
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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 8, 2018

ARCUS BIOSCIENCES, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-38419
(Commission
File Number)

47-3898435
(I.R.S. Employer
Identification No.)

3928 Point Eden Way
Hayward, CA 94545
(Address of principal executive offices)

Registrant's telephone number, including area code: (510) 694-6200

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:

- 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 November 8, 2018, Arcus Biosciences, Inc. issued a press release announcing its financial results for the third quarter ended September 30, 2018. The full text of the press release is furnished as Exhibit 99.1 hereto and is incorporated herein by reference.

The information in this Item 2.02 of this Form 8-K (including Exhibit 99.1) is intended to be furnished and 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 filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated November 8, 2018.

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 thereunto duly authorized.

Date: November 8, 2018

ARCUS BIOSCIENCES, INC.

By: /s/ Jennifer Jarrett
Jennifer Jarrett
Chief Operating & Financial Officer

Arcus Biosciences Announces Third Quarter 2018 Financial Results and Recent Corporate Updates

- Three dose-escalation trials evaluating AB928, the Company's dual adenosine receptor antagonist, in combination with other agents are now enrolling patients; Initial data from the dose-escalation trials expected in the second quarter of 2019 -
- Initiated dosing in patients for the Company's third clinical candidate, AB154, an anti-TIGIT antibody -
- Ended the quarter with \$265.6 million in cash and investments and funding into 2021 -

Hayward, CA. – (BUSINESS WIRE) – November [6], 2018 - Arcus Biosciences, Inc. (NYSE:RCUS), a clinical-stage biopharmaceutical company focused on creating innovative cancer immunotherapies, today announced financial results for the third quarter ended September 30, 2018 and provided updates on its clinical and preclinical programs.

"This was another productive quarter for Arcus as we began dosing patients with our third product candidate, AB154, and made significant progress advancing our initial combination trials for AB928," said Terry Rosen, Ph.D., Chief Executive Officer at Arcus. "The starting dose for the dose-escalation portion of our AB928 combination trials is 75 mg once-daily, a dose that demonstrated significant inhibition of the adenosine 2a receptor pathway in our healthy volunteer study. We have incorporated extensive biomarker analysis into the design of our AB928 combination trials to determine if clinical responses observed in the trials can be attributed to the mechanism of action of AB928. We look forward to reporting initial clinical data for both AB928 and AB154, as well as data from our healthy volunteer study of AB680, our small-molecule CD73 inhibitor, in 2019."

Pipeline Updates and Poster Presentations

AB928 (dual A_{2a} R/A_{2b} R antagonist)

- ***Initiated the first three AB928 combination trials in patients.*** AB928 is being evaluated in combination with other agents in the following Phase 1/1b dose-escalation trials, which are now enrolling patients:
 - AB928 in combination with Doxil® in triple negative breast (TNBC) and ovarian cancers
 - AB928 in combination with mFOLFOX in colorectal and gastroesophageal cancers
 - AB928 in combination with AB122, the Company's anti-PD-1 antibody, in advanced solid tumor types

The Company also expects the following AB928 dose-escalation trial to be open for enrollment shortly:

- AB928 in combination with carboplatin/pemetrexed and pembrolizumab in non-small cell lung cancer (NSCLC)

In the above NSCLC trial, the Company also plans to explore AB928 combinations in the relapsed/refractory setting, including in patients previously treated with anti-PD-1 therapy.

- **Six posters to be presented at the Society for Immunotherapy of Cancer (SITC) 2018 Annual Meeting taking place November 7th through 11th :**
 - *“Development of biomarkers to assess adenosine generation & activity in support of clinical trials conducted with the adenosine receptor antagonist AB928”* will highlight the development of biomarkers to enable the selection of patients and tumor types with the highest levels of CD73, the rate-limiting enzyme responsible for the production of adenosine.
 - *“Selection of optimized drug candidates, dosing regimen, pharmacodynamic endpoints, tumor types, and biomarkers for translating inhibition of the adenosine pathway into effective anti-tumor activity”* will highlight the Company’s strategy for identifying the optimal tumor types to target for each of AB928 and AB680.
 - Four *“Trial in Progress”* poster presentations will summarize the design of the Company’s four AB928 combination trials.
- **Presented final results from the Phase 1 double-blinded, randomized, placebo-controlled trial of AB928 in healthy volunteers in a poster presentation at ESMO in October.** Data presented in this poster presentation support the selection of the starting dose of AB928 for clinical trials in patients.
- **Presented a poster on the ability of AB928 to relieve adenosine-mediated immune suppression at the Fourth AACR International Cancer Immunotherapy Conference in September.** The *in vitro* data presented demonstrate that AB928 prevents adenosine-mediated gene expression changes and suppression of immune cell function and suppresses tumor growth in syngeneic mouse models when administered as a monotherapy or in combination with anti-PD-1 or chemotherapy.

AB122 (anti-PD-1 antibody)

- **Two posters to be presented at the SITC 2018 Annual Meeting in November:**
 - *“Preliminary results from an ongoing Phase 1 study of AB122 in patients with advanced solid tumors”* will include pharmacokinetic, receptor occupancy, safety and clinical activity data from the Phase 1 dose-escalation trial for AB122.
 - *“Development of a robust, simplified method to measure receptor occupancy in peripheral blood from patients treated with a novel anti-PD-1 agent, AB122”* will demonstrate, together with the previous poster, that AB122 achieved significant inhibition of PD-1 in patients treated in the first two dosing cohorts of the Phase 1 dose-escalation trial.
- **Continued dosing patients in the Company’s Phase 1 dose-escalation trial for AB122.** As of November 3, 2018, the Company had dosed 20 patients with AB122 evaluating different doses and dosing schedules. Based on data generated to date, the Company selected 240 mg as the dose for the Q2W (every 2 weeks) regimen for AB122.

AB154 (anti-TIGIT antibody)

- **Dosed the first cohort of patients in the dose-escalation portion of the ongoing Phase 1 trial for AB154 in Australia.** This Phase 1 trial is evaluating AB154 in selected solid tumor types. The dose-escalation portion will be followed by the initiation of expansion cohorts in tumor types associated with high levels of TIGIT and/or CD155, the ligand for TIGIT, once the recommended doses for
-

AB154 as a monotherapy and in combination with AB122 have been identified . The Company plans to file an Investigational New Drug (IND) Application for AB154 in the U.S. by the end of the first quarter of 2019.

- **Presented a poster on the preclinical characterization of AB154 at the Fourth AACR International Cancer Immunotherapy Conference in September.** Data presented demonstrated that AB154 enhances the T cell activation effects of our anti-PD-1 antibody (AB122) in a mixed lymphocyte assay and that AB154 has sub-nanomolar potency on peripheral blood lymphocytes derived from both healthy donors and NSCLC patients.
- **Presented a poster at the SITC 2018 Annual Meeting in November:**
 - *“Preclinical characterization of AB154, a fully humanized α -TIGIT antibody, for use in combination therapies”* will highlight the Company’s development of a TIGIT occupancy assay, which is being implemented in the ongoing Phase 1 trial of AB154.

AB680 (small molecule CD73 inhibitor)

- **Received regulatory approval in Australia to initiate a healthy volunteer trial for AB680 (IV formulation).** This trial is primarily designed to determine the safety, tolerability and pharmacokinetic profile of AB680 prior to initiating clinical testing of AB680 in cancer patients and is expected to begin dosing shortly. Preclinical data suggest that the half-life of AB680 should be sufficient for clinical dosing every two or three weeks.
- **Presented a poster on the preclinical pharmacokinetic and pharmacodynamic characterization of AB680 at the Fourth AACR International Cancer Immunotherapy Conference in September.** Data presented demonstrated that AB680 is a highly potent and selective small-molecule inhibitor of CD73 and that AB680 has a long projected human half-life.
- **IND-enabling studies for an oral formulation of AB680 are ongoing.**

Corporate Updates

- In October, Arcus announced that Kristin M. Hege, M.D., was appointed to its Board of Directors. Dr. Hege currently serves as Corporate Vice President, Translational Development, Hematology and Oncology and San Francisco site head at Celgene.

Upcoming Milestones

In the first half of 2019, the Company expects to:

- Present initial data from the dose-escalation portion of the AB928 Phase 1/1b combination trials, which will include data on safety, biomarker analysis and clinical activity for the combinations, in the second quarter.
- Initiate an expansion cohort to evaluate AB122 as a monotherapy to confirm that the activity of AB122 is similar to that of the approved anti-PD-1 antibodies.
- Report safety and pharmacokinetic data from the Phase 1 trial of AB680 in healthy volunteers, and initiate the Phase 1 clinical program for AB680 in cancer patients.

In the middle of 2019, the Company expects to:

- Initiate the first of the expansion cohorts for the AB928 combination trials.

In the second half of 2019, the Company expects to:

- Present additional data from the dose-escalation portion of the AB928 Phase 1/1b combination trials.
- Present initial data from the ongoing Phase 1 trial of AB154.

Third Quarter and Year-to-Date 2018 Financial Results

- **Cash Position:** At September 30, 2018, cash and investments (which include cash equivalents and both short-term and long-term investments) were \$265.6 million, compared to \$175.7 million at December 31, 2017. The increase was primarily due to \$124.7 million in net proceeds from the Company's initial public offering in March.
- **Revenues:** Collaboration and license revenues for the third quarter ended September 30, 2018 were \$4.3 million, compared to \$0.2 million for the same period in 2017. Collaboration and license revenues for the nine months ended September 30, 2018 were \$6.8 million, compared to \$0.2 million for the same period in 2017. The increase in revenues for both periods was attributable to revenues recognized from the Option and License Agreement the Company entered into with Taiho Pharmaceutical Co., Ltd in September 2017.
- **R&D Expenses:** Research and development expenses for the third quarter ended September 30, 2018 were \$12.9 million, compared to \$21.4 million for the same period in 2017. The decrease was due to licensing costs of \$15.0 million paid to WuXi Biologics in the third quarter ended September 30, 2017, partially offset by an increase in clinical and manufacturing costs related to the Company's initiation of its AB928 combination and AB154 clinical trials, preclinical and manufacturing costs to prepare AB680 for clinical trials, an increase in R&D headcount to support the Company's clinical operations and other programs, and an increase in lab supplies. Research and development expenses for the nine months ended September 30, 2018 were \$38.2 million, compared to \$35.1 million for the same period in 2017.
- **G&A Expenses:** General and administrative expenses for the third quarter ended September 30, 2018 were \$3.6 million, compared to \$1.9 million for the same period in 2017. The increase was primarily due to higher legal and accounting fees and additional staff in key areas required to support a public company infrastructure, as well as increased facilities and office expenses related to our expanded facility in Hayward. General and administrative expenses for the nine months ended September 30, 2018 were \$10.0 million, compared to \$5.2 million for the same period of 2017.
- **Net Loss:** Net loss for the third quarter ended September 30, 2018 was \$10.8 million, compared to \$23.1 million for the same period in 2017. The decrease in net loss was primarily attributable to the increase in revenue and changes in operating expenses noted above. Net loss for the nine months ended September 30, 2018 was \$37.3 million, compared to \$39.9 million for the same period in 2017.

Based on its current operating plan, the Company expects that its cash and investments as of September 30, 2018 will enable the Company to fund its anticipated operating expenses and capital expenditure requirements into 2021.

About Arcus Biosciences

Arcus Biosciences is a clinical-stage biopharmaceutical company focused on creating innovative cancer immunotherapies. Arcus has several programs targeting important immuno-oncology pathways, including a dual adenosine receptor antagonist, AB928, which is in a Phase 1/1b program to evaluate AB928 in combination with other agents in multiple tumor types, and an anti-PD-1 antibody, AB122, which is being evaluated in a Phase 1 trial and is being tested in combination with Arcus's other product candidates. Arcus's other programs include AB154, an anti-TIGIT antibody, which is in a Phase 1 trial to evaluate AB154 as monotherapy and in combination with AB122, and AB680, a small molecule inhibitor of CD73, which has entered clinical development. Arcus has extensive in-house expertise in medicinal chemistry, immunology, biochemistry, pharmacology and structural biology. For more information about Arcus Biosciences, please visit www.arcusbio.com.

Forward-Looking Statements

This press release contains forward-looking statements. All statements other than statements of historical facts contained herein, including, but not limited to, Arcus's clinical development plans, biomarker activities, milestones and timelines, and anticipated operating expenses and capital expenditure requirements are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All forward-looking statements involve known and unknown risks, uncertainties and other important factors that may cause Arcus's actual results, performance or achievements to differ significantly from those expressed or implied. Factors that could cause or contribute to such differences include, but are not limited to, the inherent uncertainty associated with pharmaceutical product development and clinical trials, difficulties or delays in developing and validating biomarkers and related assays, delays in our clinical trials due to difficulties or delays in the regulatory process, enrolling subjects or manufacturing or supplying product for such clinical trials, and the emergence of adverse events or other undesirable side effects. Risks and uncertainties facing Arcus are described more fully in Arcus's quarterly report on Form 10-Q for the quarter ended September 30, 2018 filed on November 8, 2018 with the SEC. You are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this press release. Arcus disclaims any obligation or undertaking to update, supplement or revise any forward-looking statements contained in this press release.

Doxil® is a registered trademark of Alza Corporation.

Source: Arcus Biosciences

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ARCUS BIOSCIENCES, INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)
(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Collaboration and license revenue	\$ 4,291	\$ 163	\$ 6,791	\$ 163
Operation expenses:				
Research and development	12,859	21,435	38,210	35,072
General and administrative	3,577	1,862	9,956	5,188
Total operating expenses	<u>16,436</u>	<u>23,297</u>	<u>48,166</u>	<u>40,260</u>
Loss from operations	(12,145)	(23,134)	(41,375)	(40,097)
Interest and other income, net	1,333	12	4,076	225
Net loss	<u>(10,812)</u>	<u>(23,122)</u>	<u>(37,299)</u>	<u>(39,872)</u>
Other comprehensive gain (loss)	(25)	14	(66)	17
Comprehensive loss	\$ (10,837)	\$ (23,108)	\$ (37,365)	\$ (39,855)
Net loss per share, basic and diluted	\$ 0.25	\$ (11.86)	\$ (1.16)	\$ (23.47)
Weighted-average number of shares used to compute basic and diluted net loss per share	<u>42,838,098</u>	<u>1,949,258</u>	<u>32,056,675</u>	<u>1,699,045</u>

ARCUS BIOSCIENCES, INC.
Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)
(unaudited)

	September 30, 2018	December 31, 2017 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 74,889	\$ 98,426
Short-term investments	182,948	77,277
Receivable from collaboration partners	5,000	—
Prepaid expenses and other current assets	2,329	1,141
Amounts owed by a related party	114	25
Total current assets	265,280	176,869
Long-term investments	7,746	—
Property and equipment, net	11,762	11,230
Equity investment in related party	1,525	682
Restricted cash	203	203
Other long-term assets	205	1,502
Total assets	\$ 286,721	\$ 190,486
LIABILITIES		
Current liabilities		
Accounts payable	\$ 2,109	\$ 3,820
Accrued liabilities	6,667	3,137
Deferred revenue, current	6,250	5,000
Other current liabilities	1,585	769
Total current liabilities	16,611	12,726
Deferred revenue, noncurrent	18,546	18,587
Deferred rent	4,396	4,740
Other long-term liabilities	2,047	565
Total liabilities	41,600	36,618
Convertible preferred stock	—	226,196
Stockholders' equity (deficit):		
Common stock	4	—
Additional paid-in capital	355,758	948
Accumulated deficit	(110,533)	(73,234)
Accumulated other comprehensive loss	(108)	(42)
Total stockholders' equity (deficit)	245,121	(72,328)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	\$ 286,721	\$ 190,486

(1) The Condensed Consolidated Balance Sheet as of December 31, 2017 has been derived from the audited financial statements as of that date.