

**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): March 26, 2019

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))

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 March 26, 2019, Arvinas, Inc. announced its financial results for the quarter and year ended December 31, 2018. 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 March 26, 2019.](#)

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: April 1, 2019

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



Arvinas Reports Fourth Quarter and Full Year 2018 Financial Results and Provides Corporate Update

Recently Announced the Initiation of Patient Dosing in the First Phase 1 Clinical Trial with a Targeted PROTAC™ Protein Degradar ARV-110

NEW HAVEN, Conn. – March 26, 2019 – Arvinas, Inc. (Nasdaq: ARVN), a biopharmaceutical company creating a new class of therapies that degrade disease-causing proteins, today reported financial results for the fourth quarter and full year ended December 31, 2018 and provided a corporate update.

“Since our founding in 2013, Arvinas has been focused on leading and advancing the field of targeted protein degradation and we are proud of our progress to date. 2018 was a transition year for Arvinas with preparations for moving into the clinic with our two lead programs. The hard work and dedication of our team recently enabled us to initiate patient dosing in our first Phase 1 clinical trial of ARV-110, our oral androgen receptor (AR)-targeted PROTAC™ protein degrader for the treatment of men with metastatic castration-resistant prostate cancer,” said John Houston, Ph.D., President and CEO of Arvinas. “We believe ARV-110 is the first in this new class of targeted protein degraders to enter human clinical trials, and we anticipate bringing ARV-471, an estrogen receptor (ER)-targeted PROTAC™ protein degrader for the treatment of women with locally advanced or metastatic ER+ / HER2- breast cancer, into the clinic in the third quarter of 2019.”

“While our initial clinical programs will be in oncology, this is just the beginning for Arvinas. There are many protein targets for which our PROTAC™ technology may be advantageous, including ‘undruggable’ targets. We are moving into new and exciting therapeutic areas, developing new PROTAC™ protein degraders against neurodegenerative targets such as tau, which is implicated in Alzheimer’s Disease. We have engineered targeted PROTAC™ protein degraders that, in preclinical studies, have achieved blood-brain barrier penetration, a key step in developing drugs with the potential to treat neurodegenerative diseases,” continued Dr. Houston.

Business Highlights and Recent Developments

- Initiated patient dosing in the first Phase 1 clinical trial of ARV-110, which will evaluate the safety and tolerability of ARV-110 in patients with metastatic castration-resistant prostate cancer (mCRPC) who have progressed on standard of care therapies. Arvinas believes ARV-110 is the first in a new class of targeted protein degraders to enter human clinical trials and anticipates preliminary data from the study in the second half of 2019.
- Completed an initial public offering (“IPO”) in October 2018, issuing an aggregate of 7,700,482 shares of common stock, including 200,482 additional shares of common stock upon the exercise in part by the underwriters of their option to purchase additional shares at a public offering price of \$16.00 per share, for aggregate gross proceeds of approximately \$123.2 million.
- Closed a \$55 million Series C financing in March 2018. The financing was led by new investor Nextech Invest, with participation from additional new investors Deerfield Management, and Hillhouse Capital. All existing investors also participated in this financing round, including Canaan Partners, 5AM Ventures, RA Capital Management, OrbiMed, and New Leaf Venture Partners.

- Presented positive preclinical data, at the 2018 San Antonio Breast Cancer Symposium (SABCS) on ARV-471, a PROTAC™ protein degrader for the degradation of the estrogen receptor (ER), which demonstrated:
 - Potent ER degradation in wild-type and mutant ER-expressing cell lines
 - Tumor shrinkage after oral administration in an orthotopic MCF7 breast cancer xenograft model, accompanied by near-complete ER degradation
 - More robust tumor growth inhibition and ER degradation compared to fulvestrant, a standard of care agent
 - Significant tumor regressions when combined with a CDK4/6 inhibitor and overall superior anti-tumor activity when compared to the combination of fulvestrant and a CDK4/6 inhibitor
 - Tumor growth inhibition of tamoxifen-resistant and ER gene (ESR1) mutant tumors while also reducing tumor ER levels
 - No ER agonist activity

Anticipated Milestones and Expectations

- Disclose preliminary data from the Phase 1 clinical trial of ARV-110 in the second half of 2019.
- Initiate a Phase 1 clinical trial of ARV-471 in women with locally advanced or metastatic ER+ positive / HER2- negative breast cancer in the third quarter of 2019 and collect preliminary clinical data in 2020.
- Present preclinical data from our tau program in the second half of 2019.

Financial Guidance

Based on its current operating plan, Arvinas expects its cash, cash equivalents, and marketable securities as of December 31, 2018 will be sufficient to fund its operating expenses and capital expenditure requirements into the first half of 2021.

Full Year and Fourth Quarter Financial Highlights

Cash, Cash Equivalents and Marketable Securities Position: As of December 31, 2018, cash, cash equivalents, and marketable securities were \$187.8 million as compared to \$39.2 million as of December 31, 2017. The increase related to net proceeds from our IPO of \$114.6 million, proceeds from our Series C financing of \$55.0 million, proceeds from our Pfizer collaboration of \$28.0 million, and proceeds from a partially forgivable loan of \$2.0 million; offset by cash used to fund operations and professional fees paid related to our IPO of \$51.0 million. Cash, cash equivalents, and marketable securities increased by \$98.0 million in the fourth quarter of 2018. This increase related to net proceeds from our IPO of \$114.6 million, offset by cash used to fund operations, and professional fees paid related to our IPO of \$16.6 million.

Research and Development Expenses: Research and development expenses were \$45.2 million and \$14.6 million for the year and quarter ended December 31, 2018, respectively as compared to \$28.8 million and \$6.7 million for the year and quarter ended December 31, 2017, respectively. The increase in research and development expenses for the year and quarter primarily related to investigational new

drug application (“IND”)-enabling costs associated with ARV-110 and ARV-471 in addition to increases in costs associated with our discovery operations.

General and Administrative Expenses: General and administrative expenses were \$12.9 million and \$5.8 million for the year and quarter ended December 31, 2018, respectively as compared to \$3.5 million and \$1.2 million for the year and quarter ended December 31, 2017, respectively. The increase in general and administrative expenses for the year and quarter primarily relate to increases in our infrastructure in preparation of becoming a publicly traded company.

Revenues: Revenue was \$14.3 million and \$3.4 million for the year and quarter ended December 31, 2018, respectively as compared to \$7.6 million and \$2.6 million for the year and quarter ended December 31, 2017, respectively. This increase in the year and quarter was due to an increase in license and rights to technology and research and development activities primarily related to the Pfizer collaboration agreement initiated in January 2018 and the expanded Genentech agreement that was initiated in November 2017.

Net Loss: Net loss was \$41.5 million and \$16.1 million for the year and quarter ended December 31, 2018, respectively as compared to \$24.0 million and \$4.7 million for the year and quarter ended December 31, 2017, respectively. The increase in net loss for the year and quarter ended December 31, 2018 was primarily due to the progression of ARV-110 through IND-enabling activities, clinical trial start-up costs for ARV-110, the initiation of IND-enabling activities for ARV-471, investments in our discovery programs and investments in our infrastructure in preparation for becoming a publicly traded company offset by an increase in revenue primarily related to the expanded Genentech collaboration agreement initiated in November 2017 and the Pfizer collaboration agreement initiated in January 2018.

About ARV-110

ARV-110 is an orally-bioavailable PROTAC™ protein degrader designed to selectively target and degrade androgen receptor (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 activity, has the potential to translate into improved clinical outcomes for patients.

About ARV-471

ARV-471 is targeting the estrogen receptor (ER) for the treatment of women with locally advanced or metastatic ER+ / HER2- breast cancer. A Phase 1 clinical trial for ARV-471 in women 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 biopharmaceutical company dedicated to improving the lives of patients suffering from debilitating and life-threatening diseases through the discovery, development, and commercialization of therapies to 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 and remove disease-causing proteins. 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 of preliminary data from our clinical trial for ARV-110 and ARV-471, and 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 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, 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, 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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Contacts for Arvinas

Investors

Randy Teel, VP Corporate Development
ir@arvinas.com

Media

Cory Tromblee, ScientPR
pr@arvinas.com

Arvinas, Inc.
Consolidated Statement of Operations (Unaudited)

	<u>Quarter Ended December 31,</u>		<u>Year Ended December 31,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
Revenue	\$ 3,440,165	\$ 2,572,293	\$ 14,323,920	\$ 7,578,876
Operating expenses:				
Research and development	14,562,299	6,690,189	45,193,830	28,792,902
General and administrative	5,821,445	1,189,122	12,932,168	3,546,241
Total operating expenses	<u>20,383,744</u>	<u>7,879,311</u>	<u>58,125,998</u>	<u>32,339,143</u>
Loss from operations	(16,943,579)	(5,307,018)	(43,802,078)	(24,760,267)
Interest and other income	855,713	578,992	2,321,612	711,061
Net loss	(16,087,866)	(4,728,026)	(41,480,466)	(24,049,206)
Change in redemption value of redeemable preferred units	—	(4,570,431)	(198,366,756)	(4,570,431)
Net loss attributable to common units/shares	<u>\$(16,087,866)</u>	<u>\$(9,298,457)</u>	<u>\$(239,847,222)</u>	<u>\$(28,619,637)</u>
Net loss per common unit/share, basic and diluted	<u>\$ (0.52)</u>	<u>\$ (4.90)</u>	<u>\$ (25.45)</u>	<u>\$ (15.08)</u>
Weighted average common units/shares outstanding, basic and diluted	<u>31,098,634</u>	<u>1,897,544</u>	<u>9,422,799</u>	<u>1,897,544</u>

Arvinas, Inc.
Consolidated Balance Sheet (Unaudited)

	December 31,	
	2018	2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 3,190,056	\$ 30,912,391
Marketable securities	184,637,640	8,258,982
Account receivable	2,775,831	25,000,000
Other receivables	2,255,966	1,040,452
Prepaid expenses and other current assets	2,818,286	316,903
Total current assets	195,677,779	65,528,728
Property, equipment and leasehold improvements, net	3,583,036	1,298,881
Other assets:		
Deposits	20,760	20,760
Total assets	<u>\$ 199,281,575</u>	<u>\$ 66,848,369</u>
Liabilities and members'/stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,758,184	\$ 596,527
Accrued expenses	4,001,276	3,545,936
Deferred revenue	16,065,957	13,553,136
Current portion of long-term debt	154,461	159,265
Total current liabilities	22,979,878	17,854,864
Deferred revenue	37,484,714	48,545,625
Long term debt, net of current portion	2,000,000	151,122
Other non-current liability	150,000	—
Preferred unit warrant liability	—	50,888
Total liabilities	62,614,592	66,602,499
Commitments and contingencies		
Redeemable convertible preferred units	—	61,480,432
Members'/Stockholders' equity:		
Common units, no par value, 1,897,544 units issued and outstanding as of December 31, 2017	—	6,167
Incentive units, no par value, 3,669,963 units issued as of December 31, 2017	—	1,186,419
Common stock, \$0.001 par value, 31,235,458 shares issued and outstanding as of December 31, 2018	31,236	—
Accumulated deficit	(302,264,619)	(62,417,397)
Additional paid-in capital	439,118,089	—
Accumulated other comprehensive loss	(217,723)	(9,751)
Total members'/stockholders' equity	136,666,983	(61,234,562)
Total liabilities and members'/stockholders' equity	<u>\$ 199,281,575</u>	<u>\$ 66,848,369</u>