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

Phase 1 data for FPI-1434 anticipated to be reported in the second half of 2022

Company continues to build a diversified pipeline of TATs and advance manufacturing and actinium supply chain capabilities

HAMILTON, ON & BOSTON, May 10, 2022 /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, 2022 and provided an update on clinical and corporate developments.

Chief Executive Officer John Valliant, Ph.D. commented, "We entered 2022 with strong momentum using our platform technology and research engine to build a diverse pipeline of targeted alpha therapies (TATs) from different classes of targeting molecules to pursue validated cancer targets, all while continuing to maintain sharp focus on actinium supply and manufacturing capabilities. Our top priority continues to be executing on our Phase 1 clinical studies. We are progressing our Phase 1 trial of FPI-1434 and look forward to reporting data from the study in the second half of this year. In addition, we continue to expect to dose our first patient in the Phase 1 study of FPI-1966 in the second quarter of this year. In parallel, we are advancing additional programs with the investigational new drug application (IND) filing for FPI-2059 anticipated in the second quarter of 2022 and the first novel TAT under our collaboration agreement with AstraZeneca in IND-enabling studies."

Portfolio Update

FPI-1434

In the Phase 1 study, Fusion is exploring various dosing 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 continues to anticipate reporting Phase 1 safety, pharmacokinetics, and imaging data, including any clinical efficacy, and details on the dosing regimen, in the second half of 2022. Fusion continues to anticipate the initiation of a Phase 1 combination study 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, intended to investigate safety, tolerability and pharmacokinetics and to establish the recommended Phase 2 dose, has been initiated. Fusion expects to dose the first patient in the second quarter of 2022 and expects preliminary pharmacokinetic, imaging and safety data from the first patient cohort in the second quarter of 2023.

FPI-2059

FPI-2059 is a small molecule radioconjugate in development as a targeted alpha therapy for various solid tumors, including neuroendocrine differentiated (NED) prostate cancer. The molecule targets neurotensin receptor 1 (NTSR1), a promising target for cancer treatment, that is overexpressed in several solid tumors. FPI-2059 combines Ipsen's IPN-1087 (previously studied in a Phase 1 clinical trial as a beta-emitting radiopharmaceutical), which Fusion acquired in 2021, with actinium-225. Fusion continues to anticipate submitting an IND application for FPI-2059 in the second quarter of 2022.

Recent Updates

- In April, Fusion entered into a loan and security agreement with Oxford Finance LLC, under which Oxford is providing term loans to Fusion in an aggregate principal amount of up to $75.0 million. The Company plans to use the proceeds of the term loans for working capital and general corporate purposes. The loan agreement provides a term loan commitment of $50.0 million in two potential tranches: (i) a $25.0 million Term A loan facility, with $10.0 million funded on the closing date and the remaining $15.0 million to be funded at the request of the Company on a one-time basis at any time prior to April 4, 2023; and (ii) a $25.0 million Term B loan facility to be funded at the request of the Company, no later than June 30, 2023. Both term loans have a maturity date of April 1, 2027. The loan agreement also provides access to an

additional Term C loan facility in the amount of $25.0 million, funded at Oxford's discretion. The debt facility strengthens Fusion's balance sheet, provides additional financing flexibility and extends the Company's cash runway into the first quarter of 2024.

First Quarter 2022 Financial Results

- **Cash and Investments:** As of March 31, 2022, Fusion held cash, cash equivalents and investments of $206.7 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 March 31, 2022, together with the proceeds available under the first tranche of the loan and security agreement with Oxford Finance LLC executed in April 2022, will be sufficient to fund operations into the first quarter of 2024.
- **Collaboration Revenue:** For the first quarter of 2022, Fusion recorded $0.6 million of revenue under the AstraZeneca collaboration agreement.
- **R&D Expenses:** Research and development expenses for the first quarter of 2022 were $12.7 million, compared to $10.7 million for the same period in 2021. The increase was primarily due to an increase in direct costs related to our FPI-1434 and FPI-1966 product candidates, specifically continued expenditures related to our Phase 1 clinical trials as well as preclinical research and manufacturing costs.
- **G&A Expenses:** General and administrative expenses for the first quarter of 2022 were $8.4 million, compared to $7.0 million for the same period in 2021. The increase was primarily due to an increase in personnel-related and corporate expenses, partially offset by a decrease in professional fees.
- **Net Loss:** For the first quarter of 2022, Fusion reported a net loss of $19.9 million, or $0.46 per share, compared with a net loss of $17.5 million, or $0.42 per share, for the same period in 2021.

Upcoming Events

- Fusion will participate in a fireside chat and panel presentation at the Guggenheim Securities Radiopharmaceutical Day on May 17, 2022 in New York. The fireside chat will be available via webcast on Fusion's website at https://ir.fusionpharma.com/events-webcasts.
- Fusion will present at the Jefferies Healthcare Conference on Friday, June 10, 2022 at 10:30am ET in New York.
- Fusion plans to present imaging data from the "cold antibody sub study" evaluating pre-administration of cold antibody (naked antibody without the isotope) prior to administration of the hot antibody (antibody with the isotope) in the Phase 1 study of FPI-1434 at the upcoming Society of Nuclear Medicine and Molecular Imaging (SNMMI) 2022 Annual Meeting taking place in Vancouver, British Columbia. The presentation titled, "Impact of Pre-Administration of Anti-IGF-1R Antibody FPI-1175 on the Dosimetry, Tumor Uptake, and Pharmacokinetics of the IGF-1R Targeted Theranostic Imaging Agent [^{111}In]-FPI-1547 in Patients with Solid Tumors" will be presented on June 14, 2022.

Impact of COVID-19

Fusion is experiencing material delays in patient recruitment, enrollment and study site initiations as a result of continued resourcing issues related to COVID-19 at trial sites.

There also remains uncertainty relating to the trajectory of the pandemic, hospital staffing and resource issues, and whether they may cause further delays in patient study recruitment. The impact of related responses and disruptions caused by the COVID-19 pandemic may result in further difficulties or delays in initiating, enrolling, conducting or completing the planned and ongoing trials and the incurrence of unforeseen costs as a result of disruptions in clinical supply or preclinical study or clinical trial delays. The continued impact of COVID-19 on results will largely depend on future developments, which are highly uncertain and cannot be predicted with confidence.

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 lead program, FPI-1434 targeting insulin-like growth factor 1 receptor, is currently in a Phase 1 clinical trial. The pipeline includes FPI-1966, targeting the fibroblast growth factor receptor 3 (FGFR3), advancing to a Phase 1 study following the investigational new drug (IND) clearance; and FPI-2059, a small molecule targeting neurotensin receptor 1 (NTSR1). 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 Repair 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. Fusion and Hamilton, Ontario-based McMaster University are building a current Good Manufacturing Practice (GMP) compliant radiopharmaceutical manufacturing facility designed to support manufacturing of the Company's growing pipeline of TATs.

Forward-Looking Statements
Certain statements set forth in this press release constitute "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements can be identified by terms such as "believes," "expects," "plans," "potential," "would" or similar expressions and the negative of those terms. Such forward-looking statements involve substantial risks and uncertainties that could cause Fusion's research and clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the drug development process, including Fusions' programs' early stage of clinical development, the ability to move in-licensed targets forward in the clinic, the process of designing and conducting preclinical and clinical trials, the regulatory approval processes, the timing of regulatory filings, the challenges associated with manufacturing drug products generally and radiopharmaceuticals specifically, Fusion's ability to successfully establish, protect and defend its intellectual property, risks relating to business interruptions resulting from the coronavirus (COVID-19) disease outbreak or similar public health crises and other matters that could affect the sufficiency of existing cash to fund operations. Fusion undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of the company in general, see Fusion's quarterly report on Form 10-K for the year ended December 31, 2021, which is available on the Securities and Exchange Commission's website at www.sec.gov and Fusion's website at www.fusionpharma.com.

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, except share amounts)
(Unaudited)

	March 31, 2022	December 31, 2021
Cash, cash equivalents and investments	$ 206,713	$ 220,782
Total assets	235,960	252,271
Total liabilities	20,534	20,815
Total stockholders' equity	215,426	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 March 31,	
	2022	2021
Collaboration revenue	$ 585	$ —
Operating expenses:		
Research and development	12,661	10,716
General and administrative	8,449	6,964
Total operating expenses	21,110	17,680
Loss from operations	(20,525)	(17,680)
Other income (expense):		
Interest income, net	83	96
Other income, net	478	48

Total other income (expense), net	561	144
Loss before benefit for income taxes	(19,964)	(17,536)
Income tax benefit	55	7
Net loss	$ (19,909)	$ (17,529)
Unrealized (loss) gain on investments	(463)	239
Comprehensive loss	$ (20,372)	$ (17,290)
Net loss per share—basic and diluted	$ (0.46)	$ (0.42)
Weighted-average common shares outstanding—basic and diluted	43,170,076	41,784,269

SOURCE Fusion Pharmaceuticals Inc.

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https://ir.fusionpharma.com/2022-05-10-Fusion-Pharmaceuticals-Announces-First-Quarter-2022-Financial-Results-and-Clinical-Program-Updates