# Fusion Pharmaceuticals Announces Third Quarter 2023 Financial Results And Clinical Program Updates

***Preliminary data for FPI-2265 ($^{225}$Ac-PSMA I&T) in approximately 20 to 30 patients on track for Q1 2024***

***Data from Cohort 2 of the FPI-1434 Phase 1 study anticipated around year-end 2023***

***FPI-2068, a bispecific IgG-based targeted alpha therapy for solid tumors that co-express EGFR-cMET, developed in collaboration with AstraZeneca, demonstrates strong preclinical anti-tumor activity***

***Fusion's state-of-the-art radiopharmaceutical manufacturing facility on track to begin producing clinical doses in early 2024***

HAMILTON, ON and BOSTON, Nov. 7, 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 third quarter ended September 30, 2023 and provided an update on clinical and corporate developments.

Chief Executive Officer John Valliant, Ph.D., commented, "In 2023, Fusion has focused on transitioning to a later stage company leading the development of next-generation radiopharmaceuticals that leverage the potency and precision of alpha-emitting particles. We believe in the potential of our diversified pipeline of targeted alpha therapy (TAT) programs, our AstraZeneca collaboration, multiple actinium supply partnerships and our proprietary, state-of-the-art radiopharmaceutical manufacturing facility to produce innovative therapies for patients with multiple cancer types and create significant value.

Dr. Valliant continued, "In the third quarter, we advanced patient enrollment in our Phase 2 clinical trial of FPI-2265, a small molecule-based TAT targeting prostate specific membrane antigen (PSMA) for the treatment of metastatic castration-resistant prostate cancer (mCRPC) which is positioned to be the first actinium-based PSMA TAT to market. We are on track to report data on approximately 20 to 30 patients in the first quarter of 2024. Following encouraging recently reported data and continued momentum in the PSMA-targeted radiopharmaceuticals space, we are increasingly excited about the substantial market and patient need that FPI-2265 could address. We are also on track to share data from the second cohort in our Phase 1 study of FPI-1434 in patients with solid tumors expressing IGF-1R around the end of this year. In addition, we were pleased to share preclinical data at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics on FPI-2068, a jointly developed TAT with AstraZeneca targeting solid tumors expressing EGFR-cMET, which showed anti-tumor efficacy and confirmatory evidence of FPI-2068's mechanism of action. These data were the basis for our investigational new drug (IND) clearance earlier this year, and we look forward to progressing the program into the previously announced Phase 1 clinical study.

"Finally, with manufacturing and supply chain expertise as a core foundation of Fusion, we are pleased with the progress in validation of our proprietary GMP radiopharmaceutical manufacturing facility, which we expect will be capable of producing up to 100,000 doses of drug per year. We look forward to beginning to produce clinical doses early in 2024 and are confident in the diversified supply chain we have invested in which supports our ability to deliver therapies to patients in need."

**Portfolio Update**

***FPI-2265***

In February 2023, Fusion acquired an 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 expects to report data on approximately 20 to 30 patients in the first quarter of 2024 including safety and efficacy results (PSA50 responses, ORR, and rPFS).

***FPI-1434***

The Phase 1, multi-center, open-label clinical 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. Interim Phase 1 data were presented at the SNMMI Annual Meeting in June 2023. Three patients were dosed in Cohort 1 at a dose of 15 kBq/kg following pre-administration of cold antibody. In this first cohort, cold/hot dosing was observed to be safe with no treatment-related serious adverse events (SAEs) or dose limiting toxicities (DLTs). Results demonstrated pre-administration of cold antibody improved tumor uptake while also reducing hematological toxicity observed in the hot only dosing arm, potentially enhancing the therapeutic index. When normalized to 15 kBq/kg, the average lesion absorbed dose and dose/volume in the cold/hot arm were nearly double the level compared to hot only. Further, the 15 kBq/kg cold/hot dosing arm showed comparable systemic exposure to approximately 40 kBq/kg of a hot only dose but with an improved hematological profile as measured by changes in platelet count.

Fusion is currently enrolling Cohort 2 in the cold/hot dosing regimen at 25 kBq/kg. The Company expects to report data from this cohort around year-end 2023.

***FPI-2059***

The Phase 1, multi-center, open-label clinical trial is 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. Patient enrollment and dosing are ongoing. 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***

Fusion announced FDA clearance of IND applications for [$^{225}$Ac]-FPI-2068 (FPI-2068) and corresponding imaging analogue [$^{111}$In]-FPI-2107 (FPI-2107). Fusion is jointly developing FPI-2068 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 and 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.

**Recent News**

- In October, Fusion announced the appointment of Jeremy Bender, Ph.D., M.B.A., Teresa Bitetti, M.B.A. and David Meek to its Board of Directors.
- In October, Fusion presented preclinical data on FPI-2068 at the 2023 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, held October 11-15 in Boston.

**Third Quarter 2023 Financial Results**

- Cash and Investments: As of September 30, 2023, Fusion held cash, cash equivalents and investments of $207.3 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 September 30, 2023 will be sufficient to fund operations into the second quarter of 2025.
- Collaboration Revenue: For the third quarter of 2023, Fusion recorded $2.0 million of revenue under the AstraZeneca collaboration agreement, compared to $0.2 million for the same period in 2022.
- R&D Expenses: Research and development expenses for the third quarter of 2023 were $14.6 million, compared to $16.6 million for the same period in 2022. The decrease was primarily due to a decrease in FPI-1966 program-related activities as a result of the Company ceasing clinical development for the program and a decrease in manufacturing-related costs for our Phase 1 clinical trial of FPI-1434, partially offset by program expenses for our Phase 2 clinical trial of FPI-2265.
- G&A Expenses: General and administrative expenses for the third quarter of 2023 were $6.8 million, compared to $7.4 million for the same period in 2022. The decrease was primarily due to a decrease in corporate and patent related legal expenses.
- Net Loss: For the third quarter of 2023, Fusion reported a net loss of $17.3 million, or $0.25 per share, compared with a net loss of $24.0 million, or $0.55 per share, for the same period in 2022.

**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; 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. The Company recently received IND clearance for FPI-2068, the first novel TAT under the collaboration, which targets EGFR-cMET. 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. 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, regulatory actions or delays, or changes in the competitive landscape; uncertainties relating to, or unsuccessful results of, clinical trials, including additional data relating to the ongoing clinical trials evaluating its product candidates; and competition in general. 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 June 30, 2023, 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.

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

| | September 30, 2023 | December 31, 2022 |
|---|---|---|
| Cash, cash equivalents and investments | $ 207,279 | $ 186,635 |
| Total assets | 253,377 | 219,064 |
| Total liabilities | 64,906 | 56,843 |
| Total stockholders' equity | 188,471 | 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 September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2023 | 2022 | 2023 | 2022 |
| Collaboration revenue | $ 2,006 | $ 166 | $ 2,068 | $ 1, |
| Operating expenses: | | | | |
| Research and development | 14,585 | 16,551 | 49,456 | 41, |
| General and administrative | 6,810 | 7,420 | 23,569 | 23, |
| Total operating expenses | 21,395 | 23,971 | 73,025 | 64, |
| Loss from operations | (19,389) | (23,805) | (70,957) | (63, |
| Other income (expense): | | | | |
| Interest income | 2,818 | 572 | 7,234 | |
| Interest expense | (1,325) | (382) | (3,830) | ( |
| Other income (expense), net | 391 | (1,159) | 326 | (1, |
| Total other income (expense), net | 1,884 | (969) | 3,730 | ( |
| Loss before benefit for income taxes | (17,505) | (24,774) | (67,227) | (64, |
| Income tax benefit | 253 | 761 | 509 | 1, |
| Net loss | $ (17,252) | $ (24,013) | $ (66,718) | $ (62, |
| Unrealized loss on investments | (589) | (196) | (372) | (1, |
| Comprehensive loss | $ (17,841) | $ (24,209) | $ (67,090) | $ (64, |
| Net loss per share—basic and diluted | $ (0.25) | $ (0.55) | $ (1.06) | $ (1 |
| Weighted-average common shares outstanding—basic and diluted | 69,050,107 | 43,683,738 | 63,090,406 | 43,405, |

SOURCE Fusion Pharmaceuticals