NEWS RELEASE

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

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- Casdatifan, a potential best-in-class HIF-2a inhibitor, demonstrated 12.2 months median progression-free survival (mPFS) and 18-month landmark PFS of 43% in a pooled analysis of 121 patients with late-line kidney cancer
- Multiple readouts from the ARC-20 study of casdatifan are expected in 2026, including additional analyses of the late-line monotherapy cohorts early in 2026, followed by more mature data from the casdatifan plus cabozantinib cohort in mid-2026 and initial data from the early-line cohorts in the second half of 2026
- Domvanalimab plus zimberelimab and chemotherapy showed a median overall survival (OS) of 26.7 months in Arm A1 of the Phase 2 EDGE-Gastric study (overall population) evaluating patients with first-line upper gastrointestinal adenocarcinomas; these data were presented at the 2025 European Society for Medical Oncology (ESMO) Congress and published in Nature Medicine in October
- Arcus unveiled its portfolio of five programs targeting inflammatory and autoimmune diseases; a small molecule targeting MRGPRX2 is in preclinical development and expected to enter the clinic in 2026
- Arcus is well positioned to advance its full pipeline with $841 million in cash, cash equivalents and marketable securities at quarter end and, with its available facilities, cash runway through the PEAK-1 Phase 3 readout

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, inflammatory and autoimmune diseases, today reported financial results for the third quarter ended September 30, 2025, and provided a pipeline update on its clinical-stage investigational molecules and discovery programs.

“Data from the ARC-20 study demonstrate that casdatifan has a best-in-class profile, based on a meaningfully higher response rate and longer PFS relative to data for the only marketed HIF-2a inhibitor,” said Terry Rosen, Ph.D., chief executive officer of Arcus. “With our global Phase 3 PEAK-1 study now enrolling, and based on the encouraging, emerging data from cohorts evaluating casdatifan-based regimens in early-line settings, we are extremely excited about the potential for casdatifan to be a transformative therapy in clear cell renal cell carcinoma (ccRCC). We remain well capitalized and funded through readout of multiple Phase 3 trials, and we are looking forward to a steady cadence of key data events in 2026 and beyond.”

Corporate Update

- In October, Taiho exercised its option for an exclusive license to casdatifan in Japan and certain territories in Asia; in exchange, Taiho will make an option payment to Arcus along with milestone payments upon achievement of clinical, regulatory and commercialization milestones, and additionally make royalty payments on net sales.

Casdatifan (HIF-2a inhibitor)

Casdatifan Development Program:

- PEAK-1, a global Phase 3 study evaluating casdatifan + cabozantinib versus cabozantinib in immunotherapy (IO)-experienced metastatic ccRCC, is enrolling and, with a primary endpoint of PFS, represents an opportunity for a rapid path to approval.
- The company is pursuing a multi-pronged strategy for the development of casdatifan in early-line ccRCC, likely in combination with standard-of-care mechanisms, with the goal of initiating a Phase 3 study in early-line ccRCC in the second half of 2026. This study will be informed by emerging data from eVOLVE-RCC02 and ARC-20.
    - eVOLVE-RCC02, a Phase 1b/3 study sponsored and operationalized by AstraZeneca, evaluating casdatifan + volrustomig, an investigational anti-PD-1/CTLA-4 bispecific antibody, in first-line (1L), metastatic ccRCC, was initiated in mid-2025.
        - The Phase 1b portion of the study has recruited rapidly, and in the context of this rapid enrollment, following observations of potential immune-mediated adverse events (AEs), none of which exceeded Grade 3, a decision was made to temporarily pause recruitment, while continuing to treat participants already enrolled in the study. No Grade 4 or 5 events were observed, and the majority of AEs were Grade 1 or 2.
        - Arcus and AstraZeneca will continue to monitor these participants to further characterize the safety profile of the combination with longer follow-up. These data, along with any discussions with health authorities, will inform next steps for the study.

- ARC-20 includes three cohorts evaluating casdatifan in earlier-line settings: casdatifan plus zimberelimab in 1L ccRCC, casdatifan monotherapy in favorable risk ccRCC and casdatifan monotherapy in immunotherapy-experienced, TKI-naive ccRCC.
  - Arcus expects to complete enrollment for these cohorts by the end of 2025 and to report data for one or more of these cohorts in the second half of 2026.

Recent Data Update:

- Data, including overall response rate (ORR) and PFS data, from the four monotherapy cohorts of the Phase 1/1b ARC-20 study in late-line ccRCC were presented at an investor event in October.
  - Casdatifan performed better on every efficacy measure evaluated, for each individual cohort and across all four monotherapy cohorts (n=121), relative to published data from studies with the only marketed HIF-2a inhibitor.
  - At the time of data cutoff (DCO, August 15, 2025), mPFS was 12.2 months, and 18-month landmark PFS was 43% in the pooled analysis of all four monotherapy cohorts.
  - In the 100mg once-daily cohort (the Phase 3 PEAK-1 dose and formulation), confirmed ORR was 35%, with two responses (including one that occurred after the DCO) pending confirmation, and mPFS had not been reached with greater than 12 months median follow-up.
  - Seventy-four percent (28 of the 38) of confirmed responders across all four cohorts remained on treatment.
  - 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:

- 1H 2026: Additional analyses from the ARC-20 cohorts evaluating casdatifan monotherapy in late-line ccRCC.
- Mid-2026: More mature data from the ARC-20 cohort evaluating casdatifan plus cabozantinib in the IO-experienced setting . This is the same setting and combination being evaluated in the ongoing Phase 3 PEAK-1 study.
- 2H 2026: Initial data from one or more ARC-20 cohorts evaluating casdatifan in early-line settings.
- 2H 2026: Data from the Phase 1b portion and a go-no-go decision on the Phase 3 portion of eVOLVE-RCC02.

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

Recent Data Presentation:

- OS data from Arm A1 of the Phase 2 EDGE-Gastric study, evaluating domvanalimab plus zimberelimab and chemotherapy in upper gastrointestinal (GI) adenocarcinomas, were presented in an oral session at the 2025

ESMO Congress in October. This is the same regimen and patient population being evaluated in the ongoing Phase 3 study, STAR-221.

- Domvanalimab plus zimberelimab and chemotherapy showed 26.7 months of median OS, well beyond what would be required to demonstrate clinically meaningful benefit over standard of care in this setting.
- The regimen was generally well tolerated and had a safety profile that is consistent with that of anti-PD-1 and chemotherapy.

Planned Data Readout:

- Data from the ongoing Phase 3 study STAR-221, evaluating domvanalimab plus zimberelimab and chemotherapy in PD-L1 all-comer 1L unresectable or metastatic upper GI adenocarcinomas are expected in 2026.

Quemliclustat (small-molecule CD73 inhibitor)

- Enrollment has been completed for PRISM-1, a Phase 3 trial of quemliclustat combined with gemcitabine/nab-paclitaxel versus gemcitabine/nab-paclitaxel in 1L metastatic pancreatic ductal adenocarcinoma, within 12 months of study initiation.

Emerging I&I Portfolio

- In October, Arcus disclosed five new research and preclinical programs addressing targets for inflammatory and autoimmune diseases. Potential new drug candidates include:
  - MRGPRX2 small-molecule inhibitor, a potential treatment for atopic dermatitis and chronic spontaneous urticaria
  - TNF-a (TNFR1) small-molecule inhibitor, a potential treatment for rheumatoid arthritis (RA), psoriasis and inflammatory bowel disease (such as ulcerative colitis)
  - CCR6 small-molecule inhibitor, a potential treatment for psoriasis
  - CD89 monoclonal antibody, a potential treatment for RA
  - CD40L small-molecule inhibitor, a potential treatment for multiple sclerosis and systemic lupus erythematosus
- Arcus expects to select development candidates for at least three of these programs within the next 12 months. The first of these, a small molecule directed against MRGPRX2, is expected to enter the clinic in 2026.

Financial Results for Third Quarter 2025:

- Cash, Cash Equivalents and Marketable Securities were $841 million as of September 30, 2025, compared to

$992 million as of December 31, 2024. The decrease during the period is primarily due to the use of cash in our research and development activities partially offset by the net proceeds from our underwritten offering in February 2025 and the additional $50 million draw down under our term loan facility in June 2025. 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 $26 million for the third quarter 2025, compared to $48 million for the same period in 2024. The decrease in revenue was primarily driven by the prior year license revenue of $15 million as a result of Taiho's exercise of its option for quemliclustat and lower revenues from the Gilead collaboration. Arcus expects to recognize GAAP revenue of between $225 million and $235 million for the full year 2025.
- Research and Development (R&D) Expenses were $141 million for the third quarter 2025, compared to $123 million for the same period in 2024. The net increase of $18 million was primarily due to costs incurred for our late-stage programs, resulting from increased enrollment and start-up activities for PRISM-1 and PEAK-1 and partially offset by lower costs from STAR-221. Non-cash stock-based compensation expense was $7 million for the third quarter 2025, compared to $9 million for the same period in 2024. For the third quarters 2025 and 2024, Arcus recognized gross reimbursements of $28 million and $37 million, respectively, for shared expenses from its collaborations. 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. Arcus expects R&D expenses to decline commencing in the fourth quarter 2025 as costs related to the domvanalimab Phase 3 development program decrease significantly.
- General and Administrative (G&A) Expenses were $27 million for the third quarter 2025, compared to $30 million for the same period in 2024. The decrease was primarily driven by a decrease in compensation and personnel costs driven by lower stock-based compensation, partially offset by an increase in expenses shared under the Gilead collaboration. Non-cash stock-based compensation expense was $7 million for the third quarter 2025, compared to $10 million for the same period in 2024.
- Net Loss was $135 million for the third quarter 2025, compared to $92 million for the same period in 2024.

About Arcus Biosciences

Arcus Biosciences is a clinical-stage, global biopharmaceutical company focused on developing differentiated molecules and combination therapies for patients with cancer, inflammatory and autoimmune diseases. In partnership with industry collaborators, patients and physicians around the world, Arcus is expediting the development of its late-stage portfolio of first- and/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 advanced multiple investigational medicines into registrational clinical trials including domvanalimab, an Fc-silent anti-TIGIT antibody being studied in combination with zimberelimab, an anti-PD-1 antibody, for upper gastrointestinal and non-small cell lung cancer, casdatifan, a

HIF-2a inhibitor for clear cell renal cell carcinoma, and quemliclustat, a small-molecule CD73 inhibitor for pancreatic cancer. For more information about Arcus Biosciences' clinical and preclinical programs, please visit **www.arcusbio.com**.

Domvanalimab, 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 is also an investigational molecule, and Arcus has not received approval from any regulatory authority for any use globally, and its 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 three investigational products, including zimberelimab (Arcus's anti-PD-1 molecule), domvanalimab (Arcus's anti-TIGIT antibody) 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. Gilead may exercise its option to each inflammation program at two separate, prespecified time points. If Gilead exercises its option at the earlier time point, Arcus would be eligible to receive up to $420 million in option and milestone payments and tiered royalties for each optioned program. For any other option exercise by Gilead for the two inflammation programs, the parties would have rights to co-develop and share global development costs and to co-promote and share profits in the United States.

Gilead's option rights to casdatifan expired; Arcus Biosciences retains full rights to casdatifan, subject to Taiho's exercise of its option for an exclusive license to casdatifan in Japan and certain territories in Asia.

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, the company's anticipated cash runway and the timing of future data readouts and study initiations. 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; difficulties associated with the management of collaboration activities; 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Revenues:				
License and development services revenue	$20	$41	$192	$204
Other collaboration revenue	6	7	22	28
Total revenues	26	48	214	232
Operating expenses:				
Research and development	141	123	402	347
General and administrative	27	30	84	92
Impairment of long-lived assets	—	—	—	20
Total operating expenses	168	153	486	459
Loss from operations	(142)	(105)	(272)	(227)
Non-operating income (expense):				
Interest and other income, net	10	14	31	40
Interest expense	(3)	(1)	(6)	(2)
Total non-operating income, net	7	13	25	38
Loss before income taxes	(135)	(92)	(247)	(189)
Income tax expense	—	—	—	—
Net loss	$(135)	$(92)	$(247)	$(189)
Net loss per share:				
Basic and diluted	$(1.27)	$(1.00)	$(2.39)	$(2.11)
Shares used to compute net loss per share:				
Basic and diluted	106.5	91.4	103.7	89.6

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

	September 30, 2025	December 31, 2024 (1)
Cash, cash equivalents and marketable securities	$841	$992
Total assets	974	1,150
Total liabilities	538	665
Total stockholders' equity	436	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.

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