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 8, 2022

Arvinas, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-38672**	**47-2566120**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

5 Science Park **395 Winchester Ave.** **New Haven, Connecticut**	**06511**
(Address of principal executive offices)	**(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 8, 2022, Arvinas, Inc. announced its financial results for the quarter ended September 30, 2022. 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 Current Report on 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.

Exhibit No.	Description
99.1	Press Release issued by the Registrant on November 8, 2022.
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 9, 2022

By: /s/ Sean Cassidy

Sean Cassidy
Chief Financial Officer

Arvinas Reports Third Quarter 2022 Financial Results and Provides Corporate Update

– On track to initiate enrollment of two Phase 3 trials with ARV-471 in patients with first- and second-line metastatic breast cancer –

– Enrolling multiple clinical trials and initiating enrollment activity across estrogen receptor (ER) and androgen receptor (AR) franchises –

NEW HAVEN, Conn. – November 8, 2022 – 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, 2022 and provided a corporate update.

"We made significant progress during the third quarter, including initiating activity to enroll four new clinical trials with ARV-471 and beginning a Phase 2 trial with ARV-766," said John Houston, Ph.D., president and chief executive officer at Arvinas. "We also further strengthened our executive team and Board of Directors as we fully transition to a late-stage development organization. We expect the initiation of two Phase 3 trials with ARV-471 in patients with metastatic breast cancer by the end of this year, and a Phase 3 trial with bavdegalutamide in men with metastatic castrate resistant prostate cancer in the second half of 2023. We look forward to the upcoming presentation on the Phase 2 VERITAC trial with ARV-471 at the San Antonio Breast Cancer Symposium in December, and Arvinas is well-positioned as we move into 2023."

Business Highlights and Recent Developments

- Initiated with Pfizer multiple clinical trials and enrollment activity with ARV-471 in patients with ER+/HER2- breast cancer:
  - Phase 1b trial (TACTIVE-E) with ARV-471 + everolimus (ClinicalTrials.gov Identifier NCT05501769)
  - Phase 1b trial with ARV-471 as a monotherapy in Japanese patients (ClinicalTrials.gov Identifier NCT05463952)
  - Activity that will enable dosing in 4Q2022 for a Phase 1b umbrella trial (TACTIVE-U) with ARV-471, including a combination arm with abemaciclib (Part A: ClinicalTrials.gov Identifier NCT05548127) and a combination arm with ribociclib (Part B: ClinicalTrials.gov Identifier NCT05573555)
  - Activity that will enable dosing in 4Q2022 for a Phase 2 trial (TACTIVE-N) with ARV-471 as a monotherapy in the neoadjuvant setting (ClinicalTrials.gov Identifier NCT05549505)
- Initiated a Phase 2 trial in metastatic castrate resistant prostate cancer (mCRPC) with ARV-766 (ClinicalTrials.gov Identifier NCT05067140).
- Appointed John Young to the Company's Board of Directors.
- Appointed Lisa Sinclair as Senior Vice President, Corporate Operations.
- Appointed Paul McInulty as Senior Vice President, Regulatory Affairs.
- Executed an agreement with PhoreMost Ltd. to expand the capabilities of our PROTAC® Discovery Engine
- Executed a research collaboration agreement with Rockefeller University to leverage innovative screening capabilities
- Launched inaugural "Arvinas Impact Day," a company-wide community service day benefiting organizations in the Greater New Haven area.
  - Nearly 200 Arvinas employees participated in activities to support important priorities for Arvinas, including science, technology, engineering, and math (STEM) initiatives, and the Greater New Haven and patient communities.

Anticipated Upcoming Milestones and Expectations

ARV-471

With Pfizer, the companies plan to:

- Initiate Phase 3 trial with ARV-471 + palbociclib as a first-line treatment in patients with metastatic breast cancer (4Q 2022)
- Initiate Phase 3 trial with ARV-471 as a second-line treatment in patients with metastatic breast cancer (4Q 2022)
- Present data from the VERITAC Phase 2 expansion trial (200 mg and 500 mg) (San Antonio Breast Cancer Symposium, December 2022)
- Initiate additional arms of the Phase 1b combination trial (TACTIVE-U) with other targeted therapies (2023)
- Present data from the Phase 1b combination trial with palbociclib at a medical conference (1H 2023)

Bavdegalutamide (ARV-110)

- Confirm final dose selection and secure final health authority feedback for global Phase 3 trial protocol (1H 2023)
- Initiate a global Phase 3 trial in metastatic castration-resistant prostate cancer (mCRPC) for patients with AR T878/H875 tumor mutations (2H 2023)
- Complete enrollment in Phase 1b combination study with abiraterone (2H 2023)

ARV-766

- Share Phase 1 dose escalation trial data in mCRPC (2Q 2023)

Pipeline:

- Present new preclinical neuroscience data at Society for Neuroscience's "Neuroscience 2022" meeting (Nov. 12-16, 2022): *Orally Administered PROTAC® Molecules Selectively Clear Pathologic Neurodegenerative Proteins in CNS & Muscle*
- Submit two investigational new drug (IND)/clinical trial authorization (CTA) applications, one in neurology and one in oncology, by year end 2023 with at least two additional programs in IND- or CTA-enabling studies

Financial Guidance

Based on its current operating plan, Arvinas believes its cash, cash equivalents, restricted cash and marketable securities as of September 30, 2022 is sufficient to fund planned operating expenses and capital expenditure requirements multiple years beyond 2024.

Third Quarter Financial Results

Cash, Cash Equivalents, Restricted Cash and Marketable Securities Position: As of September 30, 2022, cash, cash equivalents, restricted cash and marketable securities were $1,276.2 million as compared with $1,507.1 million as of December 31, 2021. The decrease in cash, cash equivalents, restricted cash and marketable securities of $230.9 million for the nine months ended September 30, 2022 was primarily related to cash used in operating activities of $209.2 million (net of $6.5 million received from two collaborators), unrealized loss on marketable securities of $20.2 million, and the purchase of lab equipment and leasehold improvements of $5.7 million, partially offset by proceeds from the exercise of stock options of $4.2 million.

Research and Development Expenses: Research and development expenses were $77.5 million for the quarter ended September 30, 2022, as compared with $40.6 million for the quarter ended September 30, 2021. The increase in research and development expenses of $36.9 million for the quarter was primarily due to an increase in our continued investment in our platform and exploratory programs of $22.3 million, as well as an increase in expenses related to our AR program of $2.8 million, which includes bavdegalutamide and ARV-766, and our ER program of $11.8 million, which is net of the cost sharing of ARV-471 under the global Pfizer collaboration agreement to develop and commercialize ARV-471 that was initiated in July 2021 (ARV-471 Collaboration Agreement).

General and Administrative Expenses: General and administrative expenses were $20.0 million for the quarter ended September 30, 2022, as compared with $16.0 million for the quarter ended September 30, 2021. The increase of $4.0 million was primarily due to an increase in personnel costs of $2.9 million and professional fees of $2.1 million.

Revenues: Revenues were $30.3 million for the quarter ended September 30, 2022 as compared with $9.3 million for the quarter ended September 30, 2021. Revenue is related to the ARV-471 Collaboration Agreement, 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 $21.0 million was primarily due to revenue from the ARV-471 Collaboration Agreement.

Income Tax Expense: Income tax expense was $2.2 million for the quarter ended September 30, 2022, as compared with zero for the quarter ended September 30, 2021 due to taxable income projected for fiscal year 2022 primarily related to revenue recognized in 2022 for tax purposes from the ARV-471 Collaboration Agreement.

Net Loss: Net loss was $66.2 million for the quarter ended September 30, 2022, as compared with $46.8 million for the quarter ended September 30, 2021. The increase in net loss for the quarter was primarily due to increased research and development expenses, general and administrative expenses, and income tax expense, partially offset by increased revenue.

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

Bavdegalutamide 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. In July 2021, Arvinas announced a global collaboration with Pfizer for the

co-development and co-commercialization of ARV-471; Arvinas and Pfizer will equally share worldwide development costs, commercialization expenses, and profits.

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 biotechnology company dedicated to improving the lives of patients suffering from debilitating and life-threatening diseases through the discovery, development, and commercialization of therapies that degrade disease-causing proteins. 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 investigational clinical-stage programs: bavdegalutamide and ARV-766 for the treatment of men with metastatic castration-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 within the meaning of The Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties, including statements regarding the potential advantages and therapeutic benefits of bavdegalutamide (ARV-110), ARV-471, and ARV-766 and our other discovery programs, the development and regulatory status of our product candidates, such as statements with respect to the potential of our lead product candidates bavdegalutamide, ARV-471, ARV-766 and other candidates in our pipeline, and , including the initiation of and timing of the timing of clinical trials, including the timing to complete enrollment, as well as the presentation and/or publication of data from those trials and plans for registration for our product candidates, and our discovery programs that may lead to our development of additional product candidates, the potential utility of our technology, our plans with respect to submission of investigational new drug/clinical trial authorization applications, the potential commercialization of any of our product candidates, and the sufficiency of our cash resources. All statements, other than statements of historical facts, contained in this press release, 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," "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: our and Pfizer, Inc.'s ("Pfizer") performance of our respective obligations with respect to our collaboration with Pfizer; whether we and Pfizer will be able to successfully conduct and complete clinical development for ARV-471; whether we will be able to successfully conduct and complete development for bavdegalutamide, ARV-766 and our other product candidates, including whether we initiate and complete clinical trials for our product candidates and receive results from our clinical trials on our expected timelines or at all; obtain marketing

approval for and commercialize ARV-471, bavdegalutamide, ARV-766 and our other product candidates on our current timelines or at all; whether our cash and cash equivalent resources will be sufficient to fund our foreseeable and unforeseeable operating expenses and capital expenditure requirements; and other important factors discussed in the "Risk Factors" section of our Annual Report of Form 10-K for the year ended December 31, 2021 and subsequent other 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.

Condensed Consolidated Balance Sheets (Unaudited)

(dollars and shares in millions)	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 132.6	$ 108.3
Restricted cash	5.5	4.5
Marketable securities	1,138.1	1,394.3
Accounts receivable	1.0	15.0
Other receivables	5.8	10.7
Prepaid expenses and other current assets	21.7	19.7
Total current assets	1,304.7	1,552.5
Property, equipment and leasehold improvements, net	14.0	12.7
Operating lease right of use assets	4.8	3.9
Collaboration contract asset and other assets	11.3	12.5
Total assets	$ 1,334.8	$ 1,581.6
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities	$ 49.7	$ 54.4
Deferred revenue	193.1	206.2
Current portion of operating lease liability	1.8	1.1
Total current liabilities	244.6	261.7
Deferred revenue	464.6	534.3
Long term debt	1.0	1.0
Operating lease liability	3.1	2.9
Total liabilities	713.3	799.9
Stockholders' equity:		
Common stock, $0.001 par value; 53.2 and 53.0 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	0.1	—
Accumulated deficit	(882.5)	(682.9)
Additional paid-in capital	1,528.7	1,469.2
Accumulated other comprehensive loss	(24.8)	(4.6)
Total stockholders' equity	621.5	781.7
Total liabilities and stockholders' equity	$ 1,334.8	$ 1,581.6

Arvinas, Inc.

Condensed Consolidated Statements of Operations (Unaudited)

(dollars and shares in millions, except per share amounts)	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Revenue	$ 30.3	$ 9.3	$ 85.8	$ 20.4
Operating expenses:				
Research and development	77.5	40.6	216.7	118.5
General and administrative	20.0	16.0	64.5	42.8
Total operating expenses	97.5	56.6	281.2	161.3
Loss from operations	(67.2)	(47.3)	(195.4)	(140.9)
Interest and other income	3.2	0.5	5.9	2.9
Net loss before income taxes	(64.0)	(46.8)	(189.5)	(138.0)
Income tax expense	(2.2)	—	(10.1)	—
Net loss	$ (66.2)	$ (46.8)	$ (199.6)	$ (138.0)
Net loss per common share, basic and diluted	$ (1.24)	$ (0.94)	$ (3.76)	$ (2.81)
Weighted average common shares outstanding, basic and diluted	53.2	49.8	53.1	49.1