Fusion Pharmaceuticals Reports Fourth Quarter And Full Year 2023 Financial Results And Announces Clinical Program Updates

Company recently announced definitive agreement to be acquired by AstraZeneca

FPI-2265 Phase 2/3 registrational program for patients with metastatic castration-resistant prostate cancer (mCRPC) expected to begin in Q2 2024

Interim data from TATCIST study of FPI-2265 to be presented at the 2024 American Association for Cancer Research (AACR) Annual Meeting in April

Fusion is now producing and shipping clinical doses of FPI-2265 from its state-of-the-art GMP manufacturing facility

HAMILTON, ON and BOSTON, March 20, 2024 /PRNewswire/ -- Fusion Pharmaceuticals Inc. (Nasdaq: FUSN), a clinical-stage oncology company focused on developing next-generation radiopharmaceuticals as precision medicines, today reported financial results for the fourth quarter and full year ended December 31, 2023, and provided an update on clinical and corporate developments.

Chief Executive Officer John Valliant, Ph.D., commented, "We entered 2024 with strong momentum focused on execution to advance our pipeline of targeted alpha therapies, and we are pleased to recently have achieved several critical milestones. For our lead program, FPI-2265, we expect to initiate the Phase 2 portion of the registrational program in metastatic castration-resistant prostate cancer (mCRPC) in the second quarter of this year. Acknowledging the substantial and expanding market for patients in the post-PLUVICTO™ setting we believe FPI-2265, which is positioned to be the first actinium-based PSMA targeted radiopharmaceutical to market, will effectively address a crucial unmet need for patients with progressive disease. We look forward to presenting data from the TATCIST trial at AACR in April.

Dr. Valliant continued, "We also continue to advance our other clinical-stage programs, including the ongoing Phase 1 study of FPI-1434, which has demonstrated a promising safety profile and early evidence of antitumor activity. We expect to provide an update on this program around mid-year 2024. Underpinning our platform, which has produced a robust pipeline of targeted alpha therapies, is our state-of-the-art GMP manufacturing facility now operational and producing clinical doses of FPI-2265. With a strong balance sheet and secured actinium supply, we are well positioned to execute on our commitment of bringing this next generation of radiopharmaceuticals to patients in need."

Corporate Update

On March 19, 2024, Fusion announced the Company has entered into a definitive agreement to be acquired by AstraZeneca. Under the terms of the agreement, AstraZeneca, through a subsidiary, will acquire all of Fusion's outstanding shares pursuant to a plan of arrangement for a price of $21.00 per share in cash at closing plus a non-transferable contingent value right (CVR) of $3.00 per share in cash payable upon the achievement of a specified regulatory milestone.

The upfront cash portion of the consideration represents a transaction value of approximately $2 billion, a 97% premium to Fusion's closing market price of $10.64 on March 18, 2024. Combined, the upfront and maximum potential contingent value payments represent, if achieved, a transaction value of approximately $2.4 billion, a 126% premium to Fusion's closing market price on March 18, 2024. As part of the transaction, AstraZeneca will acquire the cash, cash equivalents and short-term investments on Fusion's balance sheet, which totaled $234 million as of December 31, 2023.

The transaction is expected to close in the second quarter of 2024, subject to customary closing conditions, including the approval of Fusion shareholders and regulatory clearances.

Portfolio Update

FPI-2265: A ^{225}Ac based radiopharmaceutical targeting prostate specific membrane antigen (PSMA) for the treatment of patients with mCRPC.

- In January 2024, the Company announced alignment with the FDA on its Phase 2/3 protocol for FPI-2265 in patients with mCRPC with progressive disease who have previously been treated with a ^{177}Lu-based PSMA radiotherapy. The development plan includes a Phase 2 dose optimization lead-in, which aims to evaluate whether there are added safety and/or efficacy benefits of various dosing regimens in comparison to the validated regimen of 100kBq/kg every eight weeks, expected to be initiated in the second quarter of 2024. This Phase 2 portion is expected to complete enrollment of approximately 60 patients by the end of 2024. Following analysis of the Phase 2 data and an end of Phase 2 meeting to determine the recommended Phase 3 dosing regimen with the FDA, a Phase 3 global registrational trial in approximately 550 patients is expected to begin in 2025.
- The TATCIST trial, which began as an investigator sponsored study, is designed to evaluate FPI-2265 in patients with mCRPC with progressive disease, including patients who are naïve to PSMA-targeted radiopharmaceuticals and

those who have been pre-treated with ^{177}Lu-based PSMA radiopharmaceutical therapy, completed target enrollment of 25-30 patients. The Company announced that interim data will be presented at the upcoming 2024 American Association for Cancer Research (AACR) Annual Meeting in April.
- The Company is also pursuing the opportunity to potentially move this therapeutic candidate into earlier lines of treatment with combinations of FPI-2265 and olaparib. Fusion expects to initiate a combination trial in the first half of this year.

FPI-1434: Targeting insulin growth factor 1 receptor (IGF1R).

- In January 2024, Fusion announced encouraging early findings from Cohort 2 in the cold/hot dosing arm of the ongoing Phase 1, multi-center, open-label clinical trial. The trial is designed to investigate the safety, tolerability, and pharmacokinetics of FPI-1434 in patients with solid tumors expressing IGF-1R. The trial is also designed to establish the maximum tolerated dose for FPI-1434 and the recommended Phase 2 dose. No dose limiting toxicities (DLTs) were observed to date in the 25 kBq/kg dose cohort. Two out of three patients completed the DLT period, and one pancreatic cancer patient discontinued treatment due to disease progression. Evidence of anti-tumor activity was observed in a heavily pre-treated patient with Ewing sarcoma after a single dose and a second patient receiving four cycles of therapy demonstrated stable disease as best response.
- The Company plans to complete and further evaluate results from Cohort 2 and hold a Safety Review Committee (SRC) meeting to evaluate the emerging data. Fusion plans to share more details on the data and the FPI-1434 development program in mid-2024.

FPI-2059: Targeting neurotensin receptor 1 (NTSR1).

- Patient enrollment and dosing is ongoing in the Phase 1, multi-center, open-label clinical trial designed to investigate the safety, tolerability, dosimetry, biodistribution, and pharmacokinetics of FPI-2059 as well as preliminary anti-tumor activity in participants with NTSR1 expressing advanced metastatic solid tumors. Fusion plans to provide guidance on timing for pharmacokinetic, imaging and safety data following early experience with FPI-2059 patient screening and enrollment.

FPI-2068: A bispecific IgG-based targeted alpha therapy (TAT) targeting EGFR-cMET.

- FPI-2068 is currently being evaluated in a Phase 1 study and is being jointly developed with AstraZeneca under the companies' multi-asset collaboration agreement. FPI-2068 is a bispecific IgG-based TAT designed to deliver actinium-225 to various solid tumors that express EGFR-cMET. EGFR and cMET are both validated targets that are co-expressed in multiple tumor types, including head and neck squamous cell carcinoma, non-small cell lung cancer, colorectal cancer, and pancreatic ductal adenocarcinoma. The investigational new drug (IND) application has been cleared and Fusion is currently activating clinical trial sites.

Other Recent Updates

- In January 2024, Fusion announced it had completed validation of its state-of-the-art GMP manufacturing facility and produced the first clinical dose of a TAT. The facility, which has clinical and commercial scale manufacturing capacity, is designed to support the Company's growing pipeline of TATs and is expected to be capable of producing more than 100,000 doses per year.
- In February 2024, Fusion announced that it has entered into a licensing agreement with Heidelberg University and Euratom represented by the European Commission, Joint Research Centre (together, the "Licensors"). The license agreement grants Fusion exclusive worldwide rights to utilize, develop, manufacture and commercialize compounds covered by the patent, which includes ^{225}Ac-PSMA I&T ("FPI-2265") for the treatment of prostate specific membrane antigen (PSMA)-expressing cancers. In addition, Fusion and the Licensors have signed an agreement to settle the parties' dispute related to an inter partes review ("IPR") of the patent which was instituted in August 2023 by the United States Patent and Trademark Board.

Fourth Quarter 2023 Financial Results

- Cash and Investments: As of December 31, 2023, Fusion held cash, cash equivalents and investments of $247.3 million, compared to cash, cash equivalents and investments of $186.6 million as of December 31, 2022. Fusion expects its existing cash, cash equivalents and investments as of December 31, 2023, together with net proceeds from sales of common shares under the Company's at-the-market equity offering program received in January and February 2024 and net proceeds of $14.9 million from a draw down under the Company's existing debt facility in January 2024, will be sufficient to fund operations into the fourth quarter of 2025.
- R&D Expenses: Research and development expenses for the fourth quarter of 2023 were $20.6 million, compared to $17.6 million for the same period in 2022. The increase was primarily due to increased manufacturing-related expenditures, as well as increased personnel-related costs.
- G&A Expenses: General and administrative expenses for the fourth quarter of 2023 were $7.6 million, compared to $6.9 million for the same period in 2022. The increase was primarily due to increased consulting and personnel-related costs.
- Net Loss: For the fourth quarter of 2023, Fusion reported a net loss of $28.2 million, or $0.39 per share, compared with a net loss of $24.6 million, or $0.55 per share, for the same period in 2022.

Upcoming Presentations

Fusion will present data in a poster presentation at the American Association for Cancer Research (AACR) Annual Meeting being held in San Diego, CA, April 5-10, 2024.

- **Title:** Preliminary efficacy and safety results from the (TACIST) trial: A PSMA-directed targeted alpha therapy with FPI-2265 (^{225}Ac-PSMA-I&T) for the treatment of metastatic castration-resistant prostate cancer (mCRPC)
- **Session:** Phase II Clinical Trials 1
- **Date and Time:** Tuesday April 9, 2024 9:00 AM - 12:30 PM PT
- **Location:** Poster Section 49
- **Abstract Number:** CT224

About Fusion

Fusion Pharmaceuticals is a clinical-stage oncology company focused on developing next-generation radiopharmaceuticals as precision medicines. Fusion connects alpha particle emitting isotopes to various targeting molecules in order to selectively deliver the alpha emitting payloads to tumors. Fusion's clinical-stage development portfolio includes lead program, FPI-2265, targeting prostate specific membrane antigen for metastatic castration resistant prostate cancer currently in a Phase 2 trial and novel targeted alpha therapies (TATs) including next-generation antibody drug conjugates (ADCs). Fusion has a collaboration with AstraZeneca to jointly develop novel TATs and combination programs between Fusion's TATs and AstraZeneca's DNA damage response inhibitors and immuno-oncology agents. Fusion has a fully operational Good Manufacturing Practice compliant state-of-the-art radiopharmaceutical manufacturing facility to meet supply demand for the Company's growing pipeline of TATs. The Company has strategic actinium supply agreements with Niowave, Inc. and BWXT Medical.

Forward-Looking Statements

This press release contains "forward-looking statements" for purposes of the safe harbor provisions of The Private Securities Litigation Reform Act of 1995, including but not limited to the statements regarding the future business and financial performance of Fusion Pharmaceuticals Inc. (the "Company"). For this purpose, any statements contained herein that are not statements of historical fact may be deemed forward-looking statements. Without limiting the foregoing, the words "expect," "plans," "anticipates," "intends," "will," and similar expressions are also intended to identify forward-looking statements, as are expressed or implied statements with respect to the risks related to the satisfaction or waiver of the conditions to closing the proposed transaction (including the failure to obtain necessary regulatory, court and Fusion's shareholder approvals) in the anticipated timeframe or at all, including the possibility that the proposed transaction does not close; risks associated with the disruption of management's attention from ongoing business operations due to the proposed transaction; and unknown liabilities and the risk of litigation and/or regulatory actions related to the proposed transaction; the Company's financial condition, liquidity, and potential drug candidates, including any expressed or implied statements regarding the successful development of FPI-2265 or FPI-1434. Actual results may differ materially from those indicated by such forward-looking statements as a result of risks and uncertainties, including but not limited to the following: there can be no guarantees that the Company will advance any clinical product candidate or other component of its potential pipeline in or to the clinic, to the regulatory process or to commercialization; management's expectations could be affected by unexpected patient recruitment delays or regulatory actions or delays; uncertainties relating to, or unsuccessful results of, clinical trials, including additional data relating to the ongoing clinical trials evaluating its product candidates; the Company's ability to obtain additional funding required to conduct its research, development and commercialization activities; changes in the Company's business plan or objectives; competition in general; the Company's ability to obtain, maintain and enforce patent and other intellectual property protection for its product candidates and its discoveries; and the Company partners' ability to advance any technology relating to actinium-225 to development. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. These and other risks which may impact management's expectations are described in greater detail under the heading "Risk Factors" in the Company's quarterly report on Form 10-Q for the period ended September 30, 2023, as filed with the Securities and Exchange Commission (the "SEC") and in any subsequent periodic or current report that the Company files with the SEC. All forward-looking statements reflect the Company's estimates only as of the date of this release (unless another date is indicated) and should not be relied upon as reflecting the Company's views, expectations, or beliefs at any date subsequent to the date of this release. While Fusion may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so, even if the Company's estimates change.

Investors and others should note that Fusion communicates with its investors and the public using the Fusion website, www.fusionpharma.com, including, but not limited to, company disclosures, investor presentations, SEC filings, and press releases. The information that Fusion posts on this website could be deemed to be material information. As a result, Fusion encourages investors, media and others interested to review the information that Fusion posts there on a regular basis.

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FUSION PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED BALANCE SHEET DATA
(In thousands)
(Unaudited)

	December 31,	
	2023	2022
Cash, cash equivalents and investments	$ 247,344	$ 186,635
Total assets	285,836	219,064
Total liabilities	63,356	56,843
Total stockholders' equity	222,480	162,221

FUSION PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Collaboration revenue	$ —	$ 140	$ 2,068	$ 1,461
Operating expenses:				
Research and development	20,647	17,607	70,103	58,895
General and administrative	7,628	6,950	31,197	30,600
Total operating expenses	28,275	24,557	101,300	89,495
Loss from operations	(28,275)	(24,417)	(99,232)	(88,034)
Other income (expense):				
Interest income	2,292	1,308	9,526	2,161
Interest expense	(1,336)	(1,168)	(5,166)	(1,801)
Other income (expense), net	436	(680)	762	(1,775)
Total other income (expense), net	1,392	(540)	5,122	(1,415)
Loss before (provision) benefit for income taxes	(26,883)	(24,957)	(94,110)	(89,449)
Income tax (provision) benefit	(1,296)	340	(787)	1,837
Net loss	$ (28,179)	$ (24,617)	$ (94,897)	$ (87,612)
Unrealized gain (loss) on investments	1,078	787	706	(354)
Comprehensive loss	$ (27,101)	$ (23,830)	$ (94,191)	$ (87,966)
Net loss per share—basic and diluted	$ (0.39)	$ (0.55)	$ (1.45)	$ (2.00)
Weighted-average common shares outstanding—basic and diluted	73,094,249	44,766,314	65,611,923	43,748,549

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https://ir.fusionpharma.com/2024-03-20-Fusion-Pharmaceuticals-Reports-Fourth-Quarter-and-Full-Year-2023-Financial-Results-and-Announces-Clinical-Program-Updates