



NEWS RELEASE

Arcus Biosciences Reports First-Quarter 2025 Financial Results and Provides a Pipeline Update

2025-05-06

- Data from the Phase 1/1b ARC-20 study cohort evaluating casdatifan plus cabozantinib in immunotherapy (IO)-experienced patients with clear cell renal cell carcinoma (ccRCC) will be presented in an oral session at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting
- Additional data from the ARC-20 cohorts evaluating casdatifan monotherapy in patients who had progressed on both an anti-PD-1 and a tyrosine kinase inhibitor (TKI) therapy are expected in the fall
- Initiation of the Phase 3 study for PEAK-1 evaluating casdatifan plus cabozantinib versus cabozantinib in IO-experienced patients with ccRCC is expected in the second quarter of 2025
- Arcus is well positioned to advance its full pipeline with \$1.0 billion in cash, cash equivalents and marketable securities at quarter end

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 first quarter ended March 31, 2025, and provided a pipeline update on its clinical-stage investigational molecules across multiple common cancers.

"Beginning with an oral presentation at ASCO for casdatifan in ccRCC, we expect to report a steady stream of data from ARC-20 throughout the remainder of 2025 and into 2026. We believe these data will support our robust development plan for casdatifan across multiple settings. This includes our Phase 3 trial, PEAK-1 in the IO-

experienced setting, our clinical trial with AstraZeneca, which will combine casdatifan with their anti-PD-1/CTLA-4 bispecific antibody in the IO-naïve setting, and three new cohorts in ARC-20 evaluating casdatifan in first- and second-line ccRCC,” said Terry Rosen, Ph.D., chief executive officer of Arcus. “We believe that casdatifan has the potential to change the treatment paradigm for ccRCC, including the displacement of TKIs in earlier line settings, and our development plan is designed to establish casdatifan as the HIF-2a inhibitor of choice. Our balance sheet remains strong, and our operational plan and priorities are focused on ensuring that casdatifan is funded through its first Phase 3 readout.”

Pipeline Highlights:

Casdatifan (HIF-2a inhibitor)

Casdatifan Updates:

- New clinical data from three monotherapy expansion cohorts in ARC-20 were presented in an oral session at the 2025 ASCO Genitourinary (GU) Cancers Symposium in February. At the time of data cut-off (DCO, January 3, 2025), the efficacy-evaluable population included a total of 87 patients with ccRCC who had received at least two prior lines of therapy, including both anti-PD-1 and a vascular endothelial growth factor receptor 2 (VEGFR)-TKI therapy. These data support the potential for casdatifan to be a best-in-class HIF-2a inhibitor for the treatment of ccRCC:
 - Despite limited follow-up, two of the cohorts exceeded 30% confirmed overall response rate (inclusive of one partial response that confirmed after the DCO)
 - A 9.7-month median progression-free survival (PFS) was reached for the 50mg twice-daily casdatifan monotherapy cohort; median PFS was not yet reached for other cohorts
 - No unexpected safety signals were observed at the time of DCO, and casdatifan had an acceptable and manageable safety profile across all doses

Planned Data Readouts:

- June 2025: Safety and initial efficacy data for the ARC-20 cohort evaluating casdatifan plus cabozantinib in IO-experienced patients will be presented in an oral session at the ASCO Annual Meeting.
- Fall 2025: More mature data from the cohorts evaluating casdatifan monotherapy in patients who had progressed on both an anti-PD-1 and a TKI therapy.
- 2026: More mature data from the casdatifan plus cabozantinib cohort and initial data from the new ARC-20 cohorts evaluating casdatifan in the first-line (1L) and IO-experienced settings.

Upcoming Study and Cohort Initiations:

- The PEAK-1 Phase 3 study evaluating casdatifan plus cabozantinib versus cabozantinib in IO-experienced ccRCC is expected to initiate in the second quarter of 2025.
- Shortly thereafter, Arcus and AstraZeneca expect to initiate a clinical study, part of AstraZeneca's eOLVE portfolio, evaluating casdatifan plus volrustomig, AstraZeneca's investigational anti-PD-1/CTLA-4 bispecific antibody, in IO-naïve ccRCC. This study will be operationalized by AstraZeneca.

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

- 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 the fall of 2025.
- The first Phase 3 data readout for domvanalimab plus zimberelimab will be from the ongoing Phase 3 study STAR-221, evaluating domvanalimab plus zimberelimab and chemotherapy in PD-L1 all-comer 1L metastatic upper GI adenocarcinomas and is expected in 2026.

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

Quemliclustat:

- In the fourth quarter of 2024, Arcus initiated PRISM-1, a Phase 3 trial of quemliclustat combined with gemcitabine/nab-paclitaxel versus gemcitabine/nab-paclitaxel in first-line treatment of metastatic pancreatic cancer. PRISM-1 is recruiting rapidly, with enrollment completion expected by the end of 2025.

Etrumadenant:

- In March 2025, we engaged with the U.S. Food and Drug Administration (FDA) regarding promising results from the ARC-9 study evaluating etrumadenant in third-line metastatic colorectal cancer (mCRC); although the FDA's feedback confirmed the potential for a registrational path for this program in third-line mCRC, based on our strategic priorities, we are not pursuing a Phase 3 study at this time.

Financial Results for First Quarter 2025:

- Cash, Cash Equivalents and Marketable Securities were \$1.0 billion as of March 31, 2025, compared to \$992 million as of December 31, 2024. The increase during the period is primarily due to the net proceeds from our underwritten offering in February 2025, partially offset by the use of cash in our research and development activities. We believe our cash, cash equivalents, and marketable securities, together with available facilities, will be sufficient to fund operations through the initial pivotal readouts for domvanalimab, quemliclustat and casdatifan, which include PEAK-1.

- Revenues were \$28 million for the first quarter 2025, compared to \$145 million for the same period in 2024. In the first quarter 2025, Arcus recognized \$20 million in license and development services revenue related to the advancement of programs, as well as \$8 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. Arcus expects to recognize GAAP revenue of between \$75 million and \$90 million for the full year 2025.
- Research and Development (R&D) Expenses were \$122 million for the first quarter 2025, compared to \$109 million for the same period in 2024. The net increase of \$13 million was primarily driven by higher costs in our early-stage development and preclinical program activities, driven by higher enrollment in our Phase 2 studies. The overall increase was partially offset by reduced spend in our late-stage development activities due to lower manufacturing costs driven by the timing of manufacturing activities. Non-cash stock-based compensation expense was \$8 million for the first quarter 2025, compared to \$10 million for the same period in 2024. For the first quarters 2025 and 2024, Arcus recognized gross reimbursements of \$38 million and \$37 million, respectively, for shared expenses from its collaborations, primarily the Gilead collaboration. R&D expenses 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 \$28 million for the first quarter 2025, compared to \$32 million for the same period in 2024. The decrease was primarily driven by the costs incurred to obtain the Third Gilead Agreement Amendment in 2024. Non-cash stock-based compensation expense was \$8 million for the first quarter 2025, compared to \$10 million for the same period in 2024.
- Net Loss was \$112 million for the first quarter 2025, compared to \$4 million for the same period in 2024.

Conference Call Information:

Arcus will host a conference call and webcast today, May 6th, at 1:30 PM PT / 4:30 PM ET to discuss its first-quarter 2025 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: 762544. Participants may also register for the call online using the following link: <https://events.q4inc.com/attendee/119512642>. 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.
Kidney Cancer				
PEAK-1	cas + cabo vs. cabo	Post-IO ccRCC	Planned Phase 3	TBD
AstraZeneca Collaboration (part of eVOLVE portfolio)	cas + volru	2L+ IO-Naive ccRCC	Planned	TBD
ARC-20	cas, cas + cabo, cas + zim	1L, 2L, and 2L+ Cancer Patients/ccRCC	Ongoing Phase 1/1b	NCT05536141
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 +/- chemo	1L/2L Upper GI Malignancies	Ongoing Randomized Phase 2	NCT05329766
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
EDGE-Lung	dom +/- zim +/- quemli +/- chemo	1L/2L NSCLC (lung cancer platform study)	Ongoing Randomized Phase 2	NCT05676931
VELOCITY-Lung	dom +/- zim +/- sacituzumab govitecan-hziy or other combos	1L/2L NSCLC (lung cancer platform study)	Ongoing Randomized Phase 2	NCT05633667
Pancreatic Cancer				
PRISM-1	quemli + gem/nab-pac vs. gem/nab-pac	1L PDAC	Ongoing Randomized Phase 3	NCT06608927
ARC-8	quemli + zim + gem/nab-pac vs. quemli + gem/nab-pac	1L PDAC	Ongoing Randomized Phase 1/1b	NCT04104672
Other				
ARC-25	AB598	Gastric Cancer	Ongoing Phase 1	NCT05891171
ARC-27	AB801	NSCLC	Ongoing Phase 1	NCT06120075

cabo: cabozantinib; cas: casdatifan; ccRCC: clear cell renal cell carcinoma; dom: domvanalimab; durva: durvalumab; EAC: esophageal adenocarcinoma; GEJ: gastroesophageal junction; gem/nab-pac: gemcitabine/nab-paclitaxel; GI: gastrointestinal; IO: immunotherapy; nivo: nivolumab; NSCLC: non-small cell lung cancer; PDAC: pancreatic ductal adenocarcinoma; pembro: pembrolizumab; quemli: quemliclustat; volru: volrustomig; zim: zimberelimab.

About Arcus Biosciences

Arcus Biosciences is a clinical-stage, global biopharmaceutical company developing differentiated molecules and combination therapies 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, A2a/A2b receptors, CD39 and AXL. For more information about Arcus Biosciences's 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.

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.

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 expectations regarding the timing of initial pivotal read-outs for domvanalimab, quemliclustat and casdatifan and our available funding through this period; plans to disclose or present study analyses or data; enrollment timelines for our studies, including when we expect to complete enrollment for PRISM-1; 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 or to change the treatment paradigm; and the initiation, design of and associated timing for future studies and cohorts, including statements about the initiation and design of PEAK-1 and the eOLVE study being operationalized by AstraZeneca. 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.

The Arcus name and logo are trademarks of Arcus Biosciences, Inc. All other trademarks belong to their respective owners.

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

	Three Months Ended March 31,	
	2025	2024
Revenues:		
License and development services revenue	\$20	\$135
Other collaboration revenue	8	10
Total revenues	28	145
Operating expenses:		
Research and development	122	109
General and administrative	28	32
Impairment of long-lived assets	—	20
Total operating expenses	150	161
Loss from operations	(122)	(16)
Non-operating income (expense):		
Interest and other income, net	11	13
Interest expense	(1)	(1)
Total non-operating income, net	10	12
Loss before income taxes	(112)	(4)
Income tax expense	—	—
Net loss	\$(112)	\$(4)
Net loss per share:		
Basic and diluted	\$(1.14)	\$(0.05)
Shares used to compute net loss per share:		
Basic and diluted	98.4	86.2

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

	March 31, 2025	December 31, 2024 (1)
Cash, cash equivalents and marketable securities	\$1,005	\$992
Total assets	1,156	1,150
Total liabilities	625	665
Total stockholders' equity	531	485

(1) Derived from the audited financial statements for the year ended December 31, 2024, included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 25, 2025

Investor Inquiries:

Pia Eaves

VP of Investor Relations & Strategy

(617) 459-2006

peaves@arcusbio.com

Media Inquiries:

Holli Kolkey

VP of Corporate Affairs

(650) 922-1269

hkolkey@arcusbio.com

Maryam Bassiri

AD, Corporate Communications

(510) 406-8520

mbassiri@arcusbio.com

Source: Arcus Biosciences