Fusion Pharmaceuticals Announces Third Quarter 2020 Financial Results And Business Update

- Multi-dosing portion of Fusion's Phase 1 study of FPI-1434 on track to be initiated in Q4 2020

- Company executes collaboration agreement with AstraZeneca to grow pipeline of next-generation radiopharmaceuticals

HAMILTON, ON and BOSTON, Nov. 10, 2020 /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, 2020 and provided an update on clinical and corporate developments.

"We are pleased with the results of the single-dose portion of our Phase 1 study of FPI-1434 that support our ability to move into the multi-dosing portion, and with trial sites now open, we continue to expect to dose our first patient in the fourth quarter," said Chief Executive Officer John Valliant, Ph.D. "Additionally, Fusion's scalable platform can support a robust pipeline of next-generation radiopharmaceuticals using our precision medicine approach. We recently executed a collaboration agreement with AstraZeneca that allows us to retain commercial rights to our existing products while expanding our pipeline. We are well-positioned with the resources and robust manufacturing and supply chain capabilities to execute on our plans, grow our business and develop potent new cancer treatments for patients in need."

Recent Highlights and Future Milestones

Corporate Updates

- On November 2, Fusion announced that the Company entered into a collaboration with AstraZeneca to develop and commercialize next-generation alpha-emitting radiopharmaceuticals and combination therapies for the treatment of cancer. The collaboration leverages Fusion's Targeted Alpha Therapies (TATs) platform and expertise in radiopharmaceuticals with AstraZeneca's leading portfolio of antibodies and cancer therapeutics, including DNA Damage Response Inhibitors (DDRis). Under the terms of the agreement, the companies will jointly discover, develop and commercialize novel TATs, which will utilize Fusion's Fast-Clear™ linker technology platform with antibodies in AstraZeneca's oncology portfolio. In addition, the companies will explore combination strategies between TATs (including Fusion's lead candidate FPI-1434) and AstraZeneca therapeutics, for the treatment of various cancers. Both companies will retain full rights to their respective assets.

FPI-1434 Monotherapy

- Fusion convened a Safety Review Committee (SRC) meeting in the third quarter of 2020 to evaluate the safety of the single-dose cohort of 40kBq/kg (cohort three). The SRC determined the safety data of cohort three allowed Fusion to begin the multi-dosing portion of the study at the next higher planned dose level. The Company expects to dose the first patient in the multi-dosing portion of the study in the fourth quarter of 2020, assuming no delays due to the spread of COVID-19.
- The available safety, dosimetry, pharmacokinetic and biodistribution data from the single dose escalation portion of the study provided justification for the initiation of FPI-1434 multi-dosing at 75 kBq/kg. Both FPI-1434, and the imaging analogue FPI-1547, have been well tolerated. No dose limiting toxicities or serious adverse events related to study treatment were reported.
- Fusion anticipates reporting Phase 1 multiple-dose safety and imaging data, and the recommended Phase 2 dose/schedule, approximately nine to eighteen months after commencing this portion of the study.

FPI-1434 Combination Therapy

- Fusion has evaluated FPI-1434 in preclinical studies in combination with approved checkpoint and DNA damage response inhibitors, including PARP inhibitors, and believes the synergies observed could expand the addressable patient populations for FPI-1434 and allow for potential use in earlier lines of treatment.
- Fusion anticipates the initiation of a Phase 1 combination study with FPI-1434 to occur six to nine months following determination of the recommended Phase 2 dose of FPI-1434 monotherapy.

FPI-1966

- FPI-1966 is designed to target and deliver Actinium-225 to tumors expressing FGFR3, a protein that is overexpressed in head and neck and bladder cancers. Following the completion of pre-clinical studies, the Company expects to submit an IND for FPI-1966 in the first half of 2021.

Third Quarter 2020 Financial Results

- **Cash and Investments:** As of September 30, 2020, Fusion held cash, cash equivalents and investments of $303.1 million, compared to cash of $65.3 million as of December 31, 2019. Fusion expects its cash, cash equivalents and investments as of September 30, 2020 will enable the Company to fund its operations into 2024.
- **R&D Expenses:** Research and development expenses for the third quarter of 2020 were $4.5 million, compared to $2.2 million for the same period in 2019. The increase was primarily due to costs related to our Phase 1 clinical trial of FPI-1434, as well as other development and personnel-related costs.
- **G&A Expenses:** General and administrative expenses for the third quarter of 2020 were $5.8 million, compared to $1.9 million for the same period in 2019. The increase was primarily due to an increase in professional fees, personnel-related costs and other costs including general corporate, insurance and facilities costs.
- **Net Loss:** For the third quarter of 2020, Fusion reported a net loss of $10.0 million, or $0.24 per share, compared with a net loss of $0.6 million, or $0.31 per share, for the same period in 2019. On a non-GAAP basis, excluding a change in fair value of preferred share tranche right liability, net loss was $4.1 million for the third quarter of 2019.

Upcoming Events

- Fusion will participate in a virtual "fireside chat" presentation at the Jefferies Virtual London Healthcare Conference on Thursday, November 19 at 1:30pm GMT / 8:30am EST.

Impact of COVID-19

Fusion is closely monitoring how the spread of COVID-19 is affecting the Company's employees, business, preclinical studies and clinical trials. In response to the COVID-19 pandemic, certain employees have transitioned to working remotely and

travel has been restricted. Fusion's research labs are operating but with reduced capacity.

While Fusion has completed enrollment, dosing and the DLT evaluation period for the third patient cohort in the ongoing Phase 1 clinical trial of FPI-1434, the Company may not be able to enroll additional patient cohorts on the planned timeline due to disruptions at clinical trial sites. Additionally, while certain preclinical activities have restarted, Fusion is currently unable to predict when the Company will fully resume all preclinical activities.

Although the single dose Phase 1 clinical trial has not been materially affected by the COVID-19 pandemic as of September 30, 2020, at this time, there is significant uncertainty relating to the trajectory of the pandemic and whether or not it may cause a delay in the dosing of the first patient in the multi-dosing portion of the study. The impact of related responses and disruptions caused by the COVID-19 pandemic may result in 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 impact of COVID-19 on future 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 antibodies and other targeting molecules in order to selectively deliver the alpha emitting payloads to tumors. Fusion's lead program, FPI-1434, is currently in a Phase 1 clinical trial.

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 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, 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, 2020 which is available on the Securities and Exchange Commission's website at www.sec.gov and Fusions website at www.fusionpharma.com.

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

	September 30, 2020	Dec
Assets		
Current assets:		
Cash and cash equivalents	$ 248,793	$
Restricted cash	280	
Short-term investments	43,159	
Prepaid expenses and other current assets	4,652	
Total current assets	296,884	
Property and equipment, net	1,981	
Deferred tax assets	106	
Restricted cash	1,465	
Long-term investments	11,102	
Other non-current assets	521	
Total assets	$ 312,059	$
Liabilities, Non-Controlling Interest, Convertible Preferred Shares and Shareholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 956	$
Accrued expenses	4,353	
Income taxes payable	—	
Total current liabilities	5,309	
Deferred rent, net of current portion	3	
Preferred share tranche right liability	—	
Income taxes payable, net of current portion	293	
Special voting shares redemption right liability (Notes 2 and 7)	—	
Total liabilities	5,605	
Commitments and contingencies (Note 12)		
Non-controlling interest in Fusion Pharmaceuticals (Ireland) Limited (Notes 2 and 7)	—	
Convertible preferred shares, no par value; 0 shares and 132,207,290 shares authorized as of September 30, 2020 and December 31, 2019, respectively; 0 shares and 73,125,790 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively; aggregate liquidation preference of $0 and $77,965 as of September 30, 2020 and December 31, 2019, respectively	—	
Shareholders' equity (deficit):		
Common shares, no par value, unlimited shares authorized as of September 30, 2020 and December 31, 2019; 41,702,384 and 1,929,555 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	—	
Additional paid-in capital	406,273	
Accumulated other comprehensive income	(1)	

Accumulated deficit		(80,213)
Total shareholders' equity (deficit)		306,454
Total liabilities, non-controlling interest, convertible preferred shares and shareholders' equity (deficit)	$ 312,059	$

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,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 4,529	$ 2,238	$ 12,231	$ 7,216
General and administrative	5,790	1,922	14,105	4,864
Total operating expenses	10,319	4,160	26,336	12,080
Loss from operations	(10,319)	(4,160)	(26,336)	(12,080
Other income (expense):				
Change in fair value of preferred share tranche right liability	—	3,485	(32,722)	3,707
Change in fair value of preferred share warrant liability	—	—	(6,399)	—
Interest income (expense), net	80	247	249	395
Refundable investment tax credits	41	44	139	132
Other income (expense), net	20	(29)	148	76
Total other income (expense), net	141	3,747	(38,585)	4,310
Loss before (provision) benefit for income taxes	(10,178)	(413)	(64,921)	(7,770
Income tax (provision) benefit	185	(181)	(27)	(213
Net loss	(9,993)	(594)	(64,948)	(7,983
Unrealized loss on investments	(1)	—	(1)	—
Comprehensive loss	(9,994)	(594)	(64,949)	(7,983
Reconciliation of net loss to net loss attributable to common shareholders:				
Net loss	(9,993)	(594)	(64,948)	(7,983
Dividends paid to preferred shareholders in the form of warrants issued	—	—	(1,382)	—
Net loss attributable to common shareholders	$ (9,993)	$ (594)	$ (66,330)	$ (7,983
Net loss per share attributable to common shareholders—basic and diluted	$ (0.24)	$ (0.31)	$ (4.30)	$ (4.18
Weighted-average common shares outstanding—basic and diluted	41,682,797	1,929,555	15,422,375	1,910,695

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

	Nine Months Ended September 30,	
	2020	2019
Cash flows from operating activities:		
Net loss	$ (64,948)	$ (7,983)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	2,025	328
Depreciation and amortization expense	373	213
Non-cash rent expense	3	(2)
Change in fair value of preferred share tranche right liability	32,722	(3,707)
Change in fair value of preferred share warrant liability	6,399	—
Amortization of premiums (accretion of discounts) on investments, net	24	—
Deferred tax benefit	(28)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(3,792)	16
Other non-current assets	(521)	—
Accounts payable	150	408
Accrued expenses	1,025	719
Income taxes payable	(117)	151
Net cash used in operating activities	(26,685)	(9,857)
Cash flows from investing activities:		
Purchases of investments	(54,286)	—
Purchases of property and equipment	(1,063)	(340)
Net cash used in investing activities	(55,349)	(340)
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	45,476
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	6,711
Proceeds from the issuance of common shares upon closing of initial public offering, net of underwriter fees	197,625	—
Payment of offering costs	(4,572)	—
Net cash provided by financing activities	265,451	52,187

Net increase in cash, cash equivalents and restricted cash	163,417	49,090
Cash, cash equivalents and restricted cash at end of period	$ 250,538	$ 71,070
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ 280	$ 40
Supplemental disclosure of non-cash investing and financing activities:		
Purchases of property and equipment included in accounts payable and accrued expenses	$ —	$ 4
Issuance of common shares upon net settlement of stock option exercise	$ —	$ 57
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	$ —

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
GAAP Net loss	$ (9,993)	$ (594)	$ (64,948)	$ (7,98
Less: Adjustments				
Change in fair value of preferred share tranche right liability	—	3,485	(32,722)	3,7(
Change in fair value of preferred share warrant liability	—	—	(6,399)	
Non-GAAP Net loss	$ (9,993)	$ (4,079)	$ (25,827)	$ (11,69

SOURCE Fusion Pharmaceuticals Inc.

For further information: Amanda Cray, Senior Director of Investor Relations & Corporate Communications, (857) 310-3631, cray@fusionpharma.com