Fusion Pharmaceuticals Announces First Quarter 2023 Financial Results And Clinical Program Updates

FPI-2265 (Ac-PSMA I&T) program enrolling patients and on track for Q1 2024 update

Preliminary Phase 1 data for FPI-1434 expected to be reported at the Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting

Clinical progress across TAT pipeline continues; first patient dosed in Phase 1 study of FPI-2059; FPI-2068, a bispecific TAT jointly developed with AZ, IND has cleared

FPI-1966 program to be discontinued due to portfolio prioritization decision

$20.0 million private placement financing with Federated Hermes Kaufmann Funds extends cash runway into Q2 2025

HAMILTON, ON and BOSTON, May 11, 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 first quarter ended March 31, 2023 and provided an update on clinical and corporate developments.

Chief Executive Officer John Valliant, Ph.D. commented, "In the first quarter, we further diversified our pipeline of alpha-emitting radiopharmaceuticals while progressing our multiple ongoing clinical programs. FPI-2265, our recently acquired small molecule-based radiopharmaceutical targeting prostate specific membrane antigen (PSMA) for the treatment of metastatic castration-resistant prostate cancer (mCRPC), holds the potential to be the first-to-market actinium-based PSMA agent to meet a significant and growing need for patients.

"Continuing our mission to build out a multi-asset portfolio, we received investigational new drug (IND) clearance from the FDA for FPI-2068, a bispecific antibody targeting EGFR-cMET, and the first candidate nominated under our broad collaboration agreement with AstraZeneca. We are also pleased that the first patient has been dosed in the Phase 1 study of FPI-2059 targeting neurotensin receptor 1 (NTSR1). These are both important milestones as we demonstrate the potential to develop novel targets for radiopharmaceuticals that reach beyond prostate and neuroendocrine cancers.

"In parallel with the progress across our pipeline, we are actively growing our actinium supply and manufacturing capabilities to ensure our ability to execute on our multiple clinical programs, most recently through our partnership with BWXT Medical and the recent opening of Fusion's cGMP targeted alpha therapy (TAT) manufacturing facility," Dr. Valliant concluded.

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 in 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.

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 ("hot only"), 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 ("cold/hot"). The Company anticipates reporting a clinical data update from the Phase 1 trial in a poster presentation at the Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting on Tuesday, June 27th from 12:30 – 2:00pm CT, followed by a webcast investor presentation (details to be provided).

Fusion expects to report molecular imaging, safety, and pharmacokinetics (PK) for both the hot only and

cold/hot dosing regimens. Previously reported results from the cold antibody sub-study (CASS), in conjunction with preclinical toxicity studies, demonstrated improved biodistribution with the cold/hot regimen, potentially leading to increased tumor absorbed dose compared to healthy tissues. As a result, Fusion has prioritized patient dosing with the cold/hot regimen. The Company expects to report the data across all dose escalation cohorts, including the first cohort (n=3) of the cold/hot regimen, which began after the hot only regimen and the completion of the CASS.

Chief Medical Officer Dmitri Bobilev, M.D. commented, "As the first industry study of its kind, the FPI-1434 Phase 1 clinical trial has produced key learnings about the development of antibody-based targeted alpha therapies. Given the encouraging safety, dosimetry and PK results suggesting an improved therapeutic index using the cold/hot administration, this method has become the preferred way of administration of FPI-1434 going forward. The study is currently enrolling patients in the second cohort of the cold/hot dose arm of the study."

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.

FPI-2068

In April 2023, Fusion announced U.S. Food and Drug Administration (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 targeted alpha therapy (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. Fusion plans to provide additional guidance on timelines for the FPI-2068 program following initial experience with patient screening to better predict the cadence of patient enrollment.

FPI-1966

Fusion announced that it is discontinuing the Phase 1, non-randomized, open-label clinical trial of FPI-1966 in patients with solid tumors expressing FGFR3. As part of a portfolio prioritization decision to focus resources on the Company's lead program, FPI-2265, and assessment of the relative portfolio value contributions of our clinical assets, Fusion no longer plans to pursue development of FPI-1966.

Recent Updates

- In May, Fusion announced the opening of its state-of-the-art radiopharmaceutical manufacturing facility. The 27,000 square foot good manufacturing practice (GMP) compliant facility, which is located adjacent to the Company's research and development labs, has clinical and commercial manufacturing scale capabilities designed to support the Company's growing pipeline of targeted alpha therapies (TATs). The facility is expected to be fully operational in 2024.
- In April, Fusion announced the clearance of investigational new drug (IND) applications for [^{225}Ac]-FPI-2068 (FPI-2068) and corresponding imaging analogue [^{111}In]-FPI-2107 (FPI-2107) to the U.S. Food and Drug Administration (FDA).

Private Placement Financing

Fusion has agreed to sell an aggregate of approximately 4.8 million common shares to Federated Hermes Kaufmann Funds in a private placement in public equity financing (the "Offering"). The Offering is expected to result in gross proceeds to Fusion of approximately $20.0 million, before deducting offering expenses payable by Fusion.

Pursuant to the terms of the securities purchase agreement, at the closing of the Offering, Fusion will issue approximately 4.8 million of its common shares at a price of $4.18 per share. The closing of the Offering is subject to customary closing conditions and is expected to occur on or about May 15, 2023.

Upon the closing of the Offering, Fusion anticipates having sufficient cash, cash equivalents, and investments to fund its planned operating expenses and capital expenditure requirements into the second quarter of 2025.

The offer and sale of the foregoing shares are being made in a transaction not involving a public offering and have not been registered under the Securities Act of 1933, as amended (the "Securities Act"). The shares being

issued in the private placement may not be offered or sold in the United States or Canada absent registration or pursuant to an exemption from the registration requirements of the Securities Act and applicable state securities laws or pursuant to an exemption from the prospectus requirements of Canadian securities laws, as applicable. Fusion has agreed to file a registration statement with the Securities and Exchange Commission covering the resale of the shares acquired by the investors in the private placement.

This press release does not constitute an offer to sell or the solicitation of an offer to buy the securities, nor shall there be any sale of the securities in any state in which such offer or sale would be unlawful prior to the registration or qualification under the securities laws of such state. Any offering of the shares under the resale registration statement will only be by means of a prospectus.

First Quarter 2023 Financial Results

- Cash and Investments: As of March 31, 2023, Fusion held cash, cash equivalents and investments of $221.2 million, compared to cash, cash equivalents and investments of $186.6 million as of December 31, 2022. The increase in cash, cash equivalents and investments was attributable to $60.0 million of gross proceeds received from a private placement financing that closed in February 2023.
- Collaboration Revenue: For the first quarter of 2023, Fusion recorded less than $0.1 million of revenue under the AstraZeneca collaboration agreement, compared to $0.6 million for the same period in 2022.
- R&D Expenses: Research and development expenses for the first quarter of 2023 were $15.9 million, compared to $12.7 million for the same period in 2022. The increase was primarily due to costs associated with the acquisition of the FPI-2265 Phase 2 clinical trial during the first quarter of 2023, as well as an increase in personnel-related costs.
- G&A Expenses: General and administrative expenses for the first quarter of 2023 were $9.0 million, compared to $8.4 million for the same period in 2022. The increase was primarily due to increased corporate and patent-related legal expenses, as well as an increase in personnel-related costs.
- Net Loss: For the first quarter of 2023, Fusion reported a net loss of $24.3 million, or $0.45 per share, compared with a net loss of $19.9 million, or $0.46 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; 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. 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 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, 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; the closing of the Offering; 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-K for the year ended December 31, 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.

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

	March 31, 2023	December 31, 2022
Cash, cash equivalents and investments	$ 221,182	$ 186,635
Total assets	266,551	219,064
Total liabilities	65,718	56,843
Total stockholders' equity	200,833	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 March 31,	
	2023	2022
Collaboration revenue	$ 28	$ 585
Operating expenses:		
Research and development	15,877	12,661
General and administrative	9,006	8,449
Total operating expenses	24,883	21,110
Loss from operations	(24,855)	(20,525)
Other income (expense):		
Interest income	1,921	83
Interest expense	(1,223)	—
Other (expense) income, net	(145)	478
Total other income, net	553	561
Loss before benefit for income taxes	(24,302)	(19,964)
Income tax benefit	11	55
	$ (24,291)	$ (19,909)

Net loss		
Unrealized gain (loss) on investments	384	(463)
Comprehensive loss	$ (23,907)	$ (20,372)
Net loss per share—basic and diluted	$ (0.45)	$ (0.46)
Weighted-average common shares outstanding—basic and diluted	53,775,985	43,170,076

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