
**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): February 23, 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 February 23, 2023, Arvinas, Inc. announced its financial results for the fourth quarter and year ended December 31, 2022 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 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 February 23, 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: February 23, 2023

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



Arvinas Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Corporate Update

– Initiated multiple trials with ARV-471, including a 2L+ Phase 3 trial for patients with metastatic breast cancer –

– Presented Phase 2 monotherapy expansion data from the VERITAC trial for the treatment of patients with metastatic or locally advanced ER+/HER2- breast cancer in a late-line setting –

– Gained alignment with FDA on an approach to the planned 1L Phase 3 trial with ARV-471 in combination with palbociclib to enable trial initiation in 2H 2023 –

NEW HAVEN, Conn., Feb. 23, 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 fourth quarter and full year ended December 31, 2022 and provided a corporate update.

“2022 was an exciting year for Arvinas as we transitioned into a late-stage development organization and laid the foundation for an important year of data readouts and trial initiations in 2023,” said John Houston, Ph.D., president and chief executive officer at Arvinas. “Notably, the initiation of our Phase 3 monotherapy trial with ARV-471 in ER+/HER2- metastatic breast cancer marks our first registrational study and if successful, will lead to our first commercial product bringing an important new treatment option to patients. We are on-track to initiate our second and third Phase 3 trials – one in the first line setting with ARV-471 and one with bavdegalutamide in metastatic castrate resistant prostate cancer – in the second half of this year, further validating our novel PROTAC® discovery engine platform.”

Recent Developments and 4Q Business Highlights

- Gained alignment with FDA on an approach to the planned 1L Phase 3 trial with ARV-471 in combination with palbociclib to enable trial initiation in 2H 2023
 - The approach includes a Phase 3 lead-in to evaluate the optimal dose of palbociclib (100 mg or 75 mg) in combination with 200 mg ARV-471
 - The approach follows the recent analysis of data from the ongoing Phase 1b combination study of ARV-471 with palbociclib, in which an increase in palbociclib exposure was observed relative to historical palbociclib pharmacokinetic data
- Initiated the VERITAC-2 Phase 3 2L+ clinical trial of ARV-471 as a monotherapy for the treatment of patients with ER+/HER2- metastatic breast cancer
- Presented results from the Phase 2 cohort expansion portion (VERITAC) of a Phase 1/2 study with ARV-471 for the treatment of ER+/HER2- metastatic breast cancer
- Initiated two arms of a Phase 1b umbrella trial with ARV-471; one in combination with ribociclib and another with abemaciclib (TACTIVE-U)
- Initiated a Phase 2 trial with ARV-471 as a monotherapy in the neoadjuvant setting (TACTIVE-N)
- Presented new preclinical neuroscience data at Society for Neuroscience’s “Neuroscience 2022” meeting demonstrating cross-species oral bioavailability and biodistribution into deep brain regions of nonhuman primates
- Disclosed a BCL6 (B-cell lymphoma 6) PROTAC degrader in oncology and a LRRK2 (leucine-rich repeat kinase 2) PROTAC degrader in neuroscience as the Company’s next IND or CTA submissions
- Appointed Everett Cunningham to the Company’s Board of Directors

Anticipated Upcoming Milestones and Expectations

ARV-471

With Pfizer, the companies plan to:

- Initiate a Phase 3 trial with ARV-471 + palbociclib as a first-line treatment in patients with ER+/HER2- locally advanced or metastatic breast cancer (2H 2023)
- Initiate additional arms of the Phase 1b combination umbrella trial (TACTIVE-U) with other targeted therapies (2023)
- Provide an update with preliminary data from the Phase 1b combination trial with palbociclib (1H 2023)
- Submit and present data from the Phase 1b combination trial with palbociclib at medical congress (2H 2023)

AR Franchise (Bavdegalutamide/ARV-110, ARV-766)

- Initiate a global Phase 3 trial with confirmed bavdegalutamide dose in metastatic castration-resistant prostate cancer (mCRPC) for patients with AR T878/H875 tumor mutations (2H 2023)
- Complete enrollment in the Phase 1b combination study with bavdegalutamide plus abiraterone (2H 2023)
- Share Phase 1 dose escalation trial data with ARV-766 in mCRPC (2Q 2023)
- Initiate a Phase 1b or Phase 2 trial in patients who have not previously received novel hormonal agents (2H 2023)

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 December 31, 2022, is sufficient to fund planned operating expenses and capital expenditure requirements into 2026.

Full Year and Fourth Quarter Financial Results

Cash, Cash Equivalents, Restricted Cash and Marketable Securities Position: As of December 31, 2022, cash, cash equivalents, restricted cash and marketable securities were \$1,210.8 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 \$296.3 million for the year was primarily related to cash used in operations of \$279.2 million (net of \$6.5 million received from two collaborators), unrealized loss on marketable securities of \$14.6 million, loss on the sales of securities of \$0.4 million and the purchase of lab equipment and leasehold improvements of \$6.8 million, partially offset by proceeds from the exercise of stock options of \$4.7 million.

Research and Development Expenses: Research and development expenses were \$315.0 million and \$98.3 million for the year and quarter ended December 31, 2022, as compared with \$180.4 million and \$61.8 million for the year and quarter ended December 31, 2021. The increase in research and development expenses of \$134.6 million for the year was primarily due to an increase in expenses associated with our platform and exploratory programs of \$77.7 million, our AR program (which includes bavdegalutamide (ARV-110) and ARV-766) of \$15.7 million and our ER program of \$41.2 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 202 (ARV-471 Collaboration Agreement). The increase in research and development expenses of \$36.5 million for the quarter was primarily due to an increase in expenses associated with our platform and exploratory programs of \$24.9 million, our AR program of \$5.5 million and our ER program of \$6.0 million.

General and Administrative Expenses: General and administrative expenses were \$79.6 million and \$15.1 million for the year and quarter ended December 31, 2022, as compared with \$61.6 million and \$18.9 million for the year and quarter ended December 31, 2021. The increase in general and administrative expenses of \$18.0 million for the year was primarily due to an increase of personnel related costs of \$15.0 million and professional fees of \$5.6 million. The decrease in general and administrative expenses of \$3.8 million for the quarter was primarily due to a decrease in facility costs attributable to our general and administrative functions.

Revenue: Revenue was \$131.4 million and \$38.0 million for the year and quarter ended December 31, 2022 as compared with \$53.6 million and \$28.7 million for the year and quarter ended December 31, 2021. 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, the amended and restated option, license and collaboration agreement with Genentech that was initiated in November 2017 and revenue related to our Oerth Bio joint venture which was initiated in July 2019. The increase in revenues of \$77.8 million and \$9.3 million for the year and quarter was primarily due to revenues from the ARV-471 Collaboration Agreement with Pfizer.

Income Tax Expense: Income tax expense was \$20.9 million and \$10.8 million for the year and quarter ended December 31, 2022, as compared with zero for the year and quarter ended December 31, 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.

Loss from Equity Method Investment: Loss from equity method investment totaled \$10.6 million and \$3.0 million for the year and quarter ended December 31, 2022, compared with \$6.9 million and \$2.3 million for the year and quarter ended December 31, 2021 due to increased operating losses incurred by Oerth Bio.

Net Loss: Net loss was \$282.5 million and \$82.9 million for the year and quarter ended December 31, 2022, as compared with \$191.0 million and \$52.9 million for the year and quarter ended December 31, 2021. The increase in net loss for the year and quarter was primarily due to increased research and development expenses, general and administrative expenses and losses from equity investment, 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 ARV-471, bavdegalutamide (ARV-110), 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 ARV-471, bavdegalutamide (ARV-110), ARV-766 and other candidates in our pipeline; the initiation of and timing related to clinical trials, for our product candidates alone or in combination trials, including the timing to complete enrollment in such trials, as well as the presentation and/or publication of data from those trials and plans for registration for our product candidates; the potential of our discovery programs that may lead to our development of additional product candidates and, the potential utility of our technology; our plans with respect to submission of investigational new drug (IND)/clinical trial authorization (CTA) applications and the initiation of new PROTAC protein degrader programs into IND- or CTA-enabling studies; 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, including anticipated timing related to any trials for ARV-471; whether we will be able to successfully conduct and complete development for bavdegalutamide (ARV-110), 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; whether we will be able to obtain marketing approval for and commercialize ARV-471, bavdegalutamide (ARV-110), ARV-766 and our other product candidates on our current timelines or at all; whether we will be able to adequately protect our intellectual property interests; 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, 2022, filed on February 28, 2022, 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.

Contacts**Investors:**

Jeff Boyle

+1 (347) 247-5089

Jeff.Boyle@arvinas.com**Media:**

Kirsten Owens

+1 (203) 584-0307

Kirsten.Owens@arvinas.com

ARVINAS, INC. AND SUBSIDIARIES

Consolidated Balance Sheets (Unaudited)

<i>(dollars and shares in millions)</i>	December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 81.3	\$ 108.3
Restricted cash	5.5	4.5
Marketable securities	1,124.0	1,394.3
Accounts receivable	1.0	15.0
Other receivables	7.0	10.7
Prepaid expenses and other current assets	21.4	19.7
Total current assets	1,240.2	1,240.2
Property, equipment and leasehold improvements, net	13.4	12.7
Operating lease right of use assets	4.4	3.9
Collaboration contract asset and other assets	10.8	12.5
Total assets	\$ 1,268.8	\$ 1,581.6
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 74.7	\$ 54.4
Deferred revenue	218.6	206.2
Current portion of operating lease liability	1.8	1.1
Total current liabilities	295.1	261.7
Deferred revenue	405.1	534.3
Long term debt	1.0	1.0
Operating lease liability	2.7	2.9
Total liabilities	703.9	799.9
Stockholders' equity:		
Common stock, \$0.001 par value, 53.2 and 53.0 shares issued and outstanding as of December 31, 2022 and 2021, respectively	0.1	—
Accumulated deficit	(965.4)	(682.9)
Additional paid-in capital	1,549.4	1,469.2
Accumulated other comprehensive loss	(19.2)	(4.6)
Total stockholders' equity	564.9	781.7
Total liabilities and stockholders' equity	\$ 1,268.8	\$ 1,581.6

ARVINAS, INC. AND SUBSIDIARIES

Consolidated Statements of Operations (Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021 (a)	2022	2021 (a)
<i>(dollars and shares in millions, except per share amounts)</i>				
Revenue	\$ 38.0	\$ 28.7	\$ 131.4	\$ 53.6
Operating expenses:				
Research and development	98.3	61.8	315.0	180.4
General and administrative	15.1	18.9	79.6	61.6
Total operating expenses	<u>113.4</u>	<u>80.7</u>	<u>394.6</u>	<u>242.0</u>
Loss from operations	(75.4)	(52.0)	(263.2)	(188.4)
Interest and other income	6.3	1.4	12.2	4.3
Net loss before income taxes and loss from equity method investment	(69.1)	(50.6)	(251.0)	(184.1)
Income tax expense	(10.8)	—	(20.9)	—
Loss from equity method investment	(3.0)	(2.3)	(10.6)	(6.9)
Net loss	<u>\$ (82.9)</u>	<u>\$ (52.9)</u>	<u>\$ (282.5)</u>	<u>\$ (191.0)</u>
Net loss per common share - basic and diluted	<u>\$ (1.56)</u>	<u>\$ (1.00)</u>	<u>\$ (5.31)</u>	<u>\$ (3.82)</u>
Weighted average common shares outstanding - basic and diluted	<u>53.2</u>	<u>52.8</u>	<u>53.2</u>	<u>50.0</u>

(a) Certain prior period amounts have been adjusted to correct an immaterial error related to the accounting for our investment in Oerth Bio, resulting in an understatement of revenue and expense of \$2.3 in the three months ended December 31, 2021 and an understatement of revenue and expense of \$6.9 in the year ended December 31, 2021. This immaterial error had no effect on Net Loss or Net loss per common share-basic and diluted.