
**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 7, 2023

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 7, 2023, Arvinas, Inc. announced its financial results for the quarter ended September 30, 2023 and provided a corporate update. 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 7, 2023.
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 7, 2023

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



Arvinas Reports Third Quarter 2023 Financial Results and Provides Corporate Update

- Enrollment continues in the 2L Phase 3 VERITAC-2 trial and study lead-in for the VERITAC-3 1L Phase 3 trial with vepdegestrant; Top-line data readout for VERITAC-2 remains on-track for 2H 2024 -
- Bavdegalutamide mCRPC data presented at ESMO showed median rPFS of 11.1 months in patients with AR 878/875 tumor mutations, demonstrating the potential for a PROTAC® AR degrader in prostate cancer -
- New interim data from second generation PROTAC AR degrader support the Company's decision to prioritize the initiation of a Phase 3 trial with ARV-766 in mCRPC instead of the previously planned Phase 3 trial for bavdegalutamide -

NEW HAVEN, Conn., November 7, 2023 -- 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, 2023 and provided a corporate update.

"We continued making strong progress in the third quarter of 2023 as we executed across our entire portfolio of PROTAC® protein degraders," said John Houston, Ph.D., chairperson, chief executive officer, and president at Arvinas. "We remain focused on developing best-in-class medicines and are very pleased with the progress of our ER and AR degraders, both of which have the potential to make meaningful differences for patients. In the second half of next year, we anticipate completion of our first Phase 3 trial with our novel PROTAC ER degrader, vepdegestrant, in a second-line metastatic breast cancer setting, which we are jointly developing with Pfizer. Additionally, the profile of our PROTAC AR degrader, ARV-766, gives us the confidence to initiate a Phase 3 trial in metastatic castration resistant prostate cancer as soon as possible. We are also preparing to move two new compounds - our LRRK2 and BCL6 PROTAC protein degraders - into the clinic in 2024, with two more PROTAC protein degraders in IND-enabling studies by the end of 2023. We have a lot of milestones to deliver on in 2024 and I look forward to Arvinas' continued success, with the ultimate, and most important goal of improving the lives of patients with serious diseases."

Recent Developments and Third Quarter Business Highlights

Androgen Receptor Franchise

- Presented data from the Phase 1/2 clinical trial with bavdegalutamide at the European Society for Medical Oncology Congress (ESMO) showing a median radiographic progression free survival (rPFS) of 11.1 months in patients with AR 878/875 tumor mutations, demonstrating the strong potential for a PROTAC® AR degrader in prostate cancer.
 - Manageable tolerability profile with no grade >4 treatment-related adverse events (TRAEs).
- Prioritized the initiation of a Phase 3 trial with ARV-766 in mCRPC instead of the previously planned Phase 3 trial for bavdegalutamide.
 - New interim data from Phase 1/2 trial with ARV-766 showed a broader efficacy profile and superior tolerability versus bavdegalutamide in the clinical setting, with a potentially differentiated profile against other AR directed therapies.
- Completed enrollment in the bavdegalutamide Phase 1b combination trial with abiraterone.

Vepdegestrant (ARV-471)

- Presented updated dose-escalation data from the Phase 1/2 trial with vepdegestrant at ESMO showing continued strong anti-tumor activity and highly differentiated tolerability.
- Continued enrollment in the study lead-in of the VERITAC-3 Phase 3 trial of vepdegestrant plus palbociclib as a first-line treatment in patients with ER+/HER2- locally advanced or metastatic breast cancer (ClinicalTrials.gov Identifier: NCT05909397).
- Continued enrollment in the VERITAC-2 Phase 3 2L+ clinical trial of vepdegestrant as a monotherapy for the treatment of patients with ER+/HER2- metastatic breast cancer (ClinicalTrials.gov Identifier: NCT05654623).

- Continued enrollment in the TACTIVE-U trial evaluating vepdegestrant with targeted therapies [ClinicalTrials.gov Identifiers: NCT05548127 and NCT05573555]).
- Continued enrollment in the TACTIVE-E trial of vepdegestrant in combination with everolimus (ClinicalTrials.gov Identifier: NCT05501769), and the TACTIVE-N trial of vepdegestrant as a monotherapy in the neoadjuvant setting (ClinicalTrials.gov Identifier: NCT05549505).
- Received Study May Proceed letter from the U.S. FDA for the Phase 1b/2 clinical trial evaluating vepdegestrant in combination with Pfizer's CDK4 inhibitor (PF-07220060).
- Awarded Innovation Passport Designation for vepdegestrant by the U.K. Innovative Licensing and Access Pathway Steering Group.

Anticipated Upcoming Milestones and Expectations

Vepdegestrant (ARV-471)

As part of Arvinas' global collaboration with Pfizer, the companies plan to:

- Present updated data for vepdegestrant at the San Antonio Breast Cancer Symposium, including new data from the Phase 1b trial assessing vepdegestrant in combination with palbociclib (December 2023).
- Continue enrollment in the study lead-in for the VERITAC-3 Phase 3 trial of vepdegestrant and palbociclib as a first-line treatment in patients with ER+/HER2- locally advanced or metastatic breast cancer.
- Initiate a Phase 1b/2 trial with vepdegestrant plus Pfizer's CDK4 (cyclin dependent kinase) inhibitor (4Q 2023).
- Continue enrollment of the Phase 1b combination umbrella trial evaluating combination of vepdegestrant with abemaciclib and with ribociclib (TACTIVE-U: ClinicalTrials.gov Identifiers: NCTC05548127 and NCTC05573555); initiate additional arm with Carrick Therapeutics' CDK7 inhibitor.
- Complete enrollment in the TACTIVE-N Phase 2 trial of vepdegestrant as a monotherapy in the neoadjuvant setting (ClinicalTrials.gov Identifier: NCT05549505) in patients with ER+/HER2- localized breast cancer (2024).
- Complete enrollment of the VERITAC-2 Phase 3 monotherapy trial (ClinicalTrials.gov Identifier: NCT05654623) in patients with metastatic breast cancer (2H 2024).

Androgen Receptor (AR) Franchise (ARV-766/bavdegalutamide (ARV-110))

- Continue enrollment of Phase 2 dose expansion study with ARV-766, with progression free survival data anticipated in 2024.
- Initiate a Phase 1b/2 dose escalation trial with ARV-766 in combination with abiraterone in patients who have not previously received novel hormonal agents (4Q 2023).
- Initiate discussions with regulatory authorities for a planned Phase 3 trial with ARV-766 in mCRPC (2Q 2024).

Pipeline:

- Submit two investigational new drug (IND)/clinical trial authorization (CTA) applications for the Company's BCL6 (oncology) and LRRK2 (neuroscience) PROTAC protein degraders by year-end 2023.
- Progress at least two additional PROTAC protein degrader programs into IND- or CTA-enabling studies by year-end 2023.

Financial Guidance

Based on its current operating plan, Arvinas believes its cash, cash equivalents, restricted cash and marketable securities as of September 30, 2023, is sufficient to fund planned operating expenses and capital expenditure requirements into 2026.

Third Quarter Financial Results

Cash, Cash Equivalents and Marketable Securities Position: As of September 30, 2023, cash, cash equivalents, restricted cash and marketable securities were \$1,004.0 million as compared with \$1,210.8 million as of December 31, 2022. The decrease in cash, cash equivalents, restricted cash and marketable securities of \$206.8 million for the nine months ended September 30, 2023 was primarily related to cash used in operations of \$253.0 million (net of \$2.5 million received from two collaborators), leasehold improvements of \$2.8 million and loss on the sale of marketable securities of \$0.9 million, partially offset by net proceeds from the issuance of common stock under our ATM offering of \$36.0 million, unrealized gains on marketable securities of \$10.0 million and proceeds from the exercise of stock options of \$3.9 million.

Research and Development Expenses: Research and development expenses were \$85.9 million for the quarter ended September 30, 2023, as compared with \$77.5 million for the quarter ended September 30, 2022. The increase in research and development expenses of \$8.4 million for the quarter was primarily due to increases our AR program of \$5.2 million, which includes ARV-766 and bavdegalutamide, and our ER program of \$6.2 million, which is net of the cost sharing of vepdegestrant under the Vepdegestrant (ARV-471) Collaboration Agreement, offset by a decrease in our platform and exploratory programs of \$3.0 million.

General and Administrative Expenses: General and administrative expenses were \$22.6 million for the quarter ended September 30, 2023, as compared with \$20.0 million for the quarter ended September 30, 2022. The increase of \$2.6 million was primarily due to increased investments in our commercial operations of \$1.0 million, an increase in personnel and infrastructure related costs of \$1.1 million, and an increase in professional fees of \$0.5 million.

Revenues: Revenues were \$34.6 million for the quarter ended September 30, 2023 as compared with \$33.2 million for the quarter ended September 30, 2022. Revenue is related to the Vepdegestrant (ARV-471) Collaboration Agreement, the collaboration and license agreement with Bayer, the collaboration and license agreement with Pfizer, the amended and restated option, license and collaboration agreement with Genentech and revenue related to our Oerth Bio joint venture which was initiated in July 2019. The increase in revenues of \$1.4 million was primarily due to an increase in revenue from the Vepdegestrant (ARV-471) Collaboration Agreement totaling \$6.4 million, partially offset by a decrease in revenue of \$2.8 million of previously constrained deferred revenue related to our Oerth Bio joint venture and a decrease of \$1.8 million related to the conclusion of the performance period under the collaboration agreement with Genentech.

Income Tax Expense: Income tax was zero for the quarter ended September 30, 2023, as compared with an income tax expense of \$2.2 million for the quarter ended September 30, 2022. Current year income tax was driven by valuation allowance recorded against the full amount of its net deferred tax assets. Prior year income tax expense was driven by revenue recognized in 2022 for tax purposes from the Vepdegestrant (ARV-471) Collaboration Agreement.

Loss from Equity Method Investment: Loss from equity method investment was \$0.1 million for the quarter ended September 30, 2023, as compared with \$2.9 million for the quarter ended September 30, 2022 due to fully recognizing the remaining Oerth Bio related constrained revenue, which limited the amount of equity method losses recognized during the quarter.

Net Loss: Net loss was \$64.0 million for the quarter ended September 30, 2023, as compared with \$66.2 million for the quarter ended September 30, 2022. The decrease in net loss for the quarter was primarily due to increased revenue and interest income from our marketable securities, as well as decreased income tax

expense and loss from equity method investments, partly offset by increased research and development expenses and general and administrative expenses.

About ARV-766 and bavdegalutamide (ARV-110)

ARV-766 and bavdegalutamide (ARV-110) are investigational orally bioavailable PROTAC[®] protein degraders designed to selectively target and degrade the androgen receptor (AR). ARV-766 and bavdegalutamide are being developed as potential treatments for men with prostate cancer. Preclinically, both investigational agents have demonstrated activity in models of wild type tumors in addition to tumors with AR mutation or amplification, both common mechanisms of resistance to currently available AR-targeted therapies.

About vepdegestrant (ARV-471)

Vepdegestrant is an investigational, orally bioavailable PROTAC protein degrader designed to specifically target and degrade the estrogen receptor (ER) for the treatment of patients with ER positive/human epidermal growth factor receptor 2 (HER2) negative (ER+/HER2-) breast cancer.

In preclinical studies, vepdegestrant demonstrated up to 97% ER degradation in tumor cells, induced robust tumor shrinkage when dosed as a single agent in multiple ER-driven xenograft models, and showed increased 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 vepdegestrant; Arvinas and Pfizer will equally share worldwide development costs, commercialization expenses, and profits. Ongoing and planned clinical trials will continue to monitor and evaluate the safety and anti-tumor activity of vepdegestrant.

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: ARV-766 and bavdegalutamide for the treatment of men with metastatic castration-resistant prostate cancer; and vepdegestrant (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, therapeutic benefits and opportunity of vepdegestrant (ARV-471), ARV-766, bavdegalutamide (ARV-110), and Arvinas' other candidates in its pipeline; the development and regulatory status of vepdegestrant (ARV-471), ARV-766, and bavdegalutamide (ARV-110), such as statements with respect to the initiation, continuation 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, discussions with regulatory authorities and plans for registration; Arvinas' plans with respect to submission of investigational new drug (IND)/clinical trial authorization (CTA) applications; Arvinas' plans to progress additional PROTAC protein degrader programs into IND- or CTA-enabling studies; and the sufficiency of Arvinas' cash resources to fund planned operating expenses and capital expenditure requirements. All statements, other than statements of historical facts, contained in this press release, including statements regarding Arvinas' 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.

Arvinas may not actually achieve the plans, intentions or expectations disclosed in its forward-looking statements, and you should not place undue reliance on its forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements Arvinas makes as a result of various risks and uncertainties, including but not limited to: Arvinas' and Pfizer, Inc.'s ("Pfizer") performance of their respective obligations with respect to the collaboration with Pfizer; whether Arvinas and Pfizer will be able to successfully conduct and complete clinical development for vepdegestrant; whether Arvinas will be able to successfully conduct and complete development for its product candidates, including whether Arvinas initiates and completes clinical trials for its product candidates and receives results from its clinical trials on its expected timelines or at all; whether Arvinas obtains marketing approval for and commercializes vepdegestrant ARV-766 and its other product candidates on Arvinas' current timelines or at all; Arvinas' ability to maintain and protect its intellectual property portfolio; whether Arvinas' cash and cash equivalent resources will be sufficient to fund its foreseeable and unforeseeable operating expenses and capital expenditure requirements; and other important factors discussed in the "Risk Factors" section of Arvinas' Annual Report on Form 10-K for the year ended December 31, 2022 and subsequent other reports on file with the U.S. Securities and Exchange Commission. The forward-looking statements contained in this press release reflect Arvinas' current views with respect to future events, and Arvinas assumes 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 Arvinas' 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, except per share amounts)

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

Arvinas, Inc.

Condensed Consolidated Statements of Operations (Unaudited)

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