



NEWS RELEASE

Arcus Biosciences Reports Third-Quarter 2024 Financial Results and Provides a Pipeline Update

2024-11-06

- Data from the Phase 1/1b ARC-20 study of casdatifan were presented at an oral plenary session at the 2024 EORTC-NCI-AACR Symposium; a low rate of primary progression (19%) and promising objective response rate (34% with 2 responses pending confirmation, 25% confirmed) for the 100mg daily (50mg twice-daily) cohort of heavily pretreated patients with clear-cell renal cell carcinoma (ccRCC) support a potential best-in-class profile
- Arcus announced a clinical trial collaboration agreement with AstraZeneca to evaluate casdatifan in combination with volrustomig, an investigational PD-1/CTLA-4 bispecific antibody, in patients with immunology (IO)-naive ccRCC
- Data from the randomized ARC-10 study will be presented at the Annual Meeting of the Society of Immunotherapy of Cancer (SITC); domvanalimab plus zimberelimab reduced the risk of death in first-line metastatic non-small cell lung cancer (NSCLC) by 36% compared to zimberelimab
- Arcus is well positioned to advance its full pipeline with \$1.1 billion in cash, cash equivalents and marketable securities and runway into mid-2027

HAYWARD, Calif.--(BUSINESS WIRE)-- Arcus Biosciences, Inc. (NYSE:RCUS), a clinical-stage, global biopharmaceutical company focused on developing differentiated molecules and combination therapies for patients with cancer, today reported financial results for the third quarter ended September 30, 2024, and provided a pipeline update on its clinical-stage investigational molecules — targeting TIGIT, HIF-2a, CD73, the A2a/A2b receptors, CD-39, AXL and PD-1 — across multiple common cancers.

“Through the course of this year, we have presented multiple compelling datasets at medical conferences that we

believe have de-risked several programs and support potential best-in-class profiles for our molecules, including our HIF-2a inhibitor casdatifan in ccRCC and our Fc-silent anti-TIGIT antibody domvanalimab in lung and upper gastrointestinal cancers,” said Terry Rosen, Ph.D., chief executive officer of Arcus. “Meanwhile, in addition to our rapidly approaching first Phase 3 readout for domvanalimab in gastric cancer, we are aggressively pursuing our development plan for casdatifan, including in the IO-naive ccRCC setting in collaboration with AstraZeneca, and in the post-IO setting with the initiation of our Phase 3 PEAK-1 study in the first half of next year.”

Corporate Updates:

- In October 2024, Arcus announced a clinical collaboration with AstraZeneca to evaluate casdatifan in combination with volrustomig, AstraZeneca’s investigational PD-1/CTLA-4 bispecific antibody, in IO-naive patients with ccRCC. AstraZeneca will operationalize the study. This is the second clinical collaboration between Arcus and AstraZeneca. Gilead retains the right to opt in to the development and commercialization for casdatifan after delivery of a qualifying data package.

Pipeline Highlights:

Casdatifan (HIF-2a inhibitor)

Casdatifan Updates:

- First clinical data from the casdatifan 100mg and 50mg expansion cohorts of ARC-20, a Phase 1/1b study in metastatic ccRCC, were presented in an oral plenary session at the 2024 EORTC-NCI-AACR Symposium in October. Observations from the 100mg daily expansion cohort included:
 - An objective response rate (ORR) of 34% (2 responses are pending confirmation; 25% confirmed ORR), a low rate of primary progression of 19% and a high disease control rate of 81%.
 - The median progression-free survival (PFS) had not been reached at the time of the data cutoff.
 - Together, these data support the potential for casdatifan to be a best-in-class HIF-2a inhibitor for the treatment of ccRCC.
- In the third quarter, Arcus had a successful Type B meeting with the U.S. Federal Drug Administration (FDA) to discuss its first Phase 3 study for casdatifan, PEAK-1, which will evaluate casdatifan in combination with cabozantinib versus cabozantinib in post-IO patients with ccRCC. Arcus is moving rapidly toward the initiation of PEAK-1 in the first half of 2025.

Upcoming Casdatifan Milestones:

- Multiple expansion cohorts of ARC-20 evaluating casdatifan in ccRCC as a monotherapy and in combination

with cabozantinib in ccRCC are underway with additional data presentations expected in the next 12 months.

- 100mg (50mg twice daily (BID), capsules) and 50mg expansion cohorts: Updated data, including median PFS, are expected to be presented in the first quarter of 2025.
- 150mg and 100mg (once daily (QD), tablets) expansion cohorts: Initial data are expected to be presented in 2025.
- 100mg of casdatifan plus cabozantinib: Safety data are expected to be presented in 2025.

Domvanalimab (Fc-silent anti-TIGIT antibody) plus Zimberelimab (anti-PD-1 antibody)

Domvanalimab-Zimberelimab Updates:

- Data from Part 1 of ARC-10, a randomized study evaluating domvanalimab plus zimberelimab in PD-L1 high NSCLC are being presented at the SITC Annual Meeting in November.
- Domvanalimab plus zimberelimab was associated with greater PFS, overall survival, and objective response rate compared with zimberelimab or chemotherapy.
 - A 36% reduction in risk of death (hazard ratio [HR]=0.64) was observed for domvanalimab plus zimberelimab compared to that of zimberelimab alone.
 - Zimberelimab reached a median overall survival of 2 years, and the median overall survival for domvanalimab plus zimberelimab was not reached.
 - Treatment-related adverse events leading to treatment discontinuation were low (10.5%) for the combination of domvanalimab and zimberelimab.
- Data from an investigator-sponsored trial evaluating domvanalimab plus zimberelimab in anti-PD-(L)1 refractory hepatocellular carcinoma will be presented in an oral session at the SITC Annual Meeting.

Upcoming Domvanalimab-Zimberelimab Milestones:

- Overall survival data from the Phase 2 EDGE-Gastric study, evaluating domvanalimab plus zimberelimab and chemotherapy in upper gastrointestinal (GI) adenocarcinomas, are expected to be presented in 2025.

CD73-Adenosine Axis: Quemliclustat (small-molecule CD73 inhibitor) and Etrumadenant (A2a/A2b receptor antagonist)

Quemliclustat

- Arcus has initiated PRISM-1, a Phase 3 trial of quemliclustat combined with gemcitabine/nab-paclitaxel versus gemcitabine/nab-paclitaxel in pancreatic cancer.

Etrumadenant

- Biomarker data from cohort B of ARC-9, a randomized Phase 1b/2 study evaluating etrumadenant plus zimberelimab, FOLFOX chemotherapy and bevacizumab (EZFB) versus regorafenib in third-line metastatic colorectal cancer (mCRC), are being presented at SITC in November.

Early Clinical Programs

- Evaluation of AB801, a potent and highly selective small-molecule AXL inhibitor, in the dose-escalation phase of a Phase 1/1b study in patients is ongoing. Arcus anticipates advancing this molecule into expansion cohorts in NSCLC in early 2025.

Financial Results for Third Quarter 2024:

- Cash, Cash Equivalents and Marketable Securities were \$1.1 billion as of September 30, 2024, compared to \$866 million as of December 31, 2023. The increase during the period is primarily due to the receipt of \$320 million in cash from Gilead for their January 2024 equity investment, the receipt of the \$100 million option continuation payment from Gilead in July 2024 and proceeds from our \$50 million term loan, partially offset by the use of cash in research and development activities. We believe our cash, cash equivalents and marketable securities on-hand will be sufficient to fund operations into mid-2027. Cash, cash equivalents and marketable securities are expected to be between \$950 million and \$985 million at the end of 2024.
- Revenues were \$48 million for the third quarter 2024, compared to \$32 million for the same period in 2023. In the third quarter 2024, Arcus recognized \$41 million in license and development services revenue related to the advancement of programs and Taiho's exercise of its option for the license of quemliclustat for the Taiho Territory of \$15 million, as well as \$7 million in other collaboration revenue primarily related to Gilead's ongoing rights to access Arcus's research and development pipeline in accordance with the Gilead collaboration agreement.
- Research and Development (R&D) Expenses were \$123 million for the third quarter 2024, compared to \$82 million for the same period in 2023. The net increase of \$41 million was primarily driven by higher clinical trial and headcount-related costs associated with our late-stage development program activities. Non-cash stock-based compensation expense was \$9 million for the third quarter 2024, compared to \$8 million for the same period in 2023. For the third quarter 2024 and 2023, Arcus recognized gross reimbursements of \$37 million and \$33 million, respectively, for shared expenses from its collaborations, primarily the Gilead collaboration. R&D expense by quarter may fluctuate due to the timing of clinical manufacturing and standard-of-care therapeutic purchases with a corresponding impact on reimbursements.
- General and Administrative (G&A) Expenses were flat for the third quarter 2024, compared to the same period in 2023. Non-cash stock-based compensation expense was \$10 million for each of the third quarter 2024 and 2023.
- Net Loss was \$92 million for the third quarter 2024, compared to \$71 million for the same period in 2023.

Conference Call Information:

Arcus will host a conference call and webcast today, November 6, at 2:00 PM PT/5:00 PM ET to discuss its third-quarter 2024 financial results and pipeline updates. To access the call, please dial +1 (404) 975-4839 (local) or +1 (833) 470-1428 (toll-free), using Access Code: 940081. Participants may also register for the call online using the following link: <https://www.netroadshow.com/events/login?show=4818aee3&confid=72838>. To access the live webcast and accompanying slide presentation, please visit the "Investors & Media" section of the Arcus Biosciences website at www.arcusbio.com. A replay of the webcast will be available following the live event.

Arcus Ongoing and Announced Clinical Studies:

Trial Name	Arms	Setting	Status	NCT No.
Lung Cancer				
STAR-121	dom + zim + chemo vs. pembro + chemo	1L NSCLC (PD-L1 all-comers)	Ongoing Registrational Phase 3	NCT05502237
PACIFIC-8	dom + durva vs. durva	Unresectable Stage 3 NSCLC	Ongoing Registrational Phase 3	NCT05211895
ARC-7	zim vs. dom + zim vs. etruma + dom + zim	1L NSCLC (PD-L1 ≥ 50%)	Ongoing Randomized Phase 2	NCT04262856
EDGE-Lung	dom +/- zim +/- quemli +/- chemo	1L/2L NSCLC (lung cancer platform study)	Ongoing Randomized Phase 2	NCT05676931
VELOCITY-Lung	dom +/- zim +/- etruma +/- sacituzumab govitecan-hzyi or other combos	1L/2L NSCLC (lung cancer platform study)	Ongoing Randomized Phase 2	NCT05633667
Upper Gastrointestinal Cancers				
STAR-221	dom + zim + chemo vs. nivo + chemo	1L Gastric, GEJ and EAC	Ongoing Registrational Phase 3	NCT05568095
EDGE-Gastric (ARC-21)	dom +/- zim +/- quemli +/- chemo	1L/2L Upper GI Malignancies	Ongoing Randomized Phase 2	NCT05329766
Colorectal Cancer				
ARC-9	etruma + zim + mFOLFOX vs. SOC	2L/3L/3L+ CRC	Ongoing Randomized Phase 2	NCT04660812
Pancreatic Cancer				
PRISM-1	quemli + gem/nab-pac vs. gem/nab-pac	1L PDAC	Ongoing Phase 3	NCT06608927
ARC-8	quemli + zim + gem/nab-pac vs. quemli + gem/nab-pac	1L, 2L PDAC	Ongoing Randomized Phase 1/1b	NCT04104672
Kidney Cancer				
PEAK-1	cas + cabo vs. cabo	Post-IO ccRCC	Planned Phase 3	TBD
ARC-20	cas, cas + cabo	Cancer Patients/ccRCC	Ongoing Phase 1/1b	NCT05536141
Other				
ARC-25	AB598	Advanced Malignancies	Ongoing	NCT05891171
ARC-27	AB801	Advanced Malignancies	Ongoing	NCT06120075

cabo: cabozantinib; cas: casdatifan; dom: domvanalimab; durva: durvalumab; etruma: etrumadenant; gem/nab-pac: gemcitabine/nab-paclitaxel; nivo: nivolumab; pembro: pembrolizumab; quemli: quemliclustat; SOC: standard of care; zim: zimberelimumab; ccRCC: clear cell renal cell carcinoma; CRC: colorectal cancer; EAC: esophageal adenocarcinoma; GEJ: gastroesophageal junction; GI: gastrointestinal; NSCLC: non-small cell lung cancer; PDAC: pancreatic ductal adenocarcinoma

About the Gilead Collaboration

In May 2020, Arcus established a 10-year collaboration with Gilead to strategically advance our portfolio. Under this collaboration, Gilead obtained time-limited exclusive option rights to all of our clinical programs arising during the collaboration term. Arcus and Gilead are co-developing four investigational products, including zimberelimab (Arcus's anti-PD-1 molecule), domvanalimab (Arcus's anti-TIGIT antibody), etrumadenant (Arcus's adenosine receptor antagonist) and quemliclustat (Arcus's CD73 inhibitor). The collaboration was expanded in November 2021 and May 2023 to include research directed to two targets for oncology and two targets for inflammatory diseases.

About Arcus Biosciences

Arcus Biosciences is a clinical-stage, global biopharmaceutical company developing differentiated molecules and combination medicines for people with cancer. In partnership with industry collaborators, patients and physicians around the world, Arcus is expediting the development of first- or best-in-class medicines against well-characterized biological targets and pathways and studying novel, biology-driven combinations that have the potential to help people with cancer live longer. Founded in 2015, the company has expedited the development of multiple investigational medicines into clinical studies, including new combination approaches that target TIGIT, PD-1, HIF-2a, CD73, dual A2a/A2b receptor, CD39 and AXL. For more information about Arcus Biosciences' clinical and preclinical programs, please visit www.arcusbio.com.

Domvanalimab, etrumadenant, quemliclustat and zimberelimab are investigational molecules, and neither Gilead nor Arcus has received approval from any regulatory authority for any use globally, and their safety and efficacy have not been established. Casdatifan, AB598 and AB801 are also investigational molecules, and Arcus has not received approval from any regulatory authority for any use globally, and their safety and efficacy have not been established.

Forward-Looking Statements

This press release contains forward-looking statements. All statements regarding events or results to occur in the future contained herein 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, including, but not limited to, the statements in Dr. Rosen's quote and statements regarding: Arcus's expectation that its cash, cash equivalents and marketable securities on-hand are sufficient to fund operations into mid-2027; plans to disclose or present study analyses or data, including any analyses or data from ARC-20 or EDGE-Gastric; whether data and results from studies validate our pipeline or support further development of a program; the potency, efficacy or safety of Arcus's investigational products, including their potential for a best-in-class profile; and the initiation, design of and associated timing for future studies, including statements about PEAK-1 and PRISM-1. All forward-looking statements involve known and unknown risks and uncertainties and other important factors that may cause Arcus's actual results, performance or achievements to differ significantly from those expressed or

implied by the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to: risks associated with preliminary and interim data not being guarantees that future data will be similar; the unexpected emergence of adverse events or other undesirable side effects in Arcus's investigational products; difficulties or delays in initiating or conducting clinical trials due to difficulties or delays in the regulatory process, enrolling subjects or manufacturing or supplying product for such clinical trials; unfavorable global economic, political and trade conditions; Arcus's dependence on the collaboration with third parties such as Gilead and Taiho for the successful development and commercialization of its optioned molecules; difficulties associated with the management of the collaboration activities or expanded clinical programs; changes in the competitive landscape for Arcus's programs; and the inherent uncertainty associated with pharmaceutical product development and clinical trials. Risks and uncertainties facing Arcus are described more fully in the "Risk Factors" section of Arcus's most recent periodic report filed with the U.S. Securities and Exchange Commission. 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 except to the extent required by law.

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ARCUS BIOSCIENCES, INC.
Consolidated Statements of Operations
(unaudited)
(In millions, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenues:				
License and development services revenue	\$ 41	\$ 22	\$ 204	\$ 58
Other collaboration revenue	7	10	28	28
Total revenues	48	32	232	86
Operating expenses:				
Research and development	123	82	347	247
General and administrative	30	30	92	88
Impairment of long-lived assets	—	—	20	—
Total operating expenses	153	112	459	335
Loss from operations	(105)	(80)	(227)	(249)
Non-operating income (expense):				
Interest and other income, net	14	12	40	30
Interest expense	(1)	(1)	(2)	(2)
Total non-operating income, net	13	11	38	28
Loss before income taxes	(92)	(69)	(189)	(221)
Income tax expense	—	(2)	—	(5)
Net loss	\$ (92)	\$ (71)	\$ (189)	\$ (226)
Net loss per share:				
Basic and diluted	\$ (1.00)	\$ (0.94)	\$ (2.11)	\$ (3.07)
Shares used to compute net loss per share:				
Basic and diluted	91.4	74.6	89.6	73.6

Selected Consolidated Balance Sheet Data
(unaudited)
(In millions)

	September 30, 2024	December 31, 2023 (1)
Cash, cash equivalents and marketable securities	\$ 1,091	\$ 866
Total assets	1,252	1,095
Total liabilities	687	633
Total stockholders' equity	565	462

(1) Derived from the audited financial statements for the quarter ended December 31, 2023, included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 21, 2024.

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