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

FPI-2059 IND cleared by FDA; Clinical portfolio expanded to include small molecule-based targeted alpha therapy

Data supporting ongoing evaluation of cold antibody pre-administration dosing regimen in Phase 1 study of FPI-1434 presented at SNMMI 2022 Annual Meeting

Company strengthens actinium-225 supply chain capabilities following collaboration and supply agreement with Niowave, Inc.

HAMILTON, ON and BOSTON, Aug. 9, 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 second quarter ended June 30, 2022 and provided an update on clinical and corporate developments.

Chief Executive Officer John Valliant, Ph.D. commented, "We are pleased with the recent FDA clearance of our FPI-2059 investigational new drug (IND) application and the initiation of the Phase 1 clinical study demonstrating our ability to progress into the clinic targeted alpha therapies based on various targeting molecules. The FPI-2059 small molecule targeting NTSR1 has the potential to address several solid tumor indications, including neuroendocrine differentiated prostate, colorectal and pancreatic cancers, for which there is substantial unmet clinical need. Further, we are encouraged by the imaging data we presented at the SNMMI 2022 Annual Meeting that showed pre-administration of cold antibody with FPI-1434 increased tumor binding with a good safety profile."

Dr. Valliant continued, "With three clinical programs and our multi-program partnership with AstraZeneca, we are committed to building a fully integrated radiopharmaceutical organization, marked most recently by our actinium-225 collaboration and supply agreement with Niowave. The agreement provides access to a pre-determined percentage of Niowave's capacity, access to any excess supply, and the option to invest in future production facilities. This agreement, together with our collaborations with TRIUMF and the Department of Energy, extend our leadership position in actinium supply and meet the needs of our growing pipeline."

Portfolio Update

FPI-1434

In the Phase 1 study, 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 Phase 1 safety, pharmacokinetics, and imaging data, including any evidence of anti-tumor activity, and details on the dosing regimen, in the first half of 2023. 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 half of 2022 and plans to provide updated guidance for preliminary pharmacokinetic, imaging and safety data from the first patient cohort following initial experience with patient screening in order to better predict the cadence of patient enrollment.

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, colorectal, and pancreatic cancers. The molecule targets neurotensin receptor 1 (NTSR1), a promising target for cancer treatment, which is overexpressed in several solid tumors. FPI-2059 is based upon Ipsen's IPN-1087 (previously studied in a Phase 1 clinical trial as a beta-emitting radiopharmaceutical), which Fusion acquired in 2021, and converted to an alpha-emitting radiopharmaceutical using actinium-225.

The U.S. Food and Drug Administration (FDA) cleared Fusion's IND application for FPI-2059 in June 2022 and study initiation activities are ongoing in a Phase 1, non-randomized, open-label clinical trial in patients with solid tumors expressing NTSR1, intended to investigate safety, tolerability and pharmacokinetics and to establish the recommended Phase 2 dose. 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 June, Fusion presented imaging data from the cold antibody sub-study in the Phase 1 study of FPI-1434 at the Society of Nuclear Medicine and Molecular Imaging (SNMMI) 2022 Annual Meeting. Imaging data from the study demonstrate a favorable gain in [^{111}In]-FPI-1547, the investigational imaging agent, tumor lesion uptake versus normal tissue when FPI-1175, the naked antibody without the isotope, was pre-administered and compared to dosing with FPI-1547 alone. Importantly, sites of improved tumor lesion uptake were independent of anatomic location of disease and included bone, lung, liver, and lymph nodes. Administration of FPI-1547 with and without pre-administration of FPI-1175 was safe without any drug-related Serious Adverse Events or Dose Limiting Toxicities.
- In June, Fusion and Niowave, Inc. announced an agreement for the development, production, and supply of actinium-225. Fusion will invest up to $5 million in Niowave to further develop their technology to increase current production capacity of actinium-225, and in return Fusion will have guaranteed access to a pre-determined percentage of Niowave's capacity of the resulting actinium-225, as well as preferred access to any excess supply produced. As part of the agreement, Fusion will also have an option to invest in future production of actinium-225 to scale with Fusion's needs.

Second Quarter 2022 Financial Results

- **Cash and Investments:** As of June 30, 2022, Fusion held cash, cash equivalents and investments of $198.4 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 June 30, 2022, will be sufficient to fund operations into the first quarter of 2024.
- **Collaboration Revenue:** For the second quarter of 2022, Fusion recorded $0.6 million of revenue under the AstraZeneca collaboration agreement.
- **R&D Expenses:** Research and development expenses for the second quarter of 2022 were $12.1 million, compared to $21.1 million for the same period in 2021. The decrease was primarily due to a decrease in platform development and unallocated research and development costs driven by discrete items that occurred during the second quarter of 2021, including common share issuances pursuant to our asset purchase agreements with Ipsen and Rainier Therapeutics, and payments made under our agreement with CPDC for services relating to the validation of Fusion's manufacturing facility currently under construction which resulted in the recognition of research and development expense during that quarter.
- **G&A Expenses:** General and administrative expenses for the second quarter of 2022 were $7.8 million, compared to $6.6 million for the same period in 2021. The increase was primarily due to an increase in personnel-related costs, corporate costs and professional fees.
- **Net Loss:** For the second quarter of 2022, Fusion reported a net loss of $19.1 million, or $0.44 per share, compared with a net loss of $26.9 million, or $0.63 per share, for the same period in 2021.

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), currently in a Phase 1 study following the investigational new drug (IND) clearance; and FPI-2059, a small molecule targeting neurotensin

receptor 1 (NTSR1), also currently in a Phase 1 study. 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

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 March 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)

	June 30, 2022	December 31, 2021
Cash, cash equivalents and investments	$ 198,423	$ 220,782
Total assets	228,135	252,271
Total liabilities	29,228	20,815

Total stockholders' equity	198,907	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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Collaboration revenue	$ 570	$ 521	$ 1,155	$ 521
Operating expenses:				
Research and development	12,076	21,146	24,737	31,862
General and administrative	7,781	6,642	16,230	13,606
Total operating expenses	19,857	27,788	40,967	45,468
Loss from operations	(19,287)	(27,267)	(39,812)	(44,947)
Other (expense) income:				
Interest (expense) income, net	(53)	97	30	193
Other (expense) income, net	(414)	331	64	379
Total other (expense) income, net	(467)	428	94	572
Loss before benefit (provision) for income taxes	(19,754)	(26,839)	(39,718)	(44,375)
Income tax benefit (provision)	681	(14)	736	(7)
Net loss	$ (19,073)	$ (26,853)	$ (38,982)	$ (44,382)
Unrealized (loss) gain on investments	(482)	54	(945)	293
Comprehensive loss	$ (19,555)	$ (26,799)	$ (39,927)	$ (44,089)
Net loss per share—basic and diluted	$ (0.44)	$ (0.63)	$ (0.90)	$ (1.05)
Weighted-average common shares outstanding—basic and diluted	43,357,240	42,501,321	43,264,175	42,145,435

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