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

FPI-1434 Phase 1 data on track to be reported in first half of 2023

Phase 1/2 Study of FPI-1966 open and enrolling patients with solid tumors expressing FGFR3

Strong balance sheet with $205.5 million in cash, cash equivalents and investments with runway into Q3 2024

HAMILTON, ON and BOSTON, Nov. 8, 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 third quarter ended September 30, 2022 and provided an update on clinical and corporate developments.

Chief Executive Officer John Valliant, Ph.D. commented, "During the third quarter of 2022, we continued to advance our pipeline of targeted alpha therapy programs to treat multiple cancer types not currently addressed by available radiopharmaceutical therapies. Leveraging our platform and radiopharmaceutical expertise, we now have three Phase 1 clinical programs. Our lead program, FPI-1434, remains on track to report Phase 1 data in the first half of 2023. Following the initiation of dosing in our Phase 1/2 study of FPI-1966, we have opened multiple study sites and are actively recruiting patients with FGFR3-expressing solid tumors. We also continue to make progress in our newest clinical program, FPI-2059, which, based on clinical imaging and preclinical data, we believe has the potential to precisely target and kill tumor cells in colorectal, pancreatic and neuroendocrine prostate cancers. Furthermore, we've demonstrated Fusion's proficiency in targeted alpha therapy (TAT) development with the first candidate under our collaboration agreement with AstraZeneca moving promptly through investigational new drug (IND) enabling studies. Our rich pipeline of cancer therapies is underpinned by an experienced internal radiopharmaceutical R&D team, and early investments in actinium supply, bolstered by our manufacturing capabilities. We look forward to providing meaningful updates on our diverse and growing pipeline of TATs in the months ahead."

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 is intended to investigate safety, tolerability and pharmacokinetics and to establish the recommended Phase 2 dose. Patient enrollment and dosing is ongoing. The company plans to provide updated guidance for preliminary pharmacokinetic, imaging and safety data from the first patient cohort following 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 August, Fusion announced first patient dosed in Phase 1/2 study of FPI-1966 in patients with advanced solid tumors expressing FGFR3. The Phase 1/2 multi-center, open-label clinical trial is designed to investigate the safety, tolerability, dosimetry, biodistribution, and pharmacokinetics of FPI-1966 in patients with FGFR3-expressing advanced, inoperable, metastatic, and/or recurrent solid tumors. The study employs a 3 + 3 dose escalation design to evaluate multiple ascending doses of FPI-1966. The first cohort will comprise sub-groups in which various doses of non-radiolabeled vofatamab ("cold antibody") will be evaluated to assess the impact of pre-dosing on tumor uptake and pharmacokinetics. As part of the trial, patients will be administered an imaging analogue of FPI-1966, FPI-1967, and only those who upon imaging meet predefined tumor uptake will go on to receive FPI-1966. The Phase 2 portion of the study will consist of two tumor-specific cohorts and one basket cohort.
- In September, Fusion drew down $25 million under the previously announced debt agreement with Oxford Finance LLC. To date, the Company has drawn down a total of $35 million. The loan agreement, as amended, provides for up to four tranches totaling $75 million. With the additional $25 million in debt funding, Fusion now expects its cash, cash

equivalents and investments will be sufficient to fund operations into the third quarter of 2024.
- On November 7, Fusion announced the appointment of Dmitri Bobilev, M.D., as chief medical officer. Dr. Bobilev joins Fusion from Checkmate Pharma, where he was vice president, head of clinical development until the company's acquisition by Regeneron earlier in 2022. At Checkmate, he was responsible for clinical development and registration strategy for vidutolimod.

Third Quarter 2022 Financial Results

- Cash and Investments: As of September 30, 2022, Fusion held cash, cash equivalents and investments of $205.5 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 September 30, 2022, will be sufficient to fund operations into the third quarter of 2024.
- Collaboration Revenue: For the third quarter of 2022, Fusion recorded $0.2 million of revenue under the AstraZeneca collaboration agreement.
- R&D Expenses: Research and development expenses for the third quarter of 2022 were $16.6 million, compared to $12.7 million for the same period in 2021. The increase was primarily due to discrete items that occurred during the third quarter of 2022, including a common share issuance and cash payment pursuant to our asset purchase agreement to acquire vofatamab from Rainier Therapeutics. Additionally, there was an increase in direct costs related to FPI-2059, specifically related to the initiation of the Phase 1 clinical trial as well as preclinical research and manufacturing costs.
- G&A Expenses: General and administrative expenses for the third quarter of 2022 were $7.4 million, compared to $7.2 million for the same period in 2021. The increase was primarily due to an increase in personnel-related costs, partially offset by a decrease in corporate costs and professional fees.
- Net Loss: For the third quarter of 2022, Fusion reported a net loss of $24.0 million, or $0.55 per share, compared with a net loss of $19.4 million, or $0.45 per share, for the same period in 2021.

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 first program, FPI-1434 targeting insulin-like growth factor 1 receptor (IGF-1R), 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; and FPI-2059, a small molecule targeting neurotensin receptor 1 (NTSR1), which has received FDA investigational new drug (IND) clearance and will begin 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. To support Fusion's growing pipeline of TATs, the company has signed strategic agreements for actinium supply with both TRIUMF and Niowave, Inc.

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 June 30, 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)

	September 30, 2022	December 31, 2021
Cash, cash equivalents and investments	$ 205,481	$ 220,782
Total assets	238,493	252,271
Total liabilities	55,351	20,815
Total stockholders' equity	183,142	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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Collaboration revenue	$ 166	$ 325	$ 1,321	$
Operating expenses:				
Research and development	16,551	12,684	41,288	44
General and administrative	7,420	7,156	23,650	20
Total operating expenses	23,971	19,840	64,938	65
Loss from operations	(23,805)	(19,515)	(63,617)	(64,
Other (expense) income:				
Interest income, net	190	107	220	
Other (expense) income, net	(1,159)	27	(1,095)	
Total other (expense) income, net	(969)	134	(875)	
Loss before benefit (provision) for income taxes	(24,774)	(19,381)	(64,492)	(63,
Income tax benefit (provision)	761	(48)	1,497	
Net loss	$ (24,013)	$ (19,429)	$ (62,995)	$ (63,
Unrealized (loss) gain on investments	(196)	(274)	(1,141)	
Comprehensive loss	$ (24,209)	$ (19,703)	$ (64,136)	$ (63,
Net loss per share—basic and diluted	$ (0.55)	$ (0.45)	$ (1.45)	$ (1
Weighted-average common shares outstanding—basic and diluted	43,683,738	43,022,762	43,405,566	42,441,

SOURCE Fusion Pharmaceuticals Inc.

https://ir.fusionpharma.com/2022-11-08-Fusion-Pharmaceuticals-Announces-Third-Quarter-2022-Financial-Results-and-Clinical-Program-Updates