

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

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): November 3, 2021

Arvinas, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38672
(Commission
File Number)

47-2566120
(IRS Employer
Identification No.)

**5 Science Park
395 Winchester Ave.
New Haven, Connecticut**
(Address of principal executive offices)

06511
(Zip Code)

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

Not applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

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

Item 2.02 Results of Operations and Financial Condition.

On November 3, 2021, Arvinas, Inc. announced its financial results for the quarter ended September 30, 2021. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Form 8-K (including Exhibit 99.1) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1 [Press Release issued by the Registrant on November 3, 2021.](#)

104 Cover Page Interactive Data File (formatted as Inline XBRL).

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 hereunto duly authorized.

ARVINAS, INC.

Date: November 3, 2021

By: /s/ Sean Cassidy
Sean Cassidy
Chief Financial Officer



Arvinas Reports Third Quarter 2021 Financial Results and Provides Corporate Update

NEW HAVEN, Conn. – November 3, 2021 – Arvinas, Inc. (Nasdaq: ARVN), a clinical-stage biotechnology company creating a new class of drugs based on targeted protein degradation, today reported financial results for the third quarter ended September 30, 2021 and provided a corporate update.

“The team at Arvinas has made a number of significant achievements throughout the year, from initiating multiple clinical trials to completing a potentially transformational collaboration with Pfizer, further establishing our leadership position in the field of targeted protein degradation,” said John Houston, Ph.D., chief executive officer at Arvinas. “We believe the upcoming presentation of data from the completed Phase 1 dose escalation study with ARV-471 for the treatment of patients with locally advanced or metastatic ER+/HER2- breast cancer sets us up for a strong finish to what so far has been an important year of execution.”

“As we look ahead, our collaboration with Pfizer has enabled us to further evaluate the most efficient development pathway for ARV-471,” continued Dr. Houston. “In addition to initiating multiple planned Phase 3 studies with ARV-471 in 2022, we now intend to initiate the Phase 1b combination study with everolimus, potentially as part of a planned umbrella study with multiple combination agents with Pfizer, as well as the neoadjuvant study, in 2022. Additionally, we expect to present the full dose escalation data from the ARV-110 Phase 1 trial and an interim readout from the ARDENT Phase 2 expansion trial at ASCO Genitourinary Cancers Symposium in February 2022, an opportunity to showcase a more complete picture of the potential of ARV-110 in metastatic castration-resistant prostate cancer.”

Business Highlights and Recent Developments

- Initiated Phase 1b combination trial with ARV-110 and abiraterone for the treatment of metastatic castration-resistant prostate cancer (mCRPC).
- Completed global collaboration with Pfizer that included an upfront payment to Arvinas of \$650 million, a \$350 million equity investment from Pfizer, and \$1.4 billion in potential milestone payments to co-develop and co-commercialize ARV-471 to the treatment of patients with ER+ breast cancer. Arvinas and Pfizer will equally share worldwide development costs, commercialization expenses, and profits.

Anticipated Milestones and Expectations

ARV-471

- Present Phase 1 dose escalation trial data (San Antonio Breast Cancer Symposium, December 2021)
- Present data from the VERITAC Phase 2 expansion trial (200 and 500 mg) (2022)
- Present safety data from the Phase 1b combination study with palbociclib (2022)
- Initiate multiple Phase 3 trials in metastatic breast cancer (as monotherapy and in combination) (2022)

- Initiate Phase 1b combination trial with everolimus in 2L/3L metastatic breast cancer, potentially as part of a planned umbrella study with Pfizer to explore multiple combination agents (2022)
- Initiate Phase 2 neoadjuvant trial in early breast cancer (2022)

ARV-110

- Present completed Phase 1 dose escalation data at ASCO Genitourinary Cancers Symposium (February 2022)
- Present interim data from the ARDENT Phase 2 dose expansion (420 mg) at ASCO Genitourinary Cancers Symposium (February 2022)

ARV-766

- Announce Phase 1 dose escalation data in mCRPC (2022)
- Initiate Phase 2 expansion trial in mCRPC (2022)

Third Quarter Financial Results

Cash, Cash Equivalents, Restricted Cash and Marketable Securities Position: As of September 30, 2021, cash, cash equivalents, restricted cash and marketable securities were \$1,549.0 million as compared with \$688.5 million as of December 31, 2020. The increase in cash, cash equivalents, restricted cash and marketable securities of \$860.5 million for the first nine months of 2021 was primarily related to cash received from the global Pfizer collaboration agreement to develop and commercialize ARV-471 (ARV-471 Collaboration Agreement) of \$650.0 million, the equity investment by Pfizer of \$350.0 million and proceeds from the exercise of stock options of \$14.7 million, partially offset by cash used in operating activities of \$133.9 million (net of \$4.2 million received from two collaborators), professional fees associated with the global Pfizer collaboration and equity investment of \$17.5 million, and the purchase of lab equipment and leasehold improvements of \$2.8 million.

Research and Development Expenses: Research and development expenses were \$40.6 million for the quarter ended September 30, 2021, as compared with \$30.0 million for the quarter ended September 30, 2020. The increase in research and development expenses of \$10.6 million for the quarter was primarily due to an increase in our continued investment in our platform and exploratory programs of \$9.0 million and an increase in expenses related to our AR program (which includes ARV-110 and ARV-766) of \$3.5 million, partially offset by a decrease in our ER program of \$1.9 million, which includes the cost sharing of ARV-471 under the ARV-471 Collaboration Agreement with Pfizer.

General and Administrative Expenses: General and administrative expenses were \$16.0 million for the quarter ended September 30, 2021, as compared with \$9.3 million for the quarter ended September 30, 2020. The increase of \$6.7 million was primarily due to an increase in personnel and facility related costs of \$5.0 million and insurance and professional fees of \$1.7 million.

Revenues: Revenues were \$9.3 million for the quarter ended September 30, 2021 as compared to \$7.6 million for the quarter ended September 30, 2020. Revenue is related to the ARV-471 Collaboration Agreement with Pfizer that was initiated in July 2021, the license and rights to technology fees and research and development activities related to the collaboration and license agreement with Bayer that was initiated in July 2019, the collaboration and license agreement with Pfizer that was initiated

in January 2018, and the amended and restated option, license and collaboration agreement with Genentech that was initiated in November 2017. The increase in revenues of \$1.7 million was primarily due to revenue from the ARV-471 Collaboration Agreement with Pfizer, partially offset by the addition of new targets added in 2020 under the January 2018 Pfizer Collaboration Agreement extending the revenue recognition period.

Net Loss: Net loss was \$46.8 million for the quarter ended September 30, 2021, as compared with \$30.8 million for the quarter ended September 30, 2020. The increase in net loss for the quarter was primarily due to increased research and development expenses and increased general and administrative expenses, partially offset by increased revenue.

About ARV-110

ARV-110 is an investigational orally bioavailable PROTAC[®] protein degrader designed to selectively target and degrade the androgen receptor (AR). ARV-110 is being developed as a potential treatment for men with metastatic castration-resistant prostate cancer.

ARV-110 has demonstrated activity in preclinical models of AR mutation or overexpression, both common mechanisms of resistance to currently available AR-targeted therapies.

About ARV-471

ARV-471 is an investigational orally bioavailable PROTAC[®] protein degrader designed to specifically target and degrade the estrogen receptor (ER) for the treatment of patients with locally advanced or metastatic ER+/HER2- breast cancer.

In preclinical studies, ARV-471 demonstrated near-complete ER degradation in tumor cells, induced robust tumor shrinkage when dosed as a single agent in multiple ER-driven xenograft models, and showed superior anti-tumor activity when compared to a standard of care agent, fulvestrant, both as a single agent and in combination with a CDK4/6 inhibitor.

About ARV-766

ARV-766 is an investigational orally bioavailable PROTAC[®] protein degrader designed to selectively target and degrade AR. In preclinical studies, ARV-766 degraded all resistance-driving point mutations of AR, including L702H, a mutation associated with treatment with abiraterone and other AR-pathway therapies.

ARV-766 is being developed as a potential treatment for men with metastatic castration-resistant prostate cancer, and ARV-766 may also have applicability in other AR-driven diseases both in and outside oncology. ARV-766 has demonstrated activity in preclinical models of resistance to currently available AR-targeted therapies.

About Arvinas

Arvinas 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. Arvinas uses its proprietary PROTAC[®] Discovery Engine platform to engineer proteolysis targeting chimeras, or PROTAC[®] targeted protein degraders, that are designed to harness the body's own natural protein disposal system to selectively and efficiently degrade and remove disease-causing proteins. In addition to its robust preclinical pipeline of PROTAC[®] protein degraders against validated and "undruggable" targets, the

company has three clinical-stage programs: ARV-110 and ARV-766 for the treatment of men with metastatic castrate-resistant prostate cancer; and ARV-471 for the treatment of patients with locally advanced or metastatic ER+/HER2- breast cancer. For more information, visit www.arvinas.com.

Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties, including statements regarding the potential benefits of the collaboration and the potential advantages and therapeutic benefits of ARV-471, ARV-110, ARV-766 and our other product candidates, the future development and potential marketing approval and commercialization of ARV-471, ARV-110, ARV-766 and our other product candidates, including the timing of data from and initiation of our clinical trials. All statements, other than statements of historical facts, contained in this press release, including statements regarding our strategy, future operations, prospects, plans and objectives of management, are forward-looking statements. The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “predict,” “project,” “target,” “potential,” “will,” “would,” “could,” “should,” “continue,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

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 as a result of various risks and uncertainties, including but not limited to: each party’s performance of its obligations under the Pfizer collaboration, whether we and, as applicable, Pfizer will be able to successfully conduct and complete clinical development, including whether we receive results from our clinical trials on our expected timelines or at all, obtain marketing approval for and commercialize ARV-471, ARV-110, ARV-766 and our other product candidates on our current timelines or at all and other important factors discussed in the “Risk Factors” sections contained in our quarterly and annual reports on file with the Securities and Exchange Commission. The forward-looking statements contained in this press release reflect our current views with respect to future events, and we assume no obligation to update any forward-looking statements except as required by applicable law. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this release.

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Arvinas, Inc.

Consolidated Balance Sheet (Unaudited)

	<u>September 30,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 255,662,835	\$ 588,373,232
Restricted cash	4,500,000	—
Marketable securities	1,288,814,399	100,157,618
Accounts receivable	1,880,180	1,000,000
Other receivables	6,755,720	7,443,654
Prepaid expenses and other current assets	18,537,587	6,113,122
Total current assets	<u>1,576,150,721</u>	<u>703,087,626</u>
Property, equipment and leasehold improvements, net	11,628,051	12,259,515
Operating lease right of use assets	4,250,463	1,992,669
Collaboration contract asset and other assets	12,835,975	28,777
Total assets	<u>\$1,604,865,210</u>	<u>\$ 717,368,587</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 4,671,605	\$ 7,121,879
Accrued expenses	13,769,220	18,859,840
Deferred revenue	162,943,830	22,150,861
Current portion of operating lease liabilities	1,123,101	952,840
Total current liabilities	<u>182,507,756</u>	<u>49,085,420</u>
Deferred revenue	600,429,165	22,938,233
Long term debt	1,000,000	2,000,000
Operating lease liability	3,191,132	1,087,422
Total liabilities	<u>787,128,053</u>	<u>75,111,075</u>
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value; 52,766,020 and 48,455,741 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	52,766	48,455
Accumulated deficit	(629,893,515)	(491,888,910)
Additional paid-in capital	1,448,254,555	1,133,537,171
Accumulated other comprehensive (loss) income	(676,649)	560,796
Total stockholders' equity	<u>817,737,157</u>	<u>642,257,512</u>
Total liabilities and stockholders' equity	<u>\$1,604,865,210</u>	<u>\$ 717,368,587</u>

Arvinas, Inc.

Consolidated Statement of Operations (Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue	\$ 9,284,785	\$ 7,596,776	\$ 20,368,568	\$ 19,584,085
Operating expenses:				
Research and development	40,603,631	30,012,918	118,481,320	75,155,694
General and administrative	16,012,384	9,331,925	42,741,962	26,072,404
Total operating expenses	<u>56,616,015</u>	<u>39,344,843</u>	<u>161,223,282</u>	<u>101,228,098</u>
Loss from operations	(47,331,230)	(31,748,067)	(140,854,714)	(81,644,013)
Interest and other income	579,478	928,201	2,850,109	3,858,437
Net loss	<u>\$ (46,751,752)</u>	<u>\$ (30,819,866)</u>	<u>\$ (138,004,605)</u>	<u>\$ (77,785,576)</u>
Net loss per common share, basic and diluted	<u>\$ (0.94)</u>	<u>\$ (0.79)</u>	<u>\$ (2.81)</u>	<u>\$ (2.01)</u>
Weighted average common shares outstanding, basic and diluted	<u>49,807,508</u>	<u>39,058,294</u>	<u>49,101,927</u>	<u>38,784,569</u>