Fusion Pharmaceuticals Announces Fourth Quarter 2022 Financial Results And Clinical Program Updates

Company recently acquired IND for ongoing Phase 2 clinical trial evaluating ^{225}Ac-PSMA I&T, a small molecule radiopharmaceutical targeting PSMA positive mCRPC

FPI-1434 preliminary Phase 1 data expected in Q2 2023

FPI-1966 and FPI-2059 Phase 1 trials open and recruiting patients

Strong balance sheet with runway into Q1 2025 supports ongoing execution of multiple clinical programs

HAMILTON, ON and BOSTON, March 16, 2023 /PRNewswire/ -- Fusion Pharmaceuticals Inc. (Nasdaq: FUSN), a clinical-stage oncology company focused on developing next-generation radiopharmaceuticals as precision medicines, today announced financial results for the fourth quarter ended December 31, 2022 and provided an update on clinical and corporate developments.

Chief Executive Officer John Valliant, Ph.D. commented, "We have made significant progress towards our goal of bringing the power of targeted alpha therapies (TATs) to patients with cancers of high unmet need, while continuing to build on our radiopharmaceutical capabilities, including actinium supply. We have an exciting and diversified pipeline that includes one Phase 2 and three Phase 1 clinical programs, and our first program under the collaboration with AstraZeneca is progressing towards Phase 1 as planned.

"We believe Fusion is well positioned for further progress in 2023 with preliminary data from the FPI-1434 Phase 1 trial expected in the second quarter of 2023. We are also advancing our newest clinical program, FPI-2265, a small molecule TAT targeting prostate specific membrane antigen (PSMA) for the treatment of metastatic castration-resistant prostate cancer (mCRPC), and are driving towards the opportunity to be first-to-market with an actinium-based PSMA agent to meet a significant and growing need for patients. Our deep pipeline of cancer therapeutic candidates continues to be underpinned by our R&D expertise, and our investments in actinium supply and manufacturing which is a critical element of success in the radiopharmaceutical space. We look forward to providing meaningful updates on our diverse pipeline of TATs in the months ahead."

Portfolio Update

FPI-2265

In February 2023, Fusion acquired an investigational new drug application (IND) for an ongoing Phase 2 clinical trial (the "TATCIST" trial) evaluating ^{225}Ac-PSMA I&T, a small molecule targeting PSMA expressed on prostate cancers. The alpha-emitting radiopharmaceutical being evaluated in the TATCIST trial is now known as FPI-2265.

The TATCIST trial is designed to evaluate 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 radiopharmaceuticals such as PLUVICTO™. Fusion plans to expand the Phase 2 program to additional sites and expects to report data on approximately 20 to 30 patients in the first quarter of 2024.

FPI-1434

In the Phase 1 trial, Fusion is exploring various dose levels of FPI-1434 as well as two dosing regimens: one with FPI-1434 alone, and another in which a small dose of cold antibody (naked IGF-1R antibody without the isotope) is administered prior to each dose of FPI-1434. The Company anticipates reporting safety, pharmacokinetics, and imaging data, including any evidence of anti-tumor activity, from the Phase 1 trial in the second quarter of 2023. Fusion continues to anticipate the initiation of a Phase 1 combination trial with FPI-1434 and KEYTRUDA® (pembrolizumab) to occur six to nine months following determination of the recommended Phase 2 dose of FPI-1434 monotherapy.

FPI-1966

The Phase 1, non-randomized, open-label clinical trial of FPI-1966 in patients with solid tumors expressing FGFR3 is intended to investigate safety, tolerability and pharmacokinetics and to establish the recommended Phase 2 dose. Patient enrollment and dosing is ongoing. The first cohort of the Phase 1 portion of this trial is designed to evaluate various doses of vofatamab ("cold antibody") to assess the impact of pre-dosing on tumor uptake and will inform the dosing regimen for the remainder of the trial. The Company anticipates providing a preliminary clinical data update in 2024.

FPI-2059

The Phase 1, non-randomized, open-label clinical trial of FPI-2059 in patients with solid tumors expressing NTSR1 is intended to investigate safety, tolerability and pharmacokinetics and to establish the recommended Phase 2 dose. Site initiation and patient screening is ongoing. Fusion plans to provide guidance on timelines for the FPI-2059 program following site activations and initial experience with patient screening and patient enrollment.

Recent Updates

- In February, Fusion announced the acquisition of a Phase 2 program for ^{225}Ac-PSMA I&T, a radiopharmaceutical targeting mCRPC now known as FPI-2265. In connection with the acquisition, Fusion announced gross proceeds of $60.0 million in a private placement of its common shares. New and existing investors in the private placement financing include Avidity Partners, Federated Hermes Kaufmann Funds, a fund affiliated with Deerfield Management

Company, L.P., Invus, Perceptive Advisors, and Woodline Master Fund LP.
- In January, Fusion and BWXT Medical announced an actinium-225 partnership to scale supply for developing targeted alpha therapies. Under the preferred partner agreement, BWXT Medical will provide predetermined amounts of Fusion's actinium supply needs at volume-based pricing. Actinium-225 is an alpha-emitting isotope used in targeted alpha therapies (TATs) that combine the isotope with specific tumor-seeking targeting vectors to kill cancer cells while minimizing the impact to healthy tissues.

Fourth Quarter 2022 Financial Results

- Cash and Investments: As of December 31, 2022, Fusion held cash, cash equivalents and investments of $186.6 million, compared to cash, cash equivalents and investments of $220.8 million as of December 31, 2021. Fusion expects its existing cash, cash equivalents and investments as of December 31, 2022, plus the proceeds of the recently announced private placement, will be sufficient to fund operations into the first quarter of 2025.
- Collaboration Revenue: For the fourth quarter of 2022, Fusion recorded $0.1 million of revenue under the AstraZeneca collaboration agreement, compared to $0.6 million for the same period in 2021.
- R&D Expenses: Research and development expenses for the fourth quarter of 2022 were $17.6 million, compared to $11.8 million for the same period in 2021. The increase was primarily due to manufacturing-related milestone payments to our collaboration partners that occurred during the fourth quarter of 2022, as well as increased personnel-related costs.
- G&A Expenses: General and administrative expenses for the fourth quarter of 2022 were $6.9 million, compared to $6.3 million for the same period in 2021. The increase was primarily due to an increase in personnel-related costs.
- Net Loss: For the fourth quarter of 2022, Fusion reported a net loss of $24.6 million, or $0.55 per share, compared with a net loss of $17.2 million, or $0.40 per share, for the same period in 2021.

Presentations at AACR Annual Meeting 2023

Fusion announced that it will present data from three preclinical studies in poster presentations at the American Association for Cancer Research (AACR) Annual Meeting being held in Orlando, Fla., April 14-19, 2023.

> **Title:** NTSR1-targeted alpha therapeutic [Ac-225]-FPI-2059 induces growth inhibition in a preclinical colorectal tumor model
> **Session:** Theranostics and Radionuclides / Pharmacologic Approaches
> **Session Date and Time:** Tuesday April 18, 2023, 1:30 PM - 5:00 PM ET
> **Location:** Poster Section 19
> **Abstract Number:** 5045
>
> **Title:** TEM-1 targeted alpha therapeutic [Ac-225]-FPI-1848 induces regression in pre-clinical sarcoma xenograft models
> **Session:** Theranostics and Radionuclides / Pharmacologic Approaches
> **Session Date and Time:** Tuesday April 18, 2023, 1:30 PM - 5:00 PM ET
> **Location:** Poster Section 19
> **Abstract Number:** 5041
>
> **Title:** EGFRvIII-targeted alpha therapy shows significant therapeutic efficacy as both a single-agent and in combination with standard of care against preclinical GBM models
> **Session:** Late-Breaking Research: Experimental and Molecular Therapeutics 3
> **Session Date and Time:** Wednesday April 19, 2023, 9:00 AM - 12:30 PM ET
> **Location:** Poster Section 35
> **Abstract Number:** LB313

The posters will be available on Fusion's website following the presentations. For more details about the AACR Annual Meeting, please visit: https://www.aacr.org/meeting/aacr-annual-meeting-2023/.

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 to selectively deliver the alpha emitting payloads to tumors. Fusion's clinical portfolio includes: FPI-2265 targeting prostate specific membrane antigen (PSMA) for metastatic castration resistant prostate cancer currently in a Phase 2 trial; FPI-1434 targeting insulin-like growth factor 1 receptor currently in a Phase 1 trial; FPI-1966, targeting the fibroblast growth factor receptor 3 (FGFR3), currently in a Phase 1 trial; and FPI-2059, a small molecule targeting neurotensin receptor 1 (NTSR1), currently in a Phase 1 trial. In addition to a robust proprietary pipeline, Fusion has a collaboration with AstraZeneca to jointly develop novel targeted alpha therapies (TATs) and combination programs between Fusion's TATs and AstraZeneca's DNA Damage Response Inhibitors (DDRis) and immuno-oncology agents. Fusion has also entered into a collaboration with Merck to evaluate FPI-1434 in combination with Merck's KEYTRUDA® (pembrolizumab) in patients with solid tumors expressing IGF-1R. To support Fusion's growing pipeline of TATs, the company has signed strategic actinium supply agreements with TRIUMF, 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 Fusion Pharmaceuticals Inc.'s (the "Company") future business and financial performance. 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 Company's potential drug candidates, including any expressed or implied statements regarding the successful development of its product candidates. 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 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; the ability of the Company to attract and retain qualified personnel; competition in general; and the Company's ability to obtain, maintain and enforce patent and other intellectual property protection for its product candidates and its discoveries. 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 quarter ended September 30, 2022, as filed with 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.

Contact:

Amanda Cray
Senior Director of Investor Relations & Corporate Communications
(617) 967-0207
cray@fusionpharma.com

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

	December 31,	
	2022	**2021**
Cash, cash equivalents and investments	$ 186,635	$ 220,782
Total assets	219,064	252,271
Total liabilities	56,843	20,815
Total stockholders' equity	162,221	231,456

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,	
	2022	**2021**	**2022**	**2021**
Collaboration revenue	$ 140	$ 594	$ 1,461	$ 1,
Operating expenses:				
Research and development	17,607	11,811	58,895	56,
General and administrative	6,950	6,336	30,600	27,
Total operating expenses	24,557	18,147	89,495	83,
Loss from operations	(24,417)	(17,553)	(88,034)	(82,
Other (expense) income:				
Interest income	1,309	81	2,161	
Interest expense	(1,169)	—	(1,801)	
Other (expense) income, net	(680)	63	(1,775)	
Total other (expense) income, net	(540)	144	(1,415)	
Loss before benefit for income taxes	(24,957)	(17,409)	(89,449)	(81,
Income tax benefit	340	173	1,837	
Net loss	$ (24,617)	$ (17,236)	$ (87,612)	$ (81,
Unrealized gain (loss) on investments	787	(178)	(354)	(
Comprehensive loss	$ (23,830)	$ (17,414)	$ (87,966)	$ (81,
Net loss per share—basic and diluted	$ (0.55)	$ (0.40)	$ (2.00)	$ (1
Weighted-average common shares outstanding—basic and diluted	44,766,314	43,066,953	43,748,549	42,598,

SOURCE Fusion Pharmaceuticals Inc.
