Arvinas Reports Second Quarter 2019 Financial Results and Provides Corporate Update

August 5, 2019

NEW HAVEN, Conn., Aug. 05, 2019 (GLOBE NEWSWIRE) -- Arvinas, Inc. (Nasdaq: ARVN), a biotechnology company creating a new class of drugs based on targeted protein degradation, today reported financial results for the second quarter of 2019 and provided a corporate update.

“We made significant progress throughout the first half of 2019, highlighted by both clinical and corporate advances. We initiated first-in-human studies with ARV-110 in metastatic castration-resistant prostate cancer and received Fast Track designation from the U.S. Food and Drug Administration (FDA) for this indication. The FDA also cleared our IND for ARV-471 in ER positive/HER2 negative breast cancer,” said John Houston, Ph.D., Chief Executive Officer of Arvinas. “The potential of our targeted protein degrader technology was further validated by our agreement with Bayer, which expands the application of our technology beyond human health and therapeutics to include agricultural applications.”

“In addition, we greatly enhanced our leadership strength with the addition of Ronald Peck, M.D., as our Chief Medical Officer and with the appointment of Leslie Norwalk, Esq., to our Board of Directors. Both are experienced executives with significant and relevant experience that will be instrumental in guiding Arvinas forward with a new class of drugs based on our proprietary targeted protein degradation platform,” added Dr. Houston.

Business Highlights and Recent Developments

- Strengthened the management team with the appointment of Ronald Peck, M.D. to the newly created position of Chief Medical Officer. Dr. Peck brings to Arvinas more than twenty years of clinical and drug development experience, most recently serving as Senior Vice President, Clinical Research at Tesaro, where he oversaw all clinical development efforts for the company’s entire pipeline, including Zejula® (niraparib) and Tesaro’s immuno-oncology programs.
- Announced the appointment of Leslie Norwalk, Esq., to the Arvinas Board of Directors. Ms. Norwalk provides strategic counsel to a number of biotechnology companies and served in the George W. Bush Administration as the Acting Administrator for the Centers for Medicare & Medicaid Services (CMS).
- Presented preclinical data from the company’s tau-targeted PROTAC® protein degrader program at the Alzheimer's Association International Conference (AAIC). In preclinical studies, the tau-targeted PROTAC® protein degrader eliminated more than 95% of disease-causing (pathologic) tau protein in the brain, in a well-characterized mouse tauopathy model, following peripheral administration. The data further indicated that the tau protein degradation is dose- and concentration-dependent, signifying the tau-targeted PROTAC® protein degrader effectively crosses the blood brain barrier.
- Entered into an agreement with Bayer to leverage Arvinas’ novel PROTAC® protein degrader technology to develop new human therapeutics for patients with cardiovascular, oncological, and gynecological diseases. In addition, Bayer and Arvinas will jointly launch a new company to leverage Arvinas’ PROTAC® technology for agricultural applications. The overall series of arrangements includes over $110 million in upfront cash and committed funding for the human disease collaboration, the agricultural joint venture, and a direct equity investment by Bayer in Arvinas.
- Announced that Arvinas’ lead PROTAC® protein degrader, ARV-110, was granted Fast Track designation by the FDA for the treatment of men with metastatic castration-resistant prostate cancer (mCRPC) whose disease has progressed after treatment with two or more systemic therapies.
- Announced that the FDA cleared the Company’s Investigational New Drug application (IND) for ARV-471, an oral estrogen receptor (ER) PROTAC® protein degrader, designed to selectively target ER for the treatment of patients with locally advanced or metastatic ER positive/HER2 negative breast cancer.

Anticipated Milestones and Expectations

- Present preliminary safety, tolerability, and pharmacokinetic data from the Phase 1 clinical trial of ARV-110 in the fourth quarter of 2019.
- Present additional clinical data from the Phase 1 trial of ARV-110 in the first half of 2020.
- Initiate a Phase 1 clinical trial of ARV-471 in patients with locally advanced or metastatic ER positive/HER2-negative breast cancer in the third quarter of 2019 and share preliminary clinical data in 2020.

Financial Guidance

Based on its current operating plan, Arvinas expects its cash, cash equivalents, marketable securities and proceeds from Bayer will be sufficient to fund its operating expenses and capital expenditure requirements into the second half of 2021.

Financial Highlights

Cash, Cash Equivalents, and Marketable Securities Position: As of June 30, 2019, cash, cash equivalents, and marketable securities were $159.2 million as compared to $187.8 million as of December 31, 2018. These amounts exclude proceeds from the private placement and collaboration agreement with Bayer, which closed on July 16, 2019 and will provide an additional $51.5 million. The decrease in cash, cash equivalents and marketable securities of $28.6 million in the first six months of 2019 was primarily related to net cash used in operating activities of $26.3 million, the purchase of lab equipment and lease hold improvements of $3.3 million partially offset by net cash provided by financing activities of $0.3 million and changes in unrealized gain on marketable securities of $0.5 million. During the six months ended June 30, 2019 we received $2.7 million from a collaborator and $1.0 million related to the exchange of research and development tax credits with the State of Connecticut. Our cash used to fund operations for the six months ended June 30, 2019 was $33.3 million.

Research and Development Expenses: Research and development expenses were $16.0 million for the quarter ended June 30, 2019, as compared to $10.3 million for the quarter ended June 30, 2018. The increase in research and development expenses for the quarter primarily related to expenses associated with the initiation of our Phase 1 clinical trial of ARV-110 and IND-enabling expenses associated with ARV-471 as well as increased personnel and other expenses related to our platform research and exploratory programs research.

General and Administrative Expenses: General and administrative expenses were $6.4 million for the quarter ended June 30, 2019, as compared to $1.6 million for the quarter ended June 30, 2018. The increase in general and administrative expenses for the quarter was primarily related to increased employee expenses and other compliance costs associated with becoming a public company in the fourth quarter of 2018.

Revenues: Revenue was $4.0 million for the quarter ended June 2019, as compared to $3.4 million for the quarter ended June 30, 2018. Revenues are generated from the license and rights to technology fees and research and development activities related to 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.

Net Loss: Net loss was $17.2 million for the quarter ended June 30, 2019, as compared to $7.9 million for the quarter ended June 30, 2018. The increase in net loss for the quarter was primarily due to increased research and development expenses and increased general and administrative expenses.

About ARV-110
ARV-110 is an orally-bioavailable PROTAC® protein degrader designed to selectively target and degrade the androgen receptor protein (AR). ARV-110 is being developed as a potential treatment for men with metastatic castration-resistant prostate cancer (mCRPC). ARV-110 has demonstrated activity in preclinical models of AR mutation or overexpression, both common mechanisms of resistance to currently available AR-targeted therapies. Arvinas believes the differentiated pharmacology of ARV-110, including its iterative mechanism of action, has the potential to translate into improved clinical outcomes for patients. Arvinas expects to present preliminary clinical data regarding ARV-110 in the fourth quarter of 2019, and to present additional clinical data for the Phase 1 trial in the first half of 2020.

About ARV-471
ARV-471 is an orally-bioavailable PROTAC® protein degrader designed to target the estrogen receptor protein (ER). A Phase 1 clinical trial for ARV-471 in patients with locally-advanced or metastatic ER positive/HER2-negative breast cancer is expected to begin in the third quarter of 2019 and preliminary clinical data is expected in 2020.

About Arvinas
Arvinas is a clinical-stage biopharmaceutical 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 technology 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 disease-causing proteins. The company's lead program, ARV-110 for the treatment of patients with metastatic castration-resistant prostate cancer, began a Phase 1 clinical trial in the first quarter of 2019. For more information, see www.arvinas.com.

Forward-Looking Statements
This press release contains forward-looking statements that involve substantial risks and uncertainties, including statements regarding the development and regulatory status of our product candidates, including the timing of our clinical trial for ARV-471, and data from our clinical trial for ARV-110 and ARV-471 and the potential advantages and therapeutic potential of our product candidates, the sufficiency of cash resources, whether the pharmaceutical collaboration with Bayer will yield any viable product candidates, and the potential benefits of the Bayer collaboration and joint venture in the human therapeutic and agricultural fields, respectively. 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 will be able to successfully conduct a Phase 1 clinical trial for ARV-110, successfully initiate and

conduct a Phase 1 clinical trial for ARV-471, complete other clinical trials for our product candidates on our expected timelines, or at all, each party's ability to perform its obligations under the Bayer collaboration and/or the joint venture, whether our cash resources will be sufficient to fund our foreseeable and unforeseeable operating expenses and capital expenditure requirements on our expected timeline 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.
Consolidated Statement of Operations (Unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
Revenue	$ 4,016,489	$ 3,399,895	$ 8,032,979	$ 7,508,491
Operating expenses:				
Research and development	16,000,638	10,337,835	30,190,996	17,481,652
General and administrative	6,440,779	1,579,605	12,081,409	2,826,492
Total operating expenses	22,441,417	11,917,440	42,272,405	20,308,144
Loss from operations	(18,424,928)	(8,517,545)	(34,239,426)	(12,799,653)
Other income (expenses)				
Other income, net	191,729	130,945	434,850	258,394
Change in fair value of preferred unit warrant	—	2,516	—	(193,779)
Interest income	1,091,331	539,413	2,281,853	750,650
Interest expense	(22,778)	(9,871)	(46,416)	(20,540)
Total other income	1,260,282	663,003	2,670,287	794,725
Net loss	(17,164,646)	(7,854,542)	(31,569,139)	(12,004,928)
Change in fair value of redeemable convertible preferred units	—	(14,834,049)	—	(86,316,147)
Net loss attributable to common shares/units	$ (17,164,646)	$ (22,688,591)	$ (31,569,139)	$ (98,321,075)
Net loss per common share/unit, basic and diluted	$ (0.55)	$ (11.96)	$ (1.01)	$ (51.81)
Weighted average common shares/units outstanding, basic and diluted	31,440,051	1,897,544	31,408,658	1,897,544

Arvinas, Inc.
Consolidated Balance Sheet (Unaudited)

	June 30, 2019	**December 31, 2018**
Assets		
Current assets:		
Cash and cash equivalents	$ 11,342,178	$ 3,190,056
Marketable securities	147,831,005	184,637,640
Account receivable	—	2,775,831

Other receivables	1,402,085	2,255,966
Prepaid expenses and other current assets	2,685,820	2,818,286
Total current assets	163,261,088	195,677,779
Property, equipment and leasehold improvements, net	6,366,491	3,583,036
Operating lease right of use assets	2,397,789	—
Other assets	20,760	20,760
Total assets	$ 172,046,128	$ 199,281,575
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,411,471	$ 2,758,184
Accrued expenses	3,998,974	4,001,276
Deferred revenue	14,815,957	16,065,957
Current portion of long-term debt	71,499	154,461
Current portion of operating lease liability	647,872	—
Total current liabilities	20,945,773	22,979,878
Deferred revenue	30,701,736	37,484,714
Long term debt, net of current portion	2,000,000	2,000,000
Operating lease liability	1,893,359	—
Other noncurrent liability	—	150,000
Total liabilities	55,540,868	62,614,592
Commitments and Contingencies		
Stockholders’ equity:		
Common stock, $0.001 par value; 31,523,474 and 31,235,458 shares issued and outstanding as of June 30, 2019 and December 31, 2018, respectively	31,524	31,236
Accumulated deficit	(333,833,758)	(302,264,619)
Additional paid-in capital	450,007,344	439,118,089
Accumulated other comprehensive income (loss)	300,150	(217,723)
Total stockholders’ equity	116,505,260	136,666,983
Total liabilities and stockholders’ equity	$ 172,046,128	$ 199,281,575



Source: Arvinas Inc.