the assigning Party shall remain responsible to the other Party for the performance of any such assigned or transferred obligations), or (ii) to any successor in interest (whether by merger, acquisition or asset purchase) to all or substantially all of the business to which this Agreement relates including, for clarity, in the case of FMI, to any successor in interest to its business with respect to the FMI Assay(s) intended for use with any Company Product; provided, however, that the assigning or transferring Party shall provide written notice to the other Party within [**] days after such assignment or transfer. All validly assigned or transferred rights or obligations of a Party shall inure to the benefit of and be enforceable by, or be binding on and be enforceable against, as applicable, the permitted successors and assigns of such Party. Any attempted assignment or other transfer in violation of this Section 11.4.1 shall be void and of no effect.

11.4.2. The rights to Know-How or other information, materials and intellectual property: (i) controlled by a Third Party permitted assignee of a Party that were controlled by such assignee (and not such Party) immediately prior to such assignment (other than as a result of a license or other grant of rights, covenant or assignment by such Party or its Affiliates to, or for the benefit of, such Third Party); or (ii) controlled by an Affiliate of a Party that becomes an Affiliate through any direct or indirect Change of Control of such Party or parent of such Party, that were controlled by such Affiliate (and not such Party) immediately prior to such Change of Control (other than as a result of a license or other grant of rights, covenant or assignment by such Party or its other Affiliates to, or for the benefit of, such Affiliate), [**].

11.4.3. Notwithstanding the foregoing, each Party shall have the right to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any Affiliate, and, in the case of FMI, through any FMI Contracting Collaborator.

11.5. **Dispute Resolution.**

11.5.1. **Referral to Senior Officers.** Except with respect to matters reserved for the final decision-making authority of one Party or the other pursuant to Section 4.2.1 or as provided in

Section 11.10, if a dispute arises between the Parties in connection with or relating to this Agreement (including any SOW), or any document or instrument delivered in connection herewith (each, a “Dispute”), then either Party shall have the right to refer such Dispute to the Senior Officers for attempted resolution by good faith negotiations during a period of [**] business days. For clarity, matters reserved for the final decision-making authority of a Party pursuant to Section 4.2.1 and matters that are subject to the provisions of Section 11.10 shall not be referable to Senior Officers for resolution.

11.5.2. Resolution. Any final decision mutually agreed to in writing by the Senior Officers shall be conclusive and binding on the Parties. If the Senior Officers are unable to resolve any such Dispute within the period set forth in Section 11.5.1, then: (i) [**]; and (ii) except as provided in clause (i), with respect to any other unresolved Dispute, either Party shall be free to exercise any right of such Party to institute litigation in accordance with Section 11.6.

11.5.3. Interim Relief. Notwithstanding anything herein to the contrary, nothing contained in this Section 11.5 shall preclude either Party from seeking interim or provisional relief, including a temporary restraining order, preliminary injunction or other interim equitable relief, including concerning a Dispute, if reasonably necessary to protect the interests of such Party. This Section 11.5.3 shall be specifically enforceable.

11.6. Governing Law, Jurisdiction and Service. This Agreement shall be governed by and construed in accordance with the laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. The Parties agree to exclude the application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods. The Parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction of the courts of the Southern District of New York for any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement and agree to not commence any action, suit or proceeding (other than appeals therefrom) related thereto except in such courts. The Parties irrevocably and unconditionally waive their right to a jury trial. The Parties further hereby irrevocably and unconditionally waive any objection to the laying of venue of any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement in the courts of the Southern District of New York and hereby further irrevocably and unconditionally waive and agree to not plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum. Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in Section 11.7 shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any such court.

11.7. Notices. Any notice, request, demand, waiver, consent, approval or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement (and any applicable SOW) and shall be deemed given only if delivered by hand or sent by electronic transmission (with transmission confirmed) or by an internationally recognized overnight delivery service that maintains records of delivery, addressed to a Party at its respective address specified below or to such other address as the Party to whom notice is to be given may have provided to the other Party in accordance with this Section 11.7. Such notice shall be deemed to have been given as of the date delivered by hand or electronically transmitted (with transmission confirmed) or on the second business day (at the place of delivery) after deposit with an internationally recognized overnight delivery service. Any notice with respect to any Dispute or breach (or alleged breach) or termination of this Agreement that is delivered by electronic transmission shall be confirmed by a hard copy delivered as soon as practicable thereafter. This Section 11.7 is not intended to govern the day-to-day business communications between the Parties in performing their obligations under the terms of this Agreement or any SOW.

<p>If to Company, to: Arvinas Operations, Inc. 5 Science Park 395 Winchester Avenue New Haven, CT 06511 U.S.A. Attention: Legal Department Facsimile: N/A Email: [**]</p> <p>If to Company Parent, to: Arvinas, Inc. 5 Science Park 395 Winchester Avenue New Haven, CT 06511 U.S.A Attention: Legal Department Facsimile: N/A Email: [**]</p>	<p>If to FMI, to: Foundation Medicine, Inc. 10 Canal Park Cambridge, MA 02141 U.S.A. Attention: VP, Business Development Facsimile: [**]</p> <p>With a copy to:</p> <p>Foundation Medicine, Inc. 10 Canal Park Cambridge, MA 02141 U.S.A. Attention: General Counsel Email: [**]</p>
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11.8. Entire Agreement; Amendments. This Agreement, together with any and all SOWs executed hereunder and incorporated herein, and any Appendix, Attachment, Annex or Schedule hereto or thereto, sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof, and all prior agreements, understandings, promises and representations, whether written or oral, with respect thereto, including the Mutual Confidentiality Agreement entered into by Company and FMI dated as of August 30, 2021, are superseded hereby. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth in this Agreement. No amendment, modification, release or discharge with respect to this Agreement (including any SOW) shall be binding upon the Parties unless in writing and duly executed by an authorized representative of each Party. Subject to Section 2.1.1, in the event of any inconsistencies between this Agreement and any schedules or other attachments hereto (including any SOW), the terms of this Agreement shall control.

11.9. English Language. This Agreement shall be written and executed in and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

11.10. Equitable Relief. Each Party acknowledges and agrees that the restrictions set forth in Article 6 and Article 7 are reasonable and necessary to protect the legitimate interests of the other Party and that such other Party would not have entered into this Agreement in the absence of such restrictions and that any breach or threatened breach of any provision of such Articles may result in irreparable injury to such other Party for which there will be no adequate remedy at law. In the event of a breach or threatened breach of any provision of such Articles, the non-breaching Party shall be authorized and entitled to seek from any court of competent jurisdiction injunctive relief, whether preliminary or permanent and specific performance, which rights shall be cumulative and in addition to any other rights or remedies to which such non-breaching Party may be entitled in law or equity. Each Party agrees to waive any requirement that the other Party (i) post a bond or other security as a condition for obtaining any such relief or (ii) show irreparable harm, balancing of harms, consideration of the public interest or inadequacy of monetary damages as a remedy. Nothing in this Section 11.10 is intended or should be

construed, to limit either Party's right to equitable relief or any other remedy for a breach of any other provision of this Agreement.

11.11. **Waiver and Non-Exclusion of Remedies.** Any term or condition of this Agreement (including any SOW) may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party of any right under this Agreement, or of the failure to perform or of a breach by the other Party, shall not be deemed a waiver of any other right under this Agreement or of any other breach or failure by such other Party whether of a similar nature or otherwise. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available except as expressly set forth herein.

11.12. **No Benefit to Third Parties.** Except as specifically provided in Sections 9.1 and 9.2, the covenants and agreements set forth in this Agreement are for the sole benefit of the Parties and their successors and permitted assigns and they shall not be construed as conferring any rights on any other Persons.

11.13. **Further Assurance.** Each Party shall duly execute and deliver or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be reasonably necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

11.14. **Relationship of the Parties.** It is expressly agreed that FMI and Company shall be independent contractors and that the relationship between the Parties under this Agreement and any SOW(s) shall not constitute a partnership, joint venture or agency. Neither FMI nor Company shall have the authority to make any statements, representations or commitments of any kind, or to take any action that will be binding on the other, without the prior written consent of the other Party to do so. All persons employed by a Party shall be employees of such Party and not of the other Party, and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such first Party.

11.15. **References.** Unless otherwise specified, (i) references in this Agreement to any Article, Section, Appendix, Attachment, Annex or Schedule shall mean references to such Article, Section, Appendix, Attachment, Annex or Schedule of this Agreement; (ii) references in any Section to any clause are references to such clause of such Section; and (iii) references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently amended, restated, replaced or supplemented from time to time, as so amended, replaced or supplemented and in effect at the relevant time of reference thereto.

11.16. **Construction.** Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. To the extent any provision of this Agreement requires for any purpose a Party's consent or approval, such consent or approval shall not be unreasonably withheld, conditioned or delayed, unless otherwise expressly provided. The headings of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. Each of the terms "including," "include," or "includes" as used herein shall mean including, without limiting the generality of any description preceding each such term. Any capitalized

term used in any SOW but not otherwise defined therein shall have the meaning provided in this Agreement. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party.

11.17. **Severability.** If any one or more provisions of this Agreement shall be found to be illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby, provided the surviving agreement materially comports with the Parties' original intent. The Parties agree that any such illegal or unenforceable provisions will be deemed replaced with valid and enforceable provisions that achieve, to the extent possible, the business purposes and intent of such invalid and unenforceable provisions.

11.18. **Counterparts.** This Agreement and any SOW(s) may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement and any SOW(s) may be executed by facsimile, PDF format via email or other electronically transmitted signatures and such signatures shall be deemed to bind each Party as if they were original signatures.

11.19. [**].

SIGNATURE PAGE FOLLOWS.

IN WITNESS THEREOF, this Agreement has been executed by the Parties and Company Parent through their duly authorized representatives as of the Effective Date.

ARVINAS OPERATIONS, INC.

FOUNDATION MEDICINE, INC.

By: /s/ Sean Cassidy

By: /s/ John Truesdell

Name: Sean Cassidy_____

Name: John Truesdell_____

Title: CFO_____

Title: VP Biopharma Partnership Development__

ARVINAS, INC.

By: /s/ Sean Cassidy

Name: Sean Cassidy_____

Title: CFO_____

Signature Page to Master In Vitro Diagnostics Agreement

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

Date: August 4, 2022

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

Date: August 4, 2022

By: _____

/s/ Sean Cassidy

Sean Cassidy
Chief Financial Officer and Treasurer
(Principal Financial and Accounting 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 June 30, 2022 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: August 4, 2022

By: _____ /s/ John Houston, Ph.D.
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 June 30, 2022 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: August 4, 2022

By: _____ /s/ Sean Cassidy
Sean Cassidy
Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)