

**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): November 5, 2020

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 November 5, 2020, Arvinas, Inc. announced its financial results for the quarter ended September 30, 2020. 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.

The following exhibit relating to Item 2.02 shall be deemed to be furnished, and not filed:

99.1 [Press Release issued by the Registrant on November 5, 2020.](#)

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: November 5, 2020

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

Arvinas Reports Third Quarter 2020 Financial Results and Provides Corporate Update

– First patient dosed in Phase 2 dose expansion cohort of ARV-110 trial –

– Dose escalation for Phase 1/2 clinical trials of ARV-110 and ARV-471 continues; program updates planned for December 2020 –

– Arvinas and Pfizer enter collaboration and supply agreement; initiation of Phase 1b combination of ARV-471 and Ibrance® expected in the fourth quarter of 2020 –

NEW HAVEN, Conn., November 5, 2020 — Arvinas, Inc. (Nasdaq: ARVN), a clinical-stage biopharmaceutical company creating a new class of drugs based on targeted protein degradation, today reported financial results for the third quarter ended September 30, 2020 and provided a corporate update.

“Beginning the Phase 2 portion of the ARV-110 clinical trial marks another significant milestone for Arvinas,” said John Houston, Ph.D., President and Chief Executive Officer at Arvinas. “Together with the expected initiation of a cohort expansion of ARV-471 in combination with a CDK4/6 inhibitor before the end of the year, we’re gratified by the strong momentum of our lead programs heading into 2021.”

“When combined with our recent disclosure of five additional programs in our preclinical pipeline, these clinical milestones further validate our PROTAC® Discovery Engine and the opportunity to create PROTAC® degraders that meaningfully improve patient care,” added Dr. Houston.

Business Highlights and Recent Developments

- Dose escalation in each of the Phase 1/2 clinical trials of ARV-110 and ARV-471 continues.
- Arvinas has initiated dosing at a first dose level in a Phase 2 cohort expansion for ARV-110.
- The company announced platform updates and disclosed five additional programs from its preclinical pipeline. Arvinas’ portfolio encompasses a range of validated and undruggable targets in oncology, immuno-oncology, and neuroscience. The newly disclosed programs were B-cell lymphoma 6 protein (BCL6), Kirsten rat sarcoma (KRAS) protein, c-Myc, hematopoietic progenitor kinase 1 (HPK1), and mutant huntingtin (mHTT).
- Arvinas entered into a collaboration and supply agreement with Pfizer in connection with a planned Phase 1b cohort expansion evaluating ARV-471 in combination with Pfizer’s Ibrance® (palbociclib), an oral CDK4/6 inhibitor.

Anticipated Milestones and Expectations

2020 Milestones and Expectations

- Arvinas expects to provide a program update for ARV-110, including a Phase 1 dose escalation update and an overview of the recently initiated Phase 2 dose expansion, in December 2020.
- For the ARV-471 program, Arvinas expects to provide an update from its Phase 1 dose escalation in December 2020.
- Arvinas expects to initiate a Phase 1b cohort expansion of ARV-471 in combination with Ibrance® (palbociclib) in the fourth quarter of 2020. The study will evaluate the safety and tolerability of ARV-471 in combination with palbociclib and identify the recommended combination dose of ARV-471 for use with palbociclib.

2021 Milestones and Expectations

- Arvinas expects to initiate the first of potentially two Phase 1b investigations of ARV-110 in combination with standard of care agents for mCRPC (e.g., abiraterone) in 2021.
- Arvinas expects to share interim data from the Phase 2 dose expansion trial of ARV-110 in 2021.
- Arvinas expects to initiate a Phase 2 dose expansion of ARV-471 in 2021.
- Arvinas expects to share data from the Phase 1b cohort expansion of ARV-471 in combination with Ibrance® (palbociclib) in the second half of 2021.
- Arvinas expects to file an investigational new drug (IND) application for ARV-766, an androgen receptor degrader, in the first half of 2021.

Financial Guidance

Based on its current operating plan, Arvinas expects its cash, cash equivalents, and marketable securities will be sufficient to fund its planned operating expenses and capital expenditures into 2022.

Financial Highlights

Cash, Cash Equivalents, and Marketable Securities Position: As of September 30, 2020, cash, cash equivalents, and marketable securities were \$248.6 million as compared with \$280.9 million as of December 31, 2019. The decrease in cash, cash equivalents and marketable securities of \$32.3 million for the first nine months of 2020 was primarily related to cash used for operations of \$64.8 million and the purchase of lab equipment and leasehold improvements of \$4.6 million, partially offset by net proceeds from the issuance of common stock and exercises of stock options of \$33.1 million and \$4.0 million received from two collaborators.

Research and Development Expenses: Research and development expenses were \$30.0 million for the quarter ended September 30, 2020, as compared with \$16.6 million for the quarter ended September 30, 2019. The increase in research and development expenses of \$13.4 million for the quarter was primarily related to increases in clinical trials and chemistry, manufacturing and controls expenses associated with our AR program of \$4.2 million and our ER program of \$5.1 million, in addition to increases in expenses of \$4.1 million associated with exploratory programs and investments in platform research.

General and Administrative Expenses: General and administrative expenses were \$9.3 million for the quarter ended September 30, 2020, as compared with \$8.0 million for the quarter ended September 30, 2019. The increase of \$1.3 million was primarily related to an increase in personnel and facility related costs of \$2.4 million, offset by a reduction in legal costs of \$1.1 million.

Revenues: Revenue related to the license and rights to technology fees and research and development activities related to the collaboration and license agreement with Bayer (Bayer Collaboration Agreement) that was initiated in July 2019, the collaboration and license agreement with Pfizer (Pfizer Collaboration Agreement) that was initiated in January 2018, and the amended and restated option, license and collaboration agreement with Genentech that was initiated in November 2017 (collectively Collaboration Revenue) was \$7.6 million for the quarter ended September 30, 2020, as compared with \$5.4 million for the quarter ended September 30, 2019. The increase in Collaboration Revenue of \$2.2 million primarily related to the revenues from the Bayer Collaboration Agreement and the Pfizer Collaboration Agreement. Total revenue of \$30.1 for the three months ended September 30, 2019 included \$24.7 million for the contribution of a license to Oerth Bio LLC (the Joint Venture).

Loss from Equity Method Investment: Loss from equity method investment for the quarter ended September 30, 2019 was \$24.7 million. This loss was generated from the Joint Venture's expensing the values associated with the contributed intellectual property from the Joint Venture partners.

Net Loss: Net loss was \$30.8 million for the quarter ended September 30, 2020, as compared with \$17.7 million for the quarter ended September 30, 2019. 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 (AR). ARV-110 is being developed as a potential treatment for men with metastatic castration-resistant prostate cancer.

ARV-110 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 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.

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 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 two clinical-stage programs: ARV-110 for the treatment of men with metastatic castrate-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 development and regulatory status of our product candidates ARV-110, ARV-471, ARV-766, and other candidates in our pipeline, the conduct of and plans for our ongoing Phase 1/2 clinical trials for ARV-110 and ARV-471, our planned Phase 1b combination trial for ARV-471, our planned Phase 1b combination trials for ARV-110, our planned IND filing for ARV-766, the plans for presentation of data from our Phase 1/1b/2 clinical trials for ARV-110 and ARV-471, the potential advantages and therapeutic potential of our product candidates and the sufficiency of cash resources. 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 Phase 1/2 clinical trials for ARV-110 and ARV-471 and Phase 1b combination trials for ARV-110 or ARV-471, complete our clinical trials for our other product candidates, and receive results from our clinical trials on our expected timelines, or at all, 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.

Contacts for Arvinas

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Arvinas, Inc. Consolidated Statement of Operations (Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenue	\$ 7,596,776	\$ 30,050,227	\$ 19,584,085	\$ 38,083,205
Operating expenses:				
Research and development	30,012,918	16,588,050	75,155,694	46,779,047
General and administrative	9,331,925	7,957,364	26,072,404	20,038,772
Total operating expenses	39,344,843	24,545,414	101,228,098	66,817,819
Income (loss) from operations	(31,748,067)	5,504,813	(81,644,013)	(28,734,614)
Other income (expenses)				
Other income, net	144,215	405,302	841,967	840,153
Interest income	800,236	1,112,415	3,065,220	3,394,269
Interest expense	(16,250)	(22,903)	(48,750)	(69,319)
Total other income	928,201	1,494,814	3,858,437	4,165,103
Loss from equity method investment	—	(24,675,000)	—	(24,675,000)
Net loss	\$(30,819,866)	\$(17,675,373)	\$(77,785,576)	\$(49,244,511)
Net loss per common share, basic and diluted	\$ (0.79)	\$ (0.54)	\$ (2.01)	\$ (1.54)
Weighted average common shares outstanding, basic and diluted	39,058,294	32,740,486	38,784,569	31,876,074

Arvinas, Inc.
Consolidated Balance Sheet (Unaudited)

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 88,988,921	\$ 9,211,057
Marketable securities	159,574,963	271,661,456
Account receivable	2,444,450	—
Other receivables	3,511,633	6,280,828
Prepaid expenses and other current assets	3,459,862	3,727,294
Total current assets	257,979,829	290,880,635
Property, equipment and leasehold improvements, net	11,712,403	8,455,411
Operating lease right of use assets	2,226,422	2,278,623
Other assets	28,777	26,757
Total assets	<u>\$ 271,947,431</u>	<u>\$ 301,641,426</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 5,088,034	\$ 4,556,827
Accrued expenses	12,143,734	7,602,904
Deferred revenue	21,358,989	19,979,525
Current portion of operating lease liability	939,761	673,896
Total current liabilities	39,530,518	32,813,152
Deferred revenue	23,945,470	38,427,882
Long term debt	2,000,000	2,000,000
Operating lease liability	1,351,476	1,714,111
Total liabilities	<u>66,827,464</u>	<u>74,955,145</u>
Commitments and Contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value; 40,096,001 and 38,461,353 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	40,096	38,461
Accumulated deficit	(450,342,422)	(372,556,846)
Additional paid-in capital	654,342,486	599,097,090
Accumulated other comprehensive income	1,079,807	107,576
Total stockholders' equity	<u>205,119,967</u>	<u>226,686,281</u>
Total liabilities and stockholders' equity	<u>\$ 271,947,431</u>	<u>\$ 301,641,426</u>