Arvinas Reports First Quarter 2023 Financial Results and Provides Corporate Update

May 5, 2023

Multiple vepdegestrant (ARV-471) studies enrolling globally, including Phase 1, 2, and 3 studies

Preliminary data from the Phase 1b combination trial of vepdegestrant + palbociclib suggests potential clinical benefit in a heavily pretreated patient population

NEW HAVEN, Conn., May 05, 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 first quarter ended March 31, 2023 and provided a corporate update.

"We made substantial progress throughout the first quarter across all areas of our early- and late-stage pipeline," said John Houston, Ph.D., president and chief executive officer at Arvinas. "Preliminary data from the ongoing Phase 1b combination study of vepdegestrant with palbociclib reinforce our confidence in the potential of vepdegestrant as an important treatment option in metastatic breast cancer. Together with Pfizer, we are on-track to initiate the safety lead-in to identify the dose of palbociclib for the planned Phase 3 trial with vepdegestrant and palbociclib. For bavdegalutamide, we are also on track to initiate a phase 3 trial in the second half of 2023, and we plan to share radiographic progression free survival data from the Phase 1/2 trial in the second half of 2023 as well. We look forward to progressing our clinical programs and new clinical candidates in the coming years."

Recent Developments and 1Q Business Highlights

- Evaluated preliminary data (November 2022 cutoff) from Part C of the ongoing Phase 1b/2 ARV-471-mBC-101 study (ClinicalTrials.gov Identifier: NCT04072952).
- Preliminary results from the Part C dose escalation (the Phase 1b combination of vepdegestrant + palbociclib 125 mg) demonstrate an observed clinical benefit rate (CBR; rate of confirmed complete response, confirmed partial response, or stable disease ≥24 weeks) of 60.7% (95% CI, 40.6 – 78.5) across all dose cohorts (17 of 28 CBR-evaluable patients; patients are CBR-evaluable if they received their first dose >24 weeks prior to the cut-off). Data are expected to be presented at a medical conference in the second half of 2023.
    - 85.7% of the 28 CBR-evaluable patients had received CDK4/6 inhibitor therapy prior to study entry.
    - An increase in palbociclib exposure was observed relative to historical palbociclib pharmacokinetic data.
    - A similar overall safety profile was observed compared with that reported in previous palbociclib and endocrine therapy combination studies, except for a higher incidence of grade 3/4 neutropenia, which was managed by monitoring and dose modification per the palbociclib label. Patients were started on palbociclib 125 mg irrespective of dose reduction during prior CDK4/6 inhibitor therapy.
- Gained alignment with the U.S. Food and Drug Administration on an approach for the planned 1L Phase 3 trial (VERITAC-3) with vepdegestrant (200 mg) in combination with palbociclib.
    - The safety lead-in is on-track to initiate in 2H 2023 and will start with a lead-in to evaluate the best starting dose of palbociclib (100 mg or 75 mg) in combination with vepdegestrant 200 mg once daily.
    - The objective is to select a dose of palbociclib (100 mg or 75 mg) that, when dosed with vepdegestrant 200 mg, results in a similar exposure and safety profile as palbociclib 125 mg in combination with aromatase inhibitors.
- 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: NCTC05548127 and NCTC05573555), 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 (Identifier: NCT01042379) will include a vepdegestrant monotherapy arm and a vepdegestrant plus letrozole arm.
- Presented vepdegestrant pre-clinical data at American Association for Cancer Research (AACR) annual meeting in April 2023 demonstrating:
    - The potential utility of vepdegestrant as an endocrine therapy backbone for combination with other targeted agents in early and late-stage ER+/HER2- breast cancer.

- The potential mechanisms of acquired resistance to vepdegestrant that may be associated with alterations within Receptor Tyrosine Kinase/MAPK signaling pathways rather than ER signaling or E3 ligase machinery.

- Presented new *in vivo* and *in vitro* data at AACR - Targeting RAS Special Conference demonstrating:
  - Arvinas' KRAS G12D PROTAC degraders are potent, selective and led to tumor stasis in a mouse xenograft model with intermittent dosing.
  - Degradation of KRAS G12D provides an advantage vs. inhibition *in vitro* and *in vivo*.
- Presented new ARV-766 preclinical data and compound structure at the AACR annual meeting in April 2023.
- Presented new preclinical data at the CHDI Foundation's Annual Huntington's Disease Therapeutics Conference showing that Arvinas PROTAC degraders potently and selectively degrade soluble mutant huntingtin (mHTT) in multiple cellular readouts, including rodent neurons, while sparing wild-type HTT.
- Appointed Kelly Page as Senior Vice President, Global Head of Oncology Strategy and Program Leadership.
- Announced that Timothy Shannon, M.D., our current Chairperson and a member of our board of directors since July 2013, will not be standing for re-election at the Annual Meeting.

"Tim's support, guidance and unwavering dedication has been instrumental in our success since our founding 10 years ago," continued Dr. Houston. "We are grateful for his years of service on the Board, and on behalf of the entire Company, we thank Tim for his strategic insight, wisdom and integrity – all of which are ingrained in our work as we make progress towards improving the lives of patients with serious diseases."

Anticipated Upcoming Milestones and Expectations

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

- Initiate the safety lead-in to identify the dose of palbociclib for the planned Phase 3 trial with vepdegestrant + palbociclib as a first-line treatment in patients with ER+/HER2- locally advanced or metastatic breast cancer (2H 2023).
- Submit and present additional data from the Phase 1b combination trial with palbociclib (ClinicalTrials.gov Identifier: NCT04072952) at a medical congress (2H 2023).
- Initiate additional arms of the Phase 1b combination umbrella trial (TACTIVE-U: ClinicalTrials.gov Identifiers: NCTC05548127 and NCTC05573555) with other targeted therapies (2H 2023).
- Complete enrollment for 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)

- Share data from the Phase 1 dose escalation trial with ARV-766 in metastatic castration-resistant prostate cancer (mCRPC) (2Q 2023).
- Submit and present additional data, including radiographic progression free survival, from the ongoing Phase 1/2 trial with bavdegalutamide at a medical congress (2H 2023).
- Initiate a global Phase 3 trial with bavdegalutamide in 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).
- 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 March 31, 2023, is sufficient to fund planned operating expenses and capital expenditure requirements into 2026.

First Quarter Financial Results

Cash, Cash Equivalents, Restricted Cash and Marketable Securities Position: As of March 31, 2023, cash, cash equivalents, restricted cash and marketable securities were $1,129.0 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 $81.8 million for the three months ended March 31, 2023 was primarily related to cash used in operations of $87.9 million (net of $2.5 million received from two collaborators), loss on the sale of marketable securities of $0.9 million and the purchase of lab equipment and leasehold improvements of $1.1 million, partially offset by unrealized gains on marketable securities of $6.6 million and proceeds from the exercise of stock options of $1.5 million.

Research and Development Expenses: Research and development expenses were $95.3 million for the quarter ended March 31, 2023, as compared with $64.0 million for the quarter ended March 31, 2022. The increase in research and development expenses of $31.3 million for the quarter was primarily due to an increase in our continued investment in our platform and exploratory programs of $18.3 million, as well as an increase

in expenses related to our AR program of $3.5 million, which includes bavdegalutamide and ARV-766, and our ER program of $9.5 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 (ARV-471 Collaboration Agreement).

General and Administrative Expenses: General and administrative expenses were $24.9 million for the quarter ended March 31, 2023, as compared with $20.2 million for the quarter ended March 31, 2022. The increase of $4.7 million was primarily due to an increase in personnel costs of $2.3 million and professional fees of $1.4 million.

Revenues: Revenues were $32.5 million for the quarter ended March 31, 2023, as compared with $26.5 million for the quarter ended March 31, 2022. 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, 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 $6.0 million was primarily due to an increase in revenue from the ARV-471 Collaboration Agreement totaling $15.9 million, partially offset by a net decrease in revenue totaling $8.2 million due to extensions of the period of revenue recognition under both the Pfizer and Bayer collaboration agreements 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 $0.4 million for the quarter ended March 31, 2023, as compared with an income tax expense of $4.5 million for the quarter ended March 31, 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 ARV-471 Collaboration Agreement.

Loss from Equity Method Investment: Loss from equity method investment was $1.1 million for the quarter ended March 31, 2023, as compared with $2.3 million for the quarter ended March 31, 2022 due to decreased operating losses incurred by Oerth Bio.

Net Loss: Net loss was $81.9 million for the quarter ended March 31, 2023, as compared with $63.4 million for the quarter ended March 31, 2022. The increase in net loss for the quarter was primarily due to increased research and development expenses and general and administrative expenses, partially offset by decreased income tax expense and 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 mCRPC.

Bavdegalutamide has demonstrated activity in preclinical models of AR mutation or overexpression, 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 bavdegalutamide (ARV-110), vepdegestrant (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, vepdegestrant, 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 vepdegestrant; 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 vepdegestrant, 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)	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 130.2	$ 81.3
Restricted cash	5.5	5.5
Marketable securities	993.3	1,124.0
Accounts receivable	—	1.0
Other receivables	4.7	7.0
Prepaid expenses and other current assets	14.5	21.4
Total current assets	1,148.2	1,240.2
Property, equipment and leasehold improvements, net	13.4	13.4
Operating lease right of use assets	3.9	4.4
Collaboration contract asset and other assets	10.3	10.8
Total assets	$ 1,175.8	$ 1,268.8
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued liabilities	$ 66.0	$ 74.7
Deferred revenue	214.9	218.6
Current portion of long term debt	0.1	—
Current portion of operating lease liability	1.9	1.8
Total current liabilities	282.9	295.1
Deferred revenue	378.9	405.1
Long term debt	0.9	1.0
Operating lease liability	2.1	2.7
Total liabilities	664.8	703.9
Stockholders' equity:		
Common stock, $0.001 par value; 53.4 and 53.2 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	0.1	0.1
Accumulated deficit	(1,047.3)	(965.4)
Additional paid-in capital	1,570.8	1,549.4
Accumulated other comprehensive loss	(12.6)	(19.2)
Total stockholders' equity	511.0	564.9
Total liabilities and stockholders' equity	$ 1,175.8	$ 1,268.8

Condensed Consolidated Statements of Operations (Unaudited)

(dollars and shares in millions, except per share amounts)	For the Three Months Ended March 31, 2023	2022
Revenue	$ 32.5	$ 26.5
Operating expenses:		
Research and development	95.3	64.0
General and administrative	24.9	20.2
Total operating expenses	120.2	84.2
Loss from operations	(87.7)	(57.7)
Interest and other income	6.5	1.1
Net loss before income taxes and loss from equity method investment	(81.2)	(56.6)
Income tax benefit (expense)	0.4	(4.5)
Loss from equity method investment	(1.1)	(2.3)
Net loss	$ (81.9)	$ (63.4)
Net loss per common share, basic and diluted	$ (1.54)	$ (1.20)
Weighted average common shares outstanding, basic and diluted	53.3	53.0