Achilles Therapeutics Reports Fourth Quarter and Year-End 2021 Financial Results and Recent Business Highlights

March 1, 2022

- Patient data from higher dose cNeT as monotherapy and cNeT in combination with checkpoint inhibitor expected in 2H 2022 -

- Strong cash position of $266 million supports clinical development and manufacturing expansion into 2H 2024 -

LONDON, March 01, 2022 (GLOBE NEWSWIRE) -- Achilles Therapeutics plc (NASDAQ: ACHL), a clinical-stage biopharmaceutical company developing precision T cell therapies to treat solid tumors, today announced its financial results for the fourth quarter and year-ended December 31, 2021, and recent business highlights.

“In 2021, we generated clinical data demonstrating the unique ability of our T cell platform to detect, quantify and track our clonal neoantigen-reactive T cells, or cNeT, *in vivo*, giving us the analytical platform to elucidate the mechanism of action of our cNeT product. cNeT dose is now being used in our clinical trials as a release parameter, highlighting our differentiated potential to develop potency assays that we believe are essential for the successful development and regulatory approval of TIL-based therapies,” said **Dr Iraj Ali, Chief Executive Officer of Achilles Therapeutics**. “In the year ahead, we will build on the important learnings from our first cohort of patients by evaluating higher doses of our tumor-targeting cNeT therapies alone and in combination with a checkpoint inhibitor. We look forward to clinical readouts in our CHIRON and THETIS trials for non-small cell lung cancer and melanoma, respectively, including 6-week clinical activity and engraftment data in the second half of 2022.

Our unique ability to prospectively target and track clonal neoantigens is possible through PELEUS™, our proprietary bioinformatics platform. PELEUS was built on an advanced statistical framework to differentiate clonal from subclonal mutations and is further enhanced using Artificial Intelligence in a range of applications, including neoantigen prioritization. PELEUS is validated through our exclusive access to the landmark TRACERx clinical study of tumor evolution, which provides the extensive longitudinal sequencing data of over 3,200 tumor samples that have been collected over five years from over 795 patients. The detailed genomic analysis from PELEUS allows us to identify the unique clonal neoantigens of each patient. These clonal neoantigens are protein markers that are present on all of an individual’s cancer cells but are absent from healthy tissue, making them ideal cancer targets. With this information, our VELOS manufacturing process uses the natural biology of dendritic cell antigen presentation to select and expand the T cells that are able to recognize the clonal neoantigen targets present in a patient’s tumor. With these powerful, proprietary tools and our forthcoming clinical data, we are well-positioned to advance our precision T cell therapy.

We expect to continue to expand our global footprint with increased manufacturing capacity in the U.K., continued addition of clinical sites, and establishment of our U.S. headquarters in Philadelphia which will house our first U.S. R&D facility. With the capital raised in our successful IPO in April 2021, we have $266 million in cash and cash equivalents to support the clinical development of our cNeT therapy in melanoma, non-small cell lung cancer, head and neck cancer, and other indications into the second half of 2024.”

2021 Business Highlights and Recent Updates

- Established a U.S. headquarters in Philadelphia, PA which will include an R&D facility
- Strengthened the Scientific Advisory Board and Board of Directors with appointments of Alena Gros, Ph.D. and Ben Creelan, M.D. (Press Release, February 2022) and Julie O’Neill and Markwin Velders, Ph.D. (Press Release, May 2021)
- Added to the NASDAQ Biotechnology Index (Press Release, December 2021) and the ICE Biotechnology Index
- Presented data at the ESMO I-O Congress on VELOS Process 2 manufacturing (Press Release, December 2021) highlighting a median dose of 200m cNeT in pre-clinical GMP runs, more than a 10-fold increase over the median dose manufactured with Process 1
- Presented data at AACR (Press Release, April 2021) and SITC Annual Meetings (Press Release, November 2021) showing the detection, quantification and tracking of patient-specific cNeT
- Received regulatory approval for the use of VELOS Process 2 manufacturing in the UK, France, Germany, and Spain in November 2021
- Presented details of the Material Acquisition Platform (MAP) at the 2021 ESGCT Congress, supporting the potential use of cNeT in a broad range of solid tumor indications (Press Release, October 2021)
- Expanded the Company’s intellectual property estate, including the grant of US and European patents supporting the approach of targeting clonal neoantigens that are identified with the proprietary PELEUS™ bioinformatics platform (Press Release, August 2021)
- Raised gross proceeds of $175.5 million in an initial public offering (Press Release, April 2021)

Financial Highlights

- **Cash and cash equivalents:** Cash and cash equivalents were $266.3 million as of December 31, 2021, as compared to

$177.8 million as of December 31, 2020. The Company anticipates that its cash and cash equivalents are sufficient to fund its planned operations into the second half of 2024, including full funding of the ongoing Phase I/IIa CHIRON and THETIS clinical trials

- **Research and development (R&D) expenses:** R&D expenses were $11.8 million for the fourth quarter ended December 31, 2021, an increase of $2.8 million compared to $9.0 million for the fourth quarter ended December 30, 2020. R&D expenses were $42.2 million for the year ended December 31, 2021, an increase of $19.6 million compared to $22.6 million for the year ended December 31, 2020. The increase was primarily driven by increased activity related to our ongoing clinical trials and overall R&D
- **General and administrative (G&A) expenses:** G&A expenses were $6.7 million for the fourth quarter ended December 31, 2021, an increase of $2.7 million compared to $4.0 million for December 31, 2020. G&A expenses were $22.0 million for the year ended December 31, 2021, an increase of $10.9 million compared to the $11.1 million for the year ended December 31, 2020. The increase was primarily driven by fees associated with the Company's public company obligations, and an increase in headcount and related personnel costs
- **Net loss:** Net loss for the fourth quarter ended December 31, 2021 was $18.2 million or $0.45 per share compared to $12.9 million or $9.32 per share for the fourth quarter ended December 31, 2020. Net loss for the year ended December 31, 2021 was $61.1 million or $2.13 per share compared to $33.2 million or $31.14 per share for the year ended December 31, 2020. The decrease in loss per share is due in part to the increased number of shares following the conversion and issuance of shares from the IPO

2022 Milestones and Upcoming Events

- **Patient Dosing:** Dose first patients with higher dose (Process 2) cNeT monotherapy and cNeT in combination with a PD-1 inhibitor in 2Q 2022
- **Higher-dose Monotherapy:** Report additional patient data from higher-dose cohort (Process 2) of cNeT monotherapy for the treatment of NSCLC and melanoma in 2H 2022
- **cNeT Combination:** Report initial patient data from cNeT in combination with a PD-1 inhibitor for the treatment of melanoma in 2H 2022
- **Manufacturing Expansion:** Increase manufacturing capacity in the United Kingdom with GMP licensure of the Cell & Gene Therapy Catapult facility in 2Q 2022
- **Tumor Archiving Program:** Initiate program in 1H 2022

Achilles will present at the upcoming conferences. Additional details will be available in the Events & Presentations section of the Company's website:

- BioCapital Europe, Organized by LSP: March 10, 2022
- Oppenheimer 32nd Annual Healthcare Conference: March 15 – 16, 2022
- Immuno-Oncology 360°: March 16 – 18, 2022

About Achilles Therapeutics

Achilles is a clinical-stage biopharmaceutical company developing precision T cell therapies targeting clonal neoantigens: protein markers unique to the individual that are expressed on the surface of every cancer cell. The Company has two ongoing Phase I/IIa trials, the CHIRON trial in patients with advanced non-small cell lung cancer (NSCLC) and the THETIS trial in patients with recurrent or metastatic melanoma. Achilles uses DNA sequencing data from each patient, together with its proprietary PELEUS™ bioinformatics platform, to identify clonal neoantigens specific to that patient, and then develop precision T cell-based product candidates specifically targeting those clonal neoantigens.

Forward-Looking Statements

This press release contains express or implied forward-looking statements that are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. The forward-looking statements in this press release represent our views as of the date of this press release. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this press release.

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ACHILLES THERAPEUTICS PLC

Consolidated Balance Sheets

(in thousands, except share and per share amounts)

(expressed in U.S. Dollars, unless otherwise stated)

	December 31,	
	2021	**2020**
ASSETS		
Current assets:		
Cash and cash equivalents	266,319	$ 177,849
Prepaid expenses and other current assets	18,430	9,948
Total current assets	284,749	187,797
Non-current assets:		
Property and equipment, net	17,743	13,369
Operating lease right of use assets	11,048	14,740
Deferred tax assets	26	4
Restricted cash	33	—
Other assets	3,507	3,008
Total non-current assets	32,357	31,121
TOTAL ASSETS	$ 317,106	$ 218,918
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,722	$ 6,314
Income taxes payable	—	7
Accrued expenses and other liabilities	10,906	6,590
Operating lease liabilities—current	4,482	3,712
Total current liabilities	19,110	16,623
Non-current liabilities:		
Operating lease liabilities-non-current	7,777	12,271
Other long-term liability	691	652
Total non-current liabilities	8,468	12,923
Total liabilities	27,578	29,546
Commitments and contingencies		
Shareholders' equity:		
Ordinary shares, £0.001 par value; 40,603,489 and 4,389,920 shares authorized, issued and outstanding at December 31,2021 and 2020, respectively	54	6
Deferred shares, £92,451.851 par value, one share authorized, issued and outstanding at December 31, 2021; Deferred shares, £0.001 par value; 30,521 shares issued and outstanding at December 31,2020	128	—
Convertible preferred shares, £0.001 par value; no shares authorized, issued and outstanding as of December 31, 2021; 104,854,673 shares authorized, issued and outstanding at December 31, 2020	—	134
Additional paid in capital	401,821	234,922
Accumulated other comprehensive income	6,636	12,322
Accumulated deficit	(119,111)	(58,012)
Total shareholders' equity	289,528	189,372
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 317,106	$ 218,918

ACHILLES THERAPEUTICS PLC

Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share amounts)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2021	**2020**	**2021**	**2020**
OPERATING EXPENSES:				
Research and development	$ 11,807	$ 8,961	$ 42,224	$ 22,629
General and administrative	6,653	3,958	21,971	11,098
Total operating expenses	18,460	12,919	64,195	33,727
LOSS FROM OPERATIONS:	(18,460)	(12,919)	(64,195)	(33,727)
OTHER INCOME (EXPENSE), NET:				
Other income (expense)	226	2	3,133	531
Total other income (expense), net	226	2	3,133	531
Loss before income taxes	(18,234)	(12,917)	(61,062)	(33,196)
Benefit (provision) for income taxes	4	(3)	(37)	(3)
Net loss	(18,230)	(12,920)	(61,099)	(33,199)
Other comprehensive (loss) income:				
Foreign exchange translation adjustment	886	7,301	(5,686)	4,213
Comprehensive loss	$ (17,344)	$ (5,619)	$ (66,785)	$ (28,986)
Net loss per share attributable to ordinary shareholders—basic and diluted	$ (0.45)	$ (9.32)	$ (2.13)	$ (31.14)
Weighted average ordinary shares outstanding—basic and diluted	40,245,543	1,386,221	28,654,760	1,066,208