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): July 30, 2024

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 July 30, 2024, Arvinas, Inc. announced its financial results for the quarter ended June 30, 2024 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 July 30, 2024.
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: July 30, 2024

By: /s/ Andrew Saik

Andrew Saik
Chief Financial Officer

Arvinas Reports Second Quarter 2024 Financial Results and Provides Corporate Update

– Completed enrollment in the study lead-in for the VERITAC-3 Phase 3 trial in the first-line setting; continued enrollment globally in multiple clinical trials of vepdegestrant in ER+/HER2- metastatic breast cancer, including the VERITAC-2 Phase 3 trial in the second-line setting–

– Completion of enrollment in VERITAC-2 expected in 4Q24 and topline data readout now expected 4Q24/1Q25 –

– Received $150 million upon close of ARV-766 license agreement and sale of preclinical AR-V7 program to Novartis; potential for up to an additional $1.01 billion based on achievement of development, regulatory and commercial milestones and future royalties –

– Strengthened executive team with the appointment of Andrew Saik as Chief Financial Officer and the promotions of Ian Taylor to President of R&D, Angela Cacace to Chief Scientific Officer, and Randy Teel to Chief Business Officer –

NEW HAVEN, Conn., July 30, 2024 -- 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 second quarter ended June 30, 2024, and provided a corporate update.

"During the second quarter, we continued making meaningful progress across our entire portfolio, with upcoming milestones that will further support our mission to improve patient lives with pioneering therapies from our revolutionary PROTAC® protein degradation platform," said John Houston, Ph.D., Chairperson, Chief Executive Officer and President at Arvinas. "The readout of VERITAC-2, our first Phase 3 clinical trial, will be a landmark event for Arvinas. We are on-track to complete enrollment in the fourth quarter of the year, with topline data anticipated in either the fourth quarter of 2024 or first quarter of 2025. If positive, we believe these results will support our first new drug application filing and our transition to a commercial-stage company, assuming regulatory approval."

"We are well on our way to becoming a multi-product, commercial-stage organization with strong leadership and a robust pipeline across several indications," continued Dr. Houston. "Our first PROTAC degrader with the potential to treat neurodegenerative diseases, ARV-102, was recently cleared to initiate the multiple ascending dose portion of our Phase 1 clinical trial. In addition, we initiated the first-in-human Phase 1 clinical in trial patients with B-cell lymphomas with our PROTAC BCL6 degrader ARV-393. I'm excited by the progress we have made and the ongoing confidence we have in our PROTAC platform, which was further validated by our recent strategic transaction with Novartis. We believe Novartis will accelerate and broaden the development of ARV-766 as a potential best-in-class treatment for patients with prostate cancer."

Recent Developments and 2Q Business Highlights

Vepdegestrant

- Evaluated enrollment and blinded event rates in the ongoing VERITAC-2 Phase 3 monotherapy clinical trial (NCT05654623) in patients with metastatic breast cancer.
    - The trial is on track to complete enrollment in 4Q24.Based on current trial status, the primary completion date has been reprojected to November 2024, with topline data now anticipated in 4Q24/1Q25.
- Completed enrollment of the study lead-in for the VERITAC-3 Phase 3 clinical trial of vepdegestrant in combination with palbociclib as a first-line treatment in patients with

estrogen receptor (ER) positive/human growth epidermal growth factor 2 (HER2) negative (ER+/HER2-) locally advanced or metastatic breast cancer.

- Continued enrollment globally in multiple clinical studies of vepdegestrant in ER+/HER2- metastatic breast cancer.
- Presented updated clinical data from a Phase 1b clinical trial combination cohort evaluating vepdegestrant in combination with palbociclib in heavily pre-treated patients with locally advanced or metastatic ER+/HER2- breast cancer at the 2024 European Society for Medical Oncology (ESMO) Breast Cancer Annual Congress.
    - After six months of additional follow-up, updated data from the trial continued to demonstrate an encouraging clinical benefit rate, objective response rate and progression-free survival, and a consistent safety profile as previously reported at the San Antonio Breast Cancer Symposium (SABCS) in December 2023.
    - The clinical benefit rate across all dose levels (n=46) was 63%; the objective response rate in evaluable patients with measurable disease at baseline (n=31) was 42%; median progression-free survival based on 27 (59%) events across all dose levels was 11.2 months (95% CI: 8.2 – 16.5) and the safety profile of vepdegestrant in combination with palbociclib were consistent with data previously reported at SABCS in December 2023.
    - Patients receiving the recommended Phase 3 dose of vepdegestrant (200mg) in combination with palbociclib 125mg (n=21), achieved a median progression-free survival of 13.9 months (95% CI: 8.1-NR).

Strategic Transaction with Novartis

- Entered into a license agreement and asset purchase agreement with Novartis (NYSE: NVS) for the exclusive, worldwide development, manufacture and commercialization of ARV-766, Arvinas' second generation PROTAC® androgen receptor (AR) degrader for patients with prostate cancer, and the sale of Arvinas' preclinical AR-V7 program, which closed on May 28, 2024.
    - Arvinas received a one-time, upfront payment in the aggregate amount of $150.0 million in accordance with the terms of the license agreement and the asset purchase agreement. Under the terms of the license agreement, Arvinas is also eligible to receive up to an additional $1.01 billion as contingent payments based on specified development, regulatory, and commercial milestones for ARV-766 being met, as well as tiered royalties based upon worldwide net sales of ARV-766.

Pipeline

ARV-102: Oral PROTAC LRRK2 degrader

- Presented preclinical data at the Biennial International LRRK2 Meeting further supporting the potential of PROTAC-induced leucine-rich repeat kinase 2 (LRRK2) degradation as a potential treatment for neurodegenerative diseases. Key findings included:
    - With Arvinas' PROTAC LRRK2 degrader, near-complete LRRK2 target engagement, as well as LRRK2 degradation, in mouse and non-human primate lung and brain.
    - Differing effects of the LRRK2 PROTAC degraders in the lungs compared to kinase inhibitors, suggesting reduced pulmonary function risk.
        - Substantially less Type II pneumocyte enlargement compared to MLi-2, an experimental LRRK2 kinase inhibitor.

  - Surfactant protein accumulation in mouse lung observed after treatment with the LRRK2 kinase inhibitor MLi-2, but not after treatment with the PROTAC LRRK2 degrader.
  - No evidence of collagen deposition in lung to date with PROTAC LRRK2 degraders in non-human primates.
- Received health authority approval to initiate the multiple ascending dose portion of the ongoing Phase 1 clinical trial in healthy volunteers with the PROTAC LRRK2 degrader ARV-102.

ARV-393: Oral PROTAC BCL6 degrader

- Presented preclinical data for ARV-393 at the European Hematology Association 2024 Annual Congress that showed ARV-393:
  - Potently and rapidly degraded the BCL6 protein and inhibited cell growth in diffuse large B-cell lymphoma (DLBCL) and Burkitt cell lines.
  - Showed tumor growth inhibition, including tumor regression, in various DLBCL cell line-derived xenograft (CDX) models and in multiple patient-derived xenograft (PDX) models of non-Hodgkin lymphoma (NHL), including germinal center B-cell-like (GCB), activated B-cell (ABC), GCB/ABC, BCL not otherwise specified (BCL/NOS) subtypes of DLBCL, and Burkitt lymphoma.
- Initiated the first-in-human Phase 1 clinical trial in patients with B-cell lymphomas with PROTAC BCL6 degrader ARV-393.

Corporate

- Announced the appointment of Andrew Saik, MBA, to the role of Chief Financial Officer.
- Announced the promotion of Ian Taylor, Ph.D., to President of Research and Development.
- Announced the promotion of Angela Cacace, Ph.D., to Chief Scientific Officer.
- Announced the promotion of Randy Teel, Ph.D., to Chief Business Officer.

Anticipated Upcoming Milestones and Expectations

Vepdegestrant (ARV-471)

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

- Complete enrollment (4Q24) and announce topline data (4Q24/1Q25) for the VERITAC-2 Phase 3 monotherapy clinical trial.
- Evaluate data from the study lead-in of the VERITAC-3 Phase 3 trial to support dose selection for vepdegestrant plus palbociclib in planned Phase 3 combination trials in patients with ER+/HER2- locally advanced or metastatic breast cancer (2H24).
- Present initial safety and pharmacokinetic data from the abemaciclib arm of the ongoing TACTIVE-U trial (2H24).
- Continue enrollment of the ongoing Phase 1b/2 combination umbrella trial evaluating combinations of vepdegestrant with abemaciclib, ribociclib, or samuraciclib (TACTIVE-U; ClinicalTrials.gov Identifiers: NCT05548127, NCT05573555, and NCT06125522).
- Continue enrollment and evaluate preliminary data from the ongoing clinical trial with vepdegestrant plus Pfizer's novel CDK4 inhibitor atirmociclib (TACTIVE-K; ClinicalTrials.gov Identifier: NCT06206837) to inform the study design for the planned Phase 3 first line combination trial with either atirmociclib or palbociclib, with planned initiation in 2025.

Pipeline

- Continue enrollment in the single ascending dose portion of the Phase 1 clinical trial in healthy volunteers with the PROTAC LRRK2 degrader ARV-102 and begin enrolling the multiple ascending dose portion by the end of 2024.
- Continue enrollment in the first-in-human Phase 1 clinical trial in patients with B-cell lymphomas with PROTAC BCL6 degrader ARV-393.

Financial Guidance

Based on its current operating plan, Arvinas believes its cash, cash equivalents, restricted cash and marketable securities as of June 30, 2024, is sufficient to fund planned operating expenses and capital expenditure requirements into 2027.

Second Quarter Financial Results

Cash, Cash Equivalents, Restricted Cash and Marketable Securities Position: As of June 30, 2024, cash, cash equivalents, restricted cash and marketable securities were $1,234.2 million as compared with $1,266.5 million as of December 31, 2023. The decrease in cash, cash equivalents, restricted cash and marketable securities of $32.3 million for the six months ended June 30, 2024 was primarily related to cash used in operations of $36.0 million (net of $150.0 million received from the Novartis agreements), unrealized losses on marketable securities of $0.7 million and the purchase of lab equipment and leasehold improvements of $0.8 million, partially offset by proceeds from the exercise of stock options of $5.3 million.

Research and Development Expenses: Research and development expenses were $93.7 million for the quarter ended June 30, 2024, as compared with $103.4 million for the quarter ended June 30, 2023. The decrease in research and development expenses of $9.7 million for the quarter was primarily due to decreases in expenses related to our ER program (which includes the cost sharing of vepdegestrant under the Vepdegestrant (ARV-471) Collaboration Agreement with Pfizer) of $6.6 million and our platform and exploratory programs of $5.7 million, partially offset by an increase in our AR program (which includes ARV-766 and bavdegalutamide (ARV-110)) of $2.6 million.

General and Administrative Expenses: General and administrative expenses were $31.3 million for the quarter ended June 30, 2024, as compared with $25.7 million for the quarter ended June 30, 2023. The increase in general and administrative expenses of $5.6 million for the quarter was primarily due to an increase in personnel and infrastructure related costs of $4.0 million and professional fees of $1.6 million.

Revenues: Revenues were $76.5 million for the quarter ended June 30, 2024 as compared with $54.5 million for the quarter ended June 30, 2023. Revenue for the quarter is related to the license agreement and the asset purchase agreement with Novartis, the Vepdegestrant (ARV-471) Collaboration Agreement with Pfizer, the collaboration and license agreement with Bayer, the collaboration and license agreement with Pfizer, and revenue related to our Oerth Bio joint venture. The increase in revenue of $22.0 million was primarily due to revenue from the Novartis agreements, which were entered into during the quarter, of $45.4 million, offset by a decrease in revenue from the Vepdegestrant (ARV-471) Collaboration Agreement with Pfizer of $22.2 million and a decrease of $1.3 million of previously constrained deferred revenue related to our Oerth Bio joint venture.

About Vepdegestrant

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 (ER+)/human epidermal growth factor receptor 2 (HER2) negative (ER+/HER2-) breast cancer. Vepdegestrant is being

developed as a potential monotherapy and as part of combination therapy across multiple treatment settings for ER+/HER2- metastatic breast cancer.

In July 2021, Arvinas announced a global collaboration with Pfizer for the co-development and co-commercialization of vepdegestrant; Arvinas and Pfizer will share worldwide development costs, commercialization expenses, and profits.

The U.S. Food and Drug Administration (FDA) has granted vepdegestrant Fast Track designation as a monotherapy in the treatment of adults with ER+/HER2- locally advanced or metastatic breast cancer previously treated with endocrine-based therapy.

About Arvinas
Arvinas (Nasdaq: ARVN) is a clinical-stage biotechnology company dedicated to improving the lives of patients suffering from debilitating and life-threatening diseases. Through its PROTAC® (PROteolysis Targeting Chimera) protein degrader platform, the Company is pioneering the development of protein degradation therapies designed to harness the body's natural protein disposal system to selectively and efficiently degrade and remove disease-causing proteins. Arvinas is currently progressing multiple investigational drugs through clinical development programs, including vepdegestrant, targeting the estrogen receptor for patients with locally advanced or metastatic ER+/HER2- breast cancer; ARV-102, targeting LRRK2 for neurodegenerative disorders; and ARV-393, targeting BCL6 for relapsed/refractory non-Hodgkin Lymphoma. Arvinas is headquartered in New Haven, Connecticut. For more information about Arvinas, visit www.arvinas.com and connect on LinkedIn and X.

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 expected timing in connection with the completion of enrollment and readout of topline data from the VERITAC-2 clinical trial, submission of Arvinas' first new drug application filing and transition to a commercial-stage company, assuming regulatory approval, the availability and timing of data from other clinical trials, the receipt of milestone and royalty payments in connection with the transaction with Novartis and the future development, potential marketing approval and commercialization of ARV-766, the potential of Arvinas' PROTAC protein degrader platform and its potential to deliver new treatments, Arvinas' and Pfizer's plans to determine the recommended palbociclib dose to be combined with vepdegestrant in the planned Phase 3 combination trials in patients with ER+/HER2- locally advanced or metastatic breast cancer, and statements regarding Arvinas' cash, cash equivalents, restricted cash and marketable securities. All statements, other than statements of historical fact, 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 these forward-looking statements, and you should not place undue reliance on such 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's performance of the respective obligations with respect to Arvinas' 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 other product candidates and including whether Arvinas initiates and completes clinical trials for its product candidates and receive results from its clinical trials on its expected timelines or at all; whether Arvinas and Pfizer, as appropriate,

will be able to obtain marketing approval for and commercialize vepdegestrant and other product candidates on current timelines or at all; Arvinas' and Novartis' performance of their respective obligations under the license agreement; whether Novartis will be able to successfully conduct and complete clinical development, obtain marketing approval for and commercialize ARV-766; Arvinas' ability to 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, 2023 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)	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 154.8	$ 311.7
Restricted cash	5.5	5.5
Marketable securities	1,073.9	949.3
Other receivables	10.0	7.2
Prepaid expenses and other current assets	12.5	6.5
Total current assets	1,256.7	1,280.2
Property, equipment and leasehold improvements, net	9.8	11.5
Operating lease right of use assets	1.5	2.5
Collaboration contract asset and other assets	11.6	10.4
Total assets	$ 1,279.6	$ 1,304.6
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities	$ 78.1	$ 92.2
Deferred revenue	267.9	163.0
Current portion of operating lease liabilities	1.2	1.9
Total current liabilities	347.2	257.1
Deferred revenue	331.3	386.2
Long term debt	0.7	0.8
Operating lease liabilities	0.2	0.5
Total liabilities	679.4	644.6
Stockholders' equity:		
Preferred stock, $0.001 par value, zero shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	—	—
Common stock, $0.001 par value; 68.6 and 68.0 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	0.1	0.1
Accumulated deficit	(1,437.3)	(1,332.7)
Additional paid-in capital	2,041.2	1,995.7
Accumulated other comprehensive loss	(3.8)	(3.1)
Total stockholders' equity	600.2	660.0
Total liabilities and stockholders' equity	$ 1,279.6	$ 1,304.6

Arvinas, Inc.

Condensed Consolidated Statements of Operations (Unaudited)

(dollars and shares in millions, except per share amounts)	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Revenue	$ 76.5	$ 54.5	$ 101.8	$ 87.0
Operating expenses:				
Research and development	93.7	103.4	178.0	198.6
General and administrative	31.3	25.7	55.6	50.7
Total operating expenses	125.0	129.1	233.6	249.3
Loss from operations	(48.5)	(74.6)	(131.8)	(162.3)
Interest and other income	13.5	9.0	27.5	15.5
Net loss before income taxes and loss from equity method investment	(35.0)	(65.6)	(104.2)	(146.8)
Income tax (expense) benefit	(0.2)	0.3	(0.3)	0.7
Loss from equity method investment	—	(1.3)	—	(2.4)
Net loss	$ (35.2)	$ (66.6)	$ (104.6)	$ (148.5)
Net loss per common share, basic and diluted	$ (0.49)	$ (1.25)	$ (1.46)	$ (2.78)
Weighted average common shares outstanding, basic and diluted	71.9	53.4	71.7	53.4