



NEWS RELEASE

# Arcus Biosciences Reports Fourth Quarter and Full-Year 2021 Financial Results and Provides Corporate Update

2/23/2022

- Presentations of randomized data for domvanalimab and etrumadenant in 1L PD-L1 high non-small cell lung cancer (NSCLC; ARC-7) and quemliclustat in pancreatic cancer (ARC-8) are planned for 2H:22
- Initial pharmacokinetic (PK)/pharmacodynamic (PD) data for AB521, Arcus's HIF-2a inhibitor, in healthy volunteers confirm its potential to have an improved clinical profile compared to the approved HIF-2a inhibitor; data to be presented at a conference this March
- First patient dosed in PACIFIC-8, a registrational, Phase 3 study evaluating domvanalimab plus durvalumab in unresectable, Stage 3 NSCLC with AstraZeneca; this represents the second Phase 3 study to be initiated for domvanalimab in NSCLC
- Two additional Phase 3 studies for domvanalimab are planned for this year in lung and gastrointestinal cancers with Gilead
- Arcus is well positioned to advance its programs with \$1.4 billion in cash and cash equivalents following receipt of option payments from Gilead Sciences in January 2022, which is expected to provide Arcus with 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 fourth quarter and year ended December 31, 2021 and provided a corporate update on its six clinical-stage molecules targeting TIGIT, the adenosine axis (CD73 and dual A2a/A2b receptor), HIF-2a and PD-1 across common cancers, including lung, colon, pancreatic and prostate.

“Arcus is starting 2022 with a strong cash position and late-stage pipeline that includes two ongoing, and soon to be four, registrational Phase 3 studies for the anti-TIGIT antibody, domvanalimab,” said Terry Rosen, Ph.D., Chief Executive Officer of Arcus. “Our strategy is to efficiently investigate and advance novel combinations of our six clinical-stage molecules in areas of high unmet need. We look forward to presenting, later this year, randomized datasets from our trials in lung and pancreatic cancer, both settings with large patient populations with great need for better treatment options.”

### Anti-TIGIT program (domvanalimab and AB308)

Recent Updates:

- First patient was dosed in PACIFIC-8, a registrational Phase 3 study being conducted in collaboration with AstraZeneca. PACIFIC-8 is the second Phase 3 study for domvanalimab and is evaluating domvanalimab plus durvalumab, an anti-PD-L1 antibody, in unresectable Stage 3 NSCLC with curative intent, where durvalumab is standard of care.

2022 Milestones:

- Data from ARC-7, an ongoing randomized 150-patient three-arm study in first-line PD-L1 $\geq$ 50% NSCLC, including progression-free survival data for all three arms, are expected to be presented in 2H22.
- Arcus and Gilead plan to initiate two new Phase 3 studies for domvanalimab and zimberelimab in lung and gastrointestinal (GI) cancers, as well as additional clinical studies of domvanalimab-based combinations, in 2022.
- Presentation of initial data from the Phase 1/1b ARC-12 study evaluating AB308, an Fc-enabled anti-TIGIT antibody, in combination with zimberelimab in advanced malignancies.

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

2022 Milestones:

- Data from the etrumadenant-containing arm of ARC-7 are anticipated to be presented in 2H22.
- 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 2H22.
- Additional clinical studies for etrumadenant, including combinations with domvanalimab, are being planned with Gilead.

### Quemliclustat (small molecule CD73 inhibitor)

2022 Milestones:

- Results from the randomized portion of ARC-8, including data on progression-free survival, are expected to be presented in 2H22.
- Full enrollment of the ARC-8 cohort in 2L pancreatic cancer, an area of high unmet need, is on track to be completed in 1H22.
- Additional clinical studies for quemliclustat are being planned with Gilead.

## AB521 (HIF-2a inhibitor)

### Recent Updates:

- Initiated a Phase 1 study (ARC-14) in healthy volunteers to confirm Arcus's PK/PD and tolerability expectations for AB521 and support rapid advancement into cancer patients.

### 2022 Milestones:

- Preclinical data for AB521, alone and in combination with cabozantinib, as well as initial PK/PD data from the evaluation of AB521 in healthy volunteers, will be presented at the ESMO Targeted Anticancer Therapies Congress on March 7, 2022.
- A Phase 1/1b study to explore AB521 in clear-cell renal cell carcinoma, alone and in combination with other molecules, including those targeting the CD73-adenosine axis, is anticipated to be initiated in mid-2022.

## Discovery Programs:

### Recent Updates:

- In January, Arcus met the first milestone under an agreement with BVF, which is focused on the discovery and development of a potentially first-in-class small molecule designed to treat a wide range of inflammatory conditions.
- Arcus recently selected AB598 (CD39 antibody) as a development candidate, which is advancing into IND-enabling studies; several other oncology discovery programs continue to progress.

## Financial Results for the Fourth Quarter and Full Year Ended December 31, 2021

- Cash, cash equivalents and investments were \$681.3 million as of December 31, 2021, compared to \$735.1 million as of December 31, 2020. The decrease was primarily due to cash used in operations and purchases of property and equipment totaling \$26.1 million, partially offset by gross proceeds of \$220.4 million received under the Amended and Restated Stock Purchase Agreement with Gilead in February 2021. Upon the receipt of \$725 million in option exercise payments from Gilead in January 2022, Arcus's cash and cash equivalents

and investments totaled approximately \$1.4 billion. Arcus expects cash, cash equivalents and marketable securities on-hand to be sufficient to fund operations into 2026.

- **Revenues:** Collaboration and license revenues were \$354.5 million for the three months ended December 31, 2021, compared to \$9.5 million for the same period in 2020. The increase was primarily driven by license revenue recognized upon closing of Gilead's exercise of its options. Collaboration and license revenues were \$382.9 million for the full year ended December 31, 2021, compared to \$77.5 million for the same period in 2020.
- **R&D Expenses:** Research and development expenses were \$49.9 million for the three months ended December 31, 2021, compared to \$48.7 million for the same period in 2020. The increase was primarily driven by costs incurred to support Arcus's expanded clinical and development activities including increased compensation costs related to a larger employee base, increased clinical trial costs, and increased early-stage research costs. Approximately \$3.2 million of the increase in compensation costs is related to non-cash stock-based compensation. Research and development expenses were \$256.3 million for the full year ended December 31, 2021, compared to \$159.3 million for the same period in 2020.
- **G&A Expenses:** General and administrative expenses were \$23.3 million for the three months ended December 31, 2021, compared to \$12.8 million for the same period in 2020. The increase was driven by the increased complexity of supporting Arcus's expanding clinical pipeline and collaboration obligations, as well as compliance costs associated with Arcus's growth. Arcus's growing employee base and 2021 stock awards drove an increase in employee compensation costs, including approximately \$2.7 million of increased non-cash stock-based compensation. General and administrative expenses were \$72.3 million for the full year ended December 31, 2021, compared to \$42.4 million for the same period in 2020.
- **Net Income:** Net income was \$279.4 million for the three months ended December 31, 2021, compared to net loss of \$51.9 million for the same period in the prior year. Net income was primarily due to license revenue recognized upon closing of Gilead's exercise in December 2021 of its options. Net income was \$52.8 million for the full year ended December 31, 2021, compared to net loss of \$122.9 million for the same period in 2020.

## Arcus Clinical Study Overview

Trial Name	Arms	Setting	Status	NCT No.
<b>Lung Cancer</b>				
ARC-7	zim vs. zim + dom vs. zim + dom + etruma	1L NSCLC (PD-L1 ≥ 50%)	Ongoing Randomized Phase 2	<b>NCT04262856</b>
PACIFIC-8	durva ± dom	Curative-Intent Stage 3 NSCLC	Ongoing Registrational Phase 3	<b>NCT05211895</b>
ARC-10	chemo vs. zim vs. zim + dom	1L NSCLC (PD-L1 ≥ 50%)	Ongoing Registrational	<b>NCT04736173</b>

			Phase 3	
<b>Colon Cancer</b>				
ARC-9	etruma + zim + mFOLFOX vs. SOC	2L/3L/3L+ CRC	Ongoing Randomized Phase 2	<b>NCT04660812</b>
<b>Pancreatic Cancer</b>				
ARC-8	quemli + zim + gem/nab-pac vs. quemli + gem/nab-pac	1L, 2L PDAC	Ongoing Randomized Phase 1/1b	<b>NCT04104672</b>
<b>Prostate Cancer</b>				
ARC-6	etruma + zim + SOC vs. SOC	2L/3L CRPC	Ongoing Randomized Phase 2	<b>NCT04381832</b>
<b>Various</b>				
ARC-12	AB308 + zim	Advanced Malignancies	Ongoing Phase 1/1b	<b>NCT04772989</b>
ARC-14	AB521	Healthy Volunteer	Ongoing	<b>NCT05117554</b>

Carbo/pem: carboplatin/pemetrexed; dom: domvanalimab; durva: durvalumab; etruma: etrumadenant; gem/nab-pac: gemcitabine/nab-paclitaxel; quemli: quemliclustat; R/R: relapsed/refractory; SOC: standard of care; zim: zimberelimab CRC: colorectal cancer; CRPC: castrate-resistant prostate cancer; NSCLC: non-small cell lung cancer; PDAC: pancreatic ductal adenocarcinoma

## 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 biology 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](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, in Dr. Rosen's quote, upcoming data presentations, trial initiations and other milestones and the associated timing of such activities, including as set forth under the captions "2022 Milestones", and Arcus's future development plans 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: 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; 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; the unexpected emergence of adverse events or other undesirable side effects; risks associated with preliminary and interim data; the inherent uncertainty associated with pharmaceutical product development and clinical trials; and changes in the competitive landscape for Arcus's programs. Risks and uncertainties facing Arcus are described more fully in its Annual Report on Form 10-K for the year ended December 31, 2021, filed on February 23, 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.

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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)

	(Unaudited) Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
<b>Revenues:</b>				
License revenue	\$ 343,838	\$ -	\$ 343,838	\$ 55,096
License and development services revenue	1,135	-	1,135	-
Other collaboration revenue	9,526	9,487	37,909	22,421
<b>Total collaboration and license revenues</b>	<b>354,499</b>	<b>9,487</b>	<b>382,882</b>	<b>77,517</b>
<b>Operating expenses:</b>				
Research and development	49,936	48,712	256,348	159,348
General and administrative	23,296	12,787	72,286	42,404
<b>Total operating expenses</b>	<b>73,232</b>	<b>61,499</b>	<b>328,634</b>	<b>201,752</b>
<b>Income (loss) from operations</b>	<b>281,267</b>	<b>(52,012)</b>	<b>54,248</b>	<b>(124,235)</b>
<b>Non-operating income (expense):</b>				
Interest and other income, net	176	159	657	1,377
Effective interest on liability for sale of future royalties	(260)	-	(260)	-
Gain on deemed sale from equity method investee	-	-	-	613
Share of loss from equity method investee	-	-	-	(613)
<b>Total non-operating income, net</b>	<b>(84)</b>	<b>159</b>	<b>397</b>	<b>1,377</b>
<b>Income (loss) before income taxes</b>	<b>281,183</b>	<b>(51,853)</b>	<b>54,645</b>	<b>(122,858)</b>
Income tax expense	(1,815)	-	(1,815)	-
<b>Net income (loss)</b>	<b>\$ 279,368</b>	<b>\$ (51,853)</b>	<b>\$ 52,830</b>	<b>\$ (122,858)</b>
Other comprehensive income (loss)	(1,169)	(37)	(1,305)	(20)
<b>Comprehensive income (loss)</b>	<b>\$ 278,199</b>	<b>\$ (51,890)</b>	<b>\$ 51,525</b>	<b>\$ (122,878)</b>
<b>Net income (loss) per share, basic</b>	<b>\$ 3.97</b>	<b>\$ (0.82)</b>	<b>0.76</b>	<b>(2.24)</b>
<b>Weighted-average number of shares used to compute basic net income (loss) per share</b>	<b>70,399,507</b>	<b>63,527,932</b>	<b>69,345,490</b>	<b>54,787,118</b>
<b>Net income (loss) per share, diluted</b>	<b>\$ 3.71</b>	<b>\$ (0.82)</b>	<b>0.71</b>	<b>(2.24)</b>
<b>Weighted-average number of shares used to compute diluted net income (loss) per share</b>	<b>75,356,832</b>	<b>63,527,932</b>	<b>73,966,267</b>	<b>54,787,118</b>

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

	December 31, 2021	December 31, 2020
Cash, cash equivalents and investments in marketable securities	\$ 681,298	\$ 735,086
Total assets	1,591,898	772,292
Total liabilities	750,448	269,988
Total stockholders' equity	841,450	502,304

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