



NEWS RELEASE

# Arcus Biosciences Reports Second Quarter 2021 Financial Results and Provides Operational Highlights

8/5/2021

- All five clinical-stage molecules continue to advance with six ongoing randomized Phase 2 and Phase 3 studies in major tumor types, including lung, colon, prostate and pancreatic cancer
- AB521, a small molecule HIF-2 $\alpha$  inhibitor, expected to enter the clinic in 4Q21
- Reported encouraging results from our interim analysis for ARC-7 providing initial validation of our domvanalimab (anti-TIGIT) combinations
- Presented promising data at ASCO and AACR for etrumadenant (A2a/A2b adenosine receptor antagonist) in combination with other agents, providing further clinical evidence supporting the potential of this molecule
- Enrollment in the randomized portion of the ARC-8 study evaluating quemiclustat (small molecule CD73 inhibitor) in first-line pancreatic cancer remains brisk and is expected to complete by year-end
- Ended the quarter with \$805 million of cash and investments

HAYWARD, Calif.--(BUSINESS WIRE)-- Arcus Biosciences, Inc. (NYSE:RCUS), an oncology-focused biopharmaceutical company working to create best-in-class cancer therapies, today reported financial results for the second quarter ended June 30, 2021 and provided operational highlights. Management will host a conference call today, August 5, 2021 beginning at 1:30 pm PT/ 4:30 pm ET.

“We have made significant progress advancing our portfolio and partnerships in the first half of 2021,” said Terry Rosen, Ph.D., CEO. “We generated additional clinical data for four of our clinical-stage molecules, across trials in lung, colon, prostate, and pancreatic cancers, that continue to support our ongoing randomized studies. We also advanced our Fc-enabled anti-TIGIT antibody into a Phase 1 study and selected our HIF-2 $\alpha$  small molecule to be our sixth clinical-stage molecule, anticipated to enter the clinic by the end of the year. With over \$800 million of cash and investments as of the end of the second quarter, and our partnership with Gilead, we are confident we can address and pursue the immense need in these patient populations and the corresponding magnitude of the

market opportunities.”

## Anti-TIGIT Program

### Domvanalimab (Fc-silent anti-TIGIT antibody)

#### Recent Highlights:

- Arcus continues to enroll our ARC-7 study and ARC-10 Phase 3 registrational study as planned , based on encouraging results from the first interim analysis from ARC-7, a randomized, three-arm Phase 2 trial evaluating domvanalimab (dom) + zimberelimab (zim) vs. zim vs. dom + zim + etrumadenant (etruma) in first-line PD-L1 $\geq$ 50%, metastatic non-small cell lung cancer (NSCLC).
  - Data from the zim arm demonstrated activity similar to that of other marketed anti-PD-1 antibodies in the setting.
  - Data from the doublet and triplet arms demonstrated promising antitumor activity, and the triplet arm performed particularly well across multiple measures, including objective response rate (ORR) and depth of response. More mature data will enable us to better assess the contributions of each molecule, dom and etruma.
  - At the time of data cut off, no unexpected safety signals were observed.
  - Based on this dataset, Arcus and Gilead will continue preparations for additional Phase 3 studies of dom-based combinations. We will also explore other development opportunities for the triplet.

#### Upcoming Milestones:

- Results from the interim analysis for ARC-7 are expected to be submitted later this year for a presentation in 4Q21 or in 1H22.
- We anticipate an opt-in trigger decision by Gilead for our anti-TIGIT program by year-end 2021.
- Initiation of PACIFIC-8, in collaboration with AstraZeneca, anticipated to start in 4Q21. PACIFIC-8 is a registrational trial designed to evaluate dom and durvalumab in Stage 3 NSCLC.

### AB308 (Fc-enabled anti-TIGIT antibody)

#### Recent Highlights:

- Recommended dose for expansion (RDE) selected in the Phase 1/1b ARC-12 study evaluating AB308 plus zim in advanced malignancies . This study is designed to efficiently establish the safety, tolerability, pharmacokinetic, pharmacodynamic, and clinical activity of AB308 + zim to facilitate advancement into a late-stage trial.

#### Upcoming Milestones:

- Initiation of five expansion cohorts in the Phase 1b portion of the study is expected in the third quarter.

### Quemliclustat (also referred to as AB680; CD73 inhibitor)

#### Recent Highlights:

- Completed enrollment in the expansion cohort of our Phase 1/1b ARC-8 study of quemliclustat (quemli) plus chemotherapy and zim in patients with first-line metastatic pancreatic ductal adenocarcinoma. The data continue to look promising, particularly the safety profile of the combination and the high percentage of patients that experienced tumor shrinkage.
- Currently enrolling the randomized portion of this study which is comparing quemli + zim + gemcitabine (G)/nab-paclitaxel (NP) vs. quemli + G/NP to inform our Phase 3 registrational design.

#### Upcoming Milestones:

- Opening of a new arm to evaluate quemli in second-line pancreatic cancer is expected in 3Q21 based on encouraging first-line results and high interest from investigators.
- Updated data from the dose-escalation and dose-expansion cohorts of ARC-8 study are expected to be released in the Fall.
- Completion of enrollment of the 90-patient randomized portion of the ARC-8 study is expected by year-end 2021. We expect to present initial randomized data in mid-2022 and anticipate utilizing data from the randomization portion of the study combined with data from the dose escalation and expansion cohorts to discuss the path to registration with health authorities.

### Etrumadenant (A2a/A2b adenosine receptor antagonist)

#### Recent Highlights:

- Presented initial Phase 1b data in metastatic castrate-resistant prostate cancer (mCRPC) from ARC-6 at the 2021 ASCO Annual Meeting. The data from the Stage 1 portion of the etruma + zim + docetaxel cohort in patients with 2L+ mCRPC showed the etruma-based combination was well tolerated and demonstrated promising clinical activity in patients with advanced disease who had progressed on prior treatments.
- Demonstrated preliminary activity with etruma in combination with dom plus zim (triplet arm) in ARC-7. The clinical activity in the triplet arm is the first reported on for an anti-TIGIT and adenosine receptor antagonist combination and potentially provides a novel and differentiated therapy for this patient population.

#### Upcoming Milestones:

- Initial randomized data, including ORR and PFS, from our ARC-4 study in EGFR+ NSCLC cancer is expected to be presented in 1H22. ARC-4 is a randomized Phase 1b study evaluating etruma + zim + chemotherapy vs. zim + chemotherapy in EGFRmut tyrosine kinase inhibitor (TKI)-relapsed and refractory NSCLC.

- Initial randomized data from our ARC-6 study in prostate cancer is expected to be presented in 2022 . ARC-6 is a Phase 1b/2 randomized study evaluating the efficacy and safety of etruma-based treatment combinations.

## HIF-2 $\alpha$ inhibitor Program

### Recent Highlights:

- Selected AB521 as the lead clinical candidate for our HIF-2 $\alpha$  inhibitor program. AB521 has demonstrated excellent potency, selectivity, biological activity and pharmacokinetic properties in preclinical studies.

### Upcoming Milestones:

- Initiation of clinical development for our HIF-2 $\alpha$  inhibitor, AB521, is anticipated to occur in 4Q21. This first study is expected to be in healthy volunteers to expeditiously characterize the pharmacokinetic and safety profile of AB521 and to identify the starting dose for the Phase 1/1b study in oncology indications, which is anticipated to begin in 1H22.

## Corporate

### Recent Highlights:

- Appointed Nicole Lambert to our Board of Directors. Ms. Lambert is currently President of Myriad Genetic Laboratories and has extensive experience in the healthcare industry spanning more than 20 years, including expertise successfully growing and leading global commercial organizations. She will be a great asset to Arcus, and we are thrilled to welcome her to our team, as we continue to advance our registrational programs.

### Upcoming Milestones:

- Initiation of a Phase 1 platform study, by partner Taiho, is expected in 3Q21 . Taiho filed an IND in Japan in 2Q21 to evaluate zim in intra-portfolio combinations targeting oncology indications.

## Financial Results for the Second Quarter 2021

- Cash, cash equivalents and investments were \$805.1 million as of June 30, 2021, compared to \$735.1 million as of December 31, 2020. The increase was primarily due to gross proceeds of \$220.4 million received upon the closing of the private placement of common stock under the Amended and Restated Stock Purchase Agreement with Gilead in February 2021, partially offset by cash utilized for our operations. We expect cash, cash equivalents and marketable securities on-hand to be sufficient to fund operations at least through 2023.
- Revenues: Collaboration and license revenues were \$9.5 million for the three months ended June 30, 2021, compared to \$1.8 million for the same period in 2020. In the three months ended June 30, 2021, we

recognized \$7.7 million in collaboration revenues related to Gilead's ongoing rights to access our research and development pipeline in accordance with the Gilead Collaboration Agreement, as well as \$1.8 million under the Taiho Agreement. In the three months ended June 30, 2020, we recognized \$1.8 million under the Taiho Agreement. Collaboration and license revenues were \$18.9 million for the six months ended June 30, 2021, compared to \$3.5 million for the same period in 2020.

- R&D Expenses: Research and development expenses were \$68.8 million for the three months ended June 30, 2021, compared to \$35.7 million for the same period in 2020. The increase was primarily due to increases in employee compensation costs driven by increasing headcount and 2021 stock awards. Of the total change in employee compensation costs, approximately \$4.6 million consists of increased non-cash stock-based compensation. Clinical and manufacturing costs increased as well due to the increased number of clinical programs and studies compared to the same quarter in the prior year. Lab supplies and equipment, clinical consulting, and office and facilities expense all increased as we continued to grow. The overall increase in research and development expenses is partially offset by a decrease in milestone expense incurred and an increase in reimbursements from collaboration partners. Research and development expenses were \$135.2 million for the six months ended June 30, 2021, compared to \$58.8 million for the same period in 2020.
- G&A Expenses: General and administrative expenses were \$16.8 million for the three months ended June 30, 2021, compared to \$11.4 million for the same period in 2020. The increase in expense was due to increases in employee compensation costs driven by increasing headcount and 2021 stock awards. Of the total change in employee compensation costs, approximately \$4.3 million consists of increased non-cash stock-based compensation. We also incurred additional facilities expense due to our expanding headcount and office space. The overall increase was partially offset by decreases in legal, accounting and other consulting expenses. In 2020, we incurred significant costs related to our transaction with Gilead and other corporate development activities. General and administrative expenses were \$32.6 million for the six months ended June 30, 2021, compared to \$18.4 million for the same period in 2020.
- Net Loss: Net loss was \$76.0 million for the three months ended June 30, 2021, compared to a net loss of \$45.1 million for the same period in the prior year. Net loss was \$148.6 million for the six months ended June 30, 2021, compared to \$72.8 million for the same period in 2020.

## Conference Call

Management will host a conference call today, August 5, 2021 to discuss second quarter 2021 financial results and recent corporate highlights. The call will begin at 1:30 pm PT/ 4:30 pm ET. Investors interested in listening to the conference call may do so by dialing (844) 200-6205 in the U.S. or +44 208 0682 558 internationally, using Conference ID: 152804. In addition, the live webcast and any accompanying slides will be available on the "Investors" section of the Arcus website at [www.arcusbio.com](http://www.arcusbio.com). Following the live webcast, a replay will be available on the Company's website for at least two weeks following the live event.

## Arcus Clinical Study Overview

Trial Name	Arms	Setting	Status	NCT No.
ARC-3	Etruma + mFOLFOX	CRC	Initial Study	<a href="#">NCT03720678</a>
ARC-4	Etruma + Zim + Carbo/Pem vs. Zim + Carbo/Pem	TKI R/R EGFRmut NSCLC	Ongoing Randomized Phase 1/2	<a href="#">NCT03846310</a>
ARC-6	Etruma + Zim + SOC vs. SOC	2L/3L CRPC	Ongoing Randomized Phase 2	<a href="#">NCT04381832</a>
ARC-7	Zim vs. Zim + Dom vs. Zim + Dom + Etruma	1L NSCLC (PD-L1 $\geq$ 50%)	Ongoing Randomized Phase 2	<a href="#">NCT04262856</a>
ARC-8	Quemli + Zim + Gem/NP vs. Quemli + Gem/NP	1L PDAC	Ongoing Randomized Phase 1/1b	<a href="#">NCT04104672</a>
ARC-9	Etruma + Zim + mFOLFOX vs. SOC	2L/3L/3L+ CRC	Initiated Randomized Phase 2	<a href="#">NCT04660812</a>
ARC-10	Chemo vs. Zim mono vs. Zim + Dom	1L NSCLC (PD-L1 $\geq$ 50%)	Initiated Registrational	<a href="#">NCT04736173</a>
ARC-12	AB308 + Zim	Advanced Malignancies	Initiated Phase 1/1b	<a href="#">NCT04772989</a>
PACIFIC-8	Durva $\pm$ Dom	Curative-Intent Stage 3 NSCLC	Expected Initiation 2H21 Registrational	NA

CRC: colorectal cancer, NSCLC: non-small cell lung cancer, CRPC: castrate-resistant prostate cancer, PDAC: pancreatic ductal adenocarcinoma, Durva: durvalumab

## About Arcus Biosciences

Arcus Biosciences is an oncology-focused biopharmaceutical company leveraging its deep cross-disciplinary expertise to discover highly differentiated therapies and to develop a broad portfolio of novel combinations addressing significant unmet needs. Arcus currently has five molecules in clinical development: **Etrumadenant (AB928)**, the first dual A2a/A2b adenosine receptor antagonist to enter the clinic, is being evaluated in multiple Phase 2 and 1b studies across different indications, including prostate, colorectal, and non-small cell lung. **Quemliclustat (AB680)**, the first small-molecule CD73 inhibitor to enter the clinic, is in Phase 1/1b development in combination with zimberelimab and gemcitabine/nab-paclitaxel for first-line treatment of metastatic pancreatic cancer. **Domvanalimab (AB154)**, an anti-TIGIT monoclonal antibody and new potential immuno-oncology backbone therapy, is in a three-arm randomized Phase 2 study evaluating zimberelimab monotherapy, domvanalimab plus zimberelimab and domvanalimab plus etrumadenant plus zimberelimab for first-line treatment of PD-L1  $\geq$  50% metastatic non-small cell lung cancer (NSCLC). In addition, domvanalimab has advanced into ARC-10, Arcus's "two in one trial" to support the potential approvals of both zimberelimab and zimberelimab plus domvanalimab and is expected to advance into a registrational study, in collaboration with AstraZeneca, evaluating the curative-intent stage 3 NSCLC setting later this year. **AB308**, an anti-TIGIT antibody that is FcR-enabled, is in clinical development, with a potential focus on hematological malignancies. **Zimberelimab (AB122)**, Arcus's anti-PD-1 monoclonal antibody, is being evaluated in various combinations across the portfolio. For more information about Arcus Biosciences, please visit [www.arcusbio.com](http://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, statements under the captions “Upcoming Milestones” above, Arcus’s expectations including as to timing to advance its investigational products described herein and Arcus’s expectation that its cash, cash equivalents and marketable securities on-hand will be sufficient to fund operations through at least 2023 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. Factors that could cause or contribute to such differences include, but are not limited to: the inherent uncertainty associated with the COVID-19 pandemic, including the duration and/or severity of the pandemic and actions by government authorities to contain or slow the spread of the virus; the inherent uncertainty associated with pharmaceutical product development and clinical trials; our dependence on our collaboration with Gilead for the successful development and commercialization of our investigational products; 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; the unexpected emergence of adverse events or other undesirable side effects; risks associated with preliminary and interim data; and changes in the competitive landscape for our programs. Risks and uncertainties facing Arcus are described more fully in Arcus’s quarterly report on Form 10-Q for the quarter ended June 30, 2021 filed on August 5, 2021 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.

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Source: Arcus Biosciences

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,	
	2021	2020	2021	2020
Revenues:				
Collaboration revenue	\$ 9,461	\$ 1,750	18,922	\$ 3,500
Total collaboration and license revenues	9,461	1,750	18,922	3,500
Operating expenses:				
Research and development	68,771	35,693	135,158	58,835
General and administrative	16,826	11,432	32,647	18,440
Total operating expenses	85,597	47,125	167,805	77,275
Loss from operations	(76,136)	(45,375)	(148,883)	(73,775)
Non-operating income (expense):				
Interest and other income, net	166	301	320	948
Gain on deemed sale from equity method investee	-	131	-	613
Share of loss from equity method investee	-	(131)	-	(613)
Total non-operating income, net	166	301	320	948

Net loss	(75,970)	(45,074)	(148,563)	(72,827)
Other comprehensive income (loss)	(44)	(144)	(90)	80
Comprehensive loss	<u>\$ (76,014)</u>	<u>\$ (45,218)</u>	<u>\$ (148,653)</u>	<u>\$ (72,747)</u>
Net loss per share, basic and diluted	<u>\$ (1.09)</u>	<u>\$ (0.93)</u>	<u>\$ (2.17)</u>	<u>\$ (1.57)</u>
Weighted-average number of shares used to compute basic and diluted net loss per share	<u>69,745,297</u>	<u>48,556,843</u>	<u>68,421,086</u>	<u>46,419,724</u>

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

	June 30 2021	December 31, 2020(1)
Cash, cash equivalents and investments in marketable securities	\$ 805,108	\$ 735,086
Total assets	898,773	772,292
Total liabilities	294,218	269,988
Total stockholders' equity	604,555	502,304

(1) Derived from the audited financial statements for the year ended December 31, 2020, included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 25, 2021.

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Source: Arcus Biosciences, Inc.