Fusion Pharmaceuticals Announces Third Quarter 2021 Financial Results And Clinical Program Update

FPI-1434 Phase 1 multi-dose data now expected in 2H 2022

FPI-1966 Phase 1 study initiated; first patient expected to be dosed in Q1 2022

FPI-2059 investigational new drug application (IND) on track for first half 2022

HAMILTON, ON and BOSTON, Nov. 9, 2021 /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, 2021 and provided an update on clinical and corporate developments.

Clinical Update

FPI-1434

Fusion now expects to provide multi-dose safety and imaging data, and recommended Phase 2 dose, in the second half of 2022 rather than in the first half of 2022. The shift in timelines is primarily associated with a decrease in patient enrollment rates attributable to the impact of the COVID-19 pandemic.

Chief Executive Officer John Valliant, Ph.D. commented, "Despite our efforts to mitigate the impacts of the COVID-19 pandemic, including the addition of new trial sites in multiple geographic regions, we have seen patient enrollment rates decline largely due to resourcing and reduced staffing issues at trial sites. Longer timelines to enroll patients have persisted and therefore we are shifting our expectation for multi-dose data to the second half of 2022. We continue to make patient recruitment a top priority, are working closely with our trial sites to support their efforts and believe that with increased vaccination rates recruitment will return to previous levels."

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. In addition, the study arm exploring the impact on biodistribution and tumor uptake of administration of a dose of naked ("cold") IGF-1R antibody prior to each dose of FPI-1434 is ongoing.

Dr. Valliant continued, "Although the Phase 1 study of FPI-1434 is experiencing delays during these unprecedented times, we continue to believe in the significant opportunity we have to address a broad array of tumor types with high unmet need and we are working diligently to optimize the development program and progress the study for the benefit of patients."

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 with the first study site open to recruitment. Fusion expects to dose the first patient in the first quarter of 2022 and expects interim data from the first patient cohort in the first quarter of 2023.

FPI-2059

FPI-2059 is a small molecule radioconjugate in development as a targeted alpha therapy for various solid tumors. The molecule targets neurotensin receptor 1 (NTSR1), a promising target for cancer treatment, that is overexpressed in multiple solid tumors. FPI-2059 combines Ipsen's IPN-1087, which Fusion acquired in 2021, with actinium-225. Fusion continues to anticipate submitting an IND application for FPI-2059 in the first half of 2022.

Recent News and Highlights

- In August, Fusion and TRIUMF, Canada's particle accelerator centre, announced that the companies have entered into the next phase of their collaboration agreement for the development, production, and supply of actinium-225. Fusion will provide to TRIUMF funding to further develop technology to produce actinium-225 and in return Fusion will have rights, including preferred access and pricing, to the resulting alpha-emitting medical isotope.
- Fusion recently expanded its executive leadership team with the appointments of Mohit Rawat as president and chief business officer, and Christopher Leamon, Ph.D. as chief scientific officer, and Eric S. Hoffman, Ph.D. as senior vice president, business development.
- In October, Fusion announced the presentation of preclinical data that provide further support of its FPI-1966 and FPI-2059 targeted alpha therapies (TATs) at the 34th Annual European Association of Nuclear Medicine Congress. These data reinforce the clinical dosing regimen of FPI-1966 and highlight the potential of FPI-2059 as an actinium-225 labelled precision medicine targeting NTSR1.

Dr. Valliant said, "We are building a fully integrated radiopharmaceutical company based upon our platform, reflecting a diverse pipeline of TATs in development. We are also making strategic investments in critical areas of manufacturing and supply chain to support the growth of our business, and we are attracting top industry leaders to join Fusion in our mission to impact the cancer therapy landscape with this new generation of targeted radiopharmaceuticals."

Third Quarter 2021 Financial Results

- **Cash and Investments:** As of September 30, 2021, Fusion held cash, cash equivalents and investments of $238.2 million, compared to cash, cash equivalents and investments of $299.5 million as of December 31, 2020. Fusion expects its cash, cash equivalents and investments as of September 30, 2021 will enable the Company to fund its operations through the end of 2023.
- **Collaboration Revenue:** For the third quarter of 2021, Fusion recorded $0.3 million of revenue under the AstraZeneca collaboration agreement.
- **R&D Expenses:** Research and development expenses for the third quarter of 2021 were $12.7 million, compared to $4.5 million for the same period in 2020. The increase was primarily related to costs associated with the FPI-1434 Phase 1 clinical trial, as well as preclinical research and manufacturing costs, platform development and personnel-related costs.
- **G&A Expenses:** General and administrative expenses for the third quarter of 2021 were $7.2 million, compared to $5.8 million for the same period in 2020. The increase was primarily related to personnel-related costs and general corporate costs, partially offset by a decrease in professional fees.
- **Net Loss:** For the third quarter of 2021, Fusion reported a net loss of $19.4 million, or $0.45 per share, compared with

a net loss of $10.0 million, or $0.24 per share, for the same period in 2020.

Impact of COVID-19

Fusion is experiencing material delays in patient recruitment and enrollment 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. Employing a proprietary Fast-Clear™ linker technology, 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) and FPI-2059, a small molecule recently acquired from Ipsen, targeting neurotensin receptor 1 (NTSR1). In addition to a robust proprietary pipeline, Fusion has a collaboration with AstraZeneca to jointly develop up to three novel targeted alpha therapies (TATs) and explore up to five combination programs between Fusion's TATs and AstraZeneca's DNA Damage Repair Inhibitors (DDRis) and immuno-oncology agents. Fusion 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.

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 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-Q for the quarter ended June 30, 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.

FUSION PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share amounts)
(Unaudited)

	September 30, 2021	December 3 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 38,379	$ 90
Accounts receivable	300	
Short-term investments	154,238	131,
Prepaid expenses and other current assets	9,423	5,
Restricted cash	669	
Total current assets	203,009	228,
Property and equipment, net	2,460	1,
Deferred tax assets	1,324	
Restricted cash	1,222	1,
Long-term investments	45,554	77,
Operating lease right-of-use assets	6,946	
Other non-current assets	7,788	1,
Total assets	$ 268,303	$ 310
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 3,803	$ 3
Accrued expenses	6,146	4,
Income taxes payable	—	2,
Deferred revenue	2,287	1,
Operating lease liabilities	1,327	
Total current liabilities	13,563	11,
Deferred rent, net of current portion	—	
Income taxes payable, net of current portion	295	
Deferred revenue, net of current portion	2,167	4,
Operating lease liabilities, net of current portion	5,783	
Total liabilities	21,808	16,
Commitments and contingencies		

Shareholders' equity:		
Common shares, no par value, unlimited shares authorized as of September 30, 2021 and December 31, 2020; 43,066,219 and 41,725,797 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	—	
Additional paid-in capital	423,446	407,
Accumulated other comprehensive income	63	
Accumulated deficit	(177,014)	(113,
Total shareholders' equity	246,495	294,
Total liabilities and shareholders' equity	$ 268,303	$ 310

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 Septembe	
	2021	2020	2021	
Collaboration revenue	$ 325	$ —	$ 846	$
Operating expenses:				
Research and development	12,684	4,529	44,546	
General and administrative	7,156	5,790	20,762	
Total operating expenses	19,840	10,319	65,308	
Loss from operations	(19,515)	(10,319)	(64,462)	
Other income (expense):				
Change in fair value of preferred share tranche right liability	—	—	—	
Change in fair value of preferred share warrant liability	—	—	—	
Interest income (expense), net	107	80	300	
Refundable investment tax credits	—	41	—	
Other income (expense), net	27	20	406	
Total other income (expense), net	134	141	706	
Loss before (provision) benefit for income taxes	(19,381)	(10,178)	(63,756)	
Income tax (provision) benefit	(48)	185	(55)	
Net loss	(19,429)	(9,993)	(63,811)	
Unrealized (loss) gain on investments	(274)	(1)	19	
Comprehensive loss	(19,703)	(9,994)	(63,792)	
Reconciliation of net loss to net loss attributable to common shareholders:				
Net loss	(19,429)	(9,993)	(63,811)	
Dividends paid to preferred shareholders in the form of warrants issued	—	—	—	
Net loss attributable to common shareholders	$ (19,429)	$ (9,993)	$ (63,811)	$
Net loss per share attributable to common shareholders—basic and diluted	$ (0.45)	$ (0.24)	$ (1.50)	$
Weighted-average common shares outstanding—basic and diluted	43,022,762	41,682,797	42,441,091	

FUSION PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2021	2020
Cash flows from operating activities:		
Net loss	$ (63,811)	$ (64,948
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	6,237	2,025
Depreciation and amortization expense	450	373
Non-cash lease expense	793	3
Change in fair value of preferred share tranche right liability	—	32,722
Change in fair value of preferred share warrant liability	—	6,399
Amortization of premiums (accretion of discounts) on investments, net	1,361	24
Deferred tax benefit	(670)	(28
Common shares issued to acquire in-process research & development	8,924	—
Foreign exchange loss	5	—
Changes in operating assets and liabilities:		
Accounts receivable	(300)	—
Prepaid expenses and other current assets	(4,110)	(3,792
Other non-current assets	(6,227)	(521
Accounts payable	413	150
Accrued expenses	1,487	1,025
Deferred revenue	(546)	—
Income taxes payable	(2,800)	(117
Operating lease liabilities	(619)	—
Net cash used in operating activities	(59,413)	(26,685
Cash flows from investing activities:		
Purchases of investments	(157,424)	(54,286
Maturities of investments	165,255	—
Purchases of property and equipment	(953)	(1,063

Net cash provided by (used in) investing activities	6,878	(55,349)
Cash flows from financing activities:		
Proceeds from issuance of Class B convertible preferred shares and Class B preferred share tranche right, net of issuance costs	—	65,676
Proceeds from issuance of Class B preferred exchangeable shares of Fusion Pharmaceuticals (Ireland) Limited and Class B preferred share tranche right, net of issuance costs	—	6,722
Proceeds from the issuance of common shares upon closing of initial public offering, net of underwriter fees	—	197,625
Payment of offering costs	(216)	(4,572)
Proceeds from issuance of common shares upon exercise of stock options and ESPP	613	—
Net cash provided by financing activities	397	265,451
Net (decrease) increase in cash, cash equivalents and restricted cash	(52,138)	183,417
Cash, cash equivalents and restricted cash at beginning of period	92,408	67,121
Cash, cash equivalents and restricted cash at end of period	$ 40,270	$ 250,538
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ 3,739	$ 280
Right-of-use assets obtained in exchange for new operating lease liabilities	$ 1,166	$ —
Increase in right-of-use assets and operating lease liabilities from operating lease modifications	$ 911	$ —
Supplemental disclosure of non-cash investing and financing activities:		
Purchases of property and equipment included in accounts payable and accrued expenses	$ 25	$ —
Issuance of warrants to purchase Class B preferred shares and Class B preferred exchangeable shares as a non-cash dividend to preferred shareholders	$ —	$ 1,382
Deferred offering costs included in accounts payable and accrued expenses	$ 60	$ —

FUSION PHARMACEUTICALS INC.
RECONCILIATION OF GAAP TO NON-GAAP FINANCIAL RESULTS
(In thousands)
(Unaudited)

	Three Months Ended September 30,		Nine Months En September 3	
	2021	**2020**	**2021**	
GAAP Net loss	$ (19,429)	$ (9,993)	$ (63,811)	$
Less: Adjustments				
Change in fair value of preferred share tranche right liability	—	—	—	
Change in fair value of preferred share warrant liability	—	—	—	
Non-GAAP Net loss	$ (19,429)	$ (9,993)	$ (63,811)	$

SOURCE Fusion Pharmaceuticals Inc.

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