Arvinas Reports Second Quarter 2023 Financial Results and Provides Corporate Update

August 8, 2023

Enrollment continues globally in multiple clinical studies of vepdegestrant (ARV-471), including VERITAC-2 2L Phase 3 trial and study lead-in for the VERITAC-3 1L Phase 3 trial, both in ER+/HER2- metastatic breast cancer

Interim data from Phase 1/2 dose escalation and expansion trial with ARV-766 shows promising signals of efficacy in late-line novel hormonal therapy pre-treated mCRPC, with greatest antitumor activity among patients with AR ligand binding mutant tumors, including those with AR L702H mutations

New Phase 1/2 clinical data for bavdegalutamide and Phase 1b vepdegestrant plus palbociclib combination data to be presented at medical congresses in 2H 2023

NEW HAVEN, Conn., Aug. 08, 2023 (GLOBE NEWSWIRE) -- 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, 2023 and provided a corporate update.

“We continue to make meaningful advances across our entire portfolio and have a data and milestone rich balance to the year,” said John Houston, Ph.D., president and chief executive officer at Arvinas. “In addition to sharing promising interim data from our ongoing Phase 1/2 trial with ARV-766, and together with Pfizer, we initiated enrollment for the study lead-in for the first-line Phase 3 trial with vepdegestrant in combination with palbociclib in metastatic breast cancer. We now have two ongoing Phase 3 trials with vepdegestrant with the potential for our first Phase 3 data read-out in the second half of 2024. We are also on track to initiate a Phase 3 trial with bavdegalutamide in the second half of the year. These accomplishments are particularly meaningful as we celebrate our 10-year anniversary this year and reflect our commitment to bringing an entirely new class of transformative medicines to patients.”

Recent Developments and Second Quarter Business Highlights

- Initiated 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.
- Shared data from the Phase 1/2 dose escalation and expansion trial showing that ARV-766 was well-tolerated and demonstrated promising activity in a heavily pre-treated, post-NHA, all-comers patient population:
    - 42% of patients with AR ligand binding domain (LBD) mutations achieved PSA50.
        - In all patients with L702H mutations, 3 of 5 achieved PSA50; in patients with co-occurring T878/H875/L702 mutations, 3 of 3 achieved PSA50.
    - RECIST (Response Evaluation Criteria in Solid Tumors) partial responses were observed.
        - Of four RECIST-evaluable patients with AR LBD mutations, one achieved a confirmed partial response, and one achieved an unconfirmed partial response.
    - ARV-766 was well tolerated and the majority of treatment-related adverse events (TRAEs) have been Grade 1 or 2, with no Grade ≥4 TRAEs and no dose limiting toxicities.
    - Low rates of discontinuation (1 of 47) and dose reductions (2 of 47) were observed.
- Evaluated and announced preliminary data from Part C of the ongoing Phase 1b/2 ARV-471-mBC-101 study (ClinicalTrials.gov Identifier: NCT04072952).
- 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 study (vepdegestrant in combination with abemaciclib or ribociclib, [ClinicalTrials.gov Identifiers: NCT05548127 and NCT05573555]) and, with Pfizer, entered a collaboration and supply agreement with Carrick Therapeutics to evaluate samuraciclib in combination with vepdegestrant in the TACTIVE-U study.
- Continued enrollment in the TACTIVE-E study (vepdegestrant in combination with everolimus; ClinicalTrials.gov Identifier: NCT05501769), and the TACTIVE-N study (vepdegestrant as a monotherapy in the neoadjuvant setting; ClinicalTrials.gov Identifier: NCT05549505).
- Announced the inclusion of vepdegestrant in the I-SPY-2 (Investigation of Serial studies to Predict Your Therapeutic Response with Imaging And moLecular analysis 2) trial sponsored by Quantum Leap. The I-SPY-2 Endocrine Optimization Platform (EOP) study (ClinicalTrials.gov Identifier: NCT01042379) includes a vepdegestrant monotherapy arm and a vepdegestrant plus letrozole arm.
- Awarded Innovation Passport Designation for vepdegestrant by the U.K. Innovative Licensing and Access Pathway Steering Group.
- Announced that John Houston, Ph.D., was named Chairperson replacing Timothy Shannon, M.D., who stepped down from the role. Additionally, Sunil Agarwal, M.D., was appointed to join the company’s Board of Directors and Briggs Morrison, M.D., was appointed Lead Independent Director of the Board.

Anticipated Upcoming Milestones and Expectations

Vepdegestrant (ARV-471)
As part of Arvinas' global collaboration with Pfizer, the companies plan to:

- Present additional data from the Phase 1b combination trial with palbociclib (ClinicalTrials.gov Identifier: NCT04072952) at a medical congress (2H 2023).
- Continue enrollment in the study lead-in (SLI) of the VERITAC-3 Phase 3 trial in first-line ER+/HER2- locally advanced or metastatic breast cancer. The SLI will identify the palbociclib dose (75 or 100 mg) to combine with vepdegestrant in the randomized portion of the study.
- Initiate Phase 1b/2 trial with vepdegestrant plus Pfizer's CDK4 (cyclin dependent kinase) inhibitor (2H 2023).
- Initiate an additional arm of the Phase 1b/2 combination umbrella trial (TACTIVE-U: ClinicalTrials.gov Identifiers: NCT05548127 and NCT05573555) with Carrick Therapeutics' CDK7 inhibitor (2H 2023).
- Complete enrollment in VERITAC-2 Phase 3 monotherapy trial (ClinicalTrials.gov Identifier: NCT05654623) in patients with metastatic breast cancer (2H 2024).

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

- Present updated data, including radiographic progression free survival, from the ongoing Phase 1/2 trial with bavdegalutamide at the European Society for Medical Oncology congress in Madrid (October 2023).
- Initiate a global Phase 3 trial with bavdegalutamide in mCRPC (2H 2023).
- Complete enrollment in the Phase 1b combination study with bavdegalutamide plus abiraterone (2H 2023).
- 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 (2H 2023).
- Complete enrollment in the Phase 1b combination study with bavdegalutamide plus abiraterone (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 June 30, 2023, is sufficient to fund planned operating expenses and capital expenditure requirements into 2026.

Second Quarter Financial Results

Cash, Cash Equivalents and Marketable Securities Position: As of June 30, 2023, cash, cash equivalents, restricted cash and marketable securities were $1,044.3 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 $166.5 million for the six months ended June 30, 2023 was primarily related to cash used in operations of $172.9 million (net of $2.5 million received from two collaborators), leasehold improvements of $1.7 million and loss on the sale of marketable securities of $0.9 million, partially offset by unrealized gains on marketable securities of $7.0 million and proceeds from the exercise of stock options of $2.0 million.

Research and Development Expenses: Research and development expenses were $103.4 million for the quarter ended June 30, 2023, as compared with $75.3 million for the quarter ended June 30, 2022. The increase in research and development expenses of $28.1 million for the quarter was primarily due to increasing investment in our platform and exploratory programs of $5.4 million, as well as an increases our AR program of $7.4 million, which includes bavdegalutamide and ARV-766, and our ER program of $15.3 million, which is net of the cost sharing of vepdegestrant (ARV-471) under the global Pfizer collaboration agreement to develop and commercialize vepdegestrant that was initiated in July 2021 (Vepdegestrant (ARV-471) Collaboration Agreement).

General and Administrative Expenses: General and administrative expenses were $25.7 million for the quarter ended June 30, 2023, as compared with $24.3 million for the quarter ended June 30, 2022. The increase of $1.4 million was primarily due to an increase in professional fees of $2.0 million and increased investments in our commercial operations of $0.9 million, offset in part by reduced personnel and infrastructure related costs of $1.1 million and reduced insurance costs of $0.3 million.

Revenues: Revenues were $54.5 million for the quarter ended June 30, 2023 as compared with $33.8 million for the quarter ended June 30, 2022. Revenue is related to the Vepdegestrant (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, 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 $20.7 million was primarily due to an increase in revenue from the Vepdegestrant (ARV-471) Collaboration Agreement totaling $24.2 million, partially offset by a net decrease in revenue of $1.8 million as the performance period under the collaboration agreement with Genentech has concluded and a decrease of $1.2 million of previously constrained deferred revenue related to our Oerth Bio joint venture.

Income Tax Expense: Income tax benefit was $0.3 million for the quarter ended June 30, 2023, as compared with an income tax expense of $3.4 million for the quarter ended June 30, 2022. Current year tax benefit was driven by expected benefits from state net operating loss carryback claims. Prior year 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 $1.3 million for the quarter ended June 30, 2023, as compared with $2.5 million for the quarter ended June 30, 2022 due to decreased operating losses incurred by Oerth Bio.

Net Loss: Net loss was $66.6 million for the quarter ended June 30, 2023, as compared with $70.0 million for the quarter ended June 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, partly offset by increased research and development expenses and general and administrative expenses.

About bavdegalutamide (ARV-110) and ARV-766
Bavdegalutamide (ARV-110) and ARV-766 are investigational orally bioavailable PROTAC® protein degraders designed to selectively target and degrade the androgen receptor (AR). Bavdegalutamide and ARV-766 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 early and locally advanced or metastatic ER positive/human epidermal growth factor receptor 2 (HER2) negative (ER+/HER2-) breast cancer. Use of vepdegestrant in the ongoing and planned clinical trials will continue to monitor and evaluate patient safety and anti-tumor activity.

In preclinical studies, vepdegestrant demonstrated up to 97% ER degradation in tumor cells, induced 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.

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 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 and therapeutic benefits of vepdegestrant (ARV-471), bavdegalutamide (ARV-110), and ARV-766 and Arvinas' other discovery programs, including LRRK2 and BCL6; the development and regulatory status of Arvinas' product candidates, including the initiation of and timing of clinical trials, including the timing to complete enrollment, as well as the presentation and/or publication of data from clinical trials; Arvinas' plans with respect to submission of investigational new drug/clinical trial authorization applications for BCL6 and LRRK2; Arvinas' plans with respect to at least two additional PROTAC protein degrader programs into IND- or CTA-enabling studies; and the sufficiency of Arvinas' cash, cash equivalents, restricted cash and marketable securities 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 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, Inc.'s ("Pfizer") 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 (ARV-471); whether Arvinas will be able to successfully conduct and complete development for bavdegalutamide, ARV-766 and its other product candidates, 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 (ARV-471), bavdegalutamide, ARV-766 and other product candidates on current timelines or at all; Arvinas' ability to protect its intellectual property portfolio; whether Arvinas' 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 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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Condensed Consolidated Balance Sheets (Unaudited)

(dollars and shares in millions)	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 90.6	$ 81.3
Restricted cash	5.5	5.5
Marketable securities	948.2	1,124.0
Accounts receivable	0.1	1.0
Other receivables	4.7	7.0
Prepaid expenses and other current assets	7.6	21.4
Total current assets	1,056.7	1,240.2
Property, equipment and leasehold improvements, net	13.2	13.4
Operating lease right of use assets	3.5	4.4
Collaboration contract asset and other assets	10.1	10.8
Total assets	$ 1,083.5	$ 1,268.8
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities	$ 74.8	$ 74.7
Deferred revenue	230.1	218.6
Current portion of long term debt	0.1	—
Current portion of operating lease liability	1.9	1.8
Total current liabilities	306.9	295.1
Deferred revenue	310.5	405.1
Long term debt	0.9	1.0
Operating lease liability	1.6	2.7
Total liabilities	619.9	703.9
Stockholders' equity:		
Common stock, $0.001 par value; 53.4 and 53.2 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	0.1	0.1
Accumulated deficit	(1,113.9)	(965.4)
Additional paid-in capital	1,589.6	1,549.4
Accumulated other comprehensive loss	(12.2)	(19.2)
Total stockholders' equity	463.6	564.9
Total liabilities and stockholders' equity	$ 1,083.5	$ 1,268.8

Arvinas, Inc.

Condensed Consolidated Statements of Operations (Unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
(dollars and shares in millions, except per share amounts)	2023	2022	2023	2022
Revenue	$ 54.5	$ 33.8	$ 87.0	$ 60.3
Operating expenses:				
Research and development	103.4	75.3	198.6	139.2
General and administrative	25.7	24.3	50.7	44.5
Total operating expenses	129.1	99.6	249.3	183.7
Loss from operations	(74.6)	(65.8)	(162.3)	(123.4)
Interest and other income	9.0	1.7	15.5	2.7
Net loss before income taxes and loss from equity method investment	(65.6)	(64.1)	(146.8)	(120.7)
Income tax benefit (expense)	0.3	(3.4)	0.7	(7.9)
Loss from equity method investment	(1.3)	(2.5)	(2.4)	(4.8)
Net loss	$ (66.6)	$ (70.0)	$ (148.5)	$ (133.4)
Net loss per common share, basic and diluted	$ (1.25)	$ (1.32)	$ (2.78)	$ (2.51)
Weighted average common shares outstanding, basic and diluted	53.4	53.2	53.4	53.1