



NEWS RELEASE

Arcus Biosciences Reports Second Quarter 2022 Financial Results and Provides a Pipeline Update

8/3/2022

- Four registrational Phase 3 trials evaluating domvanalimab-based combinations are ongoing or expected to start by year-end; Arcus and Gilead Sciences continue to expand their late-stage clinical program for domvanalimab with the goal of establishing a best-in-class anti-TIGIT antibody regimen in multiple cancers.
- An interim analysis was conducted for the ongoing Phase 1/1b ARC-8 trial of quemliclustat plus chemotherapy, with or without zimberelimab, in pancreatic ductal adenocarcinoma (PDAC); based on the results, Arcus and Gilead plan to wait for mature progression-free survival (PFS) and overall survival (OS) data, expected in 2023, to inform next steps for the PDAC program.
- On track to initiate ARC-20, a Phase 1/1b study to evaluate AB521, Arcus's HIF-2a inhibitor, in cancer patients in Q3 2022; data from the ongoing healthy volunteer study enable Arcus to start dose escalation in patients at a pharmacologically relevant dose level.
- Arcus nominated a new development candidate, AB801 (an AXL inhibitor), in the second quarter; and at least two new molecules are expected to advance into the clinic in 2023.
- Arcus is well positioned to advance its expanding programs and portfolio, with \$1.3 billion in cash, and cash equivalents and funding into 2026.

HAYWARD, Calif.--(BUSINESS WIRE)-- Arcus Biosciences, Inc. (NYSE:RCUS), a clinical-stage, global biopharmaceutical company focused on developing differentiated molecules and combination therapies for people with cancer, today reported financial results for the second quarter ended June 30, 2022 and provided a pipeline update on its six clinical-stage molecules – targeting TIGIT, the adenosine axis (CD73 and A2a/A2b), HIF-2a and PD-1 – across multiple common cancers. Arcus and Gilead continue to rapidly advance Arcus's broad and diverse pipeline, and the companies remain on track to have four ongoing registrational Phase 3 trials of domvanalimab-based combinations in non-small cell lung cancer (NSCLC) and gastrointestinal (GI) cancers by year-end. Topline disclosure from the Phase 2 ARC-7 study is expected in the second half of 2022 with a planned presentation of the data at a medical conference in 2023. Arcus continues to advance its next wave of novel molecules, with at least two INDs expected in 2023.

"This is a transformational year in the evolution of Arcus, as we expand the scope of our global clinical programs to include four registrational Phase 3 trials with domvanalimab-based combinations," said Terry Rosen, Ph.D., chief executive officer of Arcus. "The data we have generated in our Phase 2 ARC-7 study support our conviction in the initiation of two new registrational Phase 3 trials with our domvanalimab plus zimberelimab anti-TIGIT / anti-PD-1 doublet regimen, and we intend to be the leader in bringing anti-TIGIT-based therapies to patients. Our strong cash position and strategic collaborations enable us to maintain competitive positioning and execute efficiently in disease areas with significant patient populations and high unmet need, including lung and upper GI cancers."

Anti-TIGIT program (domvanalimab and AB308)

Update on Domvanalimab:

- Arcus is on track to complete enrollment in Q3 2022 of 150 patients for ARC-7, a randomized Phase 2 study evaluating the safety and efficacy of zimberelimab alone vs. domvanalimab plus zimberelimab vs. domvanalimab plus zimberelimab and etrumadenant in first-line PD-L1 $\geq$ 50% metastatic NSCLC.
- Arcus and Gilead are pursuing a broad development program for domvanalimab-based combinations in NSCLC, with three ongoing or soon-to-be initiated registrational Phase 3 trials:
 - STAR-121, evaluating the combination of domvanalimab plus zimberelimab and chemotherapy versus pembrolizumab with chemotherapy in first-line NSCLC PD-L1 all-comers, is expected to achieve first site initiation in the third quarter and is being operationalized by Gilead.
 - ARC-10 is evaluating domvanalimab plus zimberelimab vs. zimberelimab alone vs. chemotherapy in first-line PD-L1 $\geq$ 50% locally advanced or metastatic NSCLC.
 - PACIFIC-8, operationalized by AstraZeneca, is evaluating domvanalimab plus durvalumab, an anti-PD-L1 antibody, in unresectable Stage III NSCLC.

- The companies are also advancing the study of domvanalimab plus zimberelimab-based combinations with two new studies in GI cancers, which are on track to start by year-end:
 - ARC-21, a Phase 2 trial evaluating domvanalimab plus zimberelimab-based combinations in upper GI cancers, is open for enrollment and is intended to support the registrational Phase 3 trial STAR-221.
 - STAR-221, a randomized Phase 3 study, will evaluate a domvanalimab plus zimberelimab-based combination in upper GI cancers.

Upcoming Anti-TIGIT Milestones:

- Topline disclosure from the Phase 2 ARC-7 study is expected in the second half of 2022 with a planned presentation of the data at a medical conference in 2023.
- Arcus and Gilead expect to initiate two Phase 2 platform lung studies evaluating novel domvanalimab-based combinations, including domvanalimab plus zimberelimab-based triplet combinations with etrumadenant, Trodelvy® (sacituzumab govitecan-hziy), and/or quemliclustat, by year-end.

Etrumadenant (A2a/A2b adenosine receptor antagonist)

Upcoming Etrumadenant Milestones:

- Topline disclosure from the Phase 2 ARC-7 study is expected in the second half of 2022 with a planned presentation of the data at a medical conference in 2023.
- Data from the randomized cohort of ARC-6 evaluating etrumadenant plus zimberelimab and docetaxel versus docetaxel in second-line metastatic castrate-resistant prostate cancer (CRPC) are anticipated in-house in the second half of 2022 with a presentation of results expected in 2023.
- Data from ARC-9, a Phase 1b/2 study evaluating etrumadenant-based combinations in second-line and third-line metastatic colorectal cancer (mCRC), are expected in the first half of 2023.

Quemliclustat (small-molecule CD73 inhibitor)

Update on ARC-8:

- The ARC-8 study includes two stages: the first stage is a dose-escalation and dose-expansion stage evaluating quemliclustat plus a chemotherapy doublet and zimberelimab (the quad) followed by the second stage, a randomized cohort comparing the quad versus quemliclustat plus a chemotherapy doublet in first-line PDAC.
- Arcus conducted an interim analysis for ARC-8, which included patients from the first stage of the trial and the initial two-thirds of patients from the second stage.
 - At this interim analysis, we continued to observe encouraging data from patients treated in the first stage of ARC-8. However, data from patients treated in the randomized portion were similar to historical

benchmarks for chemotherapy alone.

- At the time of data cut off, no unexpected safety signals were observed.
- The companies plan to wait for more mature PFS and overall survival data from all 90 patients in the randomized cohort to inform next steps for the PDAC program. These data are expected in the first half of 2023.

Upcoming Quemliclustat Milestones:

- As mentioned above, Arcus and Gilead expect to initiate a Phase 2 platform study to evaluate domvanalimab and quemliclustat combinations in NSCLC by year-end. We also expect to explore quemliclustat-based combinations in GI cancers in the ARC-21 study.

AB521 (HIF-2 a inhibitor)

AB521 Update:

- Arcus is on track to initiate ARC-20, a Phase 1/1b study to explore the safety and clinical activity of AB521 in cancer patients in Q3 2022. Data from the ongoing healthy volunteer study enable Arcus to start dose escalation in patients at a pharmacologically relevant dose level. Pharmacokinetic (PK)/pharmacodynamic (PD) data for AB521 in healthy volunteers demonstrate its potential to have an improved clinical profile compared to the approved HIF-2a inhibitor.

Discovery Programs:

- AB598 (anti-CD39 antibody) continues to progress through preclinical development, and we expect to file an Investigational New Drug (IND) application and initiate a Phase 1 trial in cancer patients in the first half of 2023.
- Arcus nominated a new small molecule development candidate, AB801, a potent and selective AXL inhibitor, which has the potential to address various treatment-resistant tumor types, such as STK11-mutant NSCLC.
- Arcus expects to nominate a potential first-in-class small molecule candidate designed to treat a wide range of inflammatory conditions in the second half of 2022.
- As part of Arcus's and Gilead's research collaboration, the companies have now selected targets for the two drug discovery programs in oncology. Upon completion of certain IND-enabling activities, Gilead has the right to exercise its option for a payment of \$60 million for each program.

Financial Results for the Second Quarter 2022

- Cash, cash equivalents and investments: were \$1,271.1 million as of June 30, 2022, compared to \$681.3 million as of December 31, 2021. The increase was primarily due to the receipt of \$725 million from Gilead in January

2022. Arcus expects cash, cash equivalents and marketable securities on-hand to be sufficient to fund operations into 2026.

- **Revenues:** Collaboration and license revenues were \$26.8 million for the three months ended June 30, 2022, compared to \$9.5 million for the same period in 2021. In the three months ended June 30, 2022, Arcus recognized \$16.7 million in license and development service revenues for all programs optioned by Gilead, based on estimates of progress made toward satisfying the related performance obligations, \$8.3 million in collaboration revenue related to Gilead's ongoing rights to access Arcus's research and development pipeline in accordance with the Gilead collaboration agreement, as well as \$1.8 million related to the collaboration agreement with Taiho. In the three months ended June 30, 2021, Arcus recognized \$7.7 million in other collaboration revenue related to Gilead's access to Arcus's research and development pipeline, as well as \$1.8 million related to the Taiho collaboration agreement. Collaboration and license revenues were \$44.8 million for the six months ended June 30, 2022, compared to \$18.9 million for the same period in 2021.
- **R&D Expenses:** Research and development expenses were \$69.9 million for the three months ended June 30, 2022, compared to \$68.8 million for the same period in 2021. Arcus's expanding clinical and development activities for domvanalimab and zimberelimab drove increases in manufacturing and clinical costs. Arcus's growing employee base and 2022 stock awards drove an increase in employee compensation costs, including a \$0.7 million increase in non-cash stock-based compensation to approximately \$7.7 million. The above increases in research and development costs were mostly offset by increased cost-sharing reimbursements compared to the same quarter in the prior year. The increase in cost-sharing reimbursements was driven by the four programs optioned by Gilead in the current quarter, compared to a single program in the same quarter of the prior year. Research and development expenses were \$131.1 million for the six months ended June 30, 2022, compared to \$135.2 million for the same period in 2021.
- **G&A Expenses:** General and administrative expenses were \$25.8 million for the three months ended June 30, 2022, compared to \$16.8 million for the same period in 2021. The increase was driven by the increased administrative costs to support the growing size and complexity of Arcus's clinical development organization associated with Arcus's expanding clinical pipeline and collaboration obligations. Arcus's growing employee base and 2022 stock awards drove increases in employee compensation costs and facilities expense, including a \$1.6 million increase in non-cash stock-based compensation to approximately \$8.0 million for the three months ended June 30, 2022 compared to the prior year period. General and administrative expenses were \$49.8 million for the six months ended June 30, 2022, compared to \$32.6 million for the same period in 2021.
- **Net Loss:** Net loss was \$66.6 million for the three months ended June 30, 2022, compared to a net loss of \$76.0 million for the same period in the prior year. Net loss was \$134.6 million for the six months ended June 30, 2022, compared to a net loss of \$148.6 million for the same period in the prior year.

Arcus Ongoing and Announced Clinical Studies

Trial Name	Arms	Setting	Status	NCT No.
Lung Cancer				
ARC-7	zim vs. dom + zim vs. etruma + dom + zim	1L NSCLC (PD-L1 ≥ 50%)	Ongoing Randomized Phase 2	NCT04262856
PACIFIC-8 (AZ)	dom + durva vs. durva	Curative-Intent Stage 3 NSCLC	Ongoing Registrational Phase 3	NCT05211895
ARC-10	dom + zim vs. zim vs. chemo	1L NSCLC (PD-L1 ≥ 50%)	Ongoing Registrational Phase 3	NCT04736173
STAR-121 (GILD)	dom + zim + chemo vs pembro + chemo	1L NSCLC (PD-L1 all-comers)	Planned Registrational Phase 3	TBD
EDGE-Lung	dom + zim +/- quemli	1L/2L NSCLC (lung cancer platform study)	In Planning Phase 2	TBD
Lung Platform (GILD)	dom + zim +/- etruma or sacituzumab govitecan (Trodelyv) or other combos	1L/2L NSCLC (lung cancer platform study)	In Planning Phase 2	TBD
Gastrointestinal Cancers				
ARC-9	etruma + zim + mFOLFOX vs. SOC	2L/3L/3L+ CRC	Ongoing Randomized Phase 2	NCT04660812
ARC-21	dom + zim ± chemo	1L/2L Upper GI Malignancies	Ongoing Phase 2	NCT05329766
STAR-221	dom + zim + chemo vs. nivo + chemo	GI Malignancies	Planned Registrational Phase 3	TBD
Pancreatic Cancer				
ARC-8	quemli + zim + gem/nab-pac vs. quemli + gem/nab-pac	1L, 2L PDAC	Ongoing Randomized Phase 1/1b	NCT04104672
Prostate Cancer				
ARC-6	etruma + zim + SOC vs. SOC (Adding sacituzumab govitecan (Trodelyv) combination cohorts)	2L/3L CRPC	Ongoing Randomized Phase 2	NCT04381832
Various				
ARC-12	AB308 + zim	Advanced Malignancies	Ongoing Phase 1/1b	NCT04772989
ARC-14	AB521	Healthy Volunteers	Ongoing	NCT05117554
ARC-20	AB521	Cancer Patients / ccRCC	Planned Phase 1/1b	TBD

dom: domvanalimab; durva: durvalumab; etruma: etrumadenant; gem/nab-pac: gemcitabine/nab-paclitaxel; nivo: nivolumab; pembro: pembrolizumab; quemli: quemliclustat; SOC: standard of care; zim: zimberelimab; ccRCC: clear-cell renal cell carcinoma

CRC: colorectal cancer; CRPC: castrate-resistant prostate cancer; GI: gastrointestinal; NSCLC: non-small cell lung cancer; PDAC: pancreatic ductal adenocarcinoma

About the Gilead Collaboration

In May 2020, Gilead and Arcus entered into a 10-year collaboration that provided Gilead immediate rights to zimberelimab and the right to opt into all other Arcus programs arising during the collaboration term. In November 2021, Gilead and Arcus amended the collaboration in connection with Gilead's option exercise for three of Arcus's then-clinical stage programs. For all other programs that are in clinical development or new programs that enter clinical development thereafter, the opt-in payments are \$150 million per program. Gilead's option, on a program-by-program basis, expires after a specified period of time following the achievement of a development milestone for such program and Arcus's delivery to Gilead of the requisite qualifying data package. Concurrent with the May

2020 collaboration agreement, Gilead and Arcus entered into a stock purchase agreement under which Gilead made a \$200 million equity investment in Arcus. That stock purchase agreement was amended and restated in February 2021 in connection with Gilead's increased equity stake in Arcus from 13% to 19.5%, with an additional \$220 million investment.

Gilead and Arcus are co-developing and equally share global development costs for five clinical candidates, including domvanalimab, an Fc-silent anti-TIGIT antibody, etrumadenant, a dual adenosine A2a/A2b receptor antagonist, quemliclustat, a small molecule inhibitor of CD73, and zimberelimab, an anti-PD1 antibody.

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 partners, 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 six investigational medicines into clinical studies, including new combination approaches that target TIGIT, PD-1, the adenosine axis (CD73 and dual A2a/A2b receptor) and most recently, HIF-2a. For more information about Arcus Biosciences' clinical and pre-clinical programs, please visit www.arcusbio.com or follow us on Twitter.

Forward-Looking Statements

This press release contains forward-looking statements. All statements regarding events or results to occur in the future contained herein, including, but not limited to, the statements in Dr. Rosen's quote, Arcus's expectation that its cash, cash equivalents and marketable securities on-hand are sufficient to fund operations into 2026, future data disclosures and presentations, the projected achievement of clinical study milestones and their associated timing (including under the captions "Upcoming Anti-TIGIT Milestones," "Upcoming Etrumadenant Milestones," "Upcoming Quemliclustat Milestones," "AB521 Update," and "Discovery Programs"), and additional clinical studies in planning or expected to be initiated this year 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 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; 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, all of which may be exacerbated by

the COVID-19 pandemic; Arcus's dependence on the collaboration with Gilead 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 its Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, filed on August 3, 2022 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 except to the extent required by law.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenues:				
License and development service revenue	\$ 16,693	\$ -	\$ 24,632	\$ -
Other collaboration revenue	10,066	9,461	20,132	18,922
Total revenues	26,759	9,461	44,764	18,922
Operating expenses:				
Research and development	69,905	68,771	131,116	135,158
General and administrative	25,836	16,826	49,810	32,647
Total operating expenses	95,741	85,597	180,926	167,805
Loss from operations	(68,982)	(76,136)	(136,162)	(148,883)
Non-operating income (expense):				
Interest and other income, net	2,861	166	3,443	320
Effective interest on liability for sale of future royalties	(511)	-	(902)	-
Total non-operating income, net	2,350	166	2,541	320
Net loss before income taxes	(66,632)	(75,970)	(133,621)	(148,563)
Income tax expense	-	-	(1,004)	-
Net loss	(66,632)	(75,970)	(134,625)	(148,563)
Other comprehensive loss	(2,584)	(44)	(5,983)	(90)
Comprehensive loss	\$ (69,216)	\$ (76,014)	\$ (140,608)	\$ (148,653)
Net loss per share, basic and diluted	\$ (0.93)	\$ (1.09)	\$ (1.88)	\$ (2.17)
Weighted-average number of shares used to compute basic and diluted net loss per share	71,814,232	69,745,297	71,506,216	68,421,086

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

	June 30, 2022	December 31, 2021(1)
Cash, cash equivalents and investments in marketable securities	\$ 1,271,105	\$ 681,298
Total assets	1,476,773	1,591,898
Total liabilities	729,387	750,448
Total stockholders' equity	747,386	841,450

(1) Derived from the audited financial statements for the year ended December 31, 2021, included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 23, 2022.

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Source: Arcus Biosciences, Inc.