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

FPI-2265 (Ac-PSMA I&T) IND transferred to Fusion; program is enrolling patients and on track for Q1 2024 update

Preliminary clinical data presented at the Society of Nuclear Medicine and Molecular Imaging (SNMMI) from the Phase 1 Trial of FPI-1434 showed the cold/hot dosing regimen demonstrated potential to improve therapeutic index; Cohort 2 in the cold/hot dosing regimen enrolling, with data expected around year-end

Opened state-of-the art 27,000 square foot manufacturing facility for production of targeted alpha therapies

HAMILTON, ON and BOSTON, Aug. 8, 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 second quarter ended June 30, 2023 and provided an update on clinical and corporate developments.

Chief Executive Officer John Valliant, Ph.D. commented, "In the second quarter, we achieved progress across our clinical pipeline of targeted alpha therapies (TATs). Patient enrollment is ongoing for the 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), and we are on track to report data in the first quarter of 2024. Patient enrollment is also ongoing in the Phase 1 study of FPI-2059 targeting neurotensin receptor 1 (NTSR1). Additionally, the U.S. Food and Drug Administration (FDA) cleared the Investigational New Drug (IND) application for FPI-2068, a bispecific TAT jointly developed with AstraZeneca for the treatment of various solid tumors that express EGFR-cMET.

Dr. Valliant continued, "We are encouraged by the interim safety, dosimetry and PK data from the dose escalation portion of the Phase 1 trial of FPI-1434 in patients with solid tumors expressing IGF-1R presented at the Society for Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting in June. These data showed pre-administration of cold antibody has the potential to significantly enhance the therapeutic index by driving more active drug to tumor sites with an improved safety profile compared to hot-only dosing, reinforcing our belief that targeted alpha therapies (TATs) could be next generation antibody drug conjugates (ADCs) for a broad array of tumor types in areas of high unmet medical need. We are evaluating the cold/hot regimen at the next dose level in Cohort 2 and look forward to sharing data around the end of this year."

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. Following completion of the acquisition from RadioMedix, the IND was transferred to Fusion. 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

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. As part of the precision medicine approach, prior to receiving the therapeutic injection of FPI-1434, patients are administered an indium-111 imaging analogue, [^{111}In]-FPI-1547 (FPI-1547). The images collected are used to confirm the presence of tumor uptake and ensure that estimated radiation doses to organs and tissues are below protocol-specified safety limits.

Following results from an imaging sub-study evaluating pre-administration of cold antibody prior to each dose of FPI-1547 that demonstrated a favorable gain in tumor lesion uptake versus normal tissue, the Company

amended the Phase 1 trial protocol to evaluate both the hot only and cold/hot dosing regimens. 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. Based on these results, Fusion has discontinued the hot-only dosing portion of the study and 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

In April 2023, 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 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. 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.

Recent News

- In June, Fusion presented at SNMMI interim data from the Phase 1 Trial of FPI-1434 in patients with solid tumors expressing IGF-1R.
- 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 IND applications for FPI-2068 and corresponding imaging analogue FPI-2107 to the FDA.

Second Quarter 2023 Financial Results

- Cash and Investments: As of June 30, 2023, Fusion held cash, cash equivalents and investments of $226.5 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 June 30, 2023 will be sufficient to fund operations into the second quarter of 2025.
- Collaboration Revenue: For the second 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 second quarter of 2023 were $19.0 million, compared to $12.1 million for the same period in 2022. The increase was primarily due to costs associated with the Phase 2 clinical trial of FPI-2265, as well as the wind down of FPI-1966 program-related activities and study close out costs, and an increase in personnel-related costs.
- G&A Expenses: General and administrative expenses for the second quarter of 2023 and 2022 each were $7.8 million.
- Net Loss: For the second quarter of 2023, Fusion reported a net loss of $25.2 million, or $0.38 per share, compared with a net loss of $19.1 million, or $0.44 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 year ended March 31, 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)

	June 30, 2023	December 31, 2022
Cash, cash equivalents and investments	$ 226,519	$ 186,635
Total assets	268,286	219,064
Total liabilities	65,325	56,843
Total stockholders' equity	202,961	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 June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Collaboration revenue	$ 34	$ 570	$ 62	$ 1,155
Operating expenses:				
Research and development	18,994	12,076	34,871	24,737
General and administrative	7,753	7,781	16,759	16,230
Total operating expenses	26,747	19,857	51,630	40,967
Loss from operations	(26,713)	(19,287)	(51,568)	(39,812)
Other income (expense):				
Interest income	2,495	198	4,416	281
Interest expense	(1,282)	(251)	(2,505)	(251)
Other income (expense), net	80	(414)	(65)	64
Total other income (expense), net	1,293	(467)	1,846	94
Loss before benefit for income taxes	(25,420)	(19,754)	(49,722)	(39,718)
Income tax benefit	245	681	256	736
Net loss	$ (25,175)	$ (19,073)	$ (49,466)	$ (38,982)
Unrealized (loss) gain on investments	(167)	(482)	217	(945)
Comprehensive loss	$ (25,342)	$ (19,555)	$ (49,249)	$ (39,927)
Net loss per share—basic and diluted	$ (0.38)	$ (0.44)	$ (0.82)	$ (0.90)
Weighted-average common shares outstanding—basic and diluted	66,277,279	43,357,240	60,061,166	43,264,175

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https://ir.fusionpharma.com/2023-08-08-Fusion-Pharmaceuticals-Announces-Second-Quarter-2023-Financial-Results-and-Clinical-Program-Updates