



Arvinas Reports Second Quarter 2022 Financial Results and Provides Corporate Update

August 4, 2022

NEW HAVEN, Conn., Aug. 04, 2022 (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, 2022 and provided a corporate update.

"This is an exciting time at Arvinas as we remain on track to initiate two pivotal programs with ARV-471 in metastatic breast cancer in the second half of this year, have a clear development pathway for bavdegalutamide in molecularly defined metastatic castration-resistant prostate cancer, and are preparing to initiate our Phase 2 trial with ARV-766 by end of year," said John Houston, Ph.D., president and chief executive officer at Arvinas. "In June, we had a collaborative meeting with the U.S. Food and Drug Administration to gain alignment on the registrational trial design for bavdegalutamide. Based on our goal of advancing this important potential treatment for prostate cancer as quickly as possible, the promising clinical data we've seen to date, and a productive meeting with the Agency, we have decided to move directly into a pivotal Phase 3 trial. If successful, we think this approach may lead to the fastest potential path to availability for patients in need, both inside and outside the United States, and who are most likely to benefit from this innovative therapy."

Business Highlights and Recent Developments

- Arvinas met with the U.S. Food and Drug Administration (FDA) to discuss the potential for an accelerated approach for bavdegalutamide based on a single arm Phase 2 trial and a confirmatory Phase 3 trial for full approval. FDA provided advice on the proposed registrational trial design, including patient eligibility, study design, and follow-up expectations.
- After considering multiple factors, including input provided by the FDA, Arvinas believes a randomized, pivotal Phase 3 trial provides the best opportunity to enable simultaneous global regulatory submissions.
 - The planned Phase 3 trial will evaluate the safety and efficacy of bavdegalutamide in patients with AR T878X/875Y tumor mutations and is expected to initiate in 2H 2023.
 - Final dose selection for the planned Phase 3 trial will be based on data from additional patients enrolled in the ongoing Phase 1/2 trial, which the company expects will confirm 400 mg as the Phase 3 dose. This further dose exploration will run concurrently with the company seeking regulatory guidance on final Phase 3 design.
- Arvinas finalized an agreement with Foundation Medicine to develop the FoundationOne@Liquid CDx as a companion diagnostic for use with bavdegalutamide.
- Arvinas launched the Global Early Career Researcher Award, which seeks to recognize the efforts of up-and-coming researchers bringing innovation, new approaches, and creative thinking to advance the field of targeted protein degradation.
- Arvinas appointed John Northcott to newly created position of Chief Commercial Officer, effective August 1, 2022.

Anticipated Upcoming Milestones and Expectations

ARV-471

- Present data from the VERITAC Phase 2 expansion trial (200 mg and 500 mg) (4Q 2022)
- Initiate two Phase 3 trials in patients with metastatic breast cancer (as monotherapy and in combination) (2H 2022)
- Initiate a Phase 1b combination trial with cyclin dependent kinase (CDK) inhibitors or other targeted therapies (2H 2022)
- Initiate a Phase 1b combination trial with everolimus (2H 2022)
- Initiate a Phase 2 neoadjuvant trial in patients with early breast cancer (2H 2022)
- Present safety data from the Phase 1b combination trial with palbociclib at a medical conference (1H 2023)

Bavdegalutamide (ARV-110)

- Initiate a Phase 3 trial in metastatic castration-resistant prostate cancer, or mCRPC, for patients with AR T878/H875 tumor mutations (2H 2023)

ARV-766

- Share Phase 1 dose escalation trial data in mCRPC (2H 2022)
- Initiate Phase 2 expansion trial in mCRPC (2H 2022)

Financial Guidance

Based on its current operating plane, Arvinas believes its cash, cash equivalents, restricted cash and marketable securities as of June 30, 2022 is sufficient to fund planned operating expenses and capital expenditure requirements multiple years beyond 2024.

Second Quarter Financial Results

Cash, Cash Equivalents, Restricted Cash and Marketable Securities Position: As of June 30, 2022, cash, cash equivalents, restricted cash and marketable securities were \$1,347.7 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 \$159.4 million for the first six months of 2022 was primarily related to cash used in operating activities of \$141.5 million (net of \$6.5 million received from two collaborators), unrealized loss on marketable securities of \$17.4 million, and the purchase of lab equipment and leasehold improvements of \$3.5 million, partially offset by proceeds from the exercise of stock options of \$3.0 million.

Research and Development Expenses: Research and development expenses were \$75.3 million for the quarter ended June 30, 2022, as compared with \$43.0 million for the quarter ended June 30, 2021. The increase in research and development expenses of \$32.3 million for the quarter was primarily due to an increase in our continued investment in our platform and exploratory programs of \$19.6 million, as well as an increase in expenses related to our ER program of \$14.1 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 2021 (ARV-471 Collaboration Agreement), offset by a decrease in our AR program (which includes bavdegalutamide and ARV-766) of \$1.4 million.

General and Administrative Expenses: General and administrative expenses were \$24.3 million for the quarter ended June 30, 2022, as compared with \$14.4 million for the quarter ended June 30, 2021. The increase of \$9.9 million was primarily due to an increase in personnel and facility related costs of \$6.9 million and insurance, taxes and professional fees of \$2.9 million.

Revenues: Revenues were \$31.3 million for the quarter ended June 30, 2022 as compared with \$5.5 million for the quarter ended June 30, 2021. 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, and the amended and restated option, license and collaboration agreement with Genentech that was initiated in November 2017. The increase in revenues of \$25.8 million was primarily due to revenue from the ARV-471 Collaboration Agreement.

Income Tax Expense: Income tax expense was \$3.4 million for the quarter ended June 30, 2022, as compared with zero for the quarter ended June 30, 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.

Net Loss: Net loss was \$70.0 million for the quarter ended June 30, 2022, as compared with \$50.3 million for the quarter ended June 30, 2021. The increase in net loss for the quarter was primarily due to increased research and development expenses, general and administrative expenses, and income tax expense, 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 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 that involve substantial risks and uncertainties, including statements regarding the potential advantages and therapeutic benefits of ARV-471, bavdegalutamide, ARV-766 and our other product candidates, the future development and potential marketing approval and commercialization of ARV-471, bavdegalutamide, ARV-766 and our other product candidates, including the initiation of and timing of data from our clinical trials. All statements, other than statements of historical facts, contained in this press release, including statements regarding our strategy, future operations, 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: whether we and, as applicable, Pfizer, will be able to successfully conduct and complete clinical development of our product candidates, including whether we initiate and receive results from our clinical trials on our expected timelines or at all, obtain marketing approval for and commercialize ARV-471, bavdegalutamide, ARV-766 and our other product candidates on our current timelines or at all and other important factors discussed in the “Risk Factors” sections contained in our quarterly and annual 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.

This press release contains forward-looking statements that involve substantial risks and uncertainties, including statements regarding the potential benefits of the Pfizer collaboration and the potential advantages and therapeutic benefits of ARV-471, bavdegalutamide, ARV-766 and our other product candidates, the future development and potential marketing approval and commercialization of ARV-471, bavdegalutamide, ARV-766 and our other product candidates, including the initiation of and timing of data from our clinical trials. All statements, other than statements of historical facts, contained in this press release, including statements regarding our strategy, future operations, 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: each party’s performance of its obligations under the Pfizer collaboration, whether we and, as applicable, Pfizer will be able to successfully conduct and complete clinical development, including whether we initiate and receive results from our clinical trials on our expected timelines or at all, obtain marketing approval for and commercialize ARV-471, bavdegalutamide, ARV-766 and our other product candidates on our current timelines or at all and other important factors discussed in the “Risk Factors” sections contained in our quarterly and annual 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)

| <i>(dollars and shares in millions)</i> | June 30, 2022 | December 31, 2021 |
|---|--------------------------|------------------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 93.2 | \$ 108.3 |
| Restricted cash | 4.5 | 4.5 |
| Marketable securities | 1,250.0 | 1,394.3 |
| Accounts receivable | 1.4 | 15.0 |
| Other receivables | 6.7 | 10.7 |
| Prepaid expenses and other current assets | 20.6 | 19.7 |
| Total current assets | 1,376.4 | 1,552.5 |
| Property, equipment and leasehold improvements, net | 13.6 | 12.7 |
| Operating lease right of use assets | 5.3 | 3.9 |
| Collaboration contract asset and other assets | 11.7 | 12.5 |
| Total assets | \$ 1,407.0 | \$ 1,581.6 |
| Liabilities and stockholders' equity | | |
| Current liabilities: | | |
| Accounts payable and accrued liabilities | \$ 42.1 | \$ 54.4 |
| Deferred revenue | 194.4 | 206.2 |
| Current portion of operating lease liability | 1.7 | 1.1 |

| | | |
|--|-------------------|-------------------|
| Total current liabilities | 238.2 | 261.7 |
| Deferred revenue | 493.6 | 534.3 |
| Long term debt | 1.0 | 1.0 |
| Operating lease liability | 3.6 | 2.9 |
| Total liabilities | <u>736.4</u> | <u>799.9</u> |
| Stockholders' equity: | | |
| Common stock, \$0.001 par value; 53.2 and 53.0 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively | 0.1 | - |
| Accumulated deficit | (816.3) | (682.9) |
| Additional paid-in capital | 1,508.8 | 1,469.2 |
| Accumulated other comprehensive loss | (22.0) | (4.6) |
| Total stockholders' equity | <u>670.6</u> | <u>781.7</u> |
| Total liabilities and stockholders' equity | <u>\$ 1,407.0</u> | <u>\$ 1,581.6</u> |

Arvinas, Inc.

Condensed Consolidated Statements of Operations (Unaudited)

| | For the Three Months Ended June 30, | | For the Six Months Ended June 30, | |
|--|-------------------------------------|------------------|-----------------------------------|------------------|
| | 2022 | 2021 | 2022 | 2021 |
| <i>(dollars and shares in millions, except per share amounts)</i> | | | | |
| Revenue | \$ 31.3 | \$ 5.5 | \$ 55.5 | \$ 11.1 |
| Operating expenses: | | | | |
| Research and development | 75.3 | 43.0 | 139.2 | 77.9 |
| General and administrative | 24.3 | 14.4 | 44.5 | 26.7 |
| Total operating expenses | <u>99.6</u> | <u>57.4</u> | <u>183.7</u> | <u>104.6</u> |
| Loss from operations | <u>(68.3)</u> | <u>(51.9)</u> | <u>(128.2)</u> | <u>(93.5)</u> |
| Interest and other income | 1.7 | 1.6 | 2.7 | 2.2 |
| Net loss before income taxes | <u>(66.6)</u> | <u>(50.3)</u> | <u>(125.5)</u> | <u>(91.3)</u> |
| Income tax expense | (3.4) | - | (7.9) | - |
| Net loss | <u>\$ (70.0)</u> | <u>\$ (50.3)</u> | <u>\$ (133.4)</u> | <u>\$ (91.3)</u> |
| Net loss per common share, basic and diluted | <u>\$ (1.32)</u> | <u>\$ (1.03)</u> | <u>\$ (2.51)</u> | <u>\$ (1.87)</u> |
| Weighted average common shares outstanding, basic and diluted | <u>53.2</u> | <u>48.9</u> | <u>53.1</u> | <u>48.7</u> |